DEC 0 9 1983

Docket No. 50-424

MEMORANDUM FOR: Elinor G. Adensam, Chief
Licensing Branch #4, DL

FROM: Wm. H. Regan, Jr., Chief
Site Analysis Branch, DE

SUBJECT: REQUEST FOR ADDITONAL INFORMATION ON VOGTLE

Please request responses to the enclosed questions from the Georgia Power Co. so that we may continue our review of the Vogtle Electric Generating Plant FSAR.

These questions were prepared by Al Brauner of my staff.

Original signed by W. H. Regan, Jr.

Wm. H. Regan, Jr., Chief
Site Analysis Branch
Division of Engineering

Enclosure:
As stated

cc: M. Miller

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REQUEST FOR ADDITIONAL INFORMATION ON VOGTLE

311.4 (2.1.2) Provide information pertaining to the proposed simulator, specifically:

a. where is it located with respect to the plant?

b. what is the size of the staff assigned to it?

c. how many trainees are expected to be involved?

d. what arrangements have been made to control the activities of personnel participating in the simulator program since it is apparently witnin the exclusion/site boundary?

311.5 (2.1.3) Provide the following information (include the distances and directions in relation to the plant)

(a) Location of closest residence as well as type of residence (i.e., permanent or temporary occupancy),

(b) A listing of all communities within 30 miles of the plant that have populations greater than 1000 persons, and

(c) Identification of the largest city within 50 miles of the plant.

311.6 (2.1.2) River Road, although relocated, still appears to run inside the exclusion/site boundary according to Figure 1.1-1.

a. If any drawings (figures) are in error, please revise.

b. If River Road is located within the property line, provide information on the arrangements that have been made to control the activity on this road, particularly during an emergency situation.

311.7 (2.1.3) Some of the numbers in the various population tables do not agree (e.g., when comparing FSAR Tables 2.1.3-1 thru 2.1.3-16 with 2.1.3-17 and 2.1.3-18, the respective year population totals do not agree). Please check for discrepancies and revise the tables in all documents for consistency.

311.8 (2.1.3) No mention is made of the Ebenezer Church located within the LPZ. Provide information on the size of the congregation, and whether it is active or not. If active, indicate the frequency of services and/or meetings that take place.

311.9 (2.1.3) Provide a listing of all prisons, hospitals, nursing/convalescent homes, day care centers, schools, churches, cemeteries or similar institutions located within ten miles of the site. Specify their locations (distance and direction), the number of persons ordinarily employed or in attendance (occupants, staff, students, employees, guests, visitors, etc.), and the capacity of each facility.

April 8, 1984

NOTE TO: Jack Spraul

FROM: Melinda Malloy

SUBJECT: RESULTS OF VOGTLE OQAP REVIEW

I have completed my review of the Vogtle OQAP and have compared my results with yours. Enclosure 1 includes my questions which are counterparts to yours and also includes a summary sheet which highlights the differences between my questions and yours.

Enclosure 2 includes new questions addressing those areas for which I was not able to locate sufficiently detailed information in the OQAP.

Whenever convenient for you in the near future, I'd like to go over any differences in our reviews in order to gain a better understanding of the applicable QA licensing philosophy.

Melinda Malloy

MELINDA MALLOY

Enclosures:
1. Questions from VEGP OQAP Review
2. New Questions

cc: WA Altman
JL Milhoan

05000424 -425

ENCLOSURE 1

QUESTIONS FROM VEGP OQAP REVIEW

Jack's	Melinda's	Jack's	Melinda's	Jack's	Melinda's
260.1	similar	260.21	similar**	260.41	similar**
260.2	similar	260.22	similar	260.42	none[4]
260.3	similar	260.23	similar	260.43	similar**
260.4	none*	260.24	none*	260.44	similar
260.5	similar	260.25	similar	260.45	similar
260.6	similar	260.26	similar	260.46	similar
260.7	similar	260.27	similar	260.47	similar**
260.8	similar	260.28	similar	260.48	similar
260.9	similar	260.29	similar	260.49	similar**
260.10	similar	260.30	similar	260.50	similar
260.11	similar**	260.31	none[1]	260.51	similar
260.12	similar	260.32	similar	260.52	similar
260.13	similar	260.33	none[2]	260.53	similar**
260.14	similar	260.34	similar**	260.54	none*
260.15	similar	260.35	similar	260.55	similar**
260.16	similar	260.36	similar		
260.17	similar	260.37	similar		
260.18	similar	260.38	similar[3]		
260.19	none*	260.39	similar**		
260.20	similar	260.40	similar		

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*Concur with the question.

**Has more/less information than Jack's question. See Melinda's question sheet for an explanation of the difference.

[1] See question on 2B2.

[2] List in FSAR seems to be all encompassing of special processes that may be encountered in operations.

[3] See question on 10B2.

[4] Section 17.2.12 #4 states that the superintendent of maintenance has responsibility for developing, approving and implementing calibration program.

1A5 Provide an organization chart that clearly identifies all the onsite and offsite organizational elements which function under the cognizance of the QA program, showing the lines of responsibility. Provide charts for the GMQA, QAM, QA site manager, QA field group and the QC supervisor's organizations. Provide a description of the criteria used for determining the size of the QA organization and the inspection staff (QC organization). Give an indication of the approximate size of the QA and QC staff planned for normal operation.

COMPARISON: Wording similar to 260.1.

1B3 Clarify whether persons/organizations performing QA functions have direct access to management levels which will assure ability to:

1. Identify quality problems.

2. Initiate, recommend or provide solutions.

3. Verify implementation of solutions.

Identify the persons and organizations with the above authority and describe how those actions are carried out.

COMPARISON: Wording similar to 260.2.

134 The Vogtle QA Manager has the authority to stop unsatisfactory work. Clarify whether this authority is delineated in writing and whether his authority extends to controlling further processing, delivery or installation of nonconforming material.

COMPARISON: Wording similar to 260.3.

136 Clarify that designated QA/QC individuals are involved in day-to-day plant safety-related activities, i.e., the QA organization routinely attends and participates in daily plant work schedule and status meetings to assure they are kept abreast of day-to-day work assignments throughout the plant and that there is adequate QA coverage relative to procedural and inspection controls, acceptance criteria and QA staffing and qualification of personnel to carry out QA assignments.

COMPARISON: Wording similar to 260.5.

102 Provide qualification requirements for the GMQA and clarify that these are established in a position description which includes:

1. Management experience through assignments to responsible positions.

2. Knowledge of QA regulations, policies, practices and standards.

3. Experience working in QA or related activity in reactor design, construction or operation or in a similar high technology industry.

In addition, provide qualification requirements for the Vogtle QA Manager.

COMPARISON: Wording similar to 260.6.

281 a. Describe the provisions established to assure that quality-affecting procedures required to implement the QA program are consistent with QA program commitments and corporate policies, and are properly documented, controlled and made mandatory through a policy statement signed by the responsible official.

b. Describe the provisions established to assure that the QA organization reviews and documents concurrence with the quality-related procedures.

COMPARISON: Wording similar to 260.7.

283 Section 1.9 of the FSAR provides a number of clarifications, exceptions and alternatives to the QA regulatory guides listed in Section VI of NUREG-0800, Chapter 17.2. For each QA guide, provide the following:

1. An indication of the specific guidance to which an exception is being taken or for which an alternative or clarification is given.

2. Clear identification of the GPC position with regard to the guidance and an identification as to whether the position is an exception or alternative to or a clarification of the guidance.

3. An appropriate discussion of how each clarification, exception or alternative provides an acceptable method of complying with the applicable rules and regulations of the Commission, i.e., provide a justification.

Describe how, for systems, components and structures covered by the ASME Code Section III (Classes 1, 2, and 3), that the QA Code requirements will be supplemented by the specific guidance addressed in the regulatory positions of the applicable RGs. Identify RGs and ANSI standards by number, title and revision/date. Clearly identify any alternatives or exceptions and provide supporting justification.

Describe how the QA organization and the necessary technical organizations participate early in the QA program definition phase to determine and identify the extent QA controls are to be applied to specific structures, systems and components, i.e., describe the graded approach used.

COMPARISON: First part above, wording similar to 260.8.
Second part above, wording similar to 260.9.
Third part above, wording similar to 260.10.

2B4 Identify existing/proposed QA procedures reflecting that 10 CFR Part 50 Appendix B, 10 CFR 50.55a and the QA RGs listed in Section VI of NUREG-0800 Chapter 17.2 will be properly carried out.

COMPARISON: Similar to 260.11, but the above requests information on 10 CFR 50.55a also.

no change

2C1 Describe the measures used by the Executive VP - Power Supply to regularly assess the scope, status, adequacy and compliance of the QA program to 10 CFR 50 Appendix B, including:

1. Frequent contact with program status through reports, meetings and/or audits.

2. Performance of an annual assessment which is preplanned and documented and corrective action is identified and tracked.

COMPARISON: Wording similar to 260.12.

2D Describe measures for assuring that:

1. Proficiency tests are given to those personnel performing and verifying activities affecting quality, and acceptance criteria are developed to determine if individuals are properly trained and qualified.

2. Certificate of qualifications clearly delineate

    a. the specific functions personnel are qualified to perform, and

    b. the criteria used to qualify personnel in each function.

3. Proficiency of personnel performing and verifying activities affecting quality is maintained by retraining, reexamining and/or recertifying as determined by management or program commitment.

COMPARISON: Wording similar to 260.13.

ED Clarify that the controls for internal and external design interfaces assure that structures, systems and components are compatible geometrically, functionally and with processes and environment.

COMPARISON: Wording similar to 260.14.

3E2 Describe the requirements established for review of design documents by the QA organization to assure that the documents are prepared, reviewed and approved in accordance with company procedures and that the documents contain the necessary quality assurance requirements such as inspection and test requirements, acceptance requirements, and the extent of documenting inspection and test results.

COMPARISON: Wording similar to 260.15.

3B3 Describe the guidelines or criteria established for determining the method of design verification.

COMPARISON: Wording similar to 260.16.

3B4 Describe the procedures established for design verification that assure:

1. The design verifier is qualified and is not directly responsible for the design.

2. Design verification, if by other than qualification testing of a prototype or lead production unit, is completed proir to release for procurement, manufacturing, construction or to another organization for use in other design activities. In those cases where this timing cannot be met, and design verification is deferred, clarify that the justification for this action is documented and the unverified portion of the design output document and all design output documents based on the unverified data are appropriately identified and controlled. Clarify that in all cases, the design verification is complete prior to fuel load or prior to relying upon the component, system or structure to perform its function.

3. Procedural controls differentiate between documents that receive formal design verification by interdisciplinary or multi-organizational teams and those which can be reviewed by a single individual (a signature and date is acceptable documentation for personal certification). Clarify which design documents are subject to procedural controls.

Clarify that the responsibilities of the verifier, the areas and features to be verified, the pertinent features to be verified and the extent of documentation are identified in procedures.

COMPARISON: Wording similar to 260.17.

3B5 If design verification is only by test, clarify that

1. The procedures provide criteria that specify when verification should be by test.

2. Prototype, component or feature testing is performed as early as possible prior to installation of plant equipment, or prior to the point when the installation would become irreversible.

COMPARISON: Wording similar to 260.18.

17.2.3 #2 Describe the measures provided to assure that responsible plant personnel are made aware of design changes/modifications which may affect the performance of their duties.

COMPARISON: Wording similar to 260.20.

4A1 Clarify that procedures are established for review of procurement documents to determine that they have been reviewed and approved in accordance with QA program requirements. Clarify that the individual who reviews and concurs in adequacy of quality requirements in procurement documents is independent of individuals who prepared the requirements and is trained and qualified in QA practices and concepts.

COMPARISON: Comparable to 260.21, but requests additional information about the training and qualification of the individual. "Knowledge-ability" as addressed in the FSAR is fairly nebulous.

260.21

4E1 Describe the organizational responsibilities, including the involvement of the QA organization for:

1. Procurement planning.

2. Preparation, review, approval and control of procurement documents.

3. Supplier selection.

4. Bid evaluation.

5. Review and concurrence of supplier QA programs prior to initiation of activities affected by the program.

Comparison: Wording similar to 260.22.

5A Describe the organizational responsibilities for assuring that activities affecting quality are prescribed by and accomplished in accordance with documented instructions, procedures or drawings, as described in Section 17.2.5 of the FSAR.

COMPARISON: Comparable to 260.23.

641 Clarify that the following documents are subject to the QA program controls, in addition to the documents listed in Section 17.2.6 of the PSAR:

1. Design documents such as calculations, specifications and analyses, and documents related to computer codes.

2. Instructions and procedures for fabrication, construction during operations and installation activities.

3. As-built documents.

4. QA manual and QC manual.

5. Topical reports.

6. Nonconformance reports.

COMPARISON: Comparable to 260.25, but item 2. above has also included "construction during operations". This seems pertinent since unit 2 will still be under construction during unit 1 operation, and also, it may be possible that some type of construction activity may occur during operations.

6.2 Describe the procedures that are established for the review, approval and issuance of documents and changes thereto to assure the technical adequacy and inclusion of appropriate quality requirements prior to implementation. Clarify that the individual who performs the quality requirement review described in FSAR 17.2.6 is qualified in quality assurance.

COMPARISON: Comparable to 260.26.

17.2.6 #2 Describe the measures used for assuring review of maintenance, modification and inspection procedures by qualified individuals knowledgeable in QA disciplines to determine:

1. The need for inspection, identification of inspection personnel and documentation of inspection results.
2. That the necessary inspection requirements, methods and acceptance criteria have been identified.

COMPARISON: Similar wording to 260.27.

7A1 Describe the organizational responsibilities, including interfaces between design, procurement, QA and QC organizations for control of purchased material, equipment and services.

COMPARISON: Wording similar to 260.28.

7A4 Section 17.2.7 of the FSAR states that spares and replacement parts for safety-related structures, systems and components are subject to controls equivalent to those used for the original equipment. Clarify that the procurement is made to QA program controls in effect at the time of the procurement, and to codes and standards and technical requirements equal to or better than the original technical standards, or that other controls are used as necessary to preclude repetition of defects.

COMPARISON: Comparable to 260.29.

7E3 Describe the measures which assure that the supplier furnishes the following records:

1. Documentation that identifies the purchased item and the specific procurement requirements (e.g., codes, standards, and specifications) met by the item.

2. Documentation identifying any procurement requirements that have not been met.

3. A description of those nonconformances from the procurement requirments dispositioned "accept as is" or "repari".

Describe how these documents are reviewed and accepted.

COMPARISON: Wording similar to 260.30.

8B2 Clarify that the exception given in Section 17.2.8 of the FSAR for identification of off-the-shelf items by a manufacturer's catalog number or other document does not preclude the item's traceability to appropriate drawings, specifications, purchase orders, manufacturer's inspection documents, nonconformance reports or manufacturer's test reports.

COMPARISON: Similar to 260.31.

8E3 Describe the measures which ensure that correct identification of material, parts and components is verified and documented prior to release for fabrication, assembly, shipping and installation.

COMPARISON: Wording similar to 260.32.

9A2 Describe involvement by the QC organization for qualification of special processes, equipemnt and personnel, if any.

COMPARISON: Wording similar to 260.34.

9B1 Clarify that equipment for special processes is qualified in accordance with applicable codes, standards, QA procedures and specifications.

COMPARISON: Wording similar to 260.35.

9B2 Describe the procedures established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

COMPARISON: Wording similar to 260.36.

10A Describe the measures which assure that the program procedures for inspection provide criteria for;

1. Determining the accuracy of inspection equipment.

2. Determining when inspections are required, or define how and when inspections are performed.

Clarify that the QC specialists and inspectors are part of the QC supervisor's organization.

COMPARISON: Wording similar to 260.37.

10B1 Section 17.2.10 of the FSAR states that the QC supervisor is responsible for administering and implementing tests and inspections "assigned" to the QC department. Identify the individuals or organizations other than the QC department with responsiblity for inspection. If these individuals or organizations are not part of the QA organization and are responsible for performing inspections, describe the measures taken to assure that the inspection procedures, personnel qualification criteria, and independence from undue pressure such as cost and schedule are reviewed and found acceptable by the QA organization prior to initiation of the inspection activity.

COMPARISON: Comparable to 260.39 but hits on some different points. / added

10B2 The first paragraph of Section 17.2.10 of the FSAR indicates that the inspection program will be consistent with RG 1.58 (ANSI N45.2.6). However, in speaking of the qualification of QC specialists, Section 17.2.10, fifth paragraph, refers to Section 13.1.3 which discusses ANSI N18.1 (RG 1.8). Clarify which standard the inspection program is consistent with in regard to QC specialist and NDE inspector qualifications.

COMPARISON: Similar to 260.38, but uses a different angle. // Clear

11A1 Describe the measures to assure that program procedures provide criteria for determining the accuracy requirements of test equipment and criteria for determining when a test is required or how and when testing activities are performed.

COMPARISON: Wording similar to 260.40.

11B1 Clarify that test procedures or instructions provide for:

1. Adequate test equipment and instrumentation, including their accuracy requirements.

2. Provisions for assuring test prerequisites have been met.

COMPARISON: Item 2. above is similar to 260.41, but item 1. is a new question.

12.3 Identify the organization responsible for review and documented concurrence of calibration procedures.

COMPARISON: Similar to 260,43, however note that the superintendent of maintenance is responsible for preparation of calibration procedures per Section 17.2.12, paragraph 4, of the FSAR.

12.5 Describe the measures used to control the calibration due date of installed process instrumentation which is not tagged or labeled with the calibration due date.

COMPARISON: Similar wording to 260.44.

12.6 When it is not possible to calibrate equipment against standards having an accuracy of at least 4X the required accuracy of the equipment being calibrated, explain the measures used to assure that the equipment being calibrated will be within the required tolerance and that the basis of acceptance is documented and authorized by responsible management.

COMPARISON: Wording similar to 260.45.

12.9 Describe the measures taken to assure that inspections and tests are repeated on items determined to be suspect, when measuring and test equipment is found to be out of calibration.

COMPARISON: Wording similar to 260.46.

13.2 Clarify the use of the expression "as required" in Section 17.2.13A of the FSAR, and describe the routine surveillance procedures used to control items in storage described therein.

Describe the inspection and testing measures used to verify that special handling tools and equipment are "adequately maintained".

COMPARISON: First part on "as required" is similar to 260.47, but requests additional information on surveillance procedures.

Second part is a new question.

14.3 Describe the procedures established to control "altering the sequence" of required tests, inspections and other safety-related operations, and clarify that such actions are subject to the same controls as the original review and approval.

COMPARISON: Wording similar to 260.48.

15.2 Describe QA and other organizational responsibilities for the definition and implementation of activities related to nonconformance control, and identify those individuals or groups with authority for the disposition on nonconforming items.

COMPARISON: First part is similar in wording to 260.49. Second part asks for additional information.

15.3 Describe measures for assuring that nonconformances are corrected or resolved prior to the initiation of the pre-operational test program on the item.

COMPARISON: Wording similar to 260.50.

15.5 Identify the QA organizational element responsible for analyzing nonconformance reports and reporting on quality trends. Define the use of the expression "periodically" in Section 17.2.15G of the FSAR.

COMPARISON: First part has wording similar to 260.51. Second part requests some additional information.

16.1 Identify the QA organizational element which reviews and documents concurrence with the corrective action procedures.

COMPARISON: This is part of 260.52.

16.2 Identify the QA organizational element which is involved in the documented concurrence of the adequacy of the corrective action.

COMPARISON: This is part of 260.52.

16.3 Identify the QA organizational element which follows up to verify proper implementation of corrective action and to close out the corrective action in a timely manner.

COMPARISON: This is part of 260.52.

