

PUBLIC COMMENTS - NUREG-800, *Standard Review Plan* (SRP), Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants"

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
1.	General Comment Progress Energy ML061110355	This document is extremely detailed compared to existing standard review plans (SRPs). A quality assurance program description (QAPD) that includes all the information specified in this SRP will also be extremely detailed; so detailed, that the utility may not need implementing procedures, in some areas.	The purpose of SRP Chapter 17.5 is to place all QA provisions in one place to ensure the quality and uniformity of staff safety reviews. SRP Chapter 17.5 is mainly based on American Society of Mechanical Engineers (ASME) Standard NQA-1 (1994 Edition). The detail in SRP Chapter 17.5 is similar to the detail in NQA-1. However, in some instances, the NRC cannot reference a standard because there is no standard available. No revision is required.
2.	General Comment Progress Energy ML061110355	Draft SRP 17.5 is written such that the resulting acceptable QAPD will be a compliance/audit based program (e.g., SRP 17.1 and 17.2) rather than a performance/assessment based program (e.g., SRP 17.3). If licensees are not allowed to reference an existing operational phase QAPD then provisions should be included in SRP 17.5 such that either a performance/assessment based program similar to SRP 17.3 or a compliance/audit based program similar to SRP 17.2 would be found acceptable for operations. This would provide the licensee with the flexibility to utilize either type of program such that the type of program would be consistent within their fleet.	This comment is incorporated. Provisions were added that describe how COL applicants could use an existing QAPD for the operational phase that was previously approved by the NRC.

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3.	General Comment Progress Energy ML061110355	It would be helpful to both the licensee and the reviewer if the SRP followed the format and structure of ASME NQA-1-1994, "Quality Assurance for Nuclear Facility Applications."	The draft SRP essentially follows the format of NQA-1, which is structured along the 18 criteria of Appendix B to 10 CFR 50. However, some exceptions were; 1) training and qualification for quality assurance, 2) training and qualification for inspection and test personnel, and 3) commercial grade dedication (CGD) . These exceptions were viewed as individual items and are treated as sub-topics in their respective areas of NQA-1. Breaking these exceptions into independent sections in the SRP was not viewed as being inconsistent with NQA-1. The guidance for CGD was found to be deficient in NQA-1. The staff provided further guidance for the reviewer in this area. No revision is required.
4.	General Comment: Laurence Gradin ML061040116	The consolidated treatment of quality in the SRP is of significant value and is found thorough. However, certain weaknesses were found in areas described in later comments.	General comment. No additional response or revision is required.
5.	General Comment NEI ML061040113 Progress Energy ML061110355	The SRP mixes construction and operational requirements together in the various sections making it unclear whether a requirement applies to the construction phase, operational phase, or both. Those requirements that are applicable only to the construction program or operational program should be segregated or clearly identified based on their applicability. This will improve and help standardize implementation of these requirements and facilitate a more efficient NRC staff review.	ASME NQA-1 is for the construction or operational phase of a plant. The staff found very few additional quality assurance requirements that were only for construction or operation. Where a requirement was only for construction or operation, the staff identified the appropriate applicability. The staff also incorporated public comments that identified provisions that applied only to construction or operations. The staff also revised II.A.4, and II.C.1.n to state that they are applicable to ESP , DC applicant, and construction programs. The staff added II.C.1.q to state that its only applicable to ESP, DC applicant and construction programs.

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6.	General Comment NEI ML061040113	This document is too detailed and will eliminate the need for implementing procedures in several sections. It is inappropriate, unnecessary and contrary to existing regulatory practice to go to this level of detail for a program description.	Please see the response to No. 1.
7.	General Comment NEI ML061040113	Draft SRP 17.5 is written such that the resulting acceptable QAPD will be a compliance/audit based program (e.g., SRP 17.1) as opposed to a performance/assessment based program (e.g., SRP 17.3). While a compliance based program is suitable for construction, we would prefer to implement our existing performance/assessment based SRP 17.3 QA Program for operations for the new plant and throughout our nuclear fleet. Therefore, provisions should be provided in SRP 17.5 to allow for a performance based QAPD (i.e., SRP 17.3) for the operational phased.	Please see the response to No. 2.
8.	General Comment NEI ML061040113	This document establishes many operational requirements that have been revised through the existing exemption process or the SER process. NUREG-0800 should have an allowance for either compliance with NUREG 0800 or an already NRC accepted Quality Assurance Program (QAP). An allowance to reference an already accepted QAP would reduce burden on the applicants as well as the staff.	The staff notes that many of the QA operational requirements that have been revised via the 10 CFR 50.54(a) process apply to documents that predate NQA-1-1994 and are not applicable to NQA-1-1994. However, the staff reviewed requirements that have been changed and revised 17.5 accordingly. Sections II.B.8, II.D.1, II.D. 8, II.G.5, II.G.22, II.J1, II.J.5, II.L.3, II.L.8, II.M.6, II.M.7, II.M.8, II.n.5, II.Q.13, II.Q.16, II.R.1, II.R.3.a, II.R.7, II.R.12, II.S.4.c, II.T.4, 5, and 6, II.U.2.a, II.U.2.b, II.2.c, II.U.2.g, II.U.2.h, and U.2.i were added, revised or deleted based on this comment.
9.	I J. McIntyre	Page 17.5-2, 1st Paragraph – Revise the 5th sentence to read “The operational phase is considered to begin once initial fuel load has commenced.” This would align the wording with Regulatory Guide 1.33.	This paragraph is revised to be consistent with SECY-05-0197. SECY -05-0197 provides guidance to the staff on operational programs.

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10.	I 17.5-2 NEI ML061040113	1 <sup>st</sup> Paragraph, Last two sentences. This section incorrectly implies that the QAPD is not required to be part of a COL application.	The last two sentence of this paragraph are deleted. The paragraph is revised to be consistent with SECY-05-0197.
11.	I 17.5-2 Progress Energy ML061110355	The first paragraph on Page 17.5-2 implies that the QAPD submitted both for the construction and operational phases for a COL application must be in accordance with SRP Sections 17.5. However, most COL applicants will have existing nuclear plants/fleets with QAPDs approved under earlier SRP sections (e.g. 17.2, 17.3). Provisions should be included in SRP Section 17.5 that permits COL applicants to reference an existing operations phase QAPD or to submit the operations phase QAPD in an SRP format consistent with that used throughout the licensee's nuclear fleet such that standardization of the fleet is maintained.	Please see the response to No. 2. No additional response is required.
12.	I 17.5-2 Laurence Gradin ML061040116	The third paragraph on page 2 of the proposed section 17.5 states; "SRP Section 17.5 is based on ASME standard NQA-1 (1994 Edition)," The current version is 2004 and should be used as a general practice. Specifically the 1994 ASME standard NQA-1 is very flawed as its definitions and approached to Commercial Grade Item Dedication is not consistent with the major 1995 update to 10CFR21 making this document inconsistent or in violation of 10CFR21.	The SRP sections for 10 CFR Part 21, Commercial Grade Dedication, and 10 CFR 50.55(e) were removed. The staff determined that these sections were not required to be submitted with a COL application. The NRC policy on commercial grade dedication is presented in GLs 89-02 and 91-05. These GLs have been added to the commitment list in Section U. Applicant will commit to follow the guidance in these GLs or provide justification for not doing so.
13.	I J. McIntyre	Page 17.5-2, 5 <sup>th</sup> Paragraph – Change the word "the" to "that" in the last sentence – "The areas that are not applicable...are not required to specify the QA controls for SSCs <i>that</i> perform..."	The staff agrees with the comment. This comment is incorporated.

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14.	II NEI ML061040113	Each draft SRP section that is identified as not applicable for various applicants or holders should state the basis for this section not being applicable.	The sections apply only to applicants that would be conducting the activity associated with that section. This is based on staff experience of when activities would be performed, and in some cases regulatory requirements. No revision is required.
15.	II NEI ML061040113	“A QAPD is considered to be acceptable if the specific criteria in this section are addressed, acceptable alternatives are justified, or an exemption to regulatory requirements is either approved, or specifically approved by the NRC in advance.”	This section was revised to be consistent with the new SRP standard format. Therefore, this comment is no longer applicable.
	II.A.4 NEI QA Task Force	What is meant by the parenthetical comment (only applicable to operation QA and ESP programs?	A.4 was deleted because it was redundant with A.15.
16.	II.A.5 NEI ML061040113 Progress Energy ML061110355	The addition of “independent review group activities” that is introduced here is not part of Appendix B or NQA-1 but is instead from ANSI N18.7, which applies only to the operational phase. Therefore, “independent review group activities” are not part of the construction program. Operational program requirements should be segregated from construction program requirements or clearly identified as operational program requirements to prevent the inappropriate application of operational program requirements to the construction program.	The staff agrees with the comment. This comment is incorporated.
17.	II.A.5  J. McIntyre	Should this read “Management positions, in which...” Presently as written this would have both audit and independent review group activities reporting to the same person.	The staff agrees with the comment. This comment is incorporated.

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18.	II.A.5.e NEI ML061040113	Item 5.e states that the person responsible for audits should "have no unrelated duties or responsibilities that would preclude FULL attention to assigned responsibilities." In operational programs this should not be a requirement. In a construction program it may occur because of the volume of work but it should not be a specific requirement since the regulations do not require it.	The staff agrees with the comment. This comment is incorporated.  A.5.e is eliminated.
19.	II.A.10 NEI ML061040113	Personnel performing work activities such as design, engineering, procurement...are responsible for achieving acceptable quality." Add the words "but not limited to" before the word design.	The staff agrees with the comment. This comment is incorporated.
	II.A.15 NEI QA Task Force	What is meant by organizational independence? The industry interprets that organizational independence meant the checking entity is independent but may be from the same organization.	II.A.15 is the same as the regulation in 10 CFR 50.34(f)(3)(iii)(A). The Statement of Considerations for this regulation (47 FR 2297, January 15, 1982) indicates that the purpose is to emphasize organizational independence rather than independence of personnel for objectivity and proficiency. Therefore, no revision is required. II.A.15 was relocated to II.A.4.
	II.B.1and B.6 NEI QA Task Force	NQA-1 states that "Management of those organizations implementing the quality assurance program, or portions thereof, shall regularly assess the adequacy of that part of the program for which they are responsible and shall assure its effective implementation." The SRP verbiage of paragraph 1 and 6 are inconsistent with this verbiage. The industry recommends that these two paragraphs B1 and B6 be combined and reworded to be consistent with NQA-1. 10 CFR 50, Appendix B states regularly. Reg Guide 1.28 states annually during construction and ANSI 18.7 requires every two years for operation. Paragraph B.6 states annually.	B.1 and B.6 are combined and worded similar to NQA-1 except that the term "regularly" is not used. Assessments are required to be done annually during ESP and construction and every two years during operation. The annual interval for construction QA programs is consistent with Reg Guide 1.28. The two year interval for operational QA programs is based on all aspects of the QA program being audited every two year period. The last paragraph of section 4.5 of ANSI 18.7 states that the assessments are to be done semiannually, however this provision is relaxed in this SRP section.

