

15.0 MANAGEMENT MEASURES

15.6 AUDITS AND ASSESSMENTS

15.6.1 PURPOSE OF REVIEW

The purpose of this review is to establish that the applicant developed and adequately described a system of audits and assessments¹ that provides reasonable assurance that an adequate level of protection will be maintained at the facility and to ensure that items relied on for safety will be available and reliable to perform their safety function when needed, as required by the proposed 10 CFR Part 70.

15.6.2 RESPONSIBILITY FOR REVIEW

Primary: Quality Assurance (QA) Engineer/Specialist

Secondary: Project Manager

Supporting: Fuel Cycle Facility Inspector

15.6.3 AREAS OF REVIEW

The applicant should submit a description of the system of audits and assessments with the application for construction approval and should submit updated information with the license application for operations. The applicant's system of audits and assessments should consist of two distinct levels of activities:

- A. An independent internal and external audit activity to evaluate the scope, status, adequacy, programmatic compliance and implementation effectiveness of QA and other management measures that ensure continued availability and reliability of items relied on for safety.
- B. An internal assessment activity to evaluate the scope, status, adequacy, programmatic compliance, and implementation effectiveness of QA and other management measures that ensure continued availability and reliability of items relied on for safety.

The following areas should be reviewed (construction approval):

- A. Audits and assessments-general;
- B. Audits;
- C. Assessments; and

¹Audits and assessments are evaluations of the scope, status, adequacy, programmatic compliance, and implementation effectiveness of QA and other management measures. Audits are conducted or led by "independent" personnel from the QA organization. Assessments are conducted by or for management above or outside the QA organization.

Management Measures

D. Applicant's provisions for continuing assurance.

15.6.4 ACCEPTANCE CRITERIA

15.6.4.1 Regulatory Requirements

The requirement for audits and assessments is 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:

- A. In §70.4, "Definitions," the term management measures is defined. Audits and assessments are included as a management measure.
- B. In §70.62(d), the applicant or licensee is required to establish management measures to provide continuing assurance of compliance with the performance requirements.
- C. 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.
- D. In §70.65(a), each application is required to include a description of the management measures.

15.6.4.2 Regulatory Guidance

There is no regulatory guidance applicable to this area of the SRP.

15.6.4.3 Regulatory Acceptance Criteria

The NRC reviewers should find that the applicant's audits and assessments provide reasonable assurance that the regulatory acceptance criteria below are adequately addressed and satisfied.

A. Audits and Assessments

General: Audits and assessments should be acceptable if:

- i. Internal audits, external audits, and assessments are to be conducted with a graded approach based on the results of the integrated safety analysis (ISA - see SRP Chapter 5). The stated objective of the audits and assessments should be to objectively evaluate the effectiveness and proper implementation of QA and other management

measures for items relied on for safety and to address the technical adequacy of the items being audited/assessed.

- ii. The applicant describes, provides a commitment to, and provides justification for a frequency and scope of audits and assessments of items relied on for safety. A commitment to perform audits and assessments in all areas where the requirements for QA and other management measures are applicable should be provided. Audits and assessments will be regularly scheduled on the basis of the status and the safety significance of the items being audited/assessed and will be initiated early enough to ensure the implementation of effective QA and other management measures.
- iii. Policy directives are established for audits and assessments. Policy directives cover schedules, guidance for conducting the audits and assessments, assigned responsibilities, and procedures for recording the audit/assessment results and ensuring that identified deficiencies are corrected in a timely and effective manner for each activity audited/assessed.
- iv. The applicant identifies the position title, qualifications, and responsibilities of the manager responsible for the overall success of the audits and assessments. Other organizational responsibilities for audits and assessments should be identified in the application.
- v. The applicant describes the training and qualification requirements for audit and assessment personnel. (SRP Section 15.4 addresses training and qualification requirements in detail.)
- vi. The applicant describes the authority each audit and assessment team has to investigate any aspect of the audited/assessed items with access to all relevant information.
- vii. Performance indicators are established so that audit and assessment personnel can determine the degree to which items relied on for safety are meeting performance requirements.
- viii. Audits and assessments are conducted according to written procedures/checklists. (SRP Section 15.5 provides procedure guidance.)
- ix. Audits and assessments include detailed walk-downs of plant areas, including out-of-the-way and limited-access areas, with provisions for accurate, documented descriptions of any deficiencies.
- x. The applicant describes provisions for on-the-spot corrective actions with appropriate documentation.
- xi. Audit and assessment results are reviewed with management having responsibility in the area audited/assessed.