17.3 Describe the measures to assure that inspection and test records contain the following information:

1. Information related to conditions adverse to quality.
2. Data recorder identification (test records only).
3. Action taken to resolve any discrepancies noted.

COMPARISON: Wording is similar to 260.53, but includes some additional information:

1. above applies to inspection and test records.
2. above does not seem to be included in the FSAR.

18A4 Describe the measures used to "selectively" audit

1. Identification and control of materials, parts and components (FSAR Section 17.2.8).

2. Test control (Section 17.2.11).

3. Handling, storage and delivery (Section 17.2.13).

Describe the measures used to audit conformance to SAR and SSAR commitments. added

COMPARISON: First part above has similar wording to 260.55. Second part is not included in any question.

NEW QUESTIONS

1A6

2B2

3A
3B

6A4
6B2 - Added
6C1

7A3
7B2 - Added 1/2
7B4
7B5

8A

9B3

12.8

13.1

14.1
14.2 - Added 1/2
14.4 - Added

15.1 - Added 2/3

18B2

ENCLOSURE 2

1A6 For each organizational element identified which functions under the cognizance of the QA program, provide a description of their QA/QC responsibilities if not already addressed in the FSAR.

Address at meeting if not responded to as part of Q-1

COMPARISON: New question. Follow on question to 1A5.

232 Clarify that QQAP changes are handled in accordance with 10CFR 50.54(a).

COMPARISON: New question. Comment in 17.2.2-12 OK

3A Clarify that the scope of the design control program includes design activities associated with the preparation and review of design documents including correct translation of applicable regulatory requirements and design bases into procurement documents.

COMPARISON: New question.

OK in 17.2.3-1 & 17.2.3-5A

3E Clarify the organizational responsibilities for preparing design change documents.

COMPARISON: New question.

OK in 17.2-3 thru 17.2-4

6A4 Section 17.2.6 of the FSAR states that "documents and changes thereto are promptly distributed to ensure availability prior to commencement of work." Clarify that the documents and changes are available at the location where the activity will be performed prior to commencing the work. Define the use of the expression "promptly".

COMPARISON: New question. Quotation satisfies 6A4

6B2 Section 17.2.6 of the FSAR states that a master status list is used to identify current revision of documents. Identify what documents it statuses and describe how often the list is updated and to whom it is distributed.

COMPARISON: New question. Added

601 Section 17.2.6 of the FSAR states that "as-built" documents are are prepared in a timely manner to accurately reflect the actual plant design. Describe the procedures established to accomplish this. Define the use of the expression "timely".

COMPARISON: New question. Commitment made SRP requirement.

7A3 Describe the type of records maintained to document supplier qualification if by other than survey (described in Section 17.2.7.1C of the FSAR).

COMPARISON: New question. OK in 17.2.7.1-1C

732 Section 17.2.7.3D of the FSAR states that items accepted "or" released are identified as to their inspection status. Clarify that items that have not been accepted can be released to the controlled storage area or can be released for installation or further work.

Section 17.2.7.3E of the FSAR states that nonconforming items are segregated "where Practical" until proper disposition is made. Define the expression "where practical". OK as is

COMPARISON: New question.

734 Describe the special verification measures established to ~~[illegible]~~ assure acceptability of commercial off-the-shelf items where specific QA controls appropriate for nuclear applications cannot be imposed in a practicable manner.

COMPARISON: New question. Commitment meets SRP

735 Clarify that when reviews of suppliers are performed in which suppliers' certificates of conformance are evaluated by audits, independent inspections or tests to ensure they are valid, the results of these evaluations are documented.

COMPARISON: New question.

OK as is 12 Q of 17.2.17 states that records include results of review.

8A Clarify that the procedures implementing the requirements for control for identification and control pertain to partially fabricated subassemblies.

COMPARISON: New question. Although partially fabricated subassemblies are not specifically called out, Qs 3, 4, & 5 of FSAR Section 17.2.8 satisfy SRP item 8A.

933 Clarify that qualification records include qualification of equipment. Ex 3-7
Explain how the qualification records of procedures, equipment and personnel are kept current.

COMPARISON: New question. → 17.2.9.-2 mate SRP

12.8 Identify the "authorized" level of management allowed to approve the basis of calibration when no national standard exists (Section 17.2.12F of FSAR).

COMPARISON: New question. — Covered in Q-48 (Old Q-45)

13.1 Describe the methods used to assure that special handling, preservation, storage, cleaning, packaging and shipping are accomplished by suitably trained individuals.

17.2.13-1 C meets SRP

COMPARISON: New question.

14.1 Clarify that the procedures of 17.2.14C of the FSAR are applicable throughout test in addition to manufacturing, installation and operation as already listed.

COMPARISON: New question. 17.2.14-2C meets SRP

14.2 Describe the procedures established to control the application and removal of inspection and welding stamps and status indicators such as tags, markings, labels and stamps. Clarify that the procedures of Section 17.2.14A of the FSAR are applicable to the application and removal of stamps such as inspection and welding stamps.

COMPARISON: New question.

14.4 Identify the organization responsible for documentation and identification of nonconforming, inoperative or malfunctioning structures, systems and components to prevent inadvertant use.

COMPARISON: New question. Added to Q-53

15.1 Clarify that the provisions of Section 17.2.15 of the FSAR for control of nonconforming material are applicable to computer codes.

Describe the measures used to identify, review and disposition nonconforming material, parts or components and as applicible, services.

Identify which individuals in the QA organization are responsible for independent review of all nonconformances, including disposition and closeout.

COMPARISON: New question.

1:32 Describe the measures used to assure that audits are conducted by "appropriately" trained and qualified individuals (FSAR Section 17.2.18, 2nd paragraph, A).

COMPARISON: New question. Covered by commitment to RG 1.146

worked { Sat. 12/10 9:45 - 6:00
Sun 12/11 9:00 - 5:00

12/11/83

Jim:

I thought you were coming in this weekend. I wanted to talk to you about the Vogtle review since I was having a problem deciding how to approach what I was finding. I decided to prepare the attached which describes my preliminary review results & my opinion of what those results indicate. I'm sure Jack did a very thorough review on his end but I can't agree that we (QUAB) should send the licensee a 15-pg enclosure of questions to answer on their program.

I will be prepared on Monday to show you specific examples of my review findings. Melinda 66

December 11, 1983

NOTE TO: J. L. MILHOAN

Preliminary Review of Vogtle Electric Generating Plant (Units 1 and 2) FSAR Quality Assurance Program, Dockets 50-424/425

On December 10 and 11, 1983, I spent over 12 hours evaluating the pertinent portions of the subject FSAR to determine acceptability to the Standard Review Plan (SRP) Chapter 17.2. In the course of this review, I ~~specifically audited~~ evaluated:

1. Georgia Power Corporation's commitments to follow 10CFR 50.34(g) and Regulatory Guide 1.70.

2. evaluated selected portions of FSAR Section 1.9 addressing conformance to NRC regulatory guides relating to quality assurance activities, i.e., RG 1.8, 1.33, 1.144, 1.30.

3. completely reviewed three of the eighteen sections of the Vogtle ~~QAPP~~ Operations Quality Assurance Program (OQAP) to the SRP, namely, procurement document control (17.2.4), document control (17.2.6), and control of

Based on ~~this~~ initial review, I am of the opinion ~~that~~ the Vogtle FSAR does not provide a reasonably complete presention of the information necessary to evaluate the acceptability of the Vogtle QQAP, and that further reivew of ~~this~~ portion of the application should be terminated. I recommend that the ~~Licensee~~ applicant be advised ~~thereof~~ of the apparent incompleteness of the application in this area. ~~and~~ (see Enclosure 1)

(continued on next page)

applicant commits
~~It is the intent~~ in this FSAR to follow
10CFR 50.34 (g), "Conformance with the
Standard Review Plan (SRP)" and the guidance
contained in Regulatory Guide 1.70, Revision 3,
"Standard Format and Content of Safety
Analysis Reports for Nuclear Power Plants,
LWR Edition", refer respectively to PSAR-FSAR-1, Sub-
sections 1.1.6.2 (page 1.1-3) and 1.1.6.1
(page 1.1-3). 10CFR 50.34(g) requires that
applicants identify differences from the SRP
acceptance criteria and evaluate how their
proposed alternatives to the SRP criteria
provide an acceptable method of complying
with the Commission's regulations. Regulatory
Guide 1.70, Section 17 (2nd paragraph) ~~states~~
~~that~~ the FSAR quality program description must
address, as a minimum, each of the Appendix
B criteria in sufficient detail to enable the
reviewer to determine whether and how all the
requirements of the appendix will be satisfied
in accordance with 10CFR 50.34. Further, Regulatory
Guide 1.70 advises (see 3rd paragraph) that the FSAR specifically
indicate whether the applicable regulatory
guides will be followed. If they will not be
followed, the FSAR should describe the specific
alternative methods that are proposed and
how they will be implemented.

~~Specific references of~~

identify all applicable references within the FSAR (required by Licensee's commitment to follow RG 1.70 and does not always

My review disclosed that ~~section~~ section 1.9 of the FSAR does not always specifically identify exceptions to the NRC regulatory guides. In a number of instances, it lists "clarifications", many of which could be construed to be "exceptions". Where exceptions are specifically noted the FSAR does not always provide or reference ~~justification~~ an explanation of the proposed alternative. There is inadequate cross-referencing of material within section 1.9. In the final analysis the burden of identifying what is an exception is often on the reviewer.

During my review of the FSAR to determine acceptability to the criteria of SRP 17.2.4, 17.2.6 and 17.2.9, I found a number of areas in which the FSAR was silent or incomplete in addressing the acceptance criteria. In other areas the description given contradicts the acceptance criteria, and the ~~Licensee~~ applicant does not identify these differences or provide an explanation. I also found at least two instances in which the information presented in one section ~~conflicts with~~ is not addressed by or conflicts with the information provided in another section.

or ~~this~~ inadequate
document such as this,

It is my understanding that the other assigned reviewer (J. Spraul) generated approximately 15 pages of questions for the ~~licensee~~ applicant on the content of the FSAR or lack thereof. This large number of questions, along with the more general findings of my review give strong evidence that the ~~licensee~~ applicant has not put forth a sincere effort to prepare a well-documented OQAP that is acceptable to the NRC. I ~~[illegible]~~ feel that the NRC reviewers should not be put in the position of doing the ~~licensee's~~ applicant's job, i.e., telling the ~~licensee~~ applicant exactly what they have missed in their description and exactly how to say it. Reviewing in this fashion unjustly places the burden of discovering the inadequacy of the program on the reviewers.

Melinda Mallory

Enclosure: Proposed memo from Parthow to Novak

DISTRIBUTION
T. Ankrum
J. Spraul

PROPOSED LETTER ENCLOSURE

Docket No. 50-424/425

Memorandum For: Thomas M. Novak, AD for Licensing

From: James G. Partlow

Subject: Vogtle Operations Quality Assurance Program

The Quality Assurance Branch has reviewed the Vogtle FSAR, Section 17, ~~description~~ describing the operations quality assurance program (OQAP). This review was made to determine acceptability to Section 17.2 of the Standard Review Plan (NUREG-0800) and it considered the licensee's commitments to follow Regulatory Guide 1.70, Revision 3, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants, LWR Edition" and 10 CFR 50.34(g). "Conformance with the Standard Review Plan (SRP)".

The QUAB reviewers have determined, based on a preliminary review of the application, ~~that~~ the FSAR provided does not provide a reasonably complete presentation of the information needed to determine the acceptability of the OQAP. In particular, this preliminary review identified the following:

1. Specific FSAR references and all applicable FSAR references are not always included in Section 1.9, which identifies compliance with the NRC regulatory guides. Cross-referencing of applicable information within Section 1.9 is inadequate.

2. "Clarifications" to various regulatory guides are listed in Section 1.9 of the FSAR, many of which constitute "exceptions" but are not presented as exceptions.

3. Where exceptions or clarifications (as in 2 above) to various regulatory guides are identified in Section 1.9 of the FSAR, the FSAR does not always provide or reference an explanation of how proposed alternative may be considered as acceptable. Often, the burden of identifying the exceptions is on the reviewer since the applicant has not provided specific information.

4. The FSAR is silent in addressing the SRP acceptance criteria in a number of areas and in other areas the FSAR contradicts the acceptance criteria but provides no explanation of the method proposed.

5. In some instances, the information provided in the FSAR is contradictory from section to section.

On the basis of the above, we recommend that the applicant be advised to reevaluate their OQAP as presented in the FSAR to assure consistency with the requirements of 10 CFR 50.34 (a) and their commitments to Regulatory Guide 1.70, revise the OQAP as necessary and resubmit the pertinent portions of the FSAR for NRC review.

Please be advised that the Q-list is currently under evaluation by the NRC Staff. ~~Their review should be completed by the time~~ Should you have any questions in regards to the review discussed in this memorandum or our recommendations, please contact _____.

You will be notified of its acceptability ~~will be addressed by~~ under separate cover.

J. G. Partlow, etc.

cc: Licensing Project Manager
Region II

15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Provisions to control the use or disposition of nonconforming materials, parts, or components.

16. CORRECTIVE ACTION

Provisions to assure that conditions adverse to quality are promptly identified and corrected and that measures are taken to preclude repetition.

17. QUALITY ASSURANCE RECORDS

Provisions for the identification, retention, retrieval, and maintenance of records that furnish evidence of activities affecting quality.

18. AUDITS

A. Provisions for audits to verify compliance with all aspects of the QA program and to determine the effectiveness of the QA program.

B. Responsibilities and procedures for auditing, documenting and reviewing audit results, and designating management levels to review and assess audit results.

II. ACCEPTANCE CRITERIA

The applicant (and its principal contractors such as the NSSS vendor, A/E, constructor and construction manager) must establish a QA program for the design and construction phases in accordance with Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The applicant's QA program (including its principal contractors) must describe in the PSAR or SSAR how each criterion of Appendix B will be met. The acceptance criteria used by the QAB to evaluate this QA program are listed in the following eighteen subsections. The acceptance criteria include a commitment to comply with the regulations, regulatory positions presented in the appropriate issue of the Regulatory Guides, and the Branch Technical Position listed in subsection V. Thus, the commitment constitutes an integral part of the QA program description and requirements. Exceptions and alternatives to these acceptance criteria may be adopted by applicants provided adequate justification is given; the QAB review allows for considerable flexibility in defining methods and controls while still satisfying pertinent regulations. When the QA program description meets the applicable acceptance criteria of this subsection or provides acceptable exceptions or alternatives, the program is considered to be in compliance with pertinent NRC regulations.

The review will ascertain that the commitments and the description of how the commitments are implemented, to the extent necessary, are objective and stated in inspectable terms.

The Organization (17.1.1) elements responsible for the QA program are acceptable if:

1A1.* The responsibility for the overall program is retained and exercised by the applicant. 17.2-1 OK

1A2. The applicant has identified and described major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations.
No major delegation - See 17.2.4 & 17.2.7 for procurements OK

1A3. When major portions of the applicant's program are delegated:

a. Applicant describes how responsibility is exercised for the overall program. The extent of management oversight should be addressed including the location, qualifications, and criteria for determining the number of personnel performing these functions.

b. Applicant evaluates the performance (frequency and method stated - once per year although longer cycle acceptable with other evaluations of individual elements) of work by the delegated organization.

c. Qualified individual(s) or organizational element(s) are identified within the applicant's organization as responsible for the quality of the delegated work prior to initiation of activities.
NA - OK

~~1A4. Clear management controls and effective lines of communication exist for QA activities among the applicant and the principal contractors to assure direction of the QA program.~~

1A5. Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program (such as design, engineering, procurement, manufacturing, construction, inspection, test, instrumentation and control, nuclear engineering, etc.), the lines of responsibility, and a description of the criteria for determining the size of the QA organization including the inspection staff. operations, maintenance, Q-1

~~1A6.~~ The applicant ~~(and principal contractors)~~ describes the QA responsibilities of each of the organizational elements noted on the organization charts. 17.2.1 OK

~~1B1.~~ The applicant ~~(and principal contractors)~~ identifies a management position that retains overall authority and responsibility for the QA program (normally, this position is the QA Manager) and this position has the following characteristics:
Vogtle QA Manager

a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as engineering, procurement, construction, and operation) and is sufficiently independent from cost and schedule.
OK

*The alphanumeric designation for each acceptance criterion in subsection II indicates its relationship to the areas of review identified in subsection I.

b. Has effective communication channels with other senior management positions. Thru the GMQA - DIRECT to the Mgr, Nuc Generation per Fig 17.2.1-1 OK

c. Has responsibility for approval of QA Manual(s). 17.2.1.3.2-2 H&I OK - IN SPITE OF GMQA's responsibilities in 17.2.1.3.1-2 B&C

d. Has no other duties or responsibilities unrelated to QA that would prevent his full attention to QA matters. 17.2.1.3.2 & Fig 17.2.1-1 OK

~~1B2.~~ Verification of conformance to established requirements (except for designs, ref. 3E2) is accomplished by individuals or groups within the QA organization who do not have direct responsibility for performing the work being verified or by individuals or groups trained and qualified in QA concepts and practices and independent of the organization responsible for performing the task. QC Supervisor & his staff OK 17.2-2F & 17.2.1.2.2 See SRP, ta 13.1a

1B3. Persons and organizations performing QA functions have [direct access to management levels] which will assure the ability to: QA & QC OK per Org Chart (Fig 17.2.1-1) Q-2

a. Identify quality problems. {by audits (QA) & inspections (QC)

b. Initiate, recommend, or provide solutions through designated channels.

c. Verify implementation of solutions. {by reaudits (QA) & reinspections (QC)

Those persons and organizations with the above authority are identified and a description of how those actions are carried out is provided. CA&QC

1B4. a. Designated QA personnel, sufficiently free from direct pressures for cost/schedule, have the responsibility delineated in writing to stop unsatisfactory work and control further processing, delivery, or installation of nonconforming material. But... Q-3

b. The organizational positions with stop work authority are identified. 17.2.1.3.4 & 17.2.1.3.2 But...

~~1B5.~~ Provisions are established for the resolution of disputes involving quality, arising from a difference of opinion between QA personnel and other department (engineering, procurement, manufacturing, etc.) personnel. 17.2.1.3.4 OK

1B6. Designated QA individuals are involved in day-to-day plant activities important to safety (i.e., the QA organization routinely attends and participates in daily plant work schedule and status meetings to assure they are kept abreast of day-to-day work assignments throughout the plant and that there is adequate QA coverage relative to procedural and inspection controls, acceptance criteria, and QA staffing and qualification of personnel to carry out QA assignments). Q-5

~~1C1.~~ Policies regarding the implementation of the QA program are documented and made mandatory. These policies are established at the Corporate President or Vice President level. Exec. VP - Power Supply 17.2-2 17.2.2-3 OK

1C2. Position description (see 1B1) assures that the individual directly responsible for the definition, direction, and effectiveness of the overall QA program has sufficient authority to effectively implement Q-6

responsibilities. This position is to be sufficiently free from cost and schedule responsibilities. Qualification requirements for this individual are established in a position description which includes the following prerequisites:

a. Management experience through assignments to responsible positions.

b. Knowledge of QA regulations, policies, practices, and standards.

c. Experience working in QA or related activity in reactor design, construction, or operation or in a similar high technological industry.

The qualifications of the QA Manager should be at least equivalent to those described in Section 4.4.5 of ANSI/ANS-3.1-1978, "Selection and Training of Nuclear Power Plant Personnel," as endorsed by the regulatory positions in Regulatory Guide 1.8.