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20.	II.B.1 Clinton Elridge ML060450068	"Management of other organizations..." What does "other" refer to? Recommend deleting "other".	The staff agrees with the comment. This comment is incorporated.
21.	II.B.3 NEI ML061040113	This section should be reworded to read, The QA program should be documented by written policies, procedures, and/or instructions.	Using "should" instead "required to," implies this is not a requirement. The staff disagrees with comment. No revision is required.
22.	II.B.4 NEI ML061040113 Progress Energy ML061110355	<p>Comment – QA program should be binding on all personnel not just management</p> <p>The term "binding" as used here needs further clarification to ensure that the appropriate controls are included in the COL application. Is this saying the QA Program is applicable to management personnel having responsibility for costs and schedule? Is this implying the QA program is NOT binding/applicable to anyone else? The specificity to "management personnel having responsibility for costs and schedules" needs to be clarified.</p>	Comment is incorporated. II.B.4 renumbered as II.B.5.
23.	II.B.5 NEI ML061040113	<p>The 'annual' requirement in this paragraph is different from Appendix B and NQA-1. The wording here should be consistent with Appendix B.</p> <p>Requires Senior-Level management to assess the adequacy of the QA program implementation annually. The vehicle for this is through the Audit program that has a nominal frequency of two years and in some programs has been allowed to be extended.</p> <p>Recommend wording that exists in " Basic Requirement 2 of NQA-1-1994, " Management of those organizations implementing the quality assurance program, or portions thereof, shall regularly assess the adequacy of the part of the program for which they are responsible and shall assure its effective implementation."</p>	<p>II.B.5 is renumber as II.B.1. Appendix B states that, "Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing." Regularly has been interpreted by the staff and industry as annual. The wording, as noted, is essentially the same in NQA-1.</p> <p>This provision has been revised for operational programs to allow extending the assessment period to two years which is consistent with the provisions in a SE.</p>

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24.	II.B.7 Progress Energy ML061110355	The "annual" requirement in this paragraph is different from Appendix B and NQA-1. The requirement in Appendix B is "regularly" which is usually interpreted to be annually. Suggest the wording here be changed to be consistent with the App. B wording.	Please see the response to No. 23. No additional response is required.
25.	II.B.7 NEI ML061040113	This should not apply to fabrication and manufacturing activities that are allowed to begin under 10 CFR 50.10.	The draft SRP does not state or imply that it does. No revision is required.
26.	II.C.1.g NEI ML061040113	Insert "used" after computer codes. The code itself would not be a design record. The design record should contain the inputs, design/calculation methodology and the outputs necessary for future design personnel to be able to reproduce, revise or update the analysis.	The sentence does not use "computer codes," it says "computer programs." No revision is required.
27.	II.C.1.h  J. McIntyre	Revise the 1 <sup>st</sup> sentence to read "Design analysis documents are legible and in a form suitable for recordkeeping."	The staff agrees with the comment. This comment is incorporated.
28.	II.C.1.i  J. McIntyre	Include the words "as applicable" at the end of the sentence "Documentation of design analyses include the following, as <i>applicable</i> :..."	The staff agrees with the comment. This comment is incorporated.
29.	II.C.1.n Progress Energy ML061110355	Delete this criterion. The only QA role, generally, in this activity would be in the audit/assessment function and would be addressed in the audit section. To have a requirement here in the design control section is not clear. Does QA mean the QA organization activities like audits or QA activities performed by the design organization? This should be clarified.	10 CFR 50.34(f)(3)(iii)(H) requires that the QA role in design and analysis activities be defined for design, construction and installation activities. II.C.1. n is revised to clarify that the objective of this provision is design documents are reviewed by individuals knowledgeable and qualified in QA to ensure the documents contain the necessary QA requirements.



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	II.C.1.n NEI QA Task Force	Remove the first parenthetical - the role to the QA is to assure the QA program related to design is effectively implemented	II.C.1.n is the same as the regulation in 10 CFR 50.34(f)(3)(iii)(H). The Statement of Considerations for this regulation (47 FR 2298, January 15, 1982) indicates that the purpose to clarify that the objective of this provision is design documents are reviewed by individuals knowledgeable and qualified in QA to ensure the documents contain the necessary QA requirements. The first parenthetical is revised to be more consistent with this wording.
30.	II.C.1.n  J. McIntyre	Do not understand the intent of "The QA role in design and analysis activities is defined."	Please see the response to No. 29. No additional response is required.
31.	II.C.1.o NEI ML061040113	This section is redundant with C.1.b.	Section II.C.1.b discusses proper translation of design inputs to design outputs in the design process. Section II.C.1.o discusses the establishment of measures for the suitability of the application of materials to the design process. The two do not appear to be related. No revision is required.
32.	II.C.2  J. McIntyre	The heading of this appears incorrect or the order of placement is incorrect. Design verification can be accomplished through design reviews, alternate calculations, and/or qualification testing. I believe letter b. "Verification methods include..." should come first and then a. "Design inputs, processes..."	The staff agrees with the comment. This comment is incorporated.

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33.	II.C.2 NEI ML061040113 Progress Energy ML061110355	<p>This paragraph starts out talking about design verification and then goes into design review, which is an acceptable method of design verification. The requirements for these two should not be mixed.</p> <p>NQA-1 for Design Review also includes the question, "Is the design output reasonable compared to the inputs?" This is not included in the SRP. Questions 6, 7, and 8 at the top of page 10, although good questions have no basis in Appendix B or NQA-1 and should be deleted.</p>	<p>See response to #32.</p> <p>This comment is incorporated. C.2.a(6), (7), and (8) are deleted and "Is the design output reasonable compared to the inputs?" is added</p>
34.	II.C.2.e  J. McIntyre	The words "and before its installation becomes irreversible..." apply to construction only.	See response to comment #35.
35.	II.C.2.e NEI ML061040113 Progress Energy ML061110355	<p>The word "independent" is not needed here. It is redundant in that it is already established (reference II.C.1.d) that the design verification process must be independent.</p> <p>Delete the words "and before its installation becomes irreversible (requiring extensive demolition or rework)." This is a financial risk only not tied to nuclear safety.</p>	<p>The staff agrees with the comment. This comment is incorporated.</p> <p>The also staff agrees with the comment. This comment is incorporated.</p>
36.	II.C.2.f J. McIntyre	While these words "...can perform the design verification, provided..." are also in SRP 17.3, they seem to contradict Regulatory Guide 1.28.	See response to comment # 37.

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37.	II.C.2.f NEI ML061040113 Progress Energy ML061110355	<p>The phrase “in exceptional circumstances” is used here without basis or definition, it should be removed.</p> <p>Items (2) and (3) of this paragraph have no basis in Appendix B or NQA-1. Recommend they be removed and replaced with the wording from NQA-1 (1994), Supplement 3S-1, Supplementary Requirements for Design Control, Section 4.</p>	<p>The staff agrees with the comment. This comment is incorporated.</p> <p>The paragraph is changed to state, “The designer’s immediate supervisor can perform the design verification, provided; the supervisor did not specify a singular design approach, or rule out certain design considerations, and did not establish the design inputs used in the design, or provided the supervisor is the only individual in the organization competent to perform the verification.”</p>
38.	II.C.2.h NEI ML061040113 Progress Energy ML061110355	<p>The word “approved” in the second sentence should be “proven” to be in accordance with NQA-1. A proven design, as stated in NQA-1 is different from an approved design.</p>	<p>The staff agrees with the comment. This comment is incorporated.</p>
39.	II.D.1  J. McIntyre	<p>Does 10 CFR 50.55(e) apply to vendors and why would you need to put it in a procurement document?</p>	<p>10 CFR 50.55(e) does not provide provisions for vendors. Therefore, the reference to 10 CFR 50.55(e) in II.D.1 is deleted.</p>
40.	II.D.2.f & h NEI ML061040113 Progress Energy ML061110355	<p>The ‘date of submission’ in paragraph h is in reference to the documentation required by paragraph f. The requirement to include the date of submission should be included in paragraph f.</p>	<p>The staff agrees with the comment. This comment is incorporated.</p>
41.	II.D.3 NEI ML061040113 Progress Energy ML061110355	<p>The SRP should address reviews of procurement documents before it discusses reviewing procurement document changes. Place this step after step II.D.4.</p>	<p>The staff agrees with the comment. This comment is incorporated.</p>

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42.	II.E.2 Progress Energy ML061110355	Delete paragraph II.E.2 since it is not specific to instructions, procedures, or drawings. The paragraph should be relocated to Section K, "Test Control."	The staff agrees that II.E.2 is not specific to this section. However, the staff has determined that II.E.2 should be moved to II.B.3.
43.	II.E.2 NEI ML061040113	<p>Insert "as prescribed in instructions, procedures and/or drawings" at the end of the first sentence of item 2.</p> <p>This should be addressed under subsection B (Quality Assurance Program) as it is in 10 CFR 50, Appendix B since this applies to numerous activities. The acceptance criteria of E.1 would then encompass the inclusion of appropriate control of conditions affecting the quality of the work into implementing procedures.</p>	<p>To avoid duplication of wording, the staff will not incorporate this comment. All quality activities are expected to be conducted with written documentation.</p> <p>The staff agrees with the comment. This comment is incorporated. Please see the response to No. 42. No additional response is required.</p>
44.	II.F.2 NEI ML061040113	This identifies "computer codes" as a document to be controlled. Computer codes are software not documents. Software is controlled as described in Section X. Reference to computer codes should be removed from this review section. Distribution of controlled documents should be clarified to equal electronically publishing of approved procedures made available through work area computers.	The staff agrees with the comment. This comment is incorporated.
45.	II.F.6 NEI ML061040113	This section is redundant to the rest of the section.	The staff does not wholly disagree with this statement. However, the staff believes the requirements act as a clarification to other statements in this section. No revision is required.

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46.	II.F.8  J. McIntyre	The requirement to review procedures no less frequently than every 2 years applies to operations only and is obsolete.	The staff agrees that this 2-year review interval applies to procedures used during the operational phase. Therefore, II.F.8 is revised to state that the 2-year review applies to procedures used during the operational phase. The staff disagrees that this 2-year interval is obsolete. Although, licensees have proposed alternatives to the 2-year procedure review interval that the NRC has approved in SEs, QAPDs include a description of how procedures are to be periodically reviewed.
47.	II.F.8.a, b, c, d, and e NEI ML061040113	What is the source of this 2 year requirement? Item 8.e. is already a requirement under Section R "Audits," and the threshold for needing a 2 year review would never be met. In addition, the focus of these requirements appear to be directed to operations and would not be applicable to ESP, DCD, or a 48 month construction schedule.	Please see the response to No. 46. No additional response is required.
48.	II.F.8.e NEI ML061040113	"QA program audit of procedures is conducted every 2 years." We do not do an audit of procedures alone although it is a part of almost every audit we do. We do have a procedure requirement that requires the owner to review annually the procedure to see if it is current or needs changes.	Please see the response to No. 46. No additional response is required.
49.	II.F.11  J. McIntyre	The requirement for temporary procedure changes is applicable to operations.	The staff agrees that the review of temporary procedure changes applies during the operational phase. Therefore, II.F.10 and 11 are revised to state that they apply during the operational phase.

