

15.0 MANAGEMENT MEASURES

15.1 QUALITY ASSURANCE

15.1.1 PURPOSE OF REVIEW

The purpose of this review is to establish that the applicant has a quality assurance (QA) program that will provide reasonable assurance against natural phenomena and the consequences of potential accidents through the QA program's application to the design, fabrication, construction, testing and operation of the applicant's structures, systems, and components¹ (SSCs); the applicant is required to describe the QA program as part of the application for construction approval under 10 CFR 70.22(f). This review also establishes that the applicant has a QA program that will provide reasonable assurance that all items relied on for safety² (IROFS) will be available and reliable to perform their designated safety functions when needed, which the applicant is required to describe as part of license application under proposed 10 CFR Part 70.

15.1.2 RESPONSIBILITY FOR REVIEW

Primary: QA Engineer/Specialist

Secondary: Project Manager

Supporting: Fuel Cycle Facility Inspector
Primary Reviewers of applicable SRP Chapters 5.0 through 15.0

15.1.3 AREAS OF REVIEW

The applicant is required to submit a description of the QA program with the application for construction approval and should update the QA program in the license application. The areas of review should include:

- A. Organization
- B. QA Function³

¹ "Structures, systems, and components" are, by definition, items relied on for safety (see Footnote 2). For the purposes of the review guidance provided under this section, references to items relied on for safety are intended to include the SSCs identified in the application for construction approval.

² "Items relied on for safety" is defined in the proposed 10 CFR 70, as revised, as "structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at the facility that could exceed the performance requirements specified in §70.61 or to mitigate their potential consequences."

³ SRP Section 15.4 addresses training and qualification of plant personnel. Section F2 of SRP Appendix F on QA addresses training and qualification of other personnel.

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- C. Design Control
- D. Procurement Document Control
- E. Instructions, Procedures,⁴ and Drawings
- F. Document Control
- G. Control of Purchased Items
- H. Identification and Control of Items
- I. Control of Special Processes
- J. Inspection
- K. Test Control
- L. Control of Measuring and Test Equipment
- M. Handling, Storage, and Shipping
- N. Inspection, Test, and Operating Status
- O. Nonconformances
- P. Corrective Action
- Q. QA Records
- R. Audits and Assessments⁵
- S. Applicant's Provisions for Continuing QA

15.1.4 ACCEPTANCE CRITERIA

15.1.4.1 Regulatory Requirements

The regulation, 10 CFR Part 70, as proposed, requires that the applicant establish an appropriate QA program to ensure that all items relied on for safety perform their designated safety functions and are continually available and reliable. The regulatory requirements for QA are addressed in the following:

Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)." *Federal Register*: Vol. 64, No. 146. pp. 41338-41357. July 30, 1999.

In addition, an applicant to possess and use special nuclear material in a plutonium processing and fuel fabrication facility such as the mixed oxide (MOX) fuel fabrication facility is required, pursuant to §70.22(f), to describe the QA program to be applied to the design, fabrication, construction, testing, and operation of the structures, systems, and components of the facility. The footnote of §70.22(f) states that the description of the QA program should include a discussion of how the criteria in Appendix B of 10 CFR Part 50 will be met.

⁴ SRP Section 15.5 addresses plant procedures. Section F5 of SRP Appendix F on QA addresses other procedures.

⁵ Guidance for audits and assessments is given in SRP Section 15.6 as referenced in SRP Appendix F on QA.

15.1.4.2 Regulatory Guidance

Guidance for QA is addressed in the following:

American Society of Mechanical Engineers, "Quality Assurance Requirements for Nuclear Facility Applications." (An American National Standard), NQA-1-1994, New York. 1994.

Note that while this standard has separate sections for "requirements" and "guidance," NRC's regulatory QA requirements exist only in the applicable Commission regulations.

15.1.4.3 Regulatory Acceptance Criteria

The NRC reviewers should find that the applicant's QA program adequately addresses and satisfies the regulatory acceptance criteria below. The applicant may reference material in other sections of application for construction approval or the license application, or incorporate material by reference, provided that these references are clear and specific.