~~1C3.~~ The person at the ~~construction~~ site responsible for directing and managing the site QA program is identified by position and has appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. This individual is free from non-QA duties and can thus give full attention to assuring that the QA program at the plant site is being effectively implemented.

17.2.1.3.3 QA Site Manager, Fig 17.2.1-1 OK

Activities related to Quality Assurance Program (17.1.2) are acceptable if:

~~2A1.~~ The scope of the QA program includes:

~~a.~~ A commitment that activities affecting safety-related structures, systems, and components ~~important to safety~~ will be subject to the applicable controls of the QA program. The structures, systems, components, and related consumables covered by the QA program are identified (QA list) in Section 3.2.1 of the SAR.* 17.2.2-2 & -3

QA List Question OWOK

~~b. A commitment that the preoperational test program will be conducted in accordance with the QA program and a description of how the QA program will be applied.~~

c. A commitment that the development, control, and use of computer code programs will be conducted in accordance with the QA program and a description of how the QA program will be applied.

17.2.2-3 (last bullet) OK

---

* Rulemaking is currently underway to clarify the requirement that structures, systems, and components important to safety as derived from the General Design Criteria of Appendix A to 10 CFR Part 50 shall be subjected to the pertinent requirements of the quality assurance criteria of Appendix B to 10 CFR 50. Until this rulemaking process is completed, staff reviewers should assure that the applicant's list of structures, systems, and components includes all those items necessary to prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public as stated in the Introduction to Appendix B. Guidance for identifying such items is provided in Regulatory Guide 1.29.

d. The identification of fire protection in SRP Section 9.5.1 as a system covered by the QA program or identification of the QA controls for fire protection. These controls are reviewed and accepted using the guidelines contained in BTP ASB 9.5-1 and 10 CFR Part 50 Appendix B as appropriate.
9.5.1.4, Appendix 9B, & 17.2.2-3 (third from last bull) O/C

e. A commitment that special equipment, environmental conditions, skills, or processes will be provided as necessary.
17.2-2 E O/C

2A2. A brief summary of the company's corporate QA policies is given.
Policies, goals, & objectives. 17.2-2 OK

2B1. a. Provisions are established to assure that quality-affecting procedures required to implement the QA program are consistent with QA program commitments and corporate policies and are properly documented, controlled, and made mandatory through a policy statement or equivalent document signed by the responsible official. 17.2.2-3

Q-7

b. The QA organization reviews and documents concurrence with these quality-related procedures.

c. The organizational group or individual having responsibility for the policy statement should be identified.

d. The quality affecting procedural controls of the [principal contractors] should be provided for the applicant's review with documented agreement of acceptance prior to initiation of activities affected by the program. N/A - Procurement controls covered under criteria 4 & 7

2B2. Provisions are included for notifying NRC of changes (1) for review and acceptance in the accepted description of the QA program as presented or referenced in the SAR or SSAR prior to implementation, and (2) in organizational elements within 30 days after announcement. (Note - editorial changes or personnel reassignments of a non-substantive nature do not require NRC notification). 17.2.2-12 OK

2B3. The applicant ~~(and the principal contractors)~~ commits to comply with the regulatory position in the appropriate issue of the [Regulatory Guides] listed in Subsection ~~VI~~ to comply with 10 CFR Part 50, §50.55a; to conduct activities under 10 CFR Part 50, §50.55(e) in accordance with the QA program; and to comply with 10 CFR Part 50 Appendix A, General Design Criterion 1. For systems, components, and structures covered by the ASME Code Section III (Classes 1, 2 and 3), the quality assurance code requirements should be supplemented by the specific guidance addressed in the regulatory positions of the applicable Regulatory Guides. The commitment identifies the Regulatory Guides and ANSI standard by number, title, and revision or date. Any alternatives or exceptions are clearly identified and supporting information presented in the docket. QA Regulatory Guides should be addressed which have an implementation date prior to the submittal or docket date of the QA program description.

Q-8 Construction Permit Holders

Codes & standards

Needs NRC clarification (Generic)

Q-9

FSAR Section 1.9

Although primary responsibility for Regulatory Guides 1.26 and 1.29 is assigned to ASB (SRP Sections 3.2.1 and 3.2.2), their use as acceptance criteria in this SRP section is necessary to assure that

adequate quality assurance requirements are specified for systems, components, and structures addressed by those guides.

The QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls are to be applied to specific structures, systems, and components. This effort involves applying a defined graded approach to certain structures, systems, and components in accordance with their importance to safety and affects such disciplines as design, procurement, document control, inspection tests, special processes, records, audits, and others described in 10 CFR Part 50, Appendix B.

2B4. Existing or proposed QA procedures are identified reflecting that Regulatory Guides listed in subsection VI, ~~General Design Criterion 1 of Appendix A to 10 CFR Part 50~~, 10 CFR Part 50, §50.55a, and each criterion of 10 CFR Part 50, Appendix B will be met by documented procedures. In addition, activities conducted under 10 CFR Part 50.21 §50.55(e) shall conform to the requirement of the QA program.

2B5. A description is provided that emphasizes how the docketed QA program description, particularly the 10 CFR Part 50 regulations and Regulatory Guides listed in subsection VI, will be properly carried out.

2C1. A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA program to 10 CFR Part 50, Appendix B. These measures should include:

a. Frequent contact with program status through reports, meetings, and/or audits.

b. Performance of an annual assessment preplanned and documented. Corrective action is identified and tracked.

~~2C2. Quality-related activities (such as design, procurement, and site investigation) initiated prior to formal NRC acceptance of the QA program are controlled under a QA program in accordance with this SRP and, accordingly, with the requirements of 10 CFR Part 50, Appendix B. Approved procedures and a sufficient number of trained personnel should be available to implement the applicable portion of the QA program prior to the initiation of the activity.~~

2C3. A summary description is provided on how responsibilities and control of quality-related activities are transferred from the principal contractors to the applicant during the phaseout of design ~~and construction and during preoperational testing and plant turnover.~~

2D. Indoctrination, training, and qualification programs are established such that:

a. Personnel responsible for performing quality-affecting activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.

b. Personnel verifying activities affecting quality are trained and qualified in the principles, techniques, and requirements of the activity being performed. 17.2.2-7 (refers to 12?) OK

c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance. 17.2.2-9 OK

Q-13 a d. Proficiency tests are given to those personnel performing and verifying activities affecting quality, and acceptance criteria are developed to determine if individuals are properly trained and qualified.

b e. Certificate of qualifications clearly delineates (a) the specific functions personnel are qualified to perform and (b) the criteria used to qualify personnel in each function.

c f. Proficiency of personnel performing and verifying activities affecting quality is maintained by retraining, reexamining, and/or recertifying as determined by management or program commitment.

g. The description of the training program provisions listed above ~~satisfies~~ does not contradict the regulatory position in Regulatory Guide 1.58. OK 17.2.2-7 thru 9

→ 17.2.2

Activities related to Design Control (17.2.3) are acceptable if:

3A The scope of the design control program includes design activities associated with the preparation and review of design documents including the correct translation of applicable regulatory requirements and design bases into design, procurement and procedural documents. Included in the scope are such activities as field design engineering; physics; seismic; stress; thermal; hydraulic; radiation; and the SAR accident analyses; associated computer programs; compatibility of materials; accessibility for inservice inspection; maintenance; and repair; and quality standards. OK in 17.2.2-1, 17.2.3-5A, OK in 17.2.3-5G, work in 17.2.2-6, 17.2.3-5B OK

3B. Organizational responsibilities are described for preparing, reviewing, approving, and verifying design ~~documents such as system descriptions, design input and criteria, design drawings, design analyses, computer programs, specifications, and procedures~~ modification. 17.2.3-2 thru 4 OK

3C1. Errors and deficiencies in approved design documents, including design methods (such as computer codes), that could adversely affect structures, systems, and components important to safety are documented; and action is taken to assure that all errors and deficiencies are corrected. 17.2.3-9 OK

3C2. Deviations from specified quality standards are identified and procedures are established to ensure their control. 17.2.3-9 E

3D. Internal and external design interface controls, procedures, and lines of communication among participating design organizations and across technical disciplines are established and described for the review, approval, release, distribution, and revision of documents involving design interfaces to assure structures, systems, and Section 17.2.15 OK

Q-14

components are compatible geometrically, functionally, and with processes and environment.

3E1. Procedures are established and described requiring a documented check to verify the dimensional accuracy and completeness of design drawing and specifications. 17.2.3-7F OK

Q-5 3E2. Procedures are established and described requiring that design drawings and specifications be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with company procedures and that the documents contain the necessary quality assurance requirements such as inspection and test requirements, acceptance requirements, and the extent of documenting inspection and test results.

#1 Q-16 3F3. Guidelines or criteria are established and described for determining the method of design verification (design review, alternate calculations, or test). 17.2.3-7, but - forget the "F" - OK in 17.2.3-1.

#1 3E4. Procedures are established and described for design verification activities which assure the following:

a. The verifier is qualified and is not directly responsible for the design (i.e., neither the performer or his immediate supervisor). In exceptional circumstances, the designer's immediate supervisor can perform the verification provided:

(1) The supervisor is the only technically qualified individual.

(2) The need is individually documented and approved in advance by the supervisor's management.

(3) QA audits cover frequency and effectiveness of use of supervisors as design verifiers to guard against abuse.

b. Design verification, if other than by qualification testing of a prototype or lead production unit, is completed prior to release for procurement, manufacturing, construction or to another organization for use in other design activities. In those cases where this timing cannot be met, the design verification may be deferred, providing that the justification for this action is documented and the unverified portion of the design output document and all design output documents, based on the unverified data, are appropriately identified and controlled. Construction site activities associated with a design or design change should not proceed without verification past the point where the installation would become irreversible (i.e., require extensive demolition and rework). In all cases, the design verification should be complete prior to fuel load for a plant under construction, or in the case of an operating plant, prior to relying upon the component, system, or structure to perform its function.

c. Procedural control is established for design documents that reflect the commitments of the SAR; this control differentiates between documents that receive formal design verification by

interdisciplinary or multi-organizational teams and those which can be reviewed by a single individual (a signature and date is acceptable documentation for personnel certification). Design documents subject to procedural control include, but are not limited to, specifications, calculations, computer programs, system descriptions, SAR when used as a design document, and drawings including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams, structural systems for major facilities, site arrangements, and equipment locations. Specialized reviews should be used when uniqueness or special design considerations warrant.] 17.2.3-7E

d. The responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in procedures.

3E2. The following provisions are included if the verification method is only by test:

a. Procedures provide criteria that specify when verification should be by test.

b. Prototype, component or feature testing is performed as early as possible prior to installation of plant equipment, or prior to the point when the installation would become irreversible.

c. Verification by test is performed under conditions that simulate the most adverse design conditions as determined by analysis.

3E4. Procedures are established to assure that verified computer codes are certified for use and that their use is specified. 17.2.3-7c OK

3F1. Design and specification changes, including fields changes, are subject to the same design controls that were applicable to the original design. commensurate 17.2.3-4 OK

3F2. The description of the design control provisions satisfies does not contradict the criteria of Regulatory Guide 1.64. 17.2.3 OK

17.2.3

Activities related to Procurement Document Control (17.2.4) are acceptable if:

4A1. Procedures are established for the review of procurement documents to determine that quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and procurement documents have been prepared, reviewed, and approved in accordance with QA program requirements. To the extent necessary, procurement documents should require contractors and subcontractors to provide an acceptable quality assurance program. The review and documented concurrence of the adequacy of quality requirements stated in procurement documents is performed by independent personnel trained and qualified in QA practices and concepts. OK

4A2. Procedures are established to assure that procurement documents identify applicable regulatory, technical, administrative, and

reporting requirements; drawings; specifications; codes and industrial standards; test and inspection requirements; and special process instructions that must be complied with by suppliers. -2E OK

Q-22 4B1. Organizational responsibilities are described for (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluations; and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described.

4B2. The description of the procurement document control provisions listed above satisfies the regulatory position in Regulatory Guide 1.123. does not contradict. OK

Activities related to Instructions, Procedures, and Drawings (17.2.5) are acceptable if:

5A. Organizational responsibilities are described for assuring that activities affecting quality are (1) prescribed by documented instructions, procedures, and drawings and (2) accomplished through implementation of these documents. -1 but...

Q-23

5B. Procedures are established to assure that instructions, procedures, and drawings include quantitative (such as dimensions, tolerances, and operating limits) and qualitative (such as workmanship samples) acceptance criteria for determining that important activities have been satisfactorily accomplished. -1 OK

Activities related to Document Control (17.2.6) are acceptable if:

6A1. The scope of the document control program is described, and the types of controlled documents are identified. As a minimum, controlled documents include:

a. Design documents (e.g., calculations, drawings, specifications, analyses) including documents related to computer codes. -1A

Q-26

b. Procurement documents. -1B

c. Instructions and procedures for such activities as fabrication, ~~construction~~, modification, installation, test, and inspection. -1C, D, & F

d. As-built documents.

e. Quality assurance and quality control manuals [and quality-affecting procedures.] -1C, D, & F

f. Topical reports.

g. SAR. > -1E

h. Nonconformance reports.

6A2. Procedures for the review, approval, and issuance of documents and changes thereto are established and described to assure technical

adequacy and inclusion of appropriate quality requirements prior to implementation. The QA organization, or an individual other than the person who generated the document but qualified in quality assurance, reviews and concurs with these documents with regards to QA-related aspects.

Q-36 -2A, but...

6A3. Procedures are established to assure that changes to documents are reviewed and approved by the same organizations that performed the initial review and approval or by other qualified responsible organizations delegated by the applicant. — authorized personnel per -2A

OK in -2C

6A4. Procedures are established to assure that documents are available at the location where the activity will be performed prior to commencing the work.

-2B OK

6B1. Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revisions in work areas in a timely manner. -2E OK

Q-27 6B2. A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents. When such a list is used, it should be updated and distributed to predetermined responsible personnel. -2D OK

6C1. Procedures are established and described to provide for the preparation of as-built drawings and related documentation in a timely manner to accurately reflect the actual plant design. -2B OK

Q-28 → 17.2.6

Activities related to Control of Purchased Material, Equipment, and Services (17.1.7) are acceptable if:

7A1. Organizational responsibilities are described for the control of purchased material, equipment, and services including interfaces between design, procurement, and QA organizations.

Q-29

7A2. Verification of suppliers' activities during fabrication, inspection, testing, and shipment of materials, equipment, and components is planned and performed with QA organization participation in accordance with written procedures to assure conformance to the purchase order requirements. These procedures, as applicable to the method of procurement, provide for:

17

17.2.7.2 OK

a. Specifying the characteristics or processes to be witnessed, inspected or verified, and accepted; the method of surveillance and the extent of documentation required; and those responsible for implementing these procedures.

-A OK

b. Audits, surveillance, or inspections which assure that the supplier complies with the quality requirements.

-B OK

7A3. Selection of suppliers is documented and filed. If an LCVIP letter of confirmation or the "CASE" Register is used to establish the qualifications of the supplier, the documentation should identify the "letter" or "audit" used.

17.2.7.1-1C OK

7A4. Procedure of spare or replacement parts for safety-related structures, systems, and components ~~important to safety~~ is subject to present QA program controls, to codes and standards, and to technical requirements equal to or better than the original technical requirements, or as required to preclude repetition of defects.

7B1. Receiving inspection is performed to assure:

a. The material, component, or equipment is properly identified and corresponds to the identification on the purchase document and the receiving documentation. 17.2.7.3-1A OK

b. Material, components, equipment, and acceptance records satisfy the inspection instructions prior to installation or use.

c. Specified inspection, test and other records, (such as certificates of conformance attesting that the material, components, and equipment conform to specified requirements) are available at the nuclear power plant prior to installation or use. 17.2.7.3-1C OK

17.2.7.3-1B OK

7B2. Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for installation or further work. 17.2.7.3-1D OK

7B3. The supplier furnishes the following records to the purchaser:

a. Documentation that identifies the purchased item and the specific procurement requirements (e.g., codes, standards, and specifications) met by the item.

b. Documentation identifying any procurement requirements that have not been met.

c. A description of those nonconformances from the procurement requirements dispositioned "accept as is" or "repair."

The review and acceptance of these documents should be described in the purchaser's QA program.

7B4. For commercial "off-the-shelf" items where specific quality assurance controls appropriate for nuclear applications cannot be imposed in a practicable manner, special quality verification requirements shall be established and described to provide the necessary assurance of an acceptable item by the purchaser. 17.2.7.3-2 OK

7B5. Suppliers' certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented. 17.2.7.1-1 OK

7B6. The description of the control of procurement provisions listed above does not contradict ~~satisifies~~ the regulatory position in Regulatory Guide 1.38 and Regulatory Guide 1.123.

OK

Activities related to Identification and Control of Materials, Parts, and Components (17.1.8) are acceptable if:

8A. Controls are established and described to identify and control materials (including consumables), parts, and components including partially fabricated subassemblies. The description should include organizational responsibilities.

8B1. Procedures are established which assure that identification is maintained either on the item or on records traceable to the item to preclude use of incorrect or defective items.

8B2. Identification of materials and parts important to the function of safety-related structures, systems, and components important to safety can be traced to the appropriate documentation such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, and physical and chemical mill test reports.

8B3. Correct identification of material, parts, and components is verified and documented prior to release for fabrication, assembling, shipping, and installation.

Activities related to Control of Special Processes (17.1.9) are acceptable if:

9A1. The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, should be provided. Some examples are welding, heat treating, NDT, and chemical cleaning.

9A2. Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.

9B1. Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. The QA organization is involved in the qualification activities to assure they are satisfactorily performed.

9B2. Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

9B3. Qualification records of procedures, equipment, and personnel associated with special processes are established, filed, and kept current.

Activities related to Inspection (17.1.10) are acceptable if:

10A. The scope of the inspection program is described that indicates an effective inspection program has been established. Program procedures provide criteria for determining the accuracy requirements of inspection equipment and criteria for determining when inspections are

required or define how and when inspections are performed. The QA organization participates in the above functions.

10B1. Organizational responsibilities for inspection are described. Individuals performing inspections are other than those who performed or directly supervised the activity being inspected and do not report directly to the immediate supervisors who are responsible for the activity being inspected. If the individuals performing inspections are not part of the QA organization, the inspection procedures, personnel qualification criteria, and independence from undue pressure such as cost and schedule should be reviewed and found acceptable by the QA organization prior to the initiation of the activity.

Inspectors are in QC - Check in Q-39 Also see Q-4

17.2.10-5

10B2. A qualification program for inspectors (including NDT personnel) is established and documented, and the qualifications and certifications of inspectors are kept current.

17.2.10-5, but

10C1. Inspection procedures, instructions, or checklists provide for the following:

a. Identification of characteristics and activities to be inspected.

b. A description of the method of inspection.

c. Identification of the individuals or groups responsible for performing the inspection operation in accordance with the provisions of item 10B1.

d. Acceptance and rejection criteria.

e. Identification of required procedures, drawings and specifications and revisions.

f. Recording inspector or data recorder and the results of the inspection operation.

g. Specifying necessary measuring and test equipment including accuracy requirements.

17.2.10-3 OK

10C2. Procedures are established and described to identify, in pertinent documents, mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.

17.2.10-6 OK

10C3. Inspection results are documented, evaluated and their acceptability determined by a responsible individual or group.

17.2.10

17.2.10-5 OK

Activities related to Test Control (17.1.11) are acceptable if:

11A1. The description of the scope of the test control program indicates an effective test program has been established for tests including proof tests prior to installation and preoperational tests. Program procedures provide criteria for determining the accuracy requirements of test equipment and criteria for determining when a test is required or how and when testing activities are performed.