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50.	II.F.12 Clinton Elridge ML060450068	Requires QA personnel to review and concur with all safety-related procedures. These reviews were eliminated at many sites because they added little value and were a severe cost burden. At least one plant's QA organization reviewed the results of several hundred of their procedure reviews and determined that their only comments were editorial. Recommend limiting required QA reviews to programmatic procedures that establish QA program requirements and procedure changes that affect those requirements. The reviews should also focus on alignment of the procedures with QA program commitments, as opposed to technical, format, and editorial correctness. Other reviewers already check technical, editorial, and format correctness.	10 CFR 50.34(f)(3)(iii)(C) requires that QA review and concur with quality related procedures associated with design, construction and installation. However, F.12 is redundant with C.1.q, therefore F.12 is deleted.
51.	II.F.12 J. McIntyre	The requirement for the QA organization to review and concur with procedures is obsolete.	Please see the response to No. 50. No additional response is required.
52.	II.F.13 NEI ML061040113	Requires provisions in place to ensure that procedures provide the best possible instructions. While we have provisions in place to provide feedback and review the term "best possible instructions" leaves too much for interpretation. Recommend changing this sentence to read, "Provisions are in place to continually improve work instructions through reviews and incorporation of feedback from users."	The staff agrees with the comment. This comment is incorporated.
53.	II.F.13 Clinton Elridge ML060450068	Requires program provisions for providing the best possible work instructions. Recommend changing this sentence to read, "Provisions are in place to continually improve work instructions through reviews and incorporation of feedback from users."	See response to Comment # 52.
54.	II.G General comment: NEI ML061040113	Safety-related supplier programs are designed to meet 10 CFR 50 Appendix B. This section appears to impose new NQA-1 requirements on suppliers. This program should only impose Appendix B requirement on suppliers and how suppliers implement that program is up to each supplier.	Section I, "Areas of Review," of the draft SRP chapter discusses applicability. Suppliers are not discussed. No revision is required.

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55.	II.G.1 NEI ML061040113	Change words “are of acceptance quality” to “conform to specified requirements.”	The staff agrees with the comment. This comment is incorporated.
56.	II.G.9 NEI ML061040113 Progress Energy ML061110355	To be consistent with NQA-1, this paragraph should be written to allow one or more of the methods for the evaluation and selection of procurement sources rather than requiring all three. Reference NQA-1 and ANSI N45.2.13.	The staff agrees with the comment. The sentence will be changed to read, “Measures for evaluation and selection of procurement sources, and the results therefrom, are documented and include any or all of the following.”
57.	II.G.10.g, h, and i NEI ML061040113 Progress Energy ML061110355	The basis for these requirements is not clear. There are no bases found in Appendix B, NQA-1, or RG 1.33. Therefore, these requirements should be deleted in the SRP.	Comment not incorporated. The basis for these provisions are from NQA-1 (1994), Supplement 4S-1, items 3.b and 3.c, and Supplement 7S-1, Paragraph 5.

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58.	II.G.12 NEI ML061040113	<p>The word "of" should be inserted between "processing" and "nonconforming" to improve the sentence structure.</p> <p>What is the source of this requirement? This violates the QA organizations independence requirements (Section R, item 3).</p> <p>The purchaser and suppliers personnel responsible methodology for the processing nonconforming items are designated in writing. Insert "methodology" as shown. This is too prescriptive and seems to be a new requirement for suppliers. To be consistent with NQA-1, this paragraph should state "The purchaser and supplier shall establish methods for disposition of items and services that do not meet procurement documentation requirements." This currently reads that the persons responsible for processing NRCs are designated in writing, rather than the program being designated or documented in writing.</p> <p>This is too prescriptive and seems to be a new requirement for suppliers. The industry relies upon the suppliers QA program to resolve nonconformances and does not need to see "ALL" nonconformances generated, only those which document noncompliance to purchase requirements.</p>	<p>See response below.</p> <p>See response below.</p> <p>The sentence in II.G.12 is revised to state, "The purchaser and supplier are required to establish a documented method for the disposition of nonconforming items."</p> <p>See response above.</p>
59.	II.G.13 J. McIntyre	Revise 1 <sup>st</sup> sentence to read "The supplier is required to send the purchaser all nonconforming reports <i>from procurement documentation requirements</i> generated during..."	The staff agrees with the comment. This comment is incorporated.
60.	II.G.13.c NEI ML061040113	e.g. should be i.e	The staff agrees with the comment. This comment is incorporated.



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61.	II.G.14 J. McIntyre	The provisions listed are not in agreement nor in total concert with NQA-1.	This comment is incorporated. First sentence revised to state "The purchaser is required to approve the supplier's recommended disposition and technical justification for nonconformances that involve any of the following:"
62.	II.G.14 NEI ML061040113	<p>The purchaser is required to approve disposition of nonconformances that involve any of the following: implies that the supplier stop work and require the purchaser to resolve the nonconformances. Items that do not meet the purchase order specifications will be either rejected at receipt inspection or evaluated and accepted.</p> <p>Draft SRP states: "The purchaser is required to approve nonconformances that involve any of..." This should say: "The purchaser is required to have authority to reject or approve nonconformances that involve any of..."</p>	<p>The staff does not believe that the statement implies a supplier stop work. No revision is required.</p> <p>The staff believes that the existing statement and the proposed statement express the same purpose. It has always been considered implicit that the purchaser is required to ensure appropriate corrective actions has been taken. No revision is required.</p>
63.	II.G.15 NEI ML061040113	Delete words "certified material test certificate."	Please see the response to No. 64. No additional response is required.
64.	II.G.15 J. McIntyre	The provisions listed are not in agreement nor in total concert with NQA-1. Should "certified material test certificate" be a means to accept an item or related service? Not listed in NQA-1, etc.	This comment is incorporated. The phrase "certified material test certificate" is deleted from II.G.15.
65.	II.G.16 NEI ML061040113	For consistency with other parts of the Review Standard, the paragraph should include the use of pre-installation tests as a part of the acceptance methods.	II.G.16.b is revised to read, "The specific procurement requirements met by the purchased material or equipment, such as codes, standards, <i>postinstallation tests</i> , and other specifications, are identified.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
66.	II.G.18 & 19 NEI ML061040113 Progress Energy ML061110355	To be consistent with NQA-1, these two paragraphs should be relocated to Section D, "Procurement Document Control."	The staff agrees with the comment. This comment is incorporated.
67.	II.G.20  J. McIntyre	Source verification should only be done when required for basic components.	<p>This comment is not incorporated. The provisions in II.G.20 are consistent with NQA-1 Section 8.2.2, Source Verification, which states the following:</p> <p>When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and it shall be implemented to monitor, witness, or observe activities. Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon Purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the Purchaser, and to the Supplier.</p>
68.	II.G.22 NEI ML061040113	When post-installation testing is used for acceptance of purchased items, post installation test requirements and acceptance documentation are required to be mutually established. Comment: Insert "for acceptance of purchased items" as shown above to differentiate from other types of post installation testing.	The staff agrees with the comment. This comment is incorporated.
69.	II.H NEI ML061040113	Identification and control of materials, parts, and components, (not applicable to DC applicants): Added "Not applicable to DC"	A sentence was added after the title that states, "(Not applicable to DC applicants)."

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
70.	II.H.2  J. McIntyre	Does this agree with NQA-1 language? Do you have to put identification on each item or should it be "when required?" (See H.4 – where it states "to the maximum extent possible.")	<p>This comment is not incorporated. The language in II.H.2 is based on Criterion VIII of Appendix B to 10 CFR Part 50, Identification and Control of Materials, Parts, and Components, which states the following:</p> <p>Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures shall assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item. These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components.</p> <p>An identification on each item is only one acceptable identification method. Other methods are also acceptable.</p>
71.	II.I NEI ML061040113	Control of special processes (not applicable to DC and ESP applicants): Added "Not applicable to DC and ESP."	A sentence was added after the title that states, "(Not applicable to DC and ESP applicants)."
72.	II.I  J. McIntyre	Some of the sections do not appear to belong under Special Processes. For example, why are 4 and 9 included here?	The comment is incorporated. II.I.4 and II.I.9 are relocated to Section M.
73.	II.I.2 J. McIntyre	The definition in the Introduction to NQA-1 should be used as the description of special processes.	The staff agrees with the comment. This comment is incorporated.
74.	II.I.4 Clinton Elridge ML060450068	This paragraph deals with special handling tools and equipment, not control of special processes. Recommend moving it to section M, "Handling, Storage, and Shipping."	See response to Comment #72.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
75.	II.I.4 NEI ML061040113 Progress Energy ML061110355	<p>Special handling tools and equipment are not considered special processes (Reference NQA-1 (1994) Supplement 13S-1, Section 3.3). To be consistent with NQA-1, this paragraph should be moved to Section M Handling, Storage, and Shipping.</p> <p>This information should be a part of the acceptance criteria related to 10 CFR 50, Appendix B, Criterion XIII (subsection M of the SRP), regarding handling of material. Although special processes may be utilized in determining the acceptability of the special handling tools and equipment, the actual items are a part of handling and are not a special process in themselves.</p>	<p>See the response to Comment # 72.</p> <p>See the response to Comment # 72.</p>
76.	II.I.5  J. McIntyre	Add the word “travelers” in the 1st sentence. “Processes are controlled by instructions, procedures, drawings, checklists, <i>travelers</i> , or...”	This comment is not incorporated. The meaning of “traveler” is not clear nor is this term defined in NQA-1.
77.	II.I.9 NEI ML061040113 Progress Energy ML061110355	<p>Qualifications of operators of special handling equipment are not considered special processes (Reference NQA-1 (1994) Supplement 13S-1, Section 3.4). To be consistent with NQA-1, this paragraph should be relocated to Section M, “Handling, Storage, and Shipping.”</p> <p>This information should either be addressed under subsection M of the SRP related to handing of materials, or under subsection B (Quality Assurance Program), where it is required that appropriately trained and qualified individuals are used to implement the requirements of the QA program.</p>	<p>See response to Comment #72.</p> <p>See response to Comment #72.</p>
78.	II.I.9 Clinton Elridge ML060450068	This paragraph deals with operators of special handling tools and equipment, not control of special processes. Recommend moving it to section M.	See response to Comment #72.
79.	II.J.2  J. McIntyre	In the 2 <sup>nd</sup> sentence, the word “techniques” may read better to be “methods”. These are not the same thing.	The staff agrees with the comment. This comment is incorporated.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
80.	II.J.4 J. McIntyre	Is the intent to have all inspection results reviewed by management?	Please see the response to No. 81. No additional response is required.
81.	II.J.4 NEI ML061040113 Progress Energy ML061110355	To be consistent with NQA-1, 10S-1, Supplementary Requirements for Inspection, Section 7.3, "reviewed by management" should be changed to "approved by authorized personnel." ANSI N 45.2.6 1978 allows a Level II or Level III inspector to "Evaluate the validity and acceptability of Inspection, examination, and testing results." Recommend that the wording be changed to allow review by the personnel with the appropriate level of knowledge and qualification.	II.J.4 was based on a similar provision in Chapter 17.3 of NUREG 0800. After further review, the staff revised the statement to read, "Inspection results are documented by the inspector, reviewed by <i>authorized personnel qualified to evaluate the technical adequacy of the inspection results</i> , and controlled by instructions, procedures, and drawings."
82.	II.J.8 NEI ML061040113 Progress Energy ML061110355	NQA-1 10S-1, Supplementary Requirements for Inspection, Section 9(e) requires that inspection records include the results or acceptability, not both. "Or" should be placed between results and acceptability.	The staff agrees with the comment. This comment is incorporated.
83.	II.J.9 J. McIntyre	Would not all inspections require inspection personnel to be qualified?	All inspection personnel would have to be trained but not necessarily qualified. For example, personnel inspecting for leakage during a routine ASME Code system pressure test of the reactor coolant system would have to be trained, but not qualified. No revision is required.
84.	II.K.4 J. McIntyre	Add the words "as applicable" in the 1 <sup>st</sup> sentence – "Test procedures are developed that include, <i>as applicable</i> ,..."	See response to Comment # 85.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
85.	II.K.4 NEI ML061040113	<p>“Inspection hold points” should be “test hold points.”</p> <p>Test Control: “Test procedures are developed that include calibrated instrumentation, instructions and prerequisites to perform the test, appropriate equipment, trained personnel, condition of test equipment.” Strike “include” and insert “specify the necessary” for clarification.</p>	<p>The staff agrees with the comment. This comment is incorporated.</p> <p>The staff agrees with the comment. This comment is incorporated.</p>
86.	II.K.7 J. McIntyre	Not sure what the basis of this requirement is and if the intent is for all test results.	This comment is incorporated. II.K.7 is based on a similar provision in Chapter 17.3 of NUREG 0800. After further review, the staff finds that it is inappropriate for management to review all inspection results. Therefore, II.K.7 is deleted.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
87	II.L Laurence Gradin ML061040116	<p>SRP Section 17.5 Area L, "CONTROL OF MEASURING AND TEST EQUIPMENT" pages 21 and 22 are a significant improvement and enhancement of 10CFR50 Appendix B, Criterion XII that only has 36 words in the criterion. An IEEE 498-1985 standard, "Standard Requirements For Calibration &amp; Control of Measuring &amp; Test Equipment use in Nuclear Facilities" with its 1990 replacement provided more definitive input on adequacy of calibration than existed in USNRC regulations. But both versions of IEEE 498 are withdrawn. The ASME endorsed the IEEE 498-1985 document in ASME NQA-1-1994, Subpart 2.16.</p> <p>The IEEE 498-1990 (update of the 1985 revision) document was withdrawn in favor of ANSI/NCSL Z540-1-1994, "Calibration Laboratories and Measuring and Test Equipment—General Requirements" by the IEEE Nuclear Power Engineering Committee after meeting between the USNRC, NIST, NCSL, ANSI, and others as it was understood that the USNRC would endorse the ANSI/NCSL Z540-1 document in a US NRC Regulatory Guide. The US Military endorsed ANSI/NCSL Z540-1 as a replacement to its decades old MIL Std 45662A. The nuclear industry through NUPIC has used a NUPIC checklist, "NUPIC COMMERCIAL GRADE SURVEY CHECKLIST CALIBRATION SERVICES" as no adequate detailed specification has been USNRC endorsed. This NUPIC checklist is considered to be seriously flawed by NIST in the NIST document, "U.S. Department Of Commerce, Technology Administration, National Institute Of Standards And Technology, Publication NISTIR 6989, Comparison Of ISO/IEC 17025 with The NUPIC Audit Checklist, May 2003".. NIST indicates use of ISO/IEC 17025-1999, "General requirements for the competence of testing and calibration laboratories" is superior.</p> <p>The coverage in ISO/IEC 17025 -2005 (current version) is very good in general but lacks some details of Test</p>	<p>The staff agrees that IEEE-498-1985 and 1990 are withdrawn. Section II.U.2.i requires a commitment to Subpart 2.16 of NQA-1-1994. Subpart 2.16 is one paragraph that endorses IEEE 498-1985 for calibration and control of M&amp;TE. Therefore, Section II.U.2.i is deleted.</p> <p>Applicants have not asked that the staff endorse ANSI/NCSL Z540-1-1994 and ISO/IEC 17025 - 2005, however, the staff would consider reviewing these standards if requested by an applicant or licensee.</p>