Management Measures

- xii. Audit and assessment findings and recommendations are documented and distributed to appropriate management for review and response. As described in SRP Section 15.1, a corrective action program is administered to ensure timely and effective corrective action.
- xiii. Audit and assessment deficiency data are analyzed and trended and resultant reports, which indicate quality trends and the effectiveness of management measures, are given to appropriate management for review, response, corrective action, and follow-up.

B. Audits

Audits should be acceptable if, in addition to addressing the acceptance criteria in Section 15.6.4.3.1 above,

- i. Audit personnel have no direct responsibility for the items they audit.
- ii. Audits are led by appropriately qualified and certified audit personnel from the QA organization.
- iii. Audit team membership may include personnel (not necessarily from the QA organization) having technical expertise in the areas being audited.
- iv. Technical and programmatic audits are performed internally (that is, within the applicant's organization) and externally (that is, within the organization of suppliers, contractors, and subcontractors) and these audits provide a comprehensive independent verification and evaluation of procedures and activities affecting the quality of items relied on for safety.
- v. Auditing organizations schedule and conduct appropriate follow-up to ensure timely and effective corrective action.
- vi. Audit reports are issued to appropriate management on a timely basis.
- vii. Reports on the status of corrective actions for audit findings are issued periodically to appropriate management.
- viii. Internal audits address compliance with selected operating limits during facility operation.

C. Assessments

Assessments should be acceptable if, in addition to addressing the acceptance criteria in Section 15.6.4.3.1 above, the application indicates that responsible management personnel (or that qualified, but not necessarily certified, personnel with no direct responsibility for the items being assessed who are designated by the responsible management) perform the assessments.

D. Applicant's Provisions for Continuing Assurance

The applicant's provisions for continuing audits and assessments should be acceptable if changes to the program of audits and assessments due to reorganizations, revised activities, lessons learned, changes to applicable regulations, and other changes are reviewed and reflected in the program description.

Also, the applicant should commit to update the system of audits and assessments to reflect any changes between the application for construction approval and the license application for operations.

15.6.5 REVIEW PROCEDURES

15.6.5.1 Acceptance Review

The primary reviewer should perform an acceptance review to determine if the application adequately addresses the specific items in Section 15.6.3, "Areas of Review." If the primary reviewer verifies that audits and assessments are adequately addressed, the primary reviewer should accept the application for the safety evaluation in Section 15.6.5.2. 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.

15.6.5.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with Section 15.6.5.1, the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 15.6.4. 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 15.6.4.

The primary reviewer should determine whether the applicant has adequately planned for audits and assessments to be accomplished and whether necessary policies, personnel, procedures, and instructions will be in place to begin audits and assessments early, that is, during the ISA process and the design of items relied on for safety.

Management Measures

The secondary reviewer should confirm that the applicant's audit and assessment commitments are consistent with other sections of the submittal.

The supporting reviewer should become familiar with the applicant's audit and assessment commitments and determine whether the ongoing audits and assessments of the applicant and the applicant's suppliers, contractors, and subcontractors are in agreement with them.

The review should result in a determination that there is reasonable assurance that the audits and assessments will provide additional assurance that items relied on for safety will perform satisfactorily in service and that activities relied on for safety will be performed satisfactorily.

When the applicant updates the system of audits and assessments, the primary reviewer should focus the review on any new or changed material. The primary reviewer should also confirm that the material presented remains consistent with the material provided in the license application for operations in support of other chapters of this SRP.

15.6.6 EVALUATION FINDINGS

The primary reviewer should document the safety evaluation by preparing material suitable for inclusion in the Safety Evaluation Report (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:

[Here the primary reviewer provides a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] Based on its review of the application for construction approval, the NRC staff concludes that the applicant has adequately described its system of audits and assessments, and the applicant's system of audits and assessments meet the requirements of 10 CFR Part 70 and provides reasonable assurance of protection of public health and safety and of the environment.

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

[Here the primary reviewer provides a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] Based on its review of the license application for operations, focusing on new or updated material when compared to the safety evaluation for construction approval, the NRC staff concludes that the applicant has adequately described its updated system of audits and assessments, and the applicant's updated system of audits and assessments meet the requirements of 10 CFR Part 70 and thus provides reasonable assurance of protection of public health and safety and of the environment.

15.6.7 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. Proposed 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material; Possession of a Critical Mass of Special Nuclear Material." 64 FRN 41338, July 30, 1999.