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RULES AND DIRECTIVES  
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ATTN: Chief, Rules Review and Directives Branch  
United States Nuclear Regulatory Commission  
Mail Stop T6-D59  
Washington, DC 20555-0001

**SUBJECT:** Comments on NUREG-0800, Section 17.5, *Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants*, Draft Revision 0 (71 FR 7079)

Ladies and Gentlemen:

On February 10, 2006, the NRC published in the Federal Register (71 FR 7079) a request for comments. Detailed comments are attached for the NRC staff's consideration. Progress Energy wishes to emphasize the following comments.

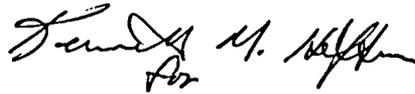
- The Standard Review Plan (SRP) mixes construction and operational requirements together in the various sections making it unclear whether a requirement applies to the construction phase, operational phase, or both. Those requirements that are applicable only to either the construction phase or operational phase should be segregated or clearly identified based on their applicability. This will result in a standardized implementation of these requirements and facilitate a more efficient review process.
- The first paragraph on page 17.5-2 implies that the Quality Assurance Program Description (QAPD) submitted for both the construction and operational phases for a combined license (COL) application must be in accordance with SRP Section 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 17.5 that permits COL applicants to reference an existing operational phase QAPD or submit the operational phase QAPD in an SRP format consistent with that used throughout the licensee's nuclear fleet such that standardization within the fleet is maintained.
- Draft SRP 17.5 is written such that the resulting acceptable Quality Assurance Program Description (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 (see comment above) 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.

SRP Review Complete  
Template = ADM-213

E-RDS = ADM-03  
Add = S. Tingen (SET)

Please contact me at (919) 546-4579 if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Brian M. McCabe". The signature is written in a cursive style with a large initial "B" and "M".

Brian McCabe  
Supervisor - Regulatory Affairs

DBM

Attachment

**Progress Energy Comments on Draft SRP Section 17.5**

#	Page / Paragraph	Comment
1.	General Comment	It would be helpful to both the licensee and the reviewer if the SRP followed the format and structure of the American Society of Mechanical Engineers (ASME) NQA-1-1994; Quality Assurance for Nuclear Facility Applications (NQA-1).
2.	General Comment	The Standard Review Plan (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 result in a standardized implementation of these requirements and facilitate a more efficient NRC staff review.
3.	General Comment	The first paragraph on page 17.5-2 implies that the Quality Assurance Program Description (QAPD) submitted for both the construction and operational phases for a combined license (COL) application must be in accordance with SRP Section 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 operational phase QAPD or to submit the operational phase QAPD in an SRP format consistent with that used throughout the licensee's nuclear fleet such that standardization within the fleet is maintained.
4.	General Comment	Draft SRP 17.5 is written such that the resulting acceptable Quality Assurance Program Description (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 (see comment 3 above) 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.
5.	General Comment	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.

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#	Page / Paragraph	Comment
6.	17.5-5 II.A.5	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.
7.	17.5-7 II.B.4	The term "binding" as used here is unclear. This 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.
8.	17.5-7 II.B.5	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.
9.	17.5-9 II.C.1.n	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 quality assurance activities performed by the design organization? This should be clarified.
10.	17.5-9 & 10 II.C.2	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.
11.	17.5-9 & 10 II.C.2	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.
12.	17.5-10 II.C.2.e	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.
13.	17.5-10 II.C.2.f	The phrase "in exceptional circumstances" is used here without basis or definition, it should be removed.
14.	17.5-11 II.C.2.f	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.