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
88.	II.L.3 J. McIntyre	The words in the 1 <sup>st</sup> sentence "and after use" are not in NQA-1.	Comment incorporated. II.L.3 relocated to II.L.5 and revised to be consistent with NQA-1-1994.
89.	II.L.5 & 8 NEI ML061040113 Progress Energy ML061110355	Both of these paragraphs are beyond the requirements of both 10CFR50 Appendix B and NQA-1. To be consistent with NQA-1, Supplement 12S-1, Section 3.1, SRP 17.5 should simply indicate that if no nationally recognized standard exists, the basis for calibration shall be documented.	II.L.5 is revised to be consistent with NQA-1-1994.  II.L.8 is deleted.
90.	II.L.5 and 10 J. McIntyre	These requirements appear to be in conflict. Sometimes it is not possible to have the "secondary standards...verified against the primary standards which must be traceable to the National Institute of Standards and Technology."	II.L.5 and 10 are combined as a new II.L.5. The reference to the National Institute of Standards and Technology has been removed.
91.	II.L.6 Clinton Elridge ML060450068	The term, "out of calibration," can mean that the equipment is simply past its calibration due date. Recommend using the term, "out of tolerance," in three places in this paragraph. These actions should only be required if the equipment is found to be reading outside of its tolerance band.	Comment not incorporated. II.L.6 is consistent with NQA-1-1994.
	II.L.8.h.and i NEI QA Task Force	These paragraphs are in addition to the SER approved for APS. Where did these two paragraphs originate? What does paragraph i. (The alternative method is applicable to sup suppliers of calibration service supplies provided the above conditions are met) mean? Industry recommends to reword as follows: "The alternative method may be applied to sub suppliers of calibration service suppliers with an Appendix B QA program."	Paragraphs h and i were added as clarifications. Paragraph i is self explanatory. The wording suggested by the commenter is not correct. This alternative method applies to subsuppliers that do not have an Appendix B QA program.
92.	II.L.10 NEI ML061040113	What about NAVLAP and A2LA which are now being accepted by NRC as an acceptable certifier for calibration.	This comment is incorporated.



No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
93.	II.L.10 Clinton Elridge ML060450068	This requires all standards to be traceable to NIST. This is not always practical and is inconsistent with paragraph L.5. Recommend replacing NIST with, "nationally recognized standards or accepted physical constants. When this is not possible, the basis for the calibration shall be documented." Some types of standards are not calibrated by NIST. They sometimes refer you to another country's national laboratory, such as the National Resource Council of Canada, which NIST has formally recognized. Some types of standards are calibrated through accepted ratio techniques and no calibration standard is used.	See response to Comment #90.
94.	II.M.3 NEI ML061040113 Progress Energy ML061110355 J. McIntyre  Clinton Elridge ML060450068	Typographical error: 'perceiving' should be 'preservation.'	The staff agrees with the comment. This comment is incorporated.
95.	II.N.1 NEI ML061040113 Progress Energy ML061110355	This paragraph is trying to combine too much information. Criterion N.1 should not address operating status since operating status is already included in Criterion N.3.	The staff agrees with the comment. This comment is incorporated.
96.	II.N.1 Clinton Elridge ML060450068	This long sentence tries to cover two paragraphs from Criterion XIV of Appendix B. It doesn't make sense, as written. For example, you can't verify test status before receipt and doing so wouldn't prevent inadvertent operation. Recommend separating inspection and test status from operating status and using the words from Appendix B, Criterion XIV.	Please see the response to No. 95. No additional response is required.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
97.	II.N.5 Clinton Elridge ML060450068	This paragraph on temporary modifications doesn't fit in the "Inspection, Test, and Operating Status" section. Recommend moving it to section C. You may also want to specify more stringent controls. Jumpers and temporary modifications have sometimes been left in place for extended periods of time without being reviewed for compliance with 50.59. I believe measures should be in place to verify that they are not a change to the Technical Specification, and do not require prior NRC approval.	It is not the intent of this SRP chapter to address 10 CFR 50.59 requirements. No revision is required.
98.	II.O NEI ML061040113 Progress Energy ML061110355	This section should, but does not, address the 10CFR50 Appendix B Criterion XV requirement for identification, documentation, segregation, disposition, or notification to affected organization. Similarly, it should, but does not, address reexamination of repaired or reworked items.	The staff agrees with the comment. This comment is incorporated by revising II.O.1. However, for the concern related to reexamination, the staff believes this is addressed by II.O.5, which requires appropriate design controls to be applied for identified nonconformances.
99.	II.O.1 J. McIntyre	The clarification in ( ) concerning nonconforming items is not in agreement with other definitions of the term.	This comment is incorporated. The NQA-1 definition for nonconformance is used.
100.	II.O.1 NEI ML061040113 Progress Energy ML061110355	<p>"Quality requirements" should be "specified requirements." Last sentence should read "They are identified, documented, and evaluated."</p> <p>II.O.1 The second sentence in O.1 is redundant to the first sentence in Section O.2. Delete the second sentence in Criterion O.1.</p>	<p>Comment incorporated except that the phrase "quality requirements" was deleted based on the response to comment #99.</p> <p>The second sentence in II.O.1 is deleted.</p>
101.	II.O.2 NEI ML061040113	Words "accepted, rejected, repaired or reworked" should be deleted and the word "dispositioned" should be put in their place.	The staff determined that the wording used in Appendix B has distinct definitions. This comment is not incorporated.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
102.	II.P.1 Clinton Elridge ML060450068	The last sentence states, "Corrective actions include actions to prevent repetition of the nonconformance." This is not always true for minor nonconformances. Appendix B requires this for significant conditions adverse to quality. Recommend changing this to say, "For significant conditions adverse to quality, corrective actions include..."	Please see the response to No. 103. No additional response is required.
103.	II.P.1 NEI ML061040113 Progress Energy ML061110355	<p>Requires that corrective actions include actions to prevent repetition of the nonconformance. This is a requirement for significant conditions adverse to quality and should not be required of all conditions adverse to quality. Recommend that wording of NQA-1-1994 Basic Requirement 16 be used that requires significant conditions adverse to quality have corrective action taken to preclude recurrence.</p> <p>This paragraph should be re-written to better explain the requirements of the corrective action process. The following wording is suggested: "A corrective action process is required to be established that includes prompt identification, documentation, classification, and correction of conditions adverse to quality. For significant conditions adverse to quality, the cause of the condition shall be determined and the corrective action taken to preclude recurrence. These shall be documented and reported to appropriate levels of management and follow-up action taken to verify implementation of corrective actions.</p>	<p>See response below.</p> <p>The staff agrees with the comment. This comment is incorporated.</p>
104.	II.P.1 J. McIntyre	<p>Is the intent for a cause analysis for all conditions adverse to quality or just significant conditions?</p> <p>Last sentence – should the word “repetition” be “recurrence”?</p>	<p>Please see the response to No. 103. No additional response is required.</p> <p>The staff agrees with the comment. This comment is incorporated.</p>