The applicant should identify the SSCs (application for construction approval) or items relied on for safety (license application) and the degree of their importance. The graded approach for the application of QA should be described unless the applicant chooses to apply the highest level of QA and quality control to all SSCs or items relied on for safety.

For SSCs (application for construction approval) or items relied on for safety (license application), the applicant should apply either Option A or Option B (whichever the applicant chooses with the application for construction approval) as described below.

Option A. Address the regulatory acceptance criteria given in this section and provide a commitment to implement and maintain the QA program in conformance with the applicable "requirements" of Parts I and II of NQA-1-1994 or equivalent.

OR

Option B. Address the checklist provided in SRP Appendix F on QA.

Depending on the option chosen, the applicant should address the criteria specified below. That is, if Option A is used, the applicant should (a) include a commitment that it will implement and maintain its QA program to comply with the applicable "requirements" of NQA-1-1994⁶ (that is, the basic and supplemental "requirements" of Parts I and II) or equivalent and should (b) be responsive to the three regulatory acceptance criteria given below. Note that, if Option A is

⁶ This SRP section refers to regulatory QA requirements and NQA-1 "requirements." Regulatory QA requirements are given in the Part 70, as revised. NQA-1 "requirements" are the Basic and Supplementary Requirements given in Parts I and II of ASME NQA-1-1994.

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used, only a verification of that commitment and of the response to the regulatory acceptance criteria given below should be performed.

A. Organization

The applicant should describe the organizational structure, functional responsibilities, charts of the lines of responsibilities, interrelationships, and areas of responsibility and authority for all organizations performing activities relied on for safety, including the applicant's organization and, if applicable, the organization of the applicant's principal contractors (architect/engineer, constructor, construction manager, and/or operator). Persons or organizations responsible for ensuring that appropriate QA has been established and verifying that activities affecting quality/safety have been correctly performed should have sufficient authority, access to work areas, and organizational independence to carry out their responsibilities.

B. QA Function

QA should be well-documented, planned, implemented, and maintained to ensure the availability and reliability of controls relied on for safety. It should be implemented during all phases of the facility's life. It should be functional prior to performing the Integrated Safety Analysis required by Part 70, as revised.

C. Applicant's Provisions for Continuing QA

The applicant's provisions for continuing QA should address review and updates based on reorganizations, revised activities, lessons learned, changes to applicable regulations, and other QA changes.

If Option B is used, the application should address the checklist items in SRP Appendix F on QA.

Also, the applicant should commit to update the QA program to reflect any changes between the application for construction approval and the application for a license.

15.1.5 REVIEW PROCEDURES

15.1.5.1 Acceptance Review

The primary reviewer should perform an acceptance review to determine if the application for construction approval or license application adequately addresses the items in Section 15.1.3, "Areas of Review."

Guidance specific to the application for construction approval and the license application is provided below.

A. Application for Construction Approval

Specifically, the application for construction approval should address Section 15.1.3 in full and should identify whether Option A or Option B of Section 15.1.4.3 has been chosen.

B. License Application

The areas of review for the updated material in the license application should include Items A through S identified in Section 15.1.3.1, with special attention on the identification of any new or changed aspects of the QA program.

Note that the applicant's commitment to implement and maintain its QA in conformance with the applicable basic and supplemental "requirements" of Parts I and II of ASME NQA-1-1994 or equivalent should satisfy the acceptance review criteria in Item A or B of this section.

If the primary reviewer verifies that QA is adequately addressed in either the application for construction approval or the license application, the primary reviewer should accept the application for the safety evaluation in Section 15.1.5.2. If the primary reviewer identifies significant deficiencies in the material provided, the primary reviewer should request that the applicant submit additional information prior to the start of the safety evaluation.

15.1.5.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with either Section 15.1.5.1(A) (application for construction approval) or 15.1.5.1(B) (license application), the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 15.1.4. On the basis of its review, the staff may request that the applicant provide additional information or modify the application to meet the acceptance criteria in SRP Section 15.1.4.

Guidance specific to the application for construction approval and the license application is provided below.