17.2.11-1

11B1. Test procedures or instructions provide as required for the following:

a. The requirements and acceptance limits contained in applicable design and procurement documents.

b. Instructions for performing the test.

c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation including their accuracy requirements, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage. > Q-40 ok

d. Mandatory inspection hold points for witness by owner, contractor, or inspector (as required).

e. Acceptance and rejection criteria.

f. Methods of documenting or recording test data and results.

Q-44 → g. Provisions for assuring test prerequisites have been met. 17.2.11-1

11C1. Test results are documented, evaluated, and their acceptability determined by a responsible individual or group. 17.2.11-3 ok

Activities related to Control of Measuring and Test Equipment (17.1.12) are acceptable if:

12.1 The scope of the program for the control of measuring and test equipment is described and the types of equipment to be controlled are established. This information indicates an effective calibration program has been established. 17.2.12-1&-2A ok 17.2.12-2A

12.2 QA and other organizations' responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program. Q-45 17.2-4

12.3 Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) that is used in the measurement, inspection, and monitoring of structures, systems, and components. The review and documented concurrence of these procedures is described and the organization responsible for these functions is identified. Q-43 46 17.2.12-4 17.2.12-2A

Q-47 12.4 Measuring and test equipment is identified and traceable to the calibration test data. -2B ok

12.5 Measuring and test equipment is labeled or tagged or "otherwise controlled" to indicate due date of the next calibration. The method of "otherwise controlled" should be described. 2B

12.6 Measuring and test equipment is calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement. 2C ok

Calibration of this equipment should be against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, have an accuracy that assures the equipment being calibrated will be within required tolerance and that the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function is identified. 17.2.12-3

12.7 Calibrating standards have greater accuracy than standards being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function is identified. 17.2.12-2 F & 17.2.12-3

12.8 Reference and transfer standards are traceable to nationally recognized standards; where national standards do not exist, provisions are established to document the basis for calibration. 17.2.12-2 F & 17.2.12-3

12.9 Measures are taken and documented to determine the validity of previous inspections performed and the acceptability of items inspected or tested since the last calibration when measuring and test equipment is found to be out of calibration. Inspections or tests are repeated on items determined to be suspect. 17.2.12-2E

Activities related to Handling, Storage, and Shipping (17.1.13) are acceptable if:

13.1 Special handling, preservation, storage, cleaning, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions. approved plant procedures per-2 qualified per 17.2.13-1c

13.2 Procedures are established and described to control the cleaning, handling, storage, packaging, and shipping of materials, components, and systems in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity. manufacturer's recommendations per 17.2.13-1 in

13.3 The description of the control of handling, storage, and shipping listed above satisfies the regulatory position in Regulatory Guide 1.38. OK

17.2.13

Activities related to Inspection, Test, and Operating Status (17.1.14) are acceptable if:

14.1 Procedures are established to indicate the inspection, test, and operating status of structures, systems, and components throughout fabrication, installation, and test. 17.2.14-2 C OK

14.2 Procedures are established and described to control the application and removal of inspection and welding stamps and status indicators such as tags, markings, labels, and stamps. 17.2.14-2 A OK but

14.3 Procedures are established and described to control altering the sequence of required tests, inspections, and other operations important to safety. Such actions should be subject to the same controls as the original review and approval.

14.4 The status of nonconforming, inoperative, or malfunctioning structures, systems, and components is documented and identified to prevent inadvertent use. The organization responsible for this function is identified.

Activities related to Nonconforming Materials, Parts, or Components (17.1.15) are acceptable if:

15.1 Procedures are established and described for identification, documentation, segregation, review, disposition, and notification to affected organizations of nonconforming materials, parts, components and as applicable to services (including computer codes) if disposition is other than to scrap. The procedures provide identification of authorized individuals for independent review of nonconformances, including disposition and closeout.

15.2 QA and other organizational responsibilities are described for the definition and implementation of activities related to nonconformance control. This includes identifying those individuals or groups with authority for the disposition of nonconforming items.

15.3 Documentation identifies the nonconforming item, describes the nonconformance, the disposition of the nonconformance, and the inspection requirements; and includes signature approval of the disposition. Nonconformances are corrected or resolved prior to the initiation of the preoperational test program on the item.

15.4 Reworked, repaired, and replacement items are inspected and tested in accordance with the original inspection and test requirements or acceptable alternatives.

15.5 Nonconformance reports are periodically analyzed by the QA organization to show quality trends, and the significant results are reported to upper management for review and assessment.

Activities related to Corrective Action (17.1.16) are acceptable if:

16.1 Procedures are established and described indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures.

16.2 Corrective action is documented and initiated following the determination of a condition adverse to quality (such as a nonconformance, failure, malfunction, deficiency, deviation, and defective material and equipment) to preclude recurrence. The QA organization is involved in the documented concurrence of the adequacy of the corrective action.

16.3 Followup action is taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner.

16.4 Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition are documented and reported to immediate management and upper levels of management for review and assessment.

Activities related to Quality Assurance Records (17.1.17) are acceptable if:

17.1 The scope of the records program is described. QA records include results of reviews,[1] inspections,[2] tests,[3] audits,[4] and material analyses,[5] monitoring of work performance,[6] qualification of personnel,[7] procedures,[8] and equipment; and other documentation such as drawings,[10] specifications,[11] procurement documents,[12] calibration procedures and reports,[13] nonconformance reports,[14] and corrective action reports.[15]

17.2 QA and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to QA records.

17.3 Inspection and test records contain the following where applicable:

		INSP(10)	TEST(11)
a.	A description of the type of observation.	A&B	A
b.	The date and results of the inspection or test.	F	D
c.	Information related to conditions adverse to quality.		E
d.	Inspector or data recorder identification.	C	F
e.	Evidence as to the acceptability of the results.	G	G
f.	Action taken to resolve any discrepancies noted.		

17.4 Suitable facilities for the storage of records are described and satisfy the regulatory position given in Regulatory Guide 1.88 (endorses N45.2.9). Alternatives to the fire protection rated provisions are acceptable if records storage facilities conform to NFPA No. 232 Class 1 for permanent-type records and that the 2-hour fire rating requirement contained in the proposed N45.2.9 standard is met by applicants in any one of the following three ways. Specifically, (1) a 2-hour vault meeting NFPA No. 232; (2) 2-hour rated file containers meeting NFPA No. 232 (Class B); or (3) a 2-hour rated fire resistant file room meeting NFPA No. 232 if the following additional provisions are provided.

1. Early warning fire detection and automatic fire suppression should be provided, with electronic supervision at a constantly attended central station.

2. Records should be stored in fully enclosed metal cabinets. Records should not be permitted on open steel shelving. No storage of records should be permitted on the floor of the facility. Adequate access and aisle ways should be maintained at all times throughout the facility.

3. Work not directly associated with records storage or retrieval should be prohibited within the records storage facility. Examples of such prohibited activities include but are not limited to: records reproduction, film developing, and fabrication of microfiche cards.

4. Smoking and eating/drinking should be prohibited throughout the records storage facility.

5. Ventilation, temperature, and humidity control equipment should be protected inside with standard fire-door dampers where they penetrate fire barriers bounding the storage facility.

17.5 The description of the control of records provisions listed above ~~satisfies~~ does not contradict the regulatory position of Regulatory Guide 1.88. Ok

OK → 17.2.17
Activities related to Audits (17.1.18) are acceptable if:

~~18A1.~~ Audits to assure that procedures and activities comply with the overall QA program are performed by:

~~a.~~ The QA organization to provide a comprehensive independent verification and evaluation of quality-related procedures and activities. -2G1

~~b.~~ The QA organization ~~applicant (and principal contractors)~~ to verify and evaluate the QA programs, procedures, and activities of suppliers. OK -2G2 OK

~~18A2.~~ An audit plan is prepared identifying audits to be performed, their frequencies, and schedules. Audits should be regularly scheduled based upon the status and safety importance of the activities being performed and are initiated early enough to assure effective QA during design, procurement, manufacturing, construction, installation, inspection, and testing. -2H OK

~~18A3.~~ Audits include an objective evaluation of quality-related practices, procedures, instructions; activities and items; and review of documents and records to ensure that the QA program is effective and properly implemented. -2E&F OK

~~18A4.~~ Provisions are established requiring that audits be performed in all areas where the requirements of Appendix B to 10 CFR Part 50 are applicable. Areas which are often neglected but should be included are activities associated with:

~~a.~~ NA The determination of site features which affect plant safety (e.g., core sampling, site and foundation preparation, and methodology). (PSAR only).

~~b.~~ NA The preparation, review, approval, and control of early procurements. (PSAR only).

~~c.~~ Indoctrination and training programs. -3P

~~d.~~ Interface control among the applicant and ~~the principal~~ supplier contractors. -3O

e. Corrective action, calibration, and nonconformance control systems.

f. SAR and SSAR commitments.

g. Activities associated with computer codes.

1881. Audit data are analyzed by the QA organization and the resulting reports indicating any quality problems and the effectiveness of the QA program, including the need for reaudit of deficient areas, are reported to management for review and assessment.

1882. Audits are performed in accordance with pre-established written procedures or checklists and conducted by trained personnel having no direct responsibilities in the areas being audited.

1883. The description of the conduct of audit provisions satisfies the regulatory position in Regulatory Guides 1.144 and 1.146.

III. REVIEW PROCEDURES

Each element of the QA program description will be reviewed against the acceptance criteria described in subsection II, including the regulations, Regulatory Guides, and Branch Technical Position listed in subsection V. QAB will interface with the secondary review branches to assure that they have documented to the QAB by memo the acceptability of the identification of structures, systems, and components covered by the QA program (Q-List). QAB will process the necessary requests for additional information to the applicant and coordinate the response with the appropriate branches for acceptance. Changes to the QA program will be evaluated to assure at a minimum that such changes have not degraded the previously approved program. Consideration should be given to the current regulatory position in the area of the change in determining acceptability of the change. The reviewer's judgment during the review is to be based on an assessment of the material presented, the similarity of the material to that recently reviewed on other plants, and whether items of special safety significance are involved. Any exceptions or alternatives to this SRP section, including the regulations and regulatory positions presented in the Regulatory Guides in subsection V, will be carefully reviewed to assure that they are clearly defined and that an adequate basis exists for acceptance.

The acceptability of the QA program is determined by the following review procedures:

1. The QA program description is reviewed in detail to determine if each of the criteria of 10 CFR Part 50, Appendix B has been acceptably addressed and if there is an adequate commitment to comply with the regulations and regulatory positions in the appropriate issue of the Regulatory Guides in subsection V, as identified by number, title, revision or date. The QA program description is also reviewed to assure that the applicant's approach to meeting the QA criteria and commitments is acceptable.

2. The measures described to implement 10 CFR Part 50, Appendix B are evaluated for:

   a. Technical acceptability (i.e., do they meet the Regulations and Regulatory Guides?)

b. Workability (i.e., do they seem to fit into an overall plan of action that can be implemented?)

c. Management support (i.e., do QA program measures have adequate review, approval, and endorsement of management?)

This evaluation is based primarily on the acceptance criteria contained in subsection II.

3. The duties, responsibility, and authority of personnel performing QA functions are reviewed to assure they provide sufficient independence to effectively perform these functions.

4. Through review of information provided, meetings with the applicant, by review of the acceptability of QA program and plant activities including performance and capability of personnel, and by review of the Office of Inspection and Enforcement position statement and inspection reports, a judgment is made of the applicant's capability to carry out its QA responsibilities.

5. Satisfaction with program commitments and descriptions of how the commitments will be met, organizational arrangements, and capabilities to fulfill QA requirements should lead to the conclusion of acceptability, as described in subsection IV.

IV. EVALUATION FINDINGS

The reviewer verifies that sufficient information has been provided and that his review is sufficiently complete and adequate to support conclusions of the following type to be included in the staff's Safety Evaluation Report:

Based on our detailed review and evaluation of the QA program description contained in the (topical report or SAR) for (nuclear facility), we conclude that:

1. The organizations and persons performing QA functions have the required independence and authority to effectively carry out the QA program without undue influence from those directly responsible for costs and schedules.

2. The QA program describes requirements, procedures, and controls that, when properly implemented, comply with the requirements of Appendix B to 10 CFR Part 50 with the requirements of 10 CFR Part 50, §50.55a and §55(e); with the criteria contained in SRP Section 17.1; and with the regulatory positions presented in the following Regulatory Guides.

Reg. Guide/ANSI Std.	Title	Revision or Date

A brief description of the applicant's QA program is provided highlighting the more important aspects of the program.

3. The QA program covers activities affecting structures, systems, and components important to safety as identified in the PSAR.

Accordingly, the staff concludes that the applicant's description of the QA program is in compliance with applicable NRC regulations and industry standards and can be implemented for the (specify) phases of (specify application).

V. IMPLEMENTATION

The following is intended to provide guidance to applicants and licensees regarding the NRC staff's plan for using this SRP Section.

Except in those cases in which the applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the method described herein will be used by the staff in its evaluation of conformance with Commission regulations.

Implementation schedules for conformance to parts of the method discussed herein are contained in the referenced guides and NUREGs.

VI. REFERENCES

1. 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

2. 10 CFR Part 50, §50.55a, "Codes and Standards."

3. 10 CFR Part 50, §50.55(e), "Conditions of Construction Permits" (reporting significant QA deficiencies). N/A

4. 10 CFR Part 50, §50.34(a.7), "Contents of Application; Technical Information" (Preliminary Safety Analysis QA program description).

5. ~~10 CFR Part 50, Appendix A, "General Design Criteria for Nuclear Power Plants."~~ N/A

6. Regulatory Guide 1.8, "Personnel Selection and Training" (endorses ANSI/ANS 3.1). pg 1.9-4 - No commitment to comply

7. Regulatory Guide 1.26, "Quality Group Classification, and Standards for Water, Steam, and Radioactive Waste Containing Components of Nuclear Power Plants." pg 1.9-22 - No commitment to comply

8. Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)" (endorses N45.2). pg 1.9-23 N/A for ops

9. Regulatory Guide 1.29, "Seismic Design Classification." OK regarding QA

10. Regulatory Guide 1.30, "Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electric Equipment" (endorses N45.2.4). Reg Guide 1.33

11. Regulatory Guide 1.37, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants" (endorses N45.2.1).

12. Regulatory Guide 1.38, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants" (endorses N45.2.2).

13. Regulatory Guide 1.39, "Housekeeping Requirements for Water-Cooled Nuclear Power Plants" (endorses N45.2.3).

14. Regulatory Guide 1.58, "Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel" (endorses N45.2.6).

15. Regulatory Guide 1.64, "Quality Assurance Requirements for the Design of Nuclear Power Plants" (endorses N45.2.11).

16. Regulatory Guide 1.74, "Quality Assurance Terms and Definitions" (endorses N45.2.10).

17. Regulatory Guide 1.88, "Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records" (endorses N45.2.9).

18. Regulatory Guide 1.94, "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants" (endorses N45.2.5).

19. Regulatory Guide 1.116, "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems" (endorses N45.2.8).

20. Regulatory Guide 1.123, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants" (endorses N45.2.13).

21. Regulatory Guide 1.144, "Auditing of Quality Assurance Programs for Nuclear Power Plants" (endorses N45.2.12).

22. Regulatory Guide 1.146, "Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants" (endorses N45.2.23).

23. Branch Technical Position (BTP) ASB 9.5-1 (attached to SRP Section 9.5.1).

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR REACTOR REGULATION

17.2 QUALITY ASSURANCE DURING THE OPERATIONS PHASE

REVIEW RESPONSIBILITIES

Primary - Quality Assurance Branch (QAB)

Secondary - Mechanical Engineering Branch
Instrumentation & Control Systems Branch
Power Systems Branch
Accident Evaluation Branch
Radiological Assessment Branch
Hydrologic & Geotechnical Engineering Branch
Containment Systems Branch

I. AREAS OF REVIEW

QAB reviews and evaluates the applicant's operational quality assurance (QA) program as described in the FSAR. The review at the operating license stage addresses both the "offsite" and "onsite" QA controls to be applied to those activities that may affect the quality of items important to safety during the operation, maintenance, and modification of a nuclear power plant. The review covers the QA controls to be applied to those activities (e.g., designing, constructing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, maintaining, modifying, operating, inspecting, and testing) that may affect the quality of structures, systems, and components important to safety. The secondary review branches review the listing of structures, systems, and components (QA list) covered by the QA program for their areas of review responsibility in accordance with 2A1 of this section of the Standard Review Plan and documents the acceptability of the listing including any items that should be added or clarified by memo to the QAB. The review by MEB in this regard also addresses the areas of review responsibility normally assigned to ASB, RSB, CEB, PSB (except electrical), and SEB.

The review extends to the determination of how the applicable requirements of the 18 criteria of Appendix B to 10 CFR Part 50 are satisfied by the proposed QA program.

where an NRC-accepted QA topical report is referenced in the application, the referenced QA program is not re-reviewed except for conformance to the applicable staff positions in this SRP section and the Regulatory Guides in effect at the time of docketing the application.

The review will not involve an evaluation of the QA program for the design and construction phase and, therefore, the QAP description for design and construction should not be addressed in the FSAR except for a commitment for continued implementation of the PSAR QA program for the remaining design and construction activities and the preoperational test program or referenced as applicable for repair and modifications only during the operations phase. However, as desired, changes to the QA program for design and construction may be presented in the FSAR for staff review and approval. Staff review will only address the program changes.

The areas of review for this SRP section are the same as those described in SRP Section 17.1 except:

1. Organization (item 1) delete from part A: "including the applicant's organization and principal contractors (architect engineer, nuclear steam supply system vendor, constructor, and construction manager when other than the constructor)."

2. Audits (item 18) add a part C: "Provisions for the audit of operating activities important to safety independent of the operating organization."

II. ACCEPTANCE CRITERIA

The applicant must establish a QA program for the operations phase, including activities such as operation, maintenance, and modification of the nuclear power plant, in accordance with Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The QA program description presented in the FSAR must discuss how each criterion of Appendix B will be met. The acceptance criteria used by the QAB to evaluate the program are listed below. The acceptance criteria include commitments to comply with the regulatory positions presented in the appropriate issue of the Regulatory Guides including the requirements of ANSI Standard N45.2.12 and the Branch Technical Position listed in subsection V of SRP Section 17.1. Thus, these commitments constitute an integral part of the QA program description and requirements. Exceptions and alternatives to these acceptance criteria may be taken by applicants provided adequate justification is given; and the QAB review allows for considerable flexibility in defining methods and controls for satisfying pertinent regulations. When the QA program description meets the acceptance criteria of this SRP section or provides acceptable exceptions or alternatives, the program is considered to be in compliance with pertinent NRC regulations. The review will ascertain that the commitments and the description of how the commitments are implemented, to the extent necessary, ~~are objective and stated in inspectable terms.~~

The Organization (SRP Section 17.2.1) elements responsible for the QA program are acceptable if:

1. The criteria described in 17.1.1* are satisfied except for:

*Refers to the acceptance criteria given in subsection II of SRP Section 17.1.

a. Item 1A4.

b. The organizational elements within the parenthesis in item 1A5 be expanded to include operations and maintenance.

c. The requirements that principal contractors describe QA responsibilities be deleted in Item 1A6.

d. The requirements that a QA position be identified for principal contractors as described in Item 1B1, be deleted.

e. "The person at the construction site responsible for directing and managing the site QA program..." described in Item 1C3, be changed to "The person...responsible for...the onsite QA program." and continue on with remaining sentence starting with "has appropriate organizational...."

The Quality Assurance Program (SRP Section 17.2.2) description is acceptable if:

1. The criteria described in 17.1.2 are satisfied except for:

   a. Item 2A1b.

   b. The requirement for the principal contractors to provide a commitment to comply with the regulations and regulatory positions in the Regulatory Guides accressed in Item 2B3.

   c. Item 2C2.

   d. Item 2C3.