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#	Page / Paragraph	Comment
15.	17.5-11 II.C.2.h	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.
16.	17.5-11 & 12 II.D.2.f & h	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'.
17.	17.5-12 II.D.3	The SRP should address reviews of procurement documents before it discusses reviewing procurement document changes. Place this step after step II.D.4.
18.	17.5-12 II.E.2	Delete paragraph II.E.2 since it is not specific to instructions, procedures, or drawings. This paragraph should be relocated to Section K, Test Control.
19.	17.5-15 II.G.9	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.
20.	17.5-16 II.G.10.g, h, and i	The basis for these requirements is not clear. No bases were found in Appendix B, NQA-1, or RG 1.33 therefore, these requirements should not be included in the SRP.
21.	17.5-18 II.G.18 & 19	To be consistent with NQA-1, these two paragraphs should be relocated to Section D, Procurement Document Control.
22.	17.5-19 II.I.4	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.
23.	17.5-20 II.I.9	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.
24.	17.5-20 II.J.4	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.
25.	17.5-21 II.J.8	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.

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#	Page / Paragraph	Comment
26.	17.5-22 II.L.5 & 8	Both of these paragraphs are good information but are above and 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.
27.	17.5-22 II.M.3	Typographical error: 'perceiving' should be 'preservation.'
28.	17.5-23 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.
29.	17.5-23 II.N.1	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.
30.	17.5-23 II.O	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.
31.	17.5-24 II.P.1	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.
32.	17.5-24 II.P.1	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.
33.	17.5-24 II.P.3	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.

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#	Page / Paragraph	Comment
34.	17.5-24 II.P.4	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.
35.	17.5-24 II.P.5	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.
36.	17.5-24 II.P.6	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 may be more appropriate for inspection guidance.
37.	17.5-24 II.P.7	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.
38.	17.5-24 II.P.8	The term "program" for root cause determination is unclear. "Measures" within the Corrective Action Program to determine the root cause are more appropriate.
39.	17.5-24 II.Q General	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.
40.	17.5-24 II.Q.1	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.
41.	17.5-25 II.Q.3	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.
42.	17.5-25 II.Q.4	Electronic, in the second sentence, should be changed to "all." This paragraph does not need to apply to only electronic records.
43.	17.5-25 II.Q.5	Recommend moving this paragraph to Section C, Design Control to be consistent with NQA-1, 3S-1, Supplementary Requirements for Design Control, Section 7.
44.	17.5-25 II.Q.6	Recommend moving this paragraph to Section J, Inspection to be consistent with NQA-1, 10S-1, Supplementary Requirements for Inspection, Section 9.

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#	Page / Paragraph	Comment
45.	17.5-25 II.Q.8	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.
46.	17.5-25 II.Q.8	Although training is necessary, it should be moved to the training section and not included in the QA Records section.
47.	17.5-27 II.Q.15, 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.
48.	17.5-28 II.Q.24	The Training and Qualification details would be more appropriately addressed in the specific sections and not addressed in the QA Records section.
49.	17.5-29 II.Q.25	The reference to the audit process would be more appropriately addressed in the Audit section of the SRP, Section R, and not in Records.
50.	17.5-29 II.R.1	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 clearly identify construction only and operational only requirements.
51.	17.5-29 II.R.2	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. Again, is it the intent of the commission to implement this portion of the SRP for the operations phase only? If yes, segregate and clearly identify construction only and operational only requirements.
52.	17.5-30 II.R.9	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.
53.	17.5-30 II.R.11	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.
54.	17.5-30 II.R.13	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.

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55.	17.5-31 II.R.13.b.7	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 NVLAP or A2LA.
56.	17.5-29-31 II.R. General	This section seems to mix assessment and audit throughout. If there is intent to address both, then there should be some separation. A subsection for each would be more helpful and provide additional clarification.
57.	17.5-32 II.R.15	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.
58.	17.5-32 II.S.1	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.
59.	17.5-32 II.S.2 & 3	There are no bases in Appendix B or NQA-1 for these requirements therefore it should be deleted.
60.	17.5-34 II.S.4.c	Five QA audits for lead auditor qualification are not unreasonable; however, alternatives approved by the NRC only require participation on one audit prior to qualification for assessment staff in the operating plants. (e.g., Safety Evaluation 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.
61.	17.5-35 II.S.4, 5, 6	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.
62.	17.5-39 II.V.1.c	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.