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
	II.P.1 NEI QA Task Force	The first sentence identified the components of a corrective action system. The remainder of the paragraph applies to significant conditions adverse to quality. Recommend removing the cause analysis from the first sentence and making the remaining sentences a separate paragraph.	Comment incorporated as suggested.
	II.P.3 NEI QA Task Force	<p>The requirement appears to mix identification of conditions by all personnel with the requirement for auditor to suggest, recommend, or provide solutions to the problems and verify resolution of the issue.</p> <p>Recommend a period after the word quality and remove the latter part of the sentence.</p>	Comment incorporated as suggested.
105.	II.P.3 NEI ML061040113 Progress Energy ML061110355	This paragraph is an industry good practice and should be deleted. Managements "attitude" regarding the 'fostering of a "no-fault" attitude towards identification of conditions adverse to quality' is something that would be evaluated during inspections and not evaluated via this SRP during a review of the Quality Program description.	The staff agrees with the comment. This comment is incorporated.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
106.	II.P.4 NEI ML061040113 Progress Energy ML061110355	<p>Requires performance and verification personnel to identify conditions that are adverse to quality and suggest, recommend, or provide solutions to the problems: and verify resolution of the issue. The current requirements are to “provide recommendations for correcting program deficiencies or improving the quality assurance program as appropriate”, and to “confirm that corrective actions are accomplished as scheduled.” Recommend using wording in NQA-1 1994, Basic requirement 16 and Basic Requirement 18 with respect to follow-up requirements.</p> <p>This should not be limited to performance and verification personnel, but to all personnel. Also, to be in line with Appendix B, the words “are required” should be replaced with “have sufficient authority and organizational freedom.” With this change, the paragraph should be moved to Section A, “Organization.”</p>	<p>Please see the response to No. 107. No additional response is required.</p> <p>Please see the response to No. 107. No additional response is required.</p>
107.	II.P.4 Clinton Elridge ML060450068	As written, this sentence requires QA personnel to provide solutions for the problems they identify. Requiring this is inappropriate and can create a conflict of interest. It may discourage identification of a problem in a situation where the QA person doesn't know how to solve it. Recommend changing this to read, "The program requires all personnel to identify conditions adverse to quality and specifies how resolution is verified, and by whom. Anyone may suggest or recommend solutions to problems they identify, if known."	The staff agrees with the comment. This comment is partially incorporated. The provision is revised to stated "The program requires all personnel to identify conditions adverse to quality."
	II.P.4 NEI QA Task Force	Appears to be redundant to paragraph 1. Recommend removing this paragraph.	See response to comment 107.
108.	II.P.5 J. McIntyre	This better belongs in Section O – it really applies to items and not services.	The staff agrees with the comment. This comment is incorporated.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
109.	II.P.5 NEI ML061040113 Progress Energy ML061110355	This paragraph should be relocated to Section O, "Nonconforming Material, Parts, and Components," to be consistent with NQA-1, 15S-1, "Supplementary Requirements for the Control of Nonconforming Items," Section 4.5.	Please see the response to No. 108. No additional response is required.
110.	II.P.6 Progress Energy ML061110355	There is no basis for this requirement in Appendix B, NQA-1-1994, or ANSI N18.7, especially the requirement to have demonstrated competence in the specific area they are evaluating. The portion on demonstrating competence is more appropriate for inspection guidance.	The staff determined this is a requirement for nonconforming materials, parts, or components. II.P.6 will be relocated to II.O.4. This provision is revised to be consistent with Section 4.3 of Supplement 15S-1 of NQA-1-1994.
111.	II.P.6 NEI ML061040113	There is no basis for this requirement in Appendix B, NQA-1-1994, or ANSI N18.7. The portion on demonstrating competence is more appropriate for inspection guidance.	Please see the response to No. 110. No additional response is required.
112.	II.P.7 NEI ML061040113 Progress Energy ML061110355	This paragraph is already jumping to a conclusion and corrective action. This paragraph is not needed here and, if included at all, should be in Section C, "Design Control."	Comment is not incorporated. P.7 is from NQA-1, Supplement 3S-1, Section 5. P.7 moved to C.1 and C.1.p.
113.	II.P.8 NEI ML061040113 Progress Energy ML061110355	The term "program" for root cause determination is unclear. "Measures" within the Corrective Action Program to determine the root cause are more appropriate.	The staff agrees with the comment. This comment is incorporated.
114.	II.P.8 J. McIntyre	10 CFR 50 Appendix B, Criteria XVI only requires that the cause of significant conditions adverse to quality be determined, this states that the <i>root</i> cause be determined.	The staff agrees with the comment. This comment is incorporated.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
115.	II.P.9 J. McIntyre	This better belongs in Section O – it really applies to items.	This comment is not incorporated. The staff determined that conditions that are adverse to quality can apply to more than items.
116.	II.Q J. McIntyre	(Overall Comment) This section appears to be a mix and match of Generic Letter (GL) and Regulatory Issue Summary language. Should stick with one or the other.	This comment is not incorporated. The commenter is correct in that the provisions in II.Q are from generic letters and regulatory issue summaries. The goal is to place all the QA program provisions in one place.
117.	II.Q General NEI ML061040113 Progress Energy ML061110355	The Records Section should concentrate on following the requirements of 10 CFR 50 Appendix B and NQA-1 Basic Requirement 17 and remove any requirements relative to Electronic Media. This should be addressed in 17.5.II.U for QA Program Commitments in the commitments to NIRMA. Reference II.U.k, l, m, and n.	The staff evaluated the NIRMA guidance. Based on that review the staff determined which specific NIRMA guidance was related to quality assurance and what the staff would expect to see implemented relative to electronic media. No new requirements are being imposed. No revision is required.
118.	II.Q.1 NEI ML061040113 Progress Energy ML061110355	Remove the details of this paragraph and change the term 'program' to 'measures.' The paragraph would read "Measures are required to ensure that sufficient records of completed items and activities affecting quality are appropriately stored.	The staff agrees with the comment. This comment is incorporated.
119.	II.Q.3 NEI ML061040113 Progress Energy ML061110355	Is GL 88-18 limited to optical disks?  This paragraph should address all records and not be specific to electronic media. Indicate that the measures shall define the records storage media and that these measures ensure that the media is appropriate, suitable for the capture or storage of records, and error/defect free.	No, see comment below.  This is addressed in II.Q.3. No additional revision is required.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
120.	II.Q.3 Clinton Elridge ML060450068	The last sentence in this section states, "The applicant's program must implement GL 88-18, "Plant Record Storage on Optical Disks." This Generic Letter is obsolete and only allows electronic storage on optical disks. Storage technology has changed significantly since 1988 and magnetic storage media are now in common use for important record storage. The draft SRP lists several NIRMA standards on page 17.5-38 which provide more current controls for electronic record storage. If you feel compliance with the Generic Letter is still necessary, I recommend changing the requirement to, "If the applicant proposes to use optical disk storage, his program shall implement Generic Letter 88-18," Plant Record Storage on Optical Disks," for this type of record storage."	This comment is not incorporated. Optical disks include "magnetic media."Optical disks are defined as a storage medium from which data is read and to which it is written by lasers and includes Compact Disks, Mini-Disks, Digital Versatile Discs and High-Definition DVD's. Therefore, GL 88-18 is still applicable.
121.	II.Q.4 NEI ML061040113 Progress Energy ML061110355	"Electronic," in the second sentence, should be changed to "all." This paragraph does not need to apply to only electronic records.	The staff agrees with the comment. This comment is incorporated.
122.	II.Q.5 NEI ML061040113 Progress Energy ML061110355	Duplications of C.1.G.  Recommend moving this paragraph to Section C, Design Control to be consistent with NQA-1, 3S-1, "Supplementary Requirements for Design Control," Section 7.	The staff determine II.C.1.G and II.Q.5 were not a duplication. No revision required.  The staff determined that the topic had more relevance to records than design control. No revision required.
123.	II.Q.6 NEI ML061040113 Progress Energy ML061110355	Duplications of J.8 & K.6.  Recommend moving this paragraph to Section J, "Inspection," to be consistent with NQA-1, 10S-1, "Supplementary Requirements for Inspection," Section 9.	See response below.  The staff determined to delete II.Q.6, as it was repetitive to II.J.8 and II.K.6.
124.	II.Q.6 J. McIntyre	May better belong in Sections J and K on Inspection and Test.	Please see the response to No. 123. No additional response is required.



No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
125.	II.Q.8 NEI ML061040113 Progress Energy ML061110355	<p>Recommend removing the word 'location' in the first sentence. Record storage locations are subject to change and identifying the location in the QA Program Description is not necessary provided the location used meets the applicable requirements.</p> <p>Although training is necessary, it should be moved to the training section and not included in the QA Records section.</p>	<p>The staff determined that including the location was necessary. Other standards, codes and/or regulatory agencies require predetermined locations for records to meet their respective requirements.</p> <p>The current training provisions in Section S focus on quality assurance, and Section T focus on inspection and test personnel. QA records training is beyond the scope of what is in Sections S and T. Therefore, the provisions of QA records training is not moved.</p>
126.	II.Q.10 NEI ML061040113	<p>Records: Documents are considered valid records only if stamped, initial, authenticated, or signed and dated by authorized personnel. This authentication may take ... For electronic records, authentication is accomplished by manually affixing a seal, signature, and electronic representation (user ID/password combination, digital signature) or other acceptable method (process controls) that ensures genuineness, validity, or reliability. Authorized personnel ... Insert "(process controls)" following method as shown above. Access to electronic record generation normally has process controls that limit access.</p>	<p>The statement is revised to read, "For electronic records, authentication is accomplished by manually affixing a seal, signature, and electronic representation (user ID/password combination, digital signature) or other acceptable <i>process controls</i> that ensure genuineness, validity, or reliability."</p>
127.	II.Q.15 J. McIntyre	<p>This applies to construction per Regulatory Guide 1.28 – it should not be imposed here.</p>	<p>This comment is incorporated. II.Q.15 is deleted.</p>
128.	II.Q.15 NEI ML061040113 Progress Energy ML061110355	<p>Footnote 1 The use of the term audit checklists used in the footnote infers that audit checklists are QA Records. Audit checklists are not typically considered to be QA records. Recommend removing audit checklists from the footnote.</p>	<p>See response to #127.</p>
129.	II.Q.17 through Q.19 J. McIntyre	<p>The reference should be made to the RIS without the necessity of putting in the detail, such as that contained on page 17-5.27.</p>	<p>This comment is not incorporated. The staff prefers to place the details in this SRP chapter.</p>

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
130.	II.Q.19 NEI ML061040113	The last sentence should continue with “and that the record system hardware/software still supports the retrieval of the records.	The staff agrees with the comment. This comment is incorporated.
131.	II.Q.24 J. McIntyre	<p>The words “qualification” and “certification” appear to be utilized interchangeably. These words do not mean the same thing.</p> <p>This section only applies to Inspectors and Testers – not everyone.</p>	This comment is incorporated. II.B.24 is revised to use the term “certification” only and to specify that it only applies to inspection and test personnel.
132.	II.Q.24 NEI ML061040113 Progress Energy ML061110355	<p>Training and qualification records for inspection and test personnel are maintained as follows: This list is associated with inspection and test personnel. Add “for inspection and test personnel” as shown above.</p> <p>The Training and Qualification details would be more appropriately addressed in the specific sections and not addressed in the QA Records section.</p>	<p>The staff agrees with the comment. This comment is incorporated.</p> <p>The staff agrees with the comment. This comment is incorporated.</p>
133.	II.Q.25 NEI ML061040113 Progress Energy ML061110355	<p>An audit process is developed and implemented. Periodic inspections of electronic records management systems, software applications, and media are performed to ensure electronic records retrievability, integrity and retention period. Auditing of software applications should not be included in the Records audit criteria. Criteria X specifies the requirements for digital equipment software verification and validation quality controls.</p> <p>The reference to the audit process would be more appropriately addressed in the Audit section of the SRP, Section R, and not in Records.</p>	<p>The discussion is on the hardware/software necessary to properly maintain electronic records, not on software applications used in safety related applications elsewhere on-site. No additional revision is necessary.</p> <p>The staff determined that the appropriate location for this requirement is II.R.5.</p>