2. Provisions are established for assuring the QA program for operations is implemented at least 90 days prior to fuel loading. 17.2.2-12 OK

3. Confirmation is provided to commit to continued implementation of the PSAR QA program for the remaining design and construction activities and the preoperational test program or an acceptable alternative is provided. 17.2.2-10 & 11 OK

Activities related to Design Control (SRP Section 17.2.3) are acceptable if:

1. The criteria described in 17.1.3 are satisfied.

Q-20 2. Measures are provided to assure that responsible plant personnel are made aware of design changes/modifications which may affect the performance of their duties.

Activities related to Procurement Document Control (17.2.4) are acceptable if:

1. The criteria described in 17.1.4 are satisfied.

Activities related to Instructions, Procedures, and Drawings (17.2.5) are acceptable if:

1. The criteria described in 17.1.5 are satisfied.

Activities related to Document Control (17.2.6) are acceptable if:

1. The criteria described in 17.1.6 are satisfied.

Q-27 → 2. Maintenance, modification and inspection procedures are reviewed by qualified personnel knowledgeable in QA disciplines (normally the QA organization) to determine.

   a. The need for inspection, identification of inspection personnel, and documentation of inspection results.

   b. That the necessary inspection requirements, methods, and acceptance criteria have been identified.

Activities related to Control of Purchased Material, Equipment, and Services (17.2.7) are acceptable if:

1. The criteria described in 17.1.7 are satisfied.

Activities related to Identification and Control of Materials, Parts, and Components (17.2.8) are acceptable if:

1. The criteria described in 17.1.8 are satisfied.

Activities related to the Control of Special Processes (17.2.9) are acceptable if:

1. The criteria described in 17.1.9 are satisfied.

Activities related to Inspection (17.2.10) are acceptable if:

1. The criteria described in 17.1.10 are satisfied.

Q-27 → 2. When inspections associated with normal operations of the plant (such as routine maintenance, surveillance, and tests) are performed by individuals other than those who performed or directly supervised the work, but are within the same group, the following controls are met:

   a. The quality of the work can be demonstrated through a functional test when the activity involves breaching a pressure retaining item.

   b. The qualification criteria for inspection personnel are reviewed and found acceptable by the QA organization prior to initiating the inspection.

Activities related to Test Control (17.2.11) are acceptable if:

1. The criteria described in 17.1.11 are satisfied.

Activities related to Control of Measuring and Test Equipment (17.2.12) are acceptable if:

1. The criteria described in 17.1.12 are satisfied.

Activities related to Handling, Storage, and Shipping (17.2.13) are acceptable

1. The criteria described in 17.1.13 are satisfied.

2. Provisions are described for the storage of chemicals, reagents (including control of shelf life), lubricants, and other consumable materials.

17.2.13-1 B
O/C

Activities related to Inspection, Test, and Operating Status (17.2.14) are acceptable if:

1. The criteria described in 17.1.14 are satisfied.

Activities related to Nonconforming Materials, Parts, or Components (17.2.15) are acceptable if:

1. The criteria described in 17.1.15 are satisfied.

Activities related to Corrective Action (17.2.16) are acceptable if:

1. The criteria described in 17.1.16 are satisfied.

Activities related to Quality Assurance Records (17.2.17) are acceptable if:

1. The criteria described in 17.1.17 are satisfied.

2. QA records include operating logs, maintenance and modification procedures, and related inspection results, reportable occurrences, and other records required by Technical Specifications.

- Not included in "typical" list, but O/C

17.2.17-1

Activities related to Audits (17.2.18) are acceptable if:

1. The criteria described in 17.1.18 are satisfied.

2. Where the "onsite" QA organization does not report to the "offsite" organization:

a. The "offsite" QA organization conducts audits sufficient to verify adequacy of activities conducted by the "onsite" QA organization. > -31

O/C

b. The "offsite" QA organization reviews and concurs in the schedule and scope of audits performed by the "onsite" QA organization.

Q-54

c. Results of audits performed by the "onsite" QA organization are provided to the "offsite" QA organization for review and assessment.

~~III. REVIEW PROCEDURES~~

Same as SRP Section 17.1 ~~except~~ that the Office of Inspection & Enforcement (I&E) does not provide a position ~~statement~~ to QAB relative to their assessment of the QA program implementation for SER input. ~~I&E provides this assessment to the Licensing Project Manager. QAB reviews a description of the I&E summary~~

of completed QA program activities to further determine that the facility has been designed and constructed in accordance with PSAR program commitments.

IV. EVALUATION FINDINGS

Same as SRP Section 17.1.

V. IMPLEMENTATION

~~Same as SRP Section 17.1.~~

VI. REFERENCES

Same as SRP Section 17.1 except replace item 8, Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)" (endorses N45.2) with Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)" (endorses N18.7); replace 10 CFR Part 50, §50.34(a.7) with 10 CFR Part 50, §50.34 (b.6ii), "Final Safety Analysis Report"; and delete 10 CFR Part 50, §50.55(e), "Conditions of Construction Permits."

VOGTLE
OQAP

4 Questions

10 CFR 50, Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

Got	Tot		
6	✓	I.	Organization
6	✓	II.	Quality Assurance Program
8	✓	III.	Design Control
2	✓	IV.	Procurement Document Control
1	✓	V.	Instructions, Procedures, and Drawings
6	✓	VI.	Document Control
7	✓	VII.	Control of Purchased Material, Equipment, and Services
3	✓	VIII.	Identification and Control of Materials, Parts, and Components
4	✓	IX.	Control of Special Processes
3	✓	X.	Inspection
2	✓	XI.	Test Control
5		XII.	Control of Measuring and Test Equipment
2	✓	XIII.	Handling, Storage, and Shipping
4	✓	XIV.	Inspection, Test, and Operating Status
4	✓	XV.	Nonconforming Materials, Parts, or Components
3	✓	XVI.	Corrective Action
1	✓	XVII.	Quality Assurance Records
2	✓	XVIII.	Audits

II. ACCEPTANCE CRITERIA

The applicant (and its principal contractors such as the NSSS vendor, A/E, constructor and construction manager) must establish a QA program for the design and construction phases in accordance with Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The applicant's QA program (including its principal contractors) must describe in the PSAR or SSAR how each criterion of Appendix B will be met. The acceptance criteria used by the QAB to evaluate this QA program are listed in the following eighteen subsections. The acceptance criteria include a commitment to comply with the regulations, regulatory positions presented in the appropriate issue of the Regulatory Guides, and the Branch Technical Position listed in subsection V. Thus, the commitment constitutes an integral part of the QA program description and requirements. Exceptions and alternatives to these acceptance criteria may be adopted by applicants provided adequate justification is given; the QAB review allows for considerable flexibility in defining methods and controls while still satisfying pertinent regulations. When the QA program description meets the applicable acceptance criteria of this subsection or provides acceptable exceptions or alternatives, the program is considered to be in compliance with pertinent NRC regulations.

The review will ascertain that the commitments and the description of how the commitments are implemented, to the extent necessary, are objective and stated in inspectable terms.

1. ORGANIZATION

A. Organizational description and charts of the lines, interrelationships and areas of responsibility and authority for all organizations performing quality-related activities. ~~including the applicant's organization and principal contractors (architect engineer, nuclear steam supply system vendor, constructor, and construction manager when other than the constructor).~~

1A1.* The responsibility for the overall program is retained and exercised by the applicant. 17.2 pg 17.2.1-1

1A2. The applicant has identified and described major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations. 17.2.4 17.2.1 17.2.9

N/A 1A3. When major portions of the applicant's program are delegated:

a. Applicant describes how responsibility is exercised for the overall program. The extent of management oversight should be addressed including the location, qualifications, and criteria for determining the number of personnel performing these functions.

b. Applicant evaluates the performance (frequency and method stated - once per year although longer cycle acceptable with other evaluations of individual elements) of work by the delegated organization.

c. Qualified individual(s) or organizational element(s) are identified within the applicant's organization as responsible for the quality of the delegated work prior to initiation of activities.

~~1A4. Clear management controls and effective lines of communication exist for QA activities among the applicant and the principal contractors to assure direction of the QA program.~~

? 1A5. Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program (such as design, engineering, procurement, manufacturing, construction, inspection, test, instrumentation and control, nuclear engineering, etc.), the lines of responsibility, and a description of the criteria for determining the size of the QA organization including the inspection staff. Indicate approximate QA staff size planned for "normal" operation. (operations, maintenance)

? 1A6. The applicant ~~(and principal contractors)~~ describes the QA responsibilities of each of the organizational elements noted on the organization charts.

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*The alphanumeric designation for each acceptance criterion in subsection II indicates its relationship to the areas of review identified in subsection I.

B. Organizational location, degree of independence from the performing organization, and authority of the individuals assigned the responsibility for performing QA functions.

1B1. The applicant ~~(and principal contractors)~~ identifies a management position that retains overall authority and responsibility for the QA program (normally, this position is the QA Manager) and this position has the following characteristics:

a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as engineering, procurement, construction, and operation) and is sufficiently independent from cost and schedule. 17.2.1.3.2 (pg 17.2.1-7) fig 17.2.1-1

b. Has effective communication channels with other senior management positions. fig 17.2.1-1

c. Has responsibility for approval of QA Manual(s). 17.2.1.3.2 H (pg 17.2.1-8)

d. Has no other duties or responsibilities unrelated to QA that would prevent his full attention to QA matters. by list of duties in 17.2.1.3.2 (pg 17.2.1-7) Not stated - implied.

1B2. Verification of conformance to established requirements (except for designs, ref. 3E2) is accomplished by individuals or groups within the QA organization who do not have direct responsibility for performing the work being verified or by individuals or groups trained and qualified in QA concepts and practices and independent of the organization responsible for performing the task. 17.2.1.3.2 F (pg 17.2.1-7)

? 1B3. Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:

a. Identify quality problems.

b. Initiate, recommend, or provide solutions through designated channels.

c. Verify implementation of solutions.

Those persons and organizations with the above authority are identified and a description of how those actions are carried out is provided.

? 1B4. a. Designated QA personnel, sufficiently free from direct pressures for cost/schedule, have the responsibility delineated in writing to stop unsatisfactory work and control further processing, delivery, or installation of nonconforming material. ? 17.2.1.3.2 (pg 17.2.1-7)

b. The organizational positions with stop work authority are identified. 17.2.1.3.1 QMQA pg 17.2.1-6 17.2.1.3.2 QA Mgr pg 17.2.1-7

1B5. Provisions are established for the resolution of disputes involving quality, arising from a difference of opinion between QA personnel and other department (engineering, procurement, manufacturing, etc.) personnel. 17.2.1.3.4 (pg 17.2.1-8)

safety-related

1B6. Designated QA individuals are involved in day-to-day plant activities ~~important to safety~~ (i.e., the QA organization routinely attends and participates in daily plant work schedule and status meetings to assure they are kept abreast of day-to-day work assignments throughout the plant and that there is adequate QA coverage relative to procedural and inspection controls, acceptance criteria, and QA staffing and qualification of personnel to carry out QA assignments).

C. Organizational provisions for assuring the proper implementation of the QA program.

1C1. Policies regarding the implementation of the QA program are documented and made mandatory. These policies are established at the Corporate President or Vice President level. — GPC exec. VP-Power Supply

17.2.2 (Pg 17.2.2-1) 17.2 (Pg 17.2.1-1)

1C2. Position description (see 1B1) assures that the individual directly responsible for the definition, direction, and effectiveness of the overall QA program has sufficient authority to effectively implement responsibilities. This position is to be "sufficiently" free from cost and schedule responsibilities. Qualification requirements for this individual are established in a position description which includes the following prerequisites:

GMQA

17.2.1.3.1 (Pg 17.2.1-6)

See Table 13.1.1-1 (Paul D. Rice) GMQA

a. Management experience through assignments to responsible positions.

b. Knowledge of QA regulations, policies, practices, and standards.

c. Experience working in QA or related activity in reactor design, construction, or operation or in a similar high technological industry.

The qualifications of the Vogtle QA Manager should be at least equivalent to those described in Section 4.4.5 of ANSI/ANS-3.1-1978, "Selection and Training of Nuclear Power Plant Personnel," as endorsed by the regulatory positions in Regulatory Guide 1.8.

1C3. The person ~~at the construction site~~ on responsible for ~~directing and managing~~ the site QA program is identified by position and has appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. This individual is free from non-QA duties and can thus give full attention to assuring that the QA program at the plant site is being effectively implemented.

See also fig 17.2.1-1 (Pg 17.2.1-7)

Vogtle QA Mgr 17.2.3.2

1A2

17.2.1.1.2 (17.2.1.7) acknowledge

Check in Procurement Section (1A3)

1A5 Provide an org. chart that clearly identifies all the onsite & offsite org. elements which function under the cognizance of the QA program, showing the lines of resp., and provide charts for GM QA, QAM, QA site mgr, QA field group and QC supervision's organizations. Provide a description of the criteria used to determine the size of the QA organization and the inspection staff (QC organization). Give an indication of the approximate size of the QA & QC staffs planned for normal operation.

See 260.1 Jacks

c.g. missing supr. & mgmt. (17.2.1.2.3) QC supv (17.2.1.2.2)

1A6 not in Jacks

For each organizational element identified with supervision under the cognizance of the QA program, provide a description of their QA responsibilities if not already addressed in FSAR.

1B1 Clarify whether the GM QA has overall authority and responsibility for the QA program.

1B1a Clarify whether the GM QA has other duties or responsibilities unrelated to QA that would prevent his full attention to QA matters.

Vogtle QA Mgr

? I am assuming that 1B1 addresses itself to the one person who has overall authority & responsibility

260.2

QA/QC org.

1B4

260.3

Vogtle QA mgr has authority to stop unsatisfactory work. Clarify whether this responsibility is delineated in writing and whether his authority extends to processing, delivery or installation of NCM.

1B6

260.5

Clarify whether designated QA/QC individuals are involved in day-to-day plant safety-related activities (i.e., ... copy from SRP)

1C1

Clarify whether the policies regarding the implementation of the QA program listed in 17.2 (pg 17.2.1-9) are made mandatory.

1C2

260.6

Re (17.2.1.B.1 clarify what is meant by the GMQA being free from "undue" influence and from resp. for cost & schedules

Provide qualification requirements for GMQA and clarify whether these are established in a position description which includes:

copy from SRP

a. mgmt experience, etc
b. knowledge of QA Reg, etc,
c. experience working in QA, etc

Provide qualification requirements for the Vogtle QA Manager

1C3

Clarify whether the Vogtle QA manger is free from non-QA duties and commits of sufficient attention to assuring that the QA program at the plant site is being effectively implemented. (implied)

Need to check w/ 9.5.1 vs BTP 5-1

2. QUALITY ASSURANCE PROGRAM

A. Scope of the QA program.

2A1. The scope of the QA program includes:

a. A commitment that activities affecting safety-related structures, systems, and components ~~important to safety~~ will be subject to the applicable controls of the QA program. The structures, systems, components, and related consumables covered by the QA program are identified (QA list) in Section 3.2.1 of the SAR.* 17.2.2 (pg 17.2.2-1) Being handled by J. Sprauls

~~b. A commitment that the preoperational test program will be conducted in accordance with the QA program and a description of how the QA program will be applied.~~

c. A commitment that the development, control, and use of computer code programs will be conducted in accordance with the QA program and a description of how the QA program will be applied. 17.2.3 G (pg 17.2.3-2) 17.2.2 #3 (pg 17.2.2-3) verification & cert. of computer code

d. The identification of fire protection in SRP Section 9.5.1 as a system covered by the QA program or identification of the QA controls for fire protection. These controls are reviewed and accepted using the guidelines contained in BTP ASB 9.5-1 and 10 CFR Part 50 Appendix B as appropriate. 17.2.2 (pg 17.2.2-2)

e. A commitment that special equipment, environmental conditions, skills, or processes will be provided as necessary. "appropriate" used 17.2 D, E (pg 17.2.1-1) 17.2.2 (pg 17.2.2-1)

2A2. A brief summary of the company's corporate QA policies is given. 17.2 A-H (pp 17.2.1-1 & 2)

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* Rulemaking is currently underway to clarify the requirement that structures, systems, and components important to safety as derived from the General Design Criteria of Appendix A to 10 CFR Part 50 shall be subjected to the pertinent requirements of the quality assurance criteria of Appendix B to 10 CFR 50. Until this rulemaking process is completed, staff reviewers should assure that the applicant's list of structures, systems, and components includes all those items necessary to prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public as stated in the Introduction to Appendix B. Guidance for identifying such items is provided in Regulatory Guide 1.29.

B. Provisions to assure proper definition of the QA program.

2B1. a. ? Provisions are established to assure that quality-affecting procedures required to implement the QA program are consistent with QA program commitments and corporate policies and are properly documented, controlled, and made mandatory through a policy statement or equivalent document signed by the responsible official.

b. ? The QA organization reviews and documents concurrence with these quality-related procedures.

✓ c. The organizational group or individual having responsibility for the policy statement should be identified. 17.2 (pg 17.2.1-1)
GPC exec VP- Power Supply

✓ d. The quality affecting procedural controls of the principal contractors should be provided for the applicant's review with documented agreement of acceptance prior to initiation of activities affected by the program. 17.2.2 (pg 17.2.2-4)

2B2. ~~Provisions are included for notifying NRC of changes (1) for review and acceptance in the accepted description of the QA program as presented or referenced in the SAR or SSAR prior to implementation, and (2) in organizational elements within 30 days after announcement. (Note - editorial changes or personnel reassignments of a non-substantive nature do not require NRC notification).~~ Substitute 10 CFR 5 (next p

17.2.2-4

2B3. The applicant ~~(and the principal contractors)~~ commits to comply with the regulatory position in the appropriate issue of the Regulatory Guides listed in Subsection V; to comply with 10 CFR Part 50, §50.55a; ~~to conduct activities under 10 CFR Part 50, §50.55(e) in accordance with the QA program~~; and to comply with 10 CFR Part 50 Appendix A, General Design Criterion 1. For systems, components, and structures covered by the ASME Code Section III (Classes 1, 2 and 3), the quality assurance code requirements should be supplemented by the specific guidance addressed in the regulatory positions of the applicable Regulatory Guides. The commitment identifies the Regulatory Guides and ANSI standard by number, title, and revision or date. Any alternatives or exceptions are clearly identified and supporting information presented in the docket. A Regulatory Guides should be addressed which have an implementation date prior to the submittal or docket date of the QA program description.

? next 2 pages
17.2.2 (pg 17.2.2-4)
3.1-1 (pp 3.1-1 & 2)
VI?
Comm only
? addressed in Sect 1.9

Comment — Although primary responsibility for Regulatory Guides 1.26 and 1.29 is assigned to ASB (SRP Sections 3.2.1 and 3.2.2), their use as acceptance criteria in this SRP section is necessary to assure that adequate quality assurance requirements are specified for systems, components, and structures addressed by those guides.

? The QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls are to be applied to specific structures, systems, and components. This effort involves applying a defined graded approach to certain structures, systems, and components in accordance with their importance to safety and affects such disciplines as design, procurement, document control, inspection tests, special processes, records, audits, and others described in 10 CFR Part 50, Appendix B.

and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 50 are published as a document subject to codification.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:

Authority: Secs. 103, 104, 161, 182, 183, 184, 186, 68 Stat. 936, 937, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 124 , as amended (42 U.S.C. 2133, 2134, 2201, 2232, 2233, 2238, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846), unless otherwise noted.