A. Application for Construction Approval

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The primary reviewer should review the application for construction approval to determine whether the applicant, for SSCs, has met either Option A or Option B as defined in Section 15.1.4.3.

In either case, the applicant should also (a) describe how the QA will be graded for items of lesser or no effect on consequences of concern (unless the applicant chooses to apply the highest level of QA and quality control to all SSCs) and (b) list the SSCs as determined in the safety assessment of the design basis. The primary reviewer should determine whether the applicant and its principal contractors have adequately planned for QA to be accomplished. Some of the information may be referenced to other sections of the application, or incorporated by reference, provided that these references are clear and specific.

The secondary reviewer should confirm that the applicant's and the applicant's principal contractors' QA commitments are consistent with other sections of the application.

The other supporting reviewers should determine, within their areas of review, whether SSCs have been specified with the appropriate level of QA.

The review should result in a determination that there is reasonable assurance that the applicant's and the applicant's principal contractors' QA programs will provide reasonable assurance against natural phenomena and the consequences of potential accidents through the QA program's application to the design, fabrication, construction, testing and operation of the applicant's SSCs.

B. License Application

When the applicant updates the QA program for the license application, new or changed material should include any items relied on for safety identified since the applicant provided the SSCs in the application for construction approval. The primary reviewer should focus the review on any new or changed material and determine whether the necessary QA policies, procedures, and instructions will be in place and will be applied to IROFS before personnel begin activities relied on for safety. The primary reviewer should also confirm that the material presented remains consistent with the material provided in the license application in support of other chapters of this SRP.

The supporting reviewer (Fuel Cycle Facility Inspector) should become familiar with the applicant's and principal contractors' QA commitments and determine whether ongoing activities are in agreement with them.

The review should result in a determination that there is reasonable assurance that the applicant's and the applicant's principal contractors' QA will provide reasonable assurance that items relied on for safety will be available and reliable to perform their safety functions in a satisfactory manner when needed.

When the safety evaluation is complete, the primary reviewer, with assistance from the other reviewers, should prepare the QA input for the Safety Evaluation Report (SER), as described in Section 15.1.6 using the acceptance criteria from Section 15.1.4. The secondary reviewer should coordinate the QA input with the balance of the reviews and the SER.

15.1.6 EVALUATION FINDINGS

The primary reviewer should document the safety evaluation by preparing material suitable for inclusion in the SER. The primary reviewer should describe the review, explain the basis for the findings, and state the conclusions.

The staff could document a safety evaluation for the application for construction approval as follows:

The staff reviewed the quality assurance (QA) program for the application for construction approval for [insert facility name] according to Chapter 15.1 of NUREG-1718. [Here the primary reviewer provides a summary statement of what was evaluated and why the reviewer finds the application acceptable.] Based on its review of the application for construction approval, the NRC staff concluded that (A) the applicant has adequately described its QA program and (B) the applicant's QA program meets the regulatory requirements of 10 CFR Part 70 and thus the applicant's QA program, as applied to SSCs, will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents.

The staff could document a safety evaluation for the license application as follows:

The staff reviewed the quality assurance (QA) program for the application for construction approval for [insert facility name] according to Chapter 15.1 of NUREG-1718. [Here the primary reviewer provides a summary statement of what was evaluated and why the reviewer finds the application acceptable.] Based on its review of the license application, focusing on new or updated material when compared to the safety evaluation for the construction approval, the NRC staff concludes that (A) the applicant has adequately described its updated QA program and (B) the applicant's updated QA program meets the regulatory requirements of 10 CFR Part 70 and thus provides reasonable assurance that all items relied on for safety will be available and reliable to perform their designated safety functions when needed.

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15.1.7 REFERENCES

- A. Code of Federal Regulations, Title 10, Part 70, Domestic Licensing of Special Nuclear Material, U.S. Government Printing Office, Washington, D.C., 1999.
- B. Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)," *Federal Register*: Vol. 64, No. 146. pp. 41338--41357. July 30, 1999.
- C. American Society of Mechanical Engineers (ASME), "Quality Assurance Requirements for Nuclear Facility Applications," (An American National Standard). ASME NQA-1-1994, New York. 1994.