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
134. a	II.R General Comment NEI ML061040113 Progress Energy ML061110355	Prescribed audit frequencies should acknowledge that a grace period for scheduling purposes is acceptable.	<p>II.R.1 was revised to read as follows:</p> <p>Internal Audits</p> <p>“Internal audits of organization and facility activities, conducted prior to placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter. Internal audits of activities, conducted after placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area within a period of two years.</p> <p>“Internal audit frequencies of well established activities, conducted after placing the facility in operation, may be extended one year at a time beyond the above two-year interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. The evaluation should include a detailed performance analysis of the functional area based upon applicable internal and external source data and due consideration of the impact of any function area changes in responsibility, resources or management. However, the internal audit frequency interval should not exceed a maximum of four years. If an adverse trend is identified in the applicable functional area, the extension of the internal audit frequency interval should be rescinded and an audit scheduled as soon as practicable.”</p>

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
1.34 b		<p>The content of this section includes independent safety committees, audits, and other independent assessments. The requirements for each differ too much to try to combine them into a single section. The requirements for audits needs to be separated from the requirements for independent safety committees and independent assessments. The current standards in use have caused too much confusion because they have not defined clearly where the requirements need to differ. This section seems to be a combination of the ANSI N 18.7/ANS 3.2 1976 requirements and the ANSI N 45.2.12 requirements. Since the N 45.2 series requirements have been incorporated into NQA-1 and the 1994 edition has been authorized through the SER process, this section should be changed to be in line with that standard. The 1976 version of ANS 3.2 has been revised several times and been reworded to be more in line with NQA-1. The specific areas called out in this section should be split. Section Z. page 17.5- 49 should have the requirements for independent safety committees spelled out in that section.</p> <p>This section seems to mix assessment and audit throughout. If there is an intent to address both, then there should be some separation. A subsection for each would be more helpful and provide additional clarification.</p>	<p>This comment is incorporated. All references to self assessments have been removed as follows.</p> <ol style="list-style-type: none"> <li>1. The phrase independent assessment is deleted from A.5.</li> <li>2. R.1 is deleted.</li> <li>3. R.2 is deleted.</li> <li>4. R.5 is addressed in A.9 and B.1 and therefore deleted.</li> <li>5. The first sentence in R.10 is deleted.</li> <li>6. The word assessments is replaced with audits in Z.2.g, Z.3.b, Z.4 and Z.6.g.</li> </ol>
135.	II.R.1 J. McIntyre	<p>The way it is currently written may be interpreted as meaning that everyone needs to be auditors to perform the functions listed (i.e, safety committee activities, etc.).</p>	<p>The staff agrees with this comment. Therefore, II.R.1 is deleted.</p>

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
136.	II.R.1 Progress Energy ML061110355	This paragraph appears to be written with a SRP 17.3 assessment program in mind. The requirements of this paragraph are not addressed in Appendix B or NQA-1. It would be very difficult to implement this paragraph in a standard construction type QA Program. Is it the intent of the commission to implement this portion of the SRP for the operations phase only? If yes, segregate and clarify. Identify construction only and operations only requirements.	Please see the response to No. 134.b. No additional response is required.
137.	II.R.1 NEI ML061040113	<p>This paragraph appears to be written with a SRP 17.3 assessment program in mind. The requirements of this paragraph are not addressed in Appendix B or NQA-1. It would be very difficult to implement this paragraph in a standard construction type QA Program. There should be a separate program description for construction than for operations</p> <p>Requires audit personnel to be cognizant of day-to-day activities so that the auditor can advise management. This is really a requirement for the independent review committee or organization or the independent assessment function. As staffing has shifted and more plants are part of a fleet, the audit function may be completed by someone that is not assigned to the operating staff for that particular plant. The day-to-day oversight functions are generally separate from the audit function. Recommend rewording this section to be more in line with NQA-1 1994 Basic Requirement 18.</p>	<p>Please see the response to No. 135. No additional response is required.</p> <p>Please see the response to No. 135. No additional response is required.</p>

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
138.	II.R.2 NEI ML061040113 Progress Energy ML061110355	<p>This paragraph appears to be more in line with a SRP 17.3 QAPD in a performance based QA Program. It does not appear to be in alignment with Appendix B or NQA-1. Is it the intent to implement this portion of the SRP for the operations phase only? If yes, construction and operational requirements should be separated or clearly referenced as being applicable to only operations or only construction.</p> <p>Requires audits to be focused primarily on the quality of the end product with a secondary focus on procedures and processes. Recommend the wording be changed to require audits to be performed to “verify compliance with all aspects of the quality assurance program and to determine its effectiveness”. The wording of NQA-1-1994 Basic Requirement 18 should be used in this area.</p>	Please see the response to No. 135. No additional response is required.
	II.R.3.b NEI QA Task Force	Remove the word “above” from the first sentence.	Comment incorporated as suggested.
139.	II.R.4 J. McIntyre	Rewrite to read, “Audits are accomplished using instructions/procedures <i>and checklists</i> by qualified personnel.”	The staff agrees with the comment. This comment is incorporated.
140.	II.R.5 J. McIntyre	Rewrite 2 <sup>nd</sup> sentence to read, “These persons or organizations report regularly on the effectiveness of the program to <i>plant management...</i> ”	R.5 is addressed in A.9 and B.1 and therefore deleted.
	II.R.5 NEI QA Task Force	Its is recommended to move this paragraph to the Q section and change audit to audit or inspection process.	Comment not incorporated. See response to comment on II.Q.25. The term audit is used throughout the SRP Section.
141.	II.R.6 J. McIntyre	Not sure of the intent of this sentence or where it came from.	The provisions in II.R.6 are addressed in Section II.Z, “Independent Review,” of this SRP section. Therefore, II.R..6 is deleted.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
142.	II.R.7 Clinton Elridge ML060450068	The first sentence requires auditing all aspects for the applicant's QA program within a two-year period. The Commission has relaxed this requirement for several existing plants. They may extend audit intervals for specific program elements, if not prohibited by other regulations, when historical audit results indicate it is appropriate. Recommend adding this flexibility to SRP 17.5.	Please see the response to No. 134. No additional response is required.
143.	II.R.9 NEI ML061040113 Progress Energy ML061110355	This definition of audits sounds more like the definition of assessment. It appears that this section is partially performance based and compliance based. The audit or compliance based requirements should be separated for construction from the assessment or performance based requirements for operations.	The first sentence in R.9 is deleted. See response to #134.b.
	II.R.9 NEI QA Task Force	Modify to be consistent with NQA-1. "Audit results shall be documented and reported to and reviewed by responsible management." Clarify to read "Follow-up action of deficient areas is initiated as necessary."	Comment incorporated
144.	II.R.11 Progress Energy ML061110355	The requirement that the assessor's management review the audit results has no basis in Appendix B or NQA-1; however, this is a good requirement and should be within most utilities' assessment process.	The staff agrees with the comment. This comment is incorporated.
145.	II.R.11 NEI ML061040113	The requirement that the assessor's management review the audit results has no basis in Appendix B or NQA-1.	Please see the response to No. 144. No additional response is required.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
146.	II.R.13 NEI ML061040113 Progress Energy ML061110355	<p>This entire paragraph should be addressed in Section G, "Control of Purchased Material, Equipment, and Services." The first sentence should be changed to state "Vendor or Supplier" audits rather than procurement audits. This might be confused with internal audits of the procurement process.</p> <p>Annual evaluations of suppliers are documented and take into account any or all of the following, <del>where applicable</del>: Delete "where applicable" and add "any or all of the" as shown above. Revision clarifies any of the listed methods alone would be an acceptable method of annual evaluation.</p>	<p>The staff determined that supplier audits should be discussed under the general area of audits. However, the staff reorganized the section to more clearly distinguish the discussion on facility internal audits external supplier audits.</p> <p>The staff determined that the existing wording was more consistent with the NRC's intent for annual evaluations.</p>
147.	II.R.13 J. McIntyre	Revise 1 <sup>st</sup> sentence to read "Procurement audits <i>of suppliers</i> are accomplished as follows:	The staff agrees with the comment. This comment is incorporated.
148.	II.R.13.b.7 NEI ML061040113 Progress Energy ML061110355 Clinton Elridge ML060450068	Propose adding a paragraph 7 here to allow the use of calibration services or labs without performing audits if they provide commercial grade calibration services and are accredited to ANSI/ISO/IEC 17025 by NAVLAP or A2LA.	This comment is incorporated. L.8 is added to address this alternative.
149.	II.R.15 J. McIntyre	What is the basis of this requirement?	II.R.15 is deleted
150.	II.R.15 NEI ML061040113 Progress Energy ML061110355	Although these requirements are good things to review when auditing records, there is no basis for this requirement in Appendix B or NQA-1; therefore, it should be deleted from the SRP.	II.R.15 is deleted
151.	II.R.15.d NEI ML061040113	"operation of the records system is in accordance with <del>site</del> written procedures." Delete "site" and replace with "written" as shown above.	II.R.15 is deleted.



No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
152.	II.S and II.T General comments NEI ML061040113	Requirements seem to be very similar to the requirements of ANSI N45.2.23 and ANSI N 45.2.6. Since these requirements have been incorporated into NQA-1 1994 it would be more appropriate to reference NQA-1	<p>The provisions in II.S are from NQA-1-1994 and ANSI/ASN-3.1-1993,"Selection, Qualification, and Training of Personnel for Nuclear Power Plants." ANSI/ASN-3.1-1993 is endorsed by Regulatory Guide 1.8, "Qualification and Training of Personnel for Nuclear Power Plants."</p> <p>The provisions in II.T are from NQA-1-1994. The staff prefers to place the provisions in this SRP chapter.</p>
153.	II.S.1 NEI ML061040113 Progress Energy ML061110355	This paragraph focuses on QA Audits or training of auditors rather than QA personnel. Recommend adding in the first sentence "QA Auditors" prior to personnel. This is consistent with NQA-1 since the remainder of the paragraph came directly from NQA-1.	The staff agrees with the comment. This comment is incorporated.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
	II.S.1 NEI QA Task Force	<p>Recommend modifying the paragraph as follows:</p> <p>“Competence of personnel for performance of the various auditing functions shall be developed by one or more of the methods given in (a) through (c) below:</p> <p>(a) orientation to provide a working knowledge and understanding of the part (Part 1) and the auditing organization’s procedures for implementing audits and reporting results.</p> <p>(b) training programs to provide general and specialized training in audit performance. General training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Specialized training shall include methods of examining, question, evaluation, and documenting specific audit items and methods of closing out audit findings.</p> <p>(c) on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.”</p>	II.S.1 revised to be consistent with the recommendation.
154.	II.S.2 J. McIntyre	Must allow for exceptions for all of the minimum requirements.	II.S.2.e already provides for exceptions. No additional response is required.
155.	II.S.2 & 3 NEI ML061040113 Progress Energy ML061110355	There are no bases in Appendix B or NQA-1 for these requirements therefore it should be deleted.	<p>This comment is not incorporated. II.S.2 &amp; 3 are from RG 1.8 (Qualification and Training of Personnel for Nuclear Power Plants) which endorses of ANSI/ANS-3.1-1993, Selection, Qualification, and Training of Personnel for Nuclear Power Plants.</p> <p>10 CFR 50.34(f)(3)(iii)(E) states that the QA program must establish qualification requirements for QA personnel</p>