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80–50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Sections 50.100–50.102 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), §§ 50.10 (a), (b), and (c), 50.44, 50.46, 50.48, 50.54, and 50.80(a) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); §§ 50.10 (b) and (c) and 50.54 are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 50.55(e), 50.59(b), 50.70, 50.71, 50.72, and 50.78 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. Section 50.54 is amended by adding a new paragraph (a) to read as follows:

§ 50.54 Conditions of licenses.

* * * * *

(a)(1) Each nuclear power plant or fuel reprocessing plant licensee subject to the quality assurance criteria in Appendix B of this part shall implement, pursuant to § 50.34(b)(6)(ii) of this part, the quality assurance program described or referenced in the Safety Analysis Report, including changes to that report.

(2) Each licensee described in paragraph (a)(1) of this section shall, by June 10, 1983, submit to the appropriate NRC Regional Office shown in Appendix D of Part 20 of this chapter the current description of the quality assurance program it is implementing for inclusion in the Safety Analysis Report, unless there are no changes to the description previously accepted by NRC. This submittal must identify changes made to the quality assurance program description since the description was submitted to NRC. (Should a licensee need additional time beyond June 10, 1983 to submit its current quality assurance program description to NRC, it shall notify the appropriate NRC Regional Office in writing, explain why additional time is needed, and provide a schedule for NRC approval showing when its current quality assurance program description will be submitted.)

(3) After March 11, 1983, each licensee described in paragraph (a)(1) of this section may make a change to a previously accepted quality assurance program description included or referenced in the Safety Analysis Report, provided the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted to the NRC at least annually in accordance with the requirements of § 50.71 of this part. Changes to the quality assurance program description that do reduce the commitments must be submitted to NRC and receive NRC approval before implementation, as follows:

(i) Changes made to the Safety Analysis Report must be submitted for review to the appropriate NRC Regional Office shown in Appendix D of Part 20 of this chapter, to the Resident Inspector, and to the Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Changes made to NRC-accepted quality assurance topical report descriptions must be submitted to the Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to the NRC Region IV Vendor Program Branch.

(ii) The submittal of a change to the Safety Analysis Report quality assurance program description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of Appendix B of this part and the Safety Analysis Report quality assurance program description commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(iii) A copy of the forwarding letter identifying the changes must be maintained as a facility record for three years.

(iv) Changes to the quality assurance program description included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

* * * * *

Accordingly, the staff concludes that the applicant's description of the QA program is in compliance with applicable NRC regulations and industry standards and can be implemented for the (specify) phases of (specify application).

V. IMPLEMENTATION

The following is intended to provide guidance to applicants and licensees regarding the NRC staff's plan for using this SRP Section.

Except in those cases in which the applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the method described herein will be used by the staff in its evaluation of conformance with Commission regulations.

Implementation schedules for conformance to parts of the method discussed herein are contained in the referenced guides and NUREGs.

VI. REFERENCES

QA Reg Guide Listing

1. 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

2. 10 CFR Part 50, §50.55a, "Codes and Standards."

3. 10 CFR Part 50, ~~§50.55(e), "Conditions of Construction Permits"~~ §50.54a, "Conditions of Operating Licenses" (reporting significant QA deficiencies).

4. 10 CFR Part 50, §50.34~~(a.7)~~ b.6.1.1, "Contents of Application; Technical Information" (~~Preliminary~~ Final Safety Analysis QA program description).

5. 10 CFR Part 50, Appendix A, "General Design Criteria for Nuclear Power Plants."

6. Regulatory Guide 1.8, "Personnel Selection and Training" (endorses ANSI/ANS 3.1). pg 1.9-4

7. Regulatory Guide 1.26, "Quality Group Classification, and Standards for Water, Steam, and Radioactive Waste Containing Components of Nuclear Power Plants." pg 1.9-22

~~8. Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)" (endorses N45.2).~~

8, 9. Regulatory Guide 1.29, "Seismic Design Classification." pp 1.9-23 & 24

9, 10. Regulatory Guide 1.30, "Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electric Equipment" (endorses N45.2.4). pp 1.9-24→27 pp 1.9-28→33 10, Regulatory Guide 1.33, Rev. 2 (endorses ANS-3.2/N18.7-1976)

11. Regulatory Guide 1.37, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants" (endorses N45.2.1). pp 1.9-34 → 36

12. Regulatory Guide 1.38, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants" (endorses N45.2.2). pp 1.9-36 → 43

13. Regulatory Guide 1.39, "Housekeeping Requirements for Water-Cooled Nuclear Power Plants" (endorses N45.2.3). pg 1.9-43

14. Regulatory Guide 1.58, "Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel" (endorses N45.2.6). pp 1.9-53 → 54

15. Regulatory Guide 1.64, "Quality Assurance Requirements for the Design of Nuclear Power Plants" (endorses N45.2.11). pp 1.9-59 → 61

16. Regulatory Guide 1.74, "Quality Assurance Terms and Definitions" (endorses N45.2.10). pp 1.9-66 → 69

17. Regulatory Guide 1.88, "Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records" (endorses N45.2.9). pg 1.9-75

18. Regulatory Guide 1.94, "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants" (endorses N45.2.5). pp 1.9-78 → 79

19. Regulatory Guide 1.116, "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems" (endorses N45.2.8). pp 1.9-89 → 92

20. Regulatory Guide 1.123, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants" (endorses N45.2.13). pp 1.9-96 → 105

21. Regulatory Guide 1.144, "Auditing of Quality Assurance Programs for Nuclear Power Plants" (endorses N45.2.12). pg 1.9-118

22. Regulatory Guide 1.146, "Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants" (endorses N45.2.23). pp 1.9-119

23. Branch Technical Position (BTP) ASB 9.5-1 (attached to SRP Section 9.5.1). Section 9.5

2B4. Existing or proposed QA procedures are identified reflecting that Regulatory Guides listed in subsection VI, General Design Criterion 1 of Appendix A to 10 CFR Part 50, 10 CFR Part 50, §50.55a, and each criterion of 10 CFR Part 50, Appendix B will be met by documented procedures. ~~In addition, activities conducted under 10 CFR Part 50, §50.55(e) shall conform to the requirement of the QA program.~~ Const only

2B5. A description is provided that emphasizes how the docketed QA program description, particularly the 10 CFR Part 50 regulations and Regulatory Guides listed in subsection VI, will be properly carried out.

redundancy this is dealt with in FSAR 17.2 of

pp 17.2.2-1 → 4

C. Programmatic provisions to assure proper implementation of the QA program.

2C1. A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA program to 10 CFR Part 50, Appendix B. These measures should include:

see VP-Power Supply

a. Frequent contact with program status through reports, meetings, and/or audits.

b. Performance of an annual assessment preplanned and documented. Corrective action is identified and tracked.

~~2C2. Quality-related activities (such as design, procurement, and site investigation) initiated prior to formal NRC acceptance of the QA program are controlled under a QA program in accordance with this SRP and, accordingly, with the requirements of 10 CFR Part 50, Appendix B. Approved procedures and a sufficient number of trained personnel should be available to implement the applicable portion of the QA program prior to the initiation of the activity.~~

~~2C3. A summary description is provided on how responsibilities and control of quality-related activities are transferred from the principal contractors to the applicant during the phaseout of design and construction and during preoperational testing and plant turnover.~~

D. Provisions to assure adequacy of personnel qualifications.

? 2D. Indoctrination, training, and qualification programs are established such that:

a. Personnel responsible for performing quality-affecting activities (does) are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.
17.2.2 #2 (pg 17.2.2-3)

b. Personnel verifying activities affecting quality (checker) are trained and qualified in the principles, techniques, and requirements of the activity being performed.
17.2.2 #8 (pg 17.2.2-3)

c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.
17.2.2 # 9 (pg 17.2.2-3)

d. Proficiency tests are given to those personnel performing and verifying activities affecting quality, and acceptance criteria are developed to determine if individuals are properly trained and qualified. not covered in 13.2 per Quirk

? e. Certificate of qualifications clearly delineates (a) the specific functions personnel are qualified to perform and (b) the criteria used to qualify personnel in each function. not covered in 13.2 per Quirk

f. Proficiency of personnel performing and verifying activities affecting quality is maintained by retraining, reexamining, and/or recertifying as determined by management or program commitment. not covered in 13.2 per Quirk

(2B3) g. The description of the training program provisions listed above does not contradict satisfies the regulatory position in Regulatory Guide 1.58.
1.9.58 shows 7 unjustified exceptions — see also 2B3 question

17.2.2 Pg 17.2.2-4 2. Provisions are established for assuring the QA program for operations is implemented at least 90 days prior to fuel loading.

3. Weak Confirmation is provided to commit to continued implementation of the PSAR QA program for the remaining design and construction activities and the preoperational test program or an acceptable alternative is provided.
17.2.2 Pg 17.2.2-3

2A1c

Clarify whether the [illegible] computer code [illegible] will be [illegible] IAW the QA program and a description of how the QA [illegible] will be applied.

2A1c

Clarify whether special skills or procedures will be provided as necessary.

2B1a

260.7

Describe the provisions established to assure that quality-affecting procedures required to implement the QA program are consistent with QA program commitments & corporate policies and are properly documented, controlled and made mandatory through a policy statement signed by the responsible official.

2B1b

260.7

Describe the provisions established to assure that the QA organization reviews and documents concurrence with the quality-related procedures.

2B1c

Identify the organizational group or individual (and to what organization he is assigned) having responsibility for the QA program policy statement.

see 17.2(pg 17.2.1-1)
GPC exec. VP - Power Supply

2B2.

not in Quick's

Clarify whether that QQAP changes are handled IAW 10CFR 50.54(a).

2B3

260.8

Section 1.9 of the FSAR provides a number of clarifications, exceptions and alternatives to the QA regulatory guides listed in Section III of NUREG-0800, 17.2. For each guide, provide

1. an indication of the specific guidance to which an exception is being taken or which an alternative or clarification is given
2. clear identification of GPC position wrt the guidance and an identification of whether the position is an exception to or a clarification of the guidance.
3. an appropriate discussion of how each clarification, exception or alternative provides an acceptable method of complying with the applicable

2B3
Cont'd

~~Provide [illegible]~~

~~Clarify whether GPC complies with ASME Section~~

Clarify whether GPC, VEGP and their major subcontractors and vendors establish and implement QA programs to provide adequate assurance that the structures, systems and components important to safety will satisfactorily perform their safety functions.

GDC 1 still applies

260.9 — Describe how, for systems, components and structures covered by the ASME Code Section III (Classes 1, 2 & 3) the QA code reqts. will be supplemented by the specific guidance addressed in the regulatory positions of the applicable RGs. Identify RGs & NRC std by #, title, and rev (date). Clearly identify any alternatives or exceptions and provide supporting information.

260.10 — Describe how the QA organization and the necessary technical organizations participate early in the QA program definition & stage to determine and identify the extent QA controls are to be applied to specific structures, systems and components, i.e. describe the graded approach used.

2B4

260.11 plus avoid like phrases ~~App A, B, etc~~ not sensible 10 CFR 50 → 50.55a App B

Identify existing/proposed QA procedures reflecting that ~~RGs~~ listed in Section VI of NUREG-0800 Chap 17.2 will be properly carried out

---

2B5

~~Provide a description which emphasizes how the docketed QA program description~~ esp. the 10 CFR 50 reqts & RGs listed in Section VI of NUREG-0800 Chap 17.2 will be properly carried out.

Redundant — 17.2 of FSAR ~~supposed to do this~~

2C1

Describe the measures taken by ~~the~~ the Elec. VP - Power Supply to regularly assess the scope, status, adequacy, and compliance of the QA program to 10 CFR 50 App B, including

260.12

1. frequent contact w/ program status thru reports, meetings and/or audits
2. Performance of an annual reassessment which is preplanned & documented and C/A is identified & tracked.

2D..

~~Need section 13.2~~

Describe measures for assuring that:

260.13

① -- (d) } copy from QAP
② -- (e) }
③ -- (f) }

3. DESIGN CONTROL

A. Scope of the QA program for design activities.

?

17.2.3#1 (pg 17.2.3-1)
17.2.3#5 (pg 17.2.3-2)

3A. The scope of the design control program includes design activities associated with the preparation and review of design documents including the correct translation of applicable regulatory requirements and design bases into design, procurement and procedural documents. Included in the scope are such activities as field design engineering; physics, seismic, stress, thermal, hydraulic, radiation, and the SAR accident analyses; associated computer programs; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; and quality standards.

leaning: procedural
17.2.3#1 (pg 17.2.3-1)
17.2.3#5A "
17.2.3#5B&6 (pg 17.2.3-2)
17.2.3#6 "

B. The organizational structure, activity, and responsibility of the positions or groups responsible for design activities.

? 3B. Organizational responsibilities are described for preparing, reviewing, approving, and verifying design documents such as system descriptions, design input and criteria, design drawings, design analyses, computer programs, specifications, and procedures.

17.2.1.2.5 sup. plant eng & services - coordinates review, approval & closeout of Δs
17.2.3#2 - plant mgmt resp for controlling, approving & implementing design mods
- plant review bd reviews all proposed mods to S-R sys
- safety review bd reviews unreviewed safety? & safety limits of Δs & proc. Δs to S-R sys
- procedures will identify positions/orgs resp. for design verification

C. Provisions to carry out design activities in a planned, controlled, and orderly manner.

✓ 3C1. Errors and deficiencies in approved design documents, including design methods (such as computer codes), that could adversely affect structures, systems, and components important to safety are documented; and action is taken to assure that all errors and deficiencies are corrected. 17.2.3#9 pg (17.2.3-3)

? for QA ✓ 3C2. Deviations from specified quality standards → for what? are identified and procedures are established to ensure their control.

17.2.3#7 (pg 17.2.3-3) → ✓ on dim. accuracy & compl of design dwgs & specs
17.2.3#9 " → QA on errors/def. in design process
17.2.3#7 (pg 17.2.3-2) → design verif. measures
17.2.3#5 (pg 17.2.3-2) →

D. Provisions for interface control.

3D. Internal and external design interface controls, procedures, and lines of communication among participating design organizations and across technical disciplines are established and described for the review, approval, release, distribution, and revision of documents involving design interfaces to assure structures, systems, and components are compatible geometrically, functionally, and with processes and environment.

17.2.3 #5F (pg 17.2.3-2)

E. Provisions to verify or check the technical adequacy of design documents.

3E1. Procedures are established and described requiring a documented check to verify the dimensional accuracy and completeness of design drawing and specifications. 17.2.3 #7F (pg 17.2.3-3)

3E2. Procedures are established and described requiring that design drawings and specifications be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with company procedures and that the documents contain the necessary quality assurance requirements such as inspection and test requirements, acceptance requirements, and the extent of documenting inspection and test results.

17.2.3 #5B (pg 17.2.3-2)

17.2.3 #8 (pg 17.2.3-3) → address comprehensive audit of the design control system

3E3. Guidelines or criteria are established and described for determining the method of design verification (design review, alternate calculations, or test).

3E4. Procedures are established and described for design verification activities which assure the following:

? a. The verifier is qualified and is not directly responsible for the design (i.e., neither the performer or his immediate supervisor). In exceptional circumstances, the designer's immediate supervisor can perform the verification provided:

(1) The supervisor is the only technically qualified individual.

(2) The need is individually documented and approved in advance by the supervisor's management.

(3) QA audits cover frequency and effectiveness of use of supervisors as design verifiers to guard against abuse.

? b. Design verification, if other than by qualification testing of a prototype or lead production unit, is completed prior to release for procurement, manufacturing, construction or to another organization for use in other design activities. In those cases where this timing cannot be met, the design verification may be deferred, providing that the justification for this action is documented and the unverified portion of the design output document and all design output documents, based on the unverified data, are appropriately identified and controlled. ~~Construction site activities associated with a design or design change should not proceed without verification past the point where the installation would become irreversible (i.e., require extensive demolition and rework)~~. In all cases, the design verification should be complete prior to fuel load for a plant under construction, or in the case of an operating plant, prior to relying upon the component, system, or structure to perform its function.

Const only

? c. Procedural control is established for design documents that reflect the commitments of the SAR; this control differentiates between documents that receive formal design verification by interdisciplinary or multi-organizational teams and those which can be reviewed by a single individual (a signature and date is acceptable documentation for personnel certification). Design documents subject to procedural control include, but are not limited to, specifications, calculations, computer programs, system descriptions, SAR when used as a design document, and drawings including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams, structural systems for major facilities, site arrangements, and equipment locations. Specialized reviews should be used when uniqueness or special design considerations warrant.

this is my given

? d. The responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in procedures.

17.2.3 #2 (pg 17.2.3-1) Procedures will define authority & responsibility of design reviewers

5

17.2.3 # 7 (pg 17.2 3-2)

3E7. The following provisions are included if the verification method is only by test:

a. Procedures provide criteria that specify when verification should be by test.

b. Prototype, component or feature testing is performed as early as possible prior to installation of plant equipment, or prior to the point when the installation would become irreversible.

✓c. Verification by test is performed under conditions that simulate the most adverse design conditions as determined by analysis.

6

✓3E8. Procedures are established to assure that verified computer codes are certified for use and that their use is specified.

17.2.3 # 5 & 6 (pg 17.2 3-2)

F. Provisions to control design changes.

✓3F1. Design and specification changes, including fields changes, are subject to the same design controls that were applicable to the original design. 1.9.64.2#1 (pg 1.9-60→61)

(283) 3F2. The description of the design control provisions does not contradict ~~satisfies~~ the criteria of Regulatory Guide 1.64.

pg 1.9-59→61, 1.9.64 does not clearly identify commitment, alternatives, exceptions - see question 2 on 283

? 2. Measures are provided to assure that responsible plant personnel are made aware of design changes/modifications which may affect the performance of their duties.

3A

Clarify that the scope of the design control program includes design activities associated w/ the prep & review of design documents including correct translation of applicable regulatory requirements and design bases into procurement documents.

not in Jack's

(17.2.4 & 2E in proc. doc. control does say that proc. doc. contain or ref applicable design bases, etc.

3B

Clarify the organizational responsibilities for preparing design change documents ~~such as ~~design inputs~~ disciplines, design input & criteria, design bases, design analyses, impacts~~

not in Jack's

3D

260.14

Clarify that the controls provisions for internal & external design interfaces assure that structures, systems and components are compatible geometrically, functionally and with processes & ~~Environment~~

3E2

260.15

Describe the ~~procedures~~ requirements established for review of design documents by the QA organization to assure that the documents are prepared reviewed & approved IAW company procedures and .... test results (copy text from SRP).

3E3

260.16

Describe the guidelines or criteria established for determining the method of design verification

3E4 Describe the procedures established for design verification ensuring that:

a. the design verifier is qualified and is not directly responsible for the design.

260.17

b. design procedures verification, if by other than qual testing ... (copy from SRP) ... in other design activities. In those cases where design verification cannot be met, (clarify that design verification is deferred) justification for this action ... controlled. Clarify that in all cases the design verification is complete ... function.

c. Procedural controls differentiate between documents that receive formal design verification by .... certification). Clarify which design documents are subject to procedural control.

Clarify that responsibilities of the verifier, the areas & features to be verified, the pertinent features to be verified & the extent & documentation are identified in procedures.

3E5 If design verification is only by test clarify that the procedures provide criteria

260.18 that specify when verification should be by test

(2) prototype, component or feature testing is performed as early as possible .... irreversible.

17.2.3 #2 Describe the measures provided to assure that responsible plant personnel are made aware of design changes/modifications which may affect the performance of their duties

260.20

4. PROCUREMENT DOCUMENT CONTROL

A. Provisions which assure that applicable regulatory requirements, technical requirements, and QA program requirements are included or referenced in procurement documents.

