

# MANAGEMENT MEASURES

## 11.1 QUALITY ASSURANCE

### 11.1.1 PURPOSE OF REVIEW

The purpose of this review is to establish that there is reasonable assurance that the applicant has the quality assurance (QA) elements that are needed to provide reasonable assurance that all items relied on for safety<sup>1</sup> will perform their designated safety functions as required by 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material, as revised"<sup>2</sup>.

### 11.1.2 RESPONSIBILITY FOR REVIEW

Primary: QA Engineer/Specialist

Secondary: Licensing Project Manager

Supporting: Site Representative/Facility Inspector  
Staff Reviewers of applicable SRP Chapters 3 through 15

### 11.1.3 AREAS OF REVIEW

The regulation, 10 CFR Part 70, as revised, requires that the applicant establish appropriate QA elements to ensure that all items relied on for safety perform their designated safety functions and are continually available and reliable. The following areas should be reviewed:

1. Organization
2. QA Function<sup>3</sup>
3. Design Control
4. Procurement Document Control
5. Instructions, Procedures,<sup>4</sup> and Drawings

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<sup>1</sup> "Items relied on for safety" is defined in the proposed 10 CFR Part 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."

<sup>2</sup> 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.

<sup>3</sup> SRP Section 11.4 addresses training and qualification of plant personnel. Section 2 of SRP Appendix C on QA addresses training and qualification of other personnel.

<sup>4</sup> SRP Section 11.5 addresses plant procedures. Section 5 of SRP Appendix C on QA addresses other procedures.

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6. Document Control
7. Control of Purchased Items
8. Identification and Control of Items
9. Control of Special Processes
10. Inspection
11. Test Control
12. Control of Measuring and Test Equipment
13. Handling, Storage, and Shipping
14. Inspection, Test, and Operating Status
15. Nonconformances
16. Corrective Action
17. QA Records
18. Audits and Assessments<sup>5</sup>
19. Applicant's Provisions for Continuing QA

### **11.1.4 ACCEPTANCE CRITERIA**

#### **11.1.4.1 Regulatory QA Requirements**

The regulatory QA requirements 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.

Specific references are as follows:

1. In § 70.4, "Definitions," the term management measures is defined to "include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements."
2. In § 70.62(d), the applicant or licensee is required to establish management measures to provide continuing assurance of compliance with the performance requirements.
3. In § 70.64(a)(1), the design of new facilities or the design of new processes at existing facilities is required to be developed and implemented in accordance with management measures.
4. In § 70.65(a), each application is required to include a description of the management measures.

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<sup>5</sup> Guidance for audits and assessments is given in SRP Section 11.7 as referenced in SRP Appendix C on QA.

#### 11.1.4.2 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.

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

#### 11.1.4.3 Regulatory Acceptance Criteria

The NRC reviewers should find that the applicant's submittal regarding QA provides reasonable assurance that the regulatory acceptance criteria below are adequately addressed and satisfied. Some of the information may be referenced to other sections of the SRP, or incorporated by reference, provided that these references are clear and specific.

The Integrated Safety Analysis (ISA - see SRP Chapter 3) should identify the items and related controls that are required for safety 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 items relied on for safety.

Depending on whether the applicant chooses Option A or Option B noted in SRP Section 11.1.5.2 below, the application should address the criteria specified in that subsection. That is, if Option A is used, the application should (a) include a commitment that the applicant will implement and maintain its QA elements to comply with the applicable "requirements" of NQA-1-1994<sup>6</sup> (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 used, only a verification of that commitment and of the response to the regulatory acceptance criteria given below should be performed.

1. 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.

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<sup>6</sup> 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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2. 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 ISA required by Part 70, as revised.
3. 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 C on QA.

In either case, the review of procedures that the applicant uses to meet its QA commitments would be performed during NRC inspections as part of a determination of adequacy of the licensee's QA implementation.

### **11.1.5 REVIEW PROCEDURES**

#### **11.1.5.1 Acceptance Review**

The primary reviewer should evaluate the application to determine whether it addresses the "Areas of Review" listed in Section 11.1.3, above, regarding the applicant's (and its principal contractors') QA. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation. 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.

#### **11.1.5.2 Safety Evaluation**

After determining that the application is acceptable for review in accordance with Section 11.1.5.1, above, the primary reviewer should review the application to determine whether the applicant, for items relied on for safety has either:

Option A. Addressed the regulatory acceptance criteria given in Subsection 11.1.4.3 above and provided a commitment to implement and maintain its QA in conformance with the applicable "requirements" of Parts I and II of NQA-1-1994 or equivalent.

**OR**

Option B. Addressed the checklist provided in SRP Appendix C on QA.

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 items relied on for safety) and (b) list the items

relied on for safety as determined by the applicant's ISA. The primary reviewer should determine whether the applicant and its principal contractors have adequately planned for QA to be accomplished and whether necessary QA policies, procedures, and instructions will be in place before personnel begin activities relied on for safety. 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 and the applicant's principal contractors' QA commitments are consistent with other sections of the submittal. The secondary reviewer should also integrate the QA input into the Safety Evaluation Report (SER).

The supporting reviewer (Site Representative/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 other supporting reviewers (Staff Reviewers of applicable SRP Chapters 3 through 12) should determine, within their areas of review, whether items relied on for safety are specified to require the appropriate level of QA.

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. The staff or applicant may also propose license conditions to ensure the applicant's QA meets the acceptance criteria. 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 perform their safety function in a satisfactory manner.

When the safety evaluation is complete, the primary staff reviewer, with assistance from the other reviewers, should prepare the QA input for the SER as described in Section 11.1.6 using the acceptance criteria from Section 11.1.4.

### **11.1.6 EVALUATION FINDINGS**

The staff's evaluation should verify that the license application provides sufficient information to satisfy the regulatory QA requirements of Part 70, as revised (as listed in SRP Section 11.1.4.1), and that the regulatory acceptance criteria in Section 11.1.4.3 have been appropriately considered in satisfying the regulatory QA requirements. On the basis of this information, the staff should conclude that this evaluation is complete. The reviewers should write material suitable for inclusion in the SER prepared for the entire application. The SER should include a summary statement of what was evaluated and the basis for the reviewers' conclusions.

The staff can document the evaluation as follows:

[Here the primary reviewer provides a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] Continued with: *Based on its review of the license application, the NRC staff concludes that:*

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1. *the applicant has adequately described its QA and*
2. *the applicant's QA meets the regulatory requirements of 10 CFR Part 70 and provides reasonable assurance of protection of public health and safety and of the environment.*

### 11.1.7 REFERENCES

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