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
	II.S.5 NEI QA Task Force	Add a period after the word maintained. Add a second sentence to read "Records for lead Auditors shall be maintained as follows"	Comment incorporated.
	II.S.6 NEI QA Task Force	Delete "Auditor" from first sentence - there is not requirement to certify auditors, just lead auditors.	Comment incorporated.
156.	II.T.3 NEI ML061040113	Words "1 year is reevaluated" should read "1 year to be reevaluated prior to performing inspections or test activities."	This comment is incorporated.
157.	II.T.4, 5, 6 NEI ML061040113 Progress Energy ML061110355	The Levels of qualifications/certifications expressed here are from SNT-TC-1A for NDE personnel and not required for inspection and test personnel, per the requirements of NQA-1. Reevaluate the inclusion of these requirements in this SRP.	The Level I, II, and III requirements in II.S.4, 5, and 6 are based on Appendix 2A-1 of NQA-1-1994 and are for inspection and test personnel. The Level I, II, and III requirements in SNT-TC-1A are for NDE personnel and are different that those in Appendix 2A-1 of NQA-1-1994. However, in response to comment # 8, II.S.4, 5, and 6 are deleted and replaced with a new T.4 that states that inspection and test personnel initial qualification requirements are based on education, training, and experience and demonstration of capability in performing the type of inspection or test commensurate with the job.
158.	II.S.4.c Progress Energy ML061110355	Five QA audits for lead auditor qualification are not reasonable; however, alternatives approved by the NRC only require participation on one audit prior to qualification for assessment staff in operating plants. (e.g., SE for Limerick Generating Station, Dockets 50-352 and 50-353, dated June 26, 1997). Recommend that the NRC staff consider decreasing the number of audits required for qualification.	Comment incorporated. S.4.c is revised to decrease the number of audits required for a lead auditor to become qualified.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
159.	II.S.4.c NEI ML061040113	Recommend that the number of audits required for qualification in the operational phase be kept consistent with statements in existing plants' safety evaluation reports. The SERs require only one audit prior to qualification for assessment staff.). The actual number of audits required for qualification varies depending on the auditor's experience and previous qualifications.	See response to Comment 158.
160.	Subsection U, QA Program Commitments: NEI ML061040113	There is no reference to a commitment to Reg. Guides 1.8, 1.28, or 1.33 regarding QA Program requirements. There were certain requirements contained within these guidance documents that are not specifically addressed in the QA Program Standards, such as NQA-1 or N45.2. There is also no indication of a requirement to commit to the Basic and Supplemental requirements of NQA-1. Without such commitments, is it expected that the acceptance criteria of this SRP will be used as the basis for judging whether a change in the QA Program constitutes a reduction in commitment to quality under the provisions of 10 CFR 50.54(a)? Or will Reg. Guides be issued coincident with the application of the SRP to describe the regulatory position on QA Program requirements? This section needs to be rewritten to clarify the above issues.	The NRC does not plan to revise RG 1.28 or RG 1.33. The purpose of SRP Chapter 17.5 is to place all QA provisions in one place to ensure the quality and uniformity of staff safety reviews. SRP Chapter 17.5 is mainly based on American Society of Mechanical Engineers (ASME) Standard NQA-1 (1994 Edition). The detail in SRP Chapter 17.5 is similar to the detail in NQA-1. Committing to use NQA-1 would significantly reduce the level of detail required in QAPD. However, in some instances, the NRC cannot reference a standard because there is no standard available. No revision is required.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
	Paragraph V. (10CFR21) NEI Task Force	<p>The industry believes that this requirement should not be placed in the Quality Assurance section of the SRP. All utilities are required to audit for conformance to regulations and why would the Part 21 be repeated here.</p> <p>The paragraph requirement appears to go beyond programmatic description and into procedural descriptions. Additionally, it appears this section goes beyond the actual regulations.</p> <p>Section II. of the SRP identifies the acceptance criteria for the content of the Quality Assurance Program Description for COL applicants and holders. Item V. of the acceptance criteria addresses the licensee's 10 CFR Part 21 and 10 CFR 50.55(e) programs for reporting defects or failures to comply with the Atomic Energy Act, or NRC regulations, etc.</p> <p>(1)The industry agrees that this regulation is very important, but the level of detail doesn't fit the pattern of the other sections of the SRP for use as acceptance criteria for a QA program description document.</p> <p>(2)Part 21/50.55(e) are two of many regulations a licensee must implement, it is not clear why these are singled out here. This section appears to be putting the language of the regulation into the SRP. Is there a particular regulatory basis for including this item in the SRP?</p> <p>(3)The current industry QAPDs have a statement regarding compliance with these regulations, however, the detail for implementing the requirements are contained within the licensee's procedures.</p> <p>(4)QAPDs for current operating plants that were recently approved by NRC Safety Evaluation do not have this level of detail in them.</p> <p>(5)The acceptance criteria presented in II.V.3.e could not be related to specific source requirements. Under Part 21, a defect is related to an item being a basic component. However, an item is not considered a basic component if it does not pass the dedication process. Therefore the criteria</p>	<p>The NRC staff agrees that these requirements are not required to be addressed in a QAPD. Therefore, Section V is removed.</p>

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
161.	II.V.1 J. McIntyre	Just reference 10 CFR 21 – no need to include all of the words.	See response to Comment 12.
162.	II.V.1.c NEI ML061040113 Progress Energy ML061110355	Including the specific locations for 10CFR21 postings is unnecessary for the submittal of the QAPD provided it is clear that posting requirements of Paragraph 21.6(a)(2) are going to be followed.	See response to Comment 12.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
163.	II.W Laurence Gradin ML061040116	<p>SRP Section 17.5 Area W, "Commercial Grade Dedication (Not Applicable To ESP And DC Applicants)." The NRC Inspection Manual, Inspection Procedure 38703, "Commercial Grade Dedication," dated 04/08/1996 has superior and detailed guidance for Commercial Grade Item Dedication. This is especially true in Appendix A, Dedication Issues, for:</p> <ol style="list-style-type: none"> <li>1. Consideration of Item's Safety Function</li> <li>2. Graded Quality Assurance</li> <li>3. Consideration of Failure Modes</li> <li>4. Reasonable Assurance</li> <li>5. Engineering Judgment. Except the requirement should use the term and intent of documented and verifiable Engineering Analysis instead of Engineering Judgement.</li> </ol> <ul style="list-style-type: none"> <li>● Traceability</li> <li>● Commercial Grade Surveys</li> <li>● Acceptance Of Certified Material Test Reports (CMTRs) And Certificates Of Compliance (CoCs)</li> </ul> <p>It is recommended that this guidance, but not reference to EPRI NP 5652, be used to expand on the coverage and expectation for adequate Commercial Grade Item Dedication. The EPRI 5652 document is approximately 18 years old, has definitions and concepts that are not acceptable as noted in Generic Letters 89-02 and 91-05 and should not be referenced or further endorsed.</p>	See response to Comment 12.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
	<p>Para W (Commercial Grade Dedication)</p> <p>NEI task Force</p>	<p>The level of detail in this section is not consistent with the level of detail in the remainder of the SRP.</p> <p>The regulatory basis for many of the requirements included in Section W are unclear. Below are some examples that would indicated where the information is unclear.</p> <p>SRP 17.5, Section W states “Measures are established to control the identification or traceability of a commercial grade item to its original manufacturer and to the results of the dedication inspections and tests.” Traceability to the OEM is not required for commercial grade items. (Reference EPRI TR-102260, Section 2.6)</p> <p>SRP 17.5, Section W states “Measures are established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures.” This is not required for commercial grade items if alternate dedication inspection and/or test methods can confirm acceptability for the item’s intended safety-related application/function.</p> <p>Much of the information included in this Section is not consistent with current regulatory requirements and industry guidance. Examples are provided for illustrative purposes. They are not intended to be all inclusive.</p> <p>SRP 17.5, Section W requires performance of a detailed FMEA. In EPRI NP-6406 an FMEA is optional.</p> <p>SRP 17.5, Section W identifies specific requirements for commercial grade items used in seismic and environmental applications including detailed analysis of vulnerabilities/sensitivities to environmental stressors, detailed material and durability analysis, required operating/mission times and design service conditions.</p>	<p>See response to comment 12.</p>



No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
164.	II.W NEI ML061040113	<p>Delete "DC and" from second sentence in first paragraph. General Comment: The use of a commercial grade SSC in the place of a safety-related SSC does not constitute a change in the design requirements. It is a different method for achieving a level of assurance that a component will perform its safety-related function as intended in lieu of a 10 CFR 50 Appendix B program.</p> <p>Draft SRP section is titled: "Commercial grade dedication (not applicable to ESP and DC applicants)." The document should state the basis for this section not being applicable to ESP and DC applicants.</p>	See response to Comment 12.
165.	II.W.2 NEI ML061040113	Engineered/designed performance requirements or specifications for commercial grade items would be no different than those for safety-related items. Engineering could propose performance or material testing requirements that would provide an acceptable level of assurance that the component will perform its safety-related function as intended.	See response to Comment 12.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
	II.X NEI QA Task Force	<p>It is not clear why SRP 17.5 Section X was added as a requirement to be addressed in QAPDs. This section belongs in Chapter 7 of the SRP, not in Chapter 17.5. 10 CFR 50, Appendix B, already applies to the safety-related functions of Digital Equipment Software. Regulatory Guide 1.168, "Verification, Validation, Reviews, and Audits for Digital Computer Software used in Safety Systems of Nuclear Power Plants, endorses IEEE Std 1012-1998, "IEEE Standard for Software Verification and Validation," and IEEE Std 1028-1997, "IEEE Standard for Software Reviews and Audits," subject to the exceptions listed in the Regulatory Guide. By committing to Regulatory Guide 1.168 and applying the QAPD to Digital Equipment Software, there is no need to have a separate section in the QAPD restating this. Further, the quality criteria listed in SRP 17.5 Section X does not appear to be consistent with either the Appendix B criteria described in SRP 17.5 nor the Regulatory Position description in RG 1.168. This means we will have three separate QA program descriptions to review, interpret, and apply for Digital Equipment Software.</p> <p>There have been, and there are, many other Regulatory Guides that establish QA requirements for specific issues. These other regulatory positions have not necessitated a separate description in the licensee's QA programs. We do not feel that SRP 17.5 Section X adds any value to the QA program description but creates a layer of confusion to the existing requirements. We suggest removing SRP 17.5 Section X, or allow a reference to our existing 10 CFR Appendix B criteria and RG 1.168 to describe our QA program applied to Digital Equipment Software.</p> <p>If the staff decides to keep a section on digital equipment software in Chapter 17.5, then it should be short and only reference Chapter 7 of the SRP. Having guidance in two places leads to inconsistencies and problems. If this section is retained, then it needs to be consistent with SRP Chapter 7, Branch Technical Position 14, and other guidance. If the decision is made to increase the detail in this section, then it</p>	<p>This comment is incorporated. Section X, Digital Equipment Software Verification and Validation Quality Controls, is deleted. However, applicants are still required to comply with Subpart 2.7, Quality Assurance Requirements of Computer Software for Nuclear Facility Applications, of NQA-1994.</p>