4A1. Procedures are established for the review of procurement documents to determine that quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and procurement documents have been prepared, reviewed, and approved in accordance with QA program requirements. To the extent necessary, procurement documents should require contractors and subcontractors to provide an acceptable quality assurance program. The review and documented concurrence of the adequacy of quality requirements stated in procurement documents is performed by "independent" personnel trained and qualified in QA practices and concepts.

17.2.4 #2A (pg 17.24-1) 17.2.4 #2D 17.24 #2B used "Knowledgable"

4A2. Procedures are established to assure that procurement documents identify applicable regulatory, technical, administrative, and reporting requirements; drawings; specifications; codes and industrial standards; test and inspection requirements; and special process instructions that must be complied with by suppliers.

17.24 #2D 17.24 #2F

(pg 17.24-1) 17.2.4 #2A → procedures for prep of proc. doc.
(pp 17.2.4-1, 2) 17.2.4 #2 E, F, G → lists of what proc. doc. identify

B. Provisions for review and approval of procurement documents.

4B1. Organizational responsibilities are described for (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluations; and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described.

4B2. The description of the procurement document control provisions listed above ~~satisfies~~ does not contradict the regulatory position in Regulatory Guide 1.123.

2B3

1.9.123 (pp 1.9-96 → 105) lists 39 clarifications without clear commitment & w/o justif for clarifications — see question 2B3

some of which are exceptions & alternatives

4A1 Clarify that procedures are established for review of proc. doc. to determine that they have been reviewed & approved IAW QA program requirements. Clarify that the individual who reviews and concurs in adequacy of quality reqts in proc. doc. plus some are independent of individuals who prepared the reqts and are trained and qualified in QA practices and concepts. (knowledge/ability is not enough)

260.21

4B1 Describe the organizational responsibilities including the involvement of the QA organization

260.22 for 1 2 3 4 5 } copy from SRP

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5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

A. Provisions for assuring that activities affecting quality are prescribed by and accomplished in accordance with documented instructions, procedures, or drawings.

? 5A. Organizational responsibilities are described for assuring that activities affecting quality are (1) prescribed by documented instructions, procedures, and drawings and (2) accomplished through implementation of these documents.

17.2.5, #1, (pg 17.2.5-1) → but does not address org. resp.

B. Provisions for including quantitative and qualitative acceptance criteria in instructions, procedures, and drawings.

✓ 5B. Procedures are established to assure that instructions, procedures, and drawings include quantitative (such as dimensions, tolerances, and operating limits) and qualitative (such as workmanship samples) acceptance criteria for determining that important activities have been satisfactorily accomplished.

17.2.5 #1 (pg 17.2.5-1)

5A

~~FSAR Section 17.2.5 addresses that~~

260.23 activities affecting Q are prescribed & accomplished in accordance with documented instructions, procedures or drawings. Describe the organizational responsibilities for assuring that Q, as described in FSAR Sect 17.2.5.

6. DOCUMENT CONTROL

A. Provisions to assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed.

6A1. The scope of the document control program is described, and the types of controlled documents are identified. As a minimum, controlled documents include:

a. Design documents (e.g., calculations, drawings, specifications, analyses) including documents related to computer codes.

b. Procurement documents.

c. Instructions and procedures for such activities as fabrication, construction, modification, installation, test and inspection.

d. As-built documents.

e. Quality assurance and quality control manuals and quality-affecting procedure.

f. Topical reports.

g. SAR.

h. Nonconformance reports.

6A2. Procedures for the review, approval, and issuance of documents and changes thereto are established and described to assure technical adequacy and inclusion of appropriate quality requirements prior to implementation. The QA organization, or an individual other than the person who generated the document but qualified in quality assurance, reviews and concurs with these documents with regards to QA-related aspects.

6A3. Procedures are established to assure that changes to documents are reviewed and approved by the same organizations that performed the initial review and approval or by other qualified responsible organizations delegated by the applicant.

6A4. Procedures are established to assure that documents are available at the location where the activity will be performed prior to commencing the work.

B. Provisions to prevent the inadvertent use of obsolete or superseded documents.

6B1. Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revisions in work areas in a timely manner. 17.2.6 #2B (pg 17.2.6-1)
17.2.6 #2E (pg 17.2.6-2)

? 6B2. A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents. When such a list is used, it should be updated and distributed to predetermined responsible personnel.
17.2.6 #2D (pg 17.2.6-2) → master status list used identify what documents does it include provide details on how often list is updated and to whom it is distributed

? 6C1. Procedures are established and described to provide for the preparation of as-built drawings and related documentation in a timely manner to accurately reflect the actual plant design. 17.2.6 #2B (pg 17.2.6-1)

17.2.6 #2. Maintenance, modification and inspection procedures are reviewed by qualified personnel knowledgeable in QA disciplines (normally the QA organization) to determine:

a. The need for inspection, identification of inspection personnel, and documentation of inspection results.

b. That the necessary inspection requirements, methods, and acceptance criteria have been identified.

6A1 Clarify that the following documents are subject to the QA program controls, in addition to the documents listed in FSAR Section 17.2.6:

(1) Design documents such as calculations specifications and analyses and documents related to computer codes

260.25 + done → (2) Instructions & procedures for fabrication construction during operations and installation activities.

(3) As-built document

(4) QA manual and QC manual

(5) Topical reports

(6) Nonconformance reports.

~~Clarify what procedures are established to assure quality of documents prior to implementation~~

6A2 Describe the procedures that are established for the review approval & issuance of documents & Δs thereto to assure the technical adequacy & inclusion of appropriate QA requirements prior to implementation. Clarify that the individual who performs the quality requirement review described in FSAR 17.2.6 is qualified in quality assurance.

similar to 260.26

6A4 Section 17.2.6 of FSAR states that documents & Δs thereto are promptly distributed to ensure availability prior to commencement of work. Clarify that the documents and changes thereto are available at the location where the activity will be performed prior to commencing the work

not in Jacko → Define the use of the expression "promptly"

~~Section 17.2.6 of FSAR states that documents and~~

6A5 Section 17.2.6 of FSAR states that As-built documents are prepared in a "timely" manner to accurately reflect the actual plant design. Define the use of the expression "timely"

See 6C1

OB2

Section 17.2.6 of FSAR states that a [illegible] list is used to identify current revision of documents. Identify what documents it pertains to & describe how often the list is updated and to whom it is distributed.

not in Gacha

6C1

17.2.6 of FSAR states that "as-built" documents are prepared in a timely manner to accurately reflect the actual plant design.

not in Gacha

Describe the procedures established to accomplish this. Define the use of the expression "timely".

17.2.6 #2

Describe the measures used for assuring review of maintenance, mod. & inspection procedures by qualified individuals knowledgeable in QA disciplines to determine;

260.27

① need for inspection, id. of insp. personnel & documentation of inspection results.

② That the necessary insp. reqts, methods & acceptance criteria have been identified.

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

A. Provisions for the control of purchased material, equipment, and services; for selection of suppliers; and for assessing the adequacy of quality.

7A1. Organizational responsibilities are described for the control of purchased material, equipment, and services including interfaces between design, procurement, and QA organizations.

7A2. Verification of suppliers' activities during fabrication, inspection, testing, and shipment of materials, equipment, and components is planned and performed with QA organization participation in accordance with written procedures to assure conformance to the purchase order requirements. These procedures, as applicable to the method of procurement, provide for:

17.2.7.2, A & B (Pg 17.2.7-2)

a. Specifying the characteristics or processes to be witnessed, inspected or verified, and accepted; the method of surveillance and the extent of documentation required; and those responsible for implementing these procedures.

b. Audits, surveillance, or inspections which assure that the supplier complies with the quality requirements.

7A3. Selection of suppliers is documented and filed. If an LCVIP letter of confirmation or the "CASE" Register is used to establish the qualifications of the supplier, the documentation should identify the "letter" or "audit" used.

supplier qualif. → 17.2.7.1 (Pg 17.2.7-1)

7A4. Procurement of spare or replacement parts for safety-related structures, systems, and components ~~important to safety~~ is subject to present QA program controls, to codes and standards, and to technical requirements equal to or better than the original technical requirements, or as required to preclude repetition of defects. 17.2.7 (pg 17.2.7-1) uses "controls"

B. Provisions to assure that documented evidence of the conformance of material and equipment to procurement requirements is available at the plant site prior to installation or use.

7B1. Receiving inspection at VEGP is performed to assure:

a. The material, component, or equipment is properly identified and corresponds to the identification on the purchase document and the receiving documentation. 17.2.7.3 A (pg 17.2.7-2)

b. Material, components, equipment, and acceptance records satisfy the inspection instructions prior to installation or use. 17.2.7.3 B & C (pg 17.2.7-2)

c. Specified inspection, test and other records, (such as certificates of conformance attesting that the material, components, and equipment conform to specified requirements) are available at the nuclear power plant prior to installation or use. 17.2.7.3 B (pg 17.2.7-2)

? 7B2. Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for installation or further work. FSAR uses "or" 17.2.7.3 C (pg 17.2.7-2)

? 7B3. The supplier furnishes the following records to the purchaser:

a. Documentation that identifies the purchased item and the specific procurement requirements (e.g., codes, standards, and specifications) met by the item.

b. Documentation identifying any procurement requirements that have not been met.

c. A description of those nonconformances from the procurement requirements dispositioned "accept as is" or "repair."

The review and acceptance of these documents should be described in the purchaser's QA program.

? 7B4. For commercial "off-the-shelf" items where specific quality assurance controls appropriate for nuclear applications cannot be imposed in a practicable manner, special quality verification requirements shall be established and described to provide the necessary assurance of an acceptable item by the purchaser. 17.2.7.3 #2 (pg 17.2.7-3)

? 7B5. Suppliers' certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented. 17.2.7.1 (pg 17.2.7-1)

2B3 7B6. The description of the control of procurement provisions listed above satisfies the regulatory position in Regulatory Guide 1.38 and Regulatory Guide 1.123.

does not contradict

1.9.123 (pg 1.9-96 → 105) lists 59 clarifications w/o clear commitment & w/o justif. for clarifications some of which are [illegible]

7A1 Describe the organizational responsibilities including interfaces between design, procurement, QA and QC organizations for control of purchased material, equipment and services.

260.28

7A3 Describe the type of records maintained to document supplier ~~evaluation~~ qualification by other than survey (as described in Sect 17.2.7.1 C of FSAR).

not in Jacks

7A4 Sect 17.2.7 of FSAR states that spares and replacement parts for S-R structures, systems & components are subject to controls equivalent to those used for the original equipment. Clarify ~~that~~ the procurement is made to QA program controls in effect at the time of procurement & to ~~FSAR~~ codes & standards and technical reqts or better than the original technical stds or that other controls are used as necessary to preclude repetition of defects.

260.29

7B2 Sect 17.2.7.3 D of FSAR states that items accepted "or" released are identified as to their inspection status. Clarify whether items that have not been accepted can be released to the controlled storage area or can be released for installation or further work.

Section 17.2.7.3 E of FSAR states that non conforming items are segregated "where practical" until proper disposition is made. Define the ~~word~~ expression "where practical".

not in Jacks

7B3 Describe the measures which ensure that the suppliers furnish the following records:

260,30

1. 2. 3. } copy from SRP

Describe how these documents are reviewed and accepted.

7B4 Describe the specific verification measures established to provide adequate assurance that commercial "off-the-shelf" items where specified QA controls appropriate for nuclear applications cannot be imposed in a practicable manner.

not in Jacks

7B5 Clarify that reviews of suppliers, which are performed in lieu of source inspection, are performed periodically and suppliers' COCs are evaluated by audit, independent insp's or tests to ensure they are valid, the results of these evaluations are documented.

not in Jack's

8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

A. Provisions to identify and control materials, parts, and components.

? 8A. Controls are established and described to identify and control materials (including consumables), parts, and components <u>including partially fabricated subassemblies.</u>? The description should include organizational responsibilities.

17.2.8 # 2 (pg 17.2.8-1)
17.2.8 # 4 (pg ") → plant staff is resp.

B. Provisions to assure that incorrect or defective items are not used.

✓ 8B1. Procedures are established which assure that "identification ? is maintained either on the item or on records traceable to the item" to preclude use of incorrect or defective items. 17.2.8 # 2, 17.2.8 # 3A (pg 17.2.8-1)
- exception for off-shelf items

8B2. Identification of materials and parts ~~important~~ to the function of ~~safety~~ related structures, systems, and components ~~important to safety~~ can be traced to the appropriate documentation such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, and physical and chemical mill test reports.
exception for off-~~shelf~~ items

? 8B3. Correct identification of material, parts, and components is verified and documented prior to release for fabrication, assembling, shipping, and installation. 17.2.8 # 3A (pg 17.2.8-1)

8A — Clarify ~~that the~~ identification and control procedures implementing the reqts for ~~includes~~ pertain to partially fabricated subassys.

Not in Jacks

8B1 — Clarify ~~that the~~ identification ~~procedures~~ require that identification is maintained either directly on the item or on records. Clarify that the exception given in 17.2.8 of FQAR for i.d. of off-the-shelf items does not contradict the.

8B2 — Clarify that the exception given in 17.2.8 of FQAR for identification of off the shelf items by a mfgr's catalog # or other document does not preclude the item's traceability to appropriate dwgs, specs, P.O.s, mfg & insp. document, nonconformance reports or mfgrs test reports

260.31

8B3 — Describe the measures which ensure ~~that~~ correct i.d. of matls, parts & components is verified & documented prior to release for fab., assy, shipping and installation.

260.32

9. CONTROL OF SPECIAL PROCESSES

A. Provisions to assure the acceptability of special processes such as welding, heat treating, nondestructive testing, and chemical cleaning.

9A1. The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, should be provided. Some examples are welding, heat treating, NDT, and chemical cleaning.

17.2.9 #1 (pg 17.2.9-1)

17.2.9 #1 (pg 17.2.9-1)

9A2. Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.

17.2.9 #4 (pg 17.2.9-1) → QA audits everything

B. Provisions to assure that special processes are performed by qualified personnel using qualified procedures and equipment.

9B1. Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. The QA organization is involved in the qualification activities to assure they are satisfactorily performed.

17.2.9 #2 (pg 17.2.9-1)

No ref 17.2.9 #4 for qualification of 9A2

9B2. Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

9B3. Qualification records of procedures, equipment, and personnel associated with special processes are established, filed, and kept current.

9A2 ~~Clarify that~~ Describe involvement by the QC organization for qualification of special processes, ~~equipment and~~ personnel if any.

260.34

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similar to 200.35 9B1 Clarify that equipment for special processes is qualified IAW applicable codes, stds, & procedures & specifics.

260.36 9B2 ~~Explain the~~ Describe the procedures ~~established~~ for recording evidence ~~that~~ of acceptable accomplishment of special processes using qualified procedures, equipment and personnel. ~~Clarify that qualification records include quality of equipment~~

---

not in Jacks 9B3 Explain how the qualification records of procedures, equip., and personnel are kept current

10. INSPECTION

A. Provisions for the inspection of activities affecting quality, including the items and activities to be covered.

10A. The scope of the inspection program is described that indicates an effective inspection program has been established. Program procedures provide criteria for determining the accuracy requirements of inspection equipment and criteria for determining when inspections are required or define how and when inspections are performed. The QA organization participates in the above functions.

"shall be" is used

17.2.10#1 (Pg 17.2.10-1)

17.2.10#2 (Pg 17.2.10-1)

no how identified

?

17.2.10 #5 Not clear that inspectors/specialists are part of QC Supervisory

B. Organizational responsibilities and qualifications established for individuals or groups performing inspections.

10B1. Organizational responsibilities for inspection are described. Individuals performing inspections are other than those who performed or directly supervised the activity being inspected and do not report directly to the immediate supervisors who are responsible for the activity being inspected. If the individuals performing inspections are not part of the QA organization, the inspection procedures, personnel qualification criteria, and independence from undue pressure such as cost and schedule should be reviewed and found acceptable by the QA organization prior to the initiation of the activity.

17.2.10#5 (pp 17.2.10-1 & 2)

? 17.2.10#5 (pg 17.2.10-2) what about those NOT assigned

QC Supervisory

? clarify

283

10B2. A qualification program for inspectors (including NDT personnel) is established and documented, and the qualifications and certifications of inspectors are kept current.

need to clean up positions of 1.9.58 1.9.8

note 17.2.10 #1 refers to RG 1.58
17.2.10 #5 " to 13.1.3 which talks about RG 1.8

which is the one that is used

C. Prerequisites to be provided in the written inspection procedures with provisions for documenting and evaluating inspection results.

10C1. Inspection procedures, instructions, or checklists provide for the following: 17.2.10 #3 (pg 17.2.10-1)

a. Identification of characteristics and activities to be inspected. 17.2.10 #3A (pg 17.2.10-1)

b. A description of the method of inspection. 17.2.10 #3B

c. Identification of the individuals or groups responsible for performing the inspection operation in accordance with the provisions of item 10B1. 17.2.10 #3C

d. Acceptance and rejection criteria. 17.2.10 #3D

e. Identification of required procedures, drawings and specifications and revisions. 17.2.10 #3E "any required"

f. Recording inspector or data recorder and the results of the inspection operation. 17.2.10 #3C & F

g. Specifying necessary measuring and test equipment including accuracy requirements. 17.2.10 #4

10C2. Procedures are established and described to identify, in pertinent documents, mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector. 17.2.10 #6

10C3. Inspection results are documented, evaluated and their acceptability determined by a responsible individual or group. 17.2.10 #3G (pg 17.2.10-1) 17.2.10 #5 (pg 17.2.10-1 & 2)

17.2.10 # 2. When inspections associated with normal operations of the plant (such as routine maintenance, surveillance, and tests) are performed by individuals other than those who performed or directly supervised the work, but are within the same group, the following controls are met:

Separate question 10B1

a. The quality of the work can be demonstrated through a functional test when the activity involves breaching a pressure retaining item.

b. The qualification criteria for inspection personnel are reviewed and found acceptable by the QA organization prior to initiating the inspection.

10A

260.37

Describe the measures which assure that the program procedures provide criteria for ① determining the necessity of insp. equip and ~~provisions~~ ② determining when inspections are required, or define how and when 'inspections' are performed. Clarify ~~who~~ that the QC specialists/ inspectors are part of the QC Supervisors organization

---

10B1

Similar to 260.39 but a lot different

~~The~~ 17.2.10 of FSAR states that QC Supervr. is responsible for administering & implementing tests & inspections "assigned" to the QC dept, Identify ~~the individuals or organizations~~ other than the QC dept with resp. for inspection. ~~If such individuals are not part of the QA org.~~

If individuals/org. are not part of the QA org. and are resp. for performing inspections, ~~Clarify that~~ describe the measures ~~taken~~ to assure that the insp. procedures,

② personnel qualif. criteria

③ independence from undue pressure such as cost & schedule

are reviewed & found acceptable by the QA org. prior to initiation of the insp. activity

---

10B2 on next page

17.2.10 #2

not in Jack's

Describe the measures taken to assure that when inspections .... inspection.

copy from SRP

10B2

Sect.

The first ¶ of 17.2.10 of FSAR indicates that the inspection program will be consistent w/ RG 1.58. (N45.2.6) However, in speaking of the qualif. of ~~insp~~ QC specialists, 17.2.10 (5th para) refers to Section 13.1.1.3 of FSAR which discusses ~~RG 1.8~~ ANSI N18.1 (RG 1.8). Clarify which standards the ~~insp~~ program is consistent w/ in regard to QC specialist qualif. Clarify ~~which~~ and ~~NDE~~ LNDE inspectors

Similar to 10.38

See 10B1

11. TEST CONTROL

A. Provisions for tests which assure that structures, systems, and components will perform satisfactorily in service.

? 11A1. N/A The description of the scope of the test control program indicates an effective test program has been established for tests including proof tests prior to installation and preoperational tests. Program procedures provide criteria for determining the accuracy requirements of test equipment and criteria for determining when a test is required or how and when testing activities are performed. ?