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
166.	II.X Laurence Gradin ML061040116	<p>SRP Section 17.5 Area X, "DIGITAL EQUIPMENT SOFTWARE VERIFICATION AND VALIDATION QUALITY CONTROLS", clause 4, "Procurement Document Control (Criterion IV of Appendix B to 10 CFR Part 50)", page 44. It is stated that:</p> <p>"The supplier must implement the guidance provided in Electric Power Research Institute (EPRI) NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety Related Applications (NCIG-07)," conditionally endorsed by Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," for the procurement of commercial-grade services related to digital equipment."</p> <p>As stated in comment 2 and 4 the EPRI NP5652 document is seriously flawed with much better guidance in INSPECTION PROCEDURE 38703, COMMERCIAL GRADE DEDICATION. Typical problems include:</p> <p>5.1. EPRI NP5652 "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)" is not a document written as a code or standard having mandatory requirements. This document should at most be used as a guideline or recommended practice only.</p> <p>5.2. EPRI NP 5652 has been recognized as not sufficient alone in USNRC Generic Letters 89-02 and 91-05. As a result many other EPRI documents on engineering support, evaluations, audits, sampling, specific equipment items has been generated as well as IEEE documents (e.g. IEEE 934) and IAEA documents on procurement, equipment upgrades, quality, and prevention of use of suspicious and fraudulent parts and items.</p> <p>5.3. Where the source of an EPRI term and definition is</p>	Section X is deleted.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
167.	II.X Laurence Gradin ML061040116 continued	<p>5.6. Paragraph 1.1.3 indicates that, "Nuclear power plants are constructed of components designated either safety-related or non-safety related. EPRI/NCIG has considered or created other designations such as Augmented Quality without truly considering such functions as post-accident monitoring of USNRC RG 1.97.</p> <p>5.7. Throughout the document the term component is used without definition and to different levels of assembly. As a component has been used to represent a complete equipment item as well as a part, the more appropriate term which will be used is Item. Item is recognized to be any level of assembly.</p> <p>5.8. Paragraph 1.1.3, page 1-4 states, "other suppliers have satisfactory undocumented controls that assure a conforming product is supplied". An "undocumented" control system would not be acceptable for Method 2, "Commercial Grade Survey of Supplier", as correctly stated in Generic Letter 89-02.</p> <p>5.9. Paragraph 1.2, page 1-5 indicates that, "the technical evaluation process provides a means to specify the correct requirements for an item in a procurement document". The USNRC position is that the technical evaluation includes consideration of the complete Dedication Process including the appropriate Acceptance Method to specify.</p> <p>5.10. Paragraph 1.3.2, Equivalent Performance, page 1-6 indicates that, "Equivalent Performance is confirmed by conducting the technical evaluation to ensure the item specified meets design requirements". Performance verification may only be practicable by validated use of nationally recognized standards, source verification, validated quality in CGI vendor's programs, or other reasonable basis.</p>	Section X is deleted.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
168.	II.X Laurence Gradin ML061040116 continued	<p>5.16. Appendix E, "Use of National Codes and Standards". When national codes and standards (including military standards) are used they shall be reviewed for applicability for the application and the independent agency inspection (UL, military) approach validated. Current guidance (which must be uniquely reviewed by each user) to use of standards and independent agency inspections may be found in EPRI TR-101752(370).</p> <p>5.17. Dozens of documents from the USNRC, IAEA, IEEE, ASME, EPRI, and others have been necessary for reasonable assurance of understanding including more than a dozen EPRI additional documents to attempt to adequately provide Commercial Grade Item Dedication.</p> <p>5.18. Finally, the issue of Commercial Grade Item Dedication is sufficiently important that it is recommended that a Regulatory Guide be issued.</p>	Section X is deleted. The staff does not plan on issuing a regulatory guide at this time.
169.	II.X.1 NEI ML061040113	<p>Two Comments: Where does the senior level management requirement to monitor QA program implementation come from? Delete all but last sentence in first paragraph.</p> <p>Insert "digital equipment and software" following "supplier's" in last sentence of first paragraph.</p>	Section X is deleted.
170.	II.X.3 NEI ML061040113	Revise last paragraph first sentence as follows: Applicant ensures that Verification and validation tasks are performed by the applicant during all the life cycles of the software development process to verify conformance of an activity to specified requirements, or to verify that activities are satisfactorily accomplished.	Section X is deleted.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
171.	II.X.4 NEI ML061040113	Revise second paragraph as follows: Applicant ensures that Commercial off-the-shelf digital equipment utilized in safety-related applications must be at have commercial quality controls and/or applicant dedication activities that provide a level of assurance equal to or above the level reached for the nuclear grade equipment safety-related equipment produced under a 10 CFR 50 Appendix B program.	Section.X.4 is deleted. Commercial grade dedication is addressed in II.W.
172.	II.X.5 NEI ML061040113	Revise last paragraph last sentence as follows: Software and hardware upgrades require appropriate technical evaluations and testing in accordance with written procedures.	Section X is deleted.
173.	II.X.7 NEI ML061040113	Revise first sentence as follows: The applicant ensures conducts periodic audits are conducted to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities.	Section X is deleted.
174.	II.X.4 J. McIntyre	I believe the words of the last paragraph are somewhat obsolete. Still have to follow requirements and Part 21 states that you must perform source verification.	Section X is deleted. Commercial grade dedication is address in II.W of this SRP chapter.
175.	II.Y Clinton Elridge ML060450068	This section provides QA program criteria for what I assume to be RISC-2 SSC's. Were requirements for RISC-3 SSC's inadvertently omitted, or were they left out intentionally? I understand that, for new generation plants, the AE may not identify low-risk SSC's as safety-related, so there may be no RISC-3 SSC's to control.	Requirements for RISC-3 SSCs were intentionally not included because 10 CFR 50.69 removes RISC-3 SSCs from the scope of the requirements of Appendix B to 10 CFR Part 50.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
	II.Y.1 NEI QA Task Force	Delete Section Y.1.	This addresses the Commission's Policy presented in SECY 95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY 94-084)," Item A, RTNSS and Item E, Reliability Assurance Program (RAP), dated June 28, 1995. The scope of the RTNSS program and the RAP includes risk-significant, nonsafety-related SSCs that provide defense in depth or result in significant improvement in the PRA evaluations. Y.1 is revised to provide this explanation.
176.	II.Y.2  J. McIntyre	Where did this list come from? Is this meant to be all inclusive? How about things such as Environmental Monitoring, Emergency Preparedness, etc	II.Y.2 is inclusive. This addresses the Commission's Policy presented in SECY 95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY 94-084)," Item A, RTNSS and Item E, Reliability Assurance Program (RAP), dated June 28, 1995. The scope of the RTNSS program and the RAP includes risk-significant, nonsafety-related SSCs that provide defense in depth or result in significant improvement in the PRA evaluations.

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
	Para Y.1.k. (Test Control) NEI Task Force	<p>Change the paragraph to read:            "Measures shall be established, as appropriate, to test equipment prior to installation, prior to operation, or post installation to demonstrate conformance with design requirements.            Tests shall be performed in accordance with test procedures. Test results shall be recorded and evaluated to ensure that test requirements have been met."            The paragraph as currently written in the SRP describes measures related to the design of test equipment. It is believed that the intent of this paragraph is to assure that the equipment (not test equipment) to be installed in the plant is properly tested. Also, the paragraph specifies that the testing must be done prior to installation. This may be impractical in some instances, in that in order to test equipment for its intended function, it must be installed in the plant and tested as part of the plant system to assure all interfaces are functioning.</p>	Comment incorporated.
	Para Y.1.p (Corrective Action) NEI Task Force	<p>Recommend eliminating the second sentence. "Cause determinations are properly identified....."            The rationale associated with this comment is to allow treatment of these components to be consistent with 10CFR50 Appendix B and 10CFR50.69 which requires cause determinations for significant conditions adverse to quality.</p>	Comment incorporated. This is addressed in SRP Section 17.4.
177.	II.Z NEI ML061040113	Discusses Independent Review Body requirements that in many cases have been revised through the SER process. ANSI N18.7/ANS3.2 1976 discusses the Independent Review Body requirements and has resulted in that body being so focused on compliance to the standard that is unable to become the management advisory function that was envisioned by the standard and that is discussed in section R.	Section Z provides two options for independent review and either option may be used. The first option is based on independent review requirements that have been revised through the SER process. The second option is based on ANSI N18.7/ANS3.2 1976. No revision is required.



No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
	Para Z (Independent Review) NEI Task Force	<p>Option I Independent Review Body-- Recommend a statement that the IRB may be composed of one or more organizational units which collectively perform the described reviews. Note that these units may be onsite or offsite, as long as they are independent of the work function under review.</p> <p>Option I Item 2.g and Option II Item 6.g-- The IRB or IRC would not necessarily be qualified to perform "audits."Therefore, this requirement should be to "Review the adequacy..." Also, the frequency standard for operational audits is 24 months, therefore , the requirement should be to perform the reviews every 24 months.</p> <p>3) Option I Item 4-- Again, the frequency standard for operational audits is 24 months, therefore, the IRB activities should be periodically reviewed, with a minimum of such reviews being conducted every 24 months.</p> <p>4) Option II Items 3, 6.a and 6.b-- Typically, reviews of changes to the facility or tests and experiments not described in the FSAR which affect nuclear safety are currently performed prior to implementation by the onsite review committee. Therefore the requirement in item 3 that no more than a minority of members be from the onsite operating organization should be deleted.</p>	<p>Comment incorporated.</p> <p>Comment incorporated.</p> <p>Comment not incorporated. This item involves reviewing matters that involve safe operation. This in not an audit function.</p> <p>Comment not incorporated. It is consistent with ANSI 18.7 that personnel not in the operating organization participate in independent review activities.</p>
	II.Z.2.a -option 1 and II.Z.6.a Option 2 NEI QA Task Force	<p>Remove requirement that changes to the facility as described in the FSAR be reviewed prior to implementation It was never a requirement in ANSI 18.7-1976 that these changes be independently reviewed prior to implementation.</p>	<p>Comment incorporated.</p>

No.	SRP 17.5 SECTION/ML No.	COMMENT	NRC RESPONSE
178.	II.Z.2.g NEI ML061040113	The term assessment is very general and there are many forms of assessments that are performed at nuclear sites. Using the term "all assessments" would place an unnecessary burden on the reviewers and possibly distract them from the more important matters. This should be clarified to focus on the types of assessments to be reviewed.	Z.2.g revised to require that the adequacy of the audit program be assessed on a yearly basis.
179.	II.Z.6.g NEI ML061040113	Same comment as for page 17.5-49 Item II.Z.2.g	Z.6.g revised to require that the adequacy of the audit program be assessed on a yearly basis.