B. Prerequisites to be provided in written test procedures with provisions for documenting and evaluating test results.

11B1. Test procedures or instructions provide as required for the following: 17.2.11 #1 (pg 17.2.11-1)

✓a. The requirements and acceptance limits contained in applicable design and procurement documents. 17.2.11 #1A (pg 17.2.11-1)

✓b. Instructions for performing the test. 17.2.11 #1B

? c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation including their accuracy requirements, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage. 17.2.11 #1C1 17.2.11 #1C4 17.2.11 #1C5 17.2.11 #1C6

✓d. Mandatory inspection hold points for witness by owner, contractor, or inspector (as required). 17.2.11 #1C7

✓e. Acceptance and rejection criteria. 17.2.11 #1C8

✓f. Methods of documenting or recording test data and results. 17.2.11 #1C9

? g. Provisions for assuring test prerequisites have been met. 17.2.11 #1B

C. Personnel qualification programs established for test personnel.

283 11C1. Test results are documented, evaluated, and their acceptability determined by a responsible individual or group.

see 1.9.58 and/or 1.9.8 and question 283

II A 1

260.40 Describe the measures to assure that program procedures provide criteria for determining ... performed. (from SAP)

II B 1

Clarify that test procedures or instructions provide for

not in Jacks [① adequate test equip & instrumentation including their accuracy reqts

② provisions for assuring

260.41 test prerequisites have been met.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

Provisions to assure that tools, gages, instruments, and other measuring and testing devices are properly identified, controlled, calibrated, and adjusted at specified intervals.

12.1 The scope of the program for the control of measuring and test equipment is described and the types of equipment to be controlled are established. This information indicates an effective calibration program has been established. 17.2.12 #2A (pg 17.2.12-1)

12.2 QA and other organizations' responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program. (17.2.12 #4 (pg 17.2.12-2)) (Supervisor of maintenance 17.2.12 #4 (pg 17.2.12-2))

12.3 Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) that is used in the measurement, inspection, and monitoring of structures, systems, and components. The review and documented concurrence of these procedures is described and the organization responsible for these functions is identified. 17.2.12 #2A pg 17.2.12-1 ? Identify

12.4 Measuring and test equipment is identified and traceable to the calibration test data. 17.2.12 #2B (pg 17.2.12-1)

12.5 Measuring and test equipment is labeled or tagged or "otherwise controlled" to indicate due date of the next calibration. The method of "otherwise controlled" should be described. 17.2.12 #2B (pg 17.2.12-1) ? exception taken to installed process instrumentation.

12.6 Measuring and test equipment is calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement. 17.2.12 #2C (pg 17.2.12-1)

Calibration of this equipment should be against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, have an accuracy that assures the equipment being calibrated will be within required tolerance and that the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function is identified. 17.2.12 #3 (pg 17.2.12-2) ? ?

12.7 Calibrating standards have greater accuracy than standards being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function is identified. 17.2.12 #3 (pg 17.2.12-2) N/A

12.8 Reference and transfer standards are traceable to nationally recognized standards; where national standards do not exist, provisions are established to document the basis for calibration. (master std) 17.2.12 #2F (pg 17.2.12-1) (1st std) 17.2.12 #3 (pg 17.2.12-2) ? #2F and approved by an individual's level of responsibility

12.9 Measures are taken and documented to determine the validity of previous inspections performed and the acceptability of items inspected or tested since the last calibration when measuring and test equipment is found to be out of calibration. Inspections or tests are repeated on items determined to be suspect. 17.2.12 #2E (pg 17.2.12-2) ?

12.3 — Identify the organization responsible for review & documented concurrence of calibration procedures.

similar to 260.43

Jack's has more but I found ref

development is resp. of super of main

12.5 Describe the measures used to control the calibration due date of installed process instrumentation which is not tagged or labeled w/ calibration due date.

similar to 260.44

12.6 Explain the measures used to assure that the equipment being calibrated will be within the reqd tolerance & that the basis of acceptance is documented and authorized by responsible management. When it is not possible to calibrate equipment against stds having an accuracy of at least as great as the required accuracy of the equipment being calibrated,

similar to 260.45

Identify the responsible management position(s) allowed to perform this function.

12.8 When no reference standard exists and the basis of calibration is based on "authorized" level of management

Identify the allowed to approve the basis of calibration (FSAR 17.2.12 F)

not in Jack's

12.9

similar to 260.4b

Describe the measures taken to assure ~~that~~ inspections or tests on items determined to be suspect when M&TE is found to be out of calibration ~~are valid~~ are repeated.

13. HANDLING, STORAGE, AND SHIPPING

Provisions to control handling, storage, shipping, cleaning, and preservation of items in accordance with work and inspection instructions to prevent damage, loss, and deterioration by environmental conditions such as temperature or humidity.

13.1 Special handling, preservation, storage, cleaning, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions. 17.2.2 #7, #1 (pg 17.2.2-3) doesn't seem to be enough

13.2 Procedures are established and described to control the cleaning, handling, storage, packaging, and shipping of materials, components, and systems in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity. 17.2.13 #3 (pg 17.2.13-1) surveillance "as required" 17.2.13 #1A " 17.2.13 #10 handling tools "adequately" maint.

2B3 13.3 The description of the control of handling, storage, and shipping listed above ~~satisfies~~ does not contradict the regulatory position in Regulatory Guide 1.38. 1.9.38 (pp 1.9-36 → 42) provides 26 clarifications, some of which are exceptions/alternatives, w/o justif — see question 2B3

17.2.2 #2. Provisions are described for the storage of chemicals, reagents (including control of shelf life), lubricants, and other consumable materials. 17.2.13 #18 (pg 17.2.13-1)

13.1 ~~Clarify that special handling instructions contain applicable~~

not in Jack's

Describe the methods used to assure that special handling, preservation, storage, cleaning, packing and shipping are accomplished by suitably trained individuals

---

13.F

not in Jack's Similar to 260.47

Describe the routine surveillance ~~procedures used to measures~~ controlon items in storage described ~~in~~ ~~of FSAR~~. Clarify the use of the expression "as required" in 17.2.13 A of FSAR and ~~describe the~~ clarify the used of ~~in~~ Describe the inspection measures used to verify that special handling tools & equip. are "adequately maintained".

not in Jack's

14. INSPECTION, TEST, AND OPERATING STATUS

Provisions to indicate the inspection, test, and operating status of items to prevent inadvertent use or bypassing of inspection and tests.

14.1 Procedures are established to indicate the inspection, test, and operating status of structures, systems, and components throughout fabrication, installation, and test. 17.2.14C (pg 17.2.14-1)

14.2 Procedures are established and described to control the application and removal of inspection and welding stamps and status indicators such as tags, markings, labels, and stamps. 17.2.14A (pg 17.2.14-1)

14.3 Procedures are established and described to control altering the sequence of required tests, inspections, and other ~~important to safety~~ safety related operations. Such actions should be subject to the same controls as the original review and approval. 17.2.14B (pg 17.2.14-1)

14.4 The status of nonconforming, inoperative, or malfunctioning structures, systems, and components is documented and identified to prevent inadvertent use. The organization responsible for this function is identified.

Clarify ~~whether~~ that the VEGP ~~has~~ ~~established~~ procedures are established for 17.2.14A ~~thru~~ & C of FSAR.

14.1 not in Jack's

Clarify whether the procedures of 17.2.14C of FSAR are applicable throughout ~~the~~ test ~~phase~~ in addition to mfg, install & operation as already listed.

14.2 not in Jack's

Describe the procedures established to control the application and removal of insp. & welding stamps and status indicators such as tags, markings, labels & stamps. Clarify that the procedures of 17.2.14A of FSAR include the application and removal of stamps such as inspection and welding stamps.

14.3 similar wdg 260.48

~~Describe the procedures~~ Clarify that the procedures and describe the procedures established to control "altering the sequence" of required tests, inspections & other safety related operations, and clarify that ~~these procedures~~ such actions are subject to the same controls as the original review and approval.

14.4 not in Jack's

Identify the organization responsible for documentation and identification of nonconforming, inoperative or malfunctioning structures, systems and components to prevent inadvertent

15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Provisions to control the use or disposition of nonconforming materials, parts, or components.

17.2.15D (pg 17.2.15-1) ?

15.1 Procedures are established and described for identification, documentation, segregation, review, disposition, and notification to affected organizations of nonconforming materials, parts, components and as applicable to services (including computer codes). if disposition is other than to scrap. The procedures provide identification of authorized individuals for independent review of nonconformances including disposition and closeout.

17.2.15A
17.2.15B (pg 17.2.15-1)
who in QA audit system? all nonconformances
17.2.15# (pg 17.2.15-

? 15.2 QA and other organizational responsibilities are described for the definition and implementation of activities related to nonconformance control. This includes identifying those individuals or groups with authority for the disposition of nonconforming items.

? 15.3 Documentation identifies the nonconforming item; describes the nonconformance, the disposition of the nonconformance, and the inspection requirements; and includes signature approval of the disposition. Nonconformances are corrected or resolved prior to the initiation of the preoperational test program on the item.

17.2.15B (pg 17.2.15-1)
?

15.4 Reworked, repaired, and replacement items are inspected and tested in accordance with the original inspection and test requirements or acceptable alternatives.

17.2.15E pg 17.2.15-

? 15.5 Nonconformance reports are periodically analyzed by the QA organization to show quality trends, and the significant results are reported to upper management for review and assessment.

17.2.15G (pg 17.2.15-2) doesn't identify org. defn of "periodically"

15.1 ~~a. Identify text in [illegible]~~
~~provisions for control of NCM~~
~~as established for 17.2.15 a, c, f, g~~
① ~~FSAR~~ Clarify whether the provisions of 17.2.1
for control of NCM are applicable to computer codes.
② Describe the measures used to identify, review and disposition NCM parts or components and as applicable services
not in Jack's
③ ~~Clarify whether that~~ Identify which individuals in the QA organization are responsible for independent review of all including disposition & closeout.
~~Clarify whether the~~

15.2 Describe QA and other org. resp. for the definition and implementation of activities related to nonconformance control and ~~including~~ identify ~~how~~ individuals or groups w/ authority for the disp. of N.C. items
similar wdg 200.49
not in Jacks

15.3 Describe measures for assuring that nonconformances are corrected or resolved prior to the initiation of the pre-op. test program on the item
similar wording 200.50 SAR

15.5 Identify the QA organizational element responsible for analyzing N.C.R.s and ~~trending~~ reporting on Q trends.
similar wording 200.51
not in Jack's Define use of the expression "periodically" in 17.2.15 a of FSAR

16. CORRECTIVE ACTION

Provisions to assure that conditions adverse to quality are promptly identified and corrected and that measures are taken to preclude repetition.

16.1 Procedures are established and described indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures. 17.2.16 #1 (pg 17.2.16-1) ?

16.2 Corrective action is documented and initiated following the determination of a condition adverse to quality (such as a nonconformance, failure, malfunction, deficiency, deviation, and defective material and equipment) to preclude recurrence. The QA organization is involved in the documented concurrence of the adequacy of the corrective action. 17.2.16 #1 (pg 17.2.16-1) ?

16.3 Followup action is taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner. ? 17.2.16 #2C (pg 17.2.16-1)

16.4 Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition are documented and reported to immediate management and upper levels of management for review and assessment. 17.2.16 #3 (pg 17.2.16-1)

16.1 ~~Describe~~ Identify the QA organizational element which reviews and documents concurrence with the procedure.

16.2 Identify the QA organizational element which is involved in the documented concurrence of the adequacy of the corrective action.

16.3 Identify the QA organizational element which verifies proper implementation of corrective action and to close out the CA in a timely manner.

Continued in 260.52

17. QUALITY ASSURANCE RECORDS

Provisions for the identification, retention, retrieval, and maintenance of records that furnish evidence of activities affecting quality.

17.1 The scope of the records program is described. QA records include results of reviews, inspections, tests, audits, and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports; nonconformance reports, and corrective action reports. 17.2.17#1 (pg 17.2.17-1)

For says procedures "will" control

17.2 QA and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to QA records. 17.2.17 #2 (pg 17.2.17-1)

17.3 Inspection and test records contain the following where applicable:

a. A description of the type of observation. ~~Insp~~ 17.2.10 #3A (pg 17.2.10-1); Test 17.2.11 #2A (pg 17.2.11-2)

b. The date and results of the inspection or test. Insp 17.2.10 #3F (pg 17.2.10-1); Test 17.2.11 #2D (pg 17.2.11-2)

? c. Information related to conditions adverse to quality. Insp — ?; Test — ?

? d. Inspector or data recorder identification. Insp 17.2.10 #3C (pg 17.2.10-1); Test ~~Insp~~ recorder? 17.2.11 #2F (pg 17.2.11-2)

e. Evidence as to the acceptability of the results. Insp 17.2.10 #3G (pg 17.2.10-1); Test 17.2.11 #2G (pg 17.2.11-2)

? f. Action taken to resolve any discrepancies noted. ~~Insp~~ — ?; Test — ?

17.4 Suitable facilities for the storage of records are described and satisfy the regulatory position given in Regulatory Guide 1.88 (endorses N45.2.9). Alternatives to the fire protection rated provisions are acceptable if records storage facilities conform to NFPA No. 232 Class 1 for permanent-type records and that the 2-hour fire rating requirement contained in the proposed N45.2.9 standard is met by applicants in any one of the following three ways. Specifically, (1) a 2-hour vault meeting NFPA No. 232; (2) 2-hour rated file containers meeting NFPA No. 232 (Class B); or (3) a 2-hour rated fire resistant file room meeting NFPA No. 232 if the following additional provisions are provided. 17.2.17#3 (pg 17.2.17-1) – but see also question 283

1. Early warning fire detection and automatic fire suppression should be provided, with electronic supervision at a constantly attended central station.

2. Records should be stored in fully enclosed metal cabinets. Records should not be permitted on open steel shelving. No storage of records should be permitted on the floor of the facility. Adequate access and aisle ways should be maintained at all times throughout the facility.

3. Work not directly associated with records storage or retrieval should be prohibited within the records storage facility. Examples of such prohibited activities include but are not limited to: records reproduction, film developing, and fabrication of microfiche cards.

4. Smoking and eating/drinking should be prohibited throughout the records storage facility.

5. Ventilation, temperature, and humidity control equipment should be protected inside with standard fire-door dampers where they penetrate fire barriers bounding the storage facility.

17.5 The description of the control of records provisions listed above ~~satisfies~~ does not contradict the regulatory position of Regulatory Guide 1.88. 1.9.88 (pg 1.9-75) – refers to NSSS record alterations & clarifications in WCAP-8370 – effect on VQAP not clearly stated – see question 283

2. QA records include operating logs, maintenance and modification procedures, and related inspection results, reportable occurrences, and other records required by Technical Specifications. 17.2.17 #1 (pg 17.2.17-1)

17.1

Clarify that ~~the~~ written procedures for control of record storage and retention ~~be~~ established per 17.2.17, 1st para. ~~states that the~~ written procedures "will" control these activities.

17.3

26053

Describe the measures to assure that inspection and test records contain the following information:

wording similar

① information related to conditions adverse to quality.

position different than Jack's

② data recorder identify (test records only)

③ action taken to resolve any discrepancies noted

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18. AUDITS

A. Provisions for audits to verify compliance with all aspects of the QA program and to determine the effectiveness of the QA program.

18A1. Audits to assure that procedures and activities comply with the overall QA program are performed by:

a. The QA organization to provide a comprehensive independent verification and evaluation of quality-related procedures and activities. 17.2.18 #1, #2 E (pg 17.2.18-1)

b. The applicant (and principal contractors) to verify and evaluate the QA programs, procedures, and activities of suppliers. 17.2.18 #2G (pg 17.2.18-2)

18A2. An audit plan is prepared identifying audits to be performed, their frequencies, and schedules. Audits should be regularly scheduled based upon the status and safety importance of the activities being performed and are initiated early enough to assure effective QA during design, procurement, manufacturing, construction, installation, inspection, and testing. 17.2.1.3.4A (pg 17.2.1-8) 17.2.18 #2H (pg 17.2.18-2)

18A3. Audits include an objective evaluation of quality-related practices, procedures, instructions; activities and items; and review of documents and records to ensure that the QA program is effective and properly implemented. 17.2.18 #2E,F,G (pg 17.2.18-1)

Sect.	Para.
2.2	#6
3	#8
4	#3
5	17.2.5.2 #2
6	#4
7	#3
8	#5 "selectively"?
9	#4
10	#7
11	#4 "selectively"?
12	#4
13	#2 "selectively"?
14	#4
15	#2
16	#3
17	#4
18	—

18A4. Provisions are established requiring that audits be performed in all areas where the requirements of Appendix B to 10 CFR Part 50 are applicable. Areas which are often neglected but should be included are activities associated with: implied in 17.2.18 #1 (pg 17.2.18-1)

~~a. The determination of site features which affect plant safety (e.g., core sampling, site and foundation preparation, and methodology). (PSAR only).~~ N/A

~~b. The preparation, review, approval, and control of early procurements. (PSAR only).~~ N/A

c. Indoctrination and training programs. 17.2.18 #3 P

d. Interface control among the applicant and the principal contractors.

e. Corrective action, calibration, and nonconformance control systems. 17.2.16 #3 (pg 17.2.16-1) 17.2.18 #3 J,K 17.2.15 #2 (pg 17.2.15-2) 17.2.12 #4 (pg 17.2.12-2)

f. SAR and SSAR commitments.

g. Activities associated with computer codes. 17.2.18 #3 L (pg 17.2.18-3)

B. Responsibilities and procedures for auditing, documenting and reviewing audit results, and designating management levels to review and assess audit results.

18B1. Audit data are analyzed by the QA organization and the resulting reports indicating any quality problems and the effectiveness of the QA program, including the need for reaudit of deficient areas, are reported to management for review and assessment.

18B2. Audits are performed in accordance with pre-established written procedures or checklists and conducted by trained personnel having no direct responsibilities in the areas being audited.

18B3. The description of the conduct of audit provisions satisfies the regulatory position in Regulatory Guides 1.144 and 1.146.

1.9.144 and 1.146 have one and none exceptions, respectively stated & refer to 17.12, which is not clear an QA commitment — see question 2B3

2. Audits (item 18) add a part C: "Provisions for the audit of operating activities important to safety independent of the operating organization."

2. Where the "onsite" QA organization does not report to the "offsite" organization:

onsite QA reports to offsite
onsite QC does not report to QA

a. The "offsite" QA organization conducts audits sufficient to verify adequacy of activities conducted by the "onsite" QA organization.

b. The "offsite" QA organization reviews and concurs in the schedule and scope of audits performed by the "onsite" QA organization.

c. Results of audits performed by the "onsite" QA organization are provided to the "offsite" QA organization for review and assessment.

DRL

wording different 260.55

Describe the measures used to "selectively" audit identification and control of matls parts and components, FSAR 17.2.8
① test control (17.2.11)
② handling storage and delivery (17.2.13)

not in Jack's [Describe the measure used to audit conformance to SAR & SSAR commitments

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18B2

not in Jack's [Describe the measures used to assure ~~that~~ audits are conducted by "appropriately" trained and qualified individuals (FSAR 17.2.18, 2nd para, A)

?. for Jack Couldn't decipher meaning of SRP 17.2.2, I #2