

MANAGEMENT MEASURES

11.7 AUDITS AND ASSESSMENTS

11.7.1 PURPOSE OF REVIEW

The purpose of this review is to establish that the applicant has 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 will be available and reliable to perform their safety function when needed, as required by 10 CFR Part 70, as revised.²

11.7.2 RESPONSIBILITY FOR REVIEW

Primary: Quality Assurance (QA) Engineer/Specialist

Secondary: Licensing Project Manager

Supporting: Site Representative/Facility Inspector

11.7.3 AREAS OF REVIEW

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:

1. Audits and assessments - general
2. Audits

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.

² 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.

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3. Assessments
4. Applicant's provisions for continuing assurance

11.7.4 ACCEPTANCE CRITERIA

The regulatory requirements, regulatory guidance, and regulatory acceptance criteria applicable to audits and self assessments are listed in the following sections.

11.7.4.1 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:

1. In § 70.4, "Definitions," the term management measures is defined. Audits and assessments are included as a management measure.
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.

11.7.4.2 Regulatory Guidance

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

11.7.4.3 Regulatory Acceptance Criteria

The NRC reviewers should find that the application regarding audits and assessments provides reasonable assurance that the regulatory acceptance criteria below are adequately addressed and satisfied.

1. Audits and Assessments - General: The description of audits and assessments should be acceptable if:
 - a. The application indicates that 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 3). The stated objective of the audits and

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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 items being audited/assessed.

- b. The application 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. The application should indicate that 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.
- c. The application describes policy directives that are established for audits and assessments. The application indicates that the policy directives cover schedules, guidance for conducting the audits/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..
- d. The application 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.
- e. The application describes the training and qualification requirements for audit and assessment personnel. (SRP Section 11.4 addresses training and qualification requirements in detail.)
- f. The application describes the authority each audit and assessment team has to investigate any aspect of the audited/assessed items with access to all relevant information.
- g. The application describes how performance indicators are established so that audit and assessment personnel can determine the degree to which selected items relied on for safety are meeting performance requirements.
- h. The application indicates that audits and assessments are conducted according to written procedures/checklists.
- i. The application indicates that 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.
- j. The application describes provisions for on-the-spot corrective actions with appropriate documentation.

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- k. The application indicates that audit and assessment results are reviewed with management having responsibility in the area audited/assessed.
 - l. The application indicates that audit and assessment findings and recommendations are documented and distributed to appropriate management for review and response. As described in SRP Section 11.1, a corrective action program is administered to ensure timely and effective corrective action.
 - m. The application indicates that 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.
2. Audits: The description of audits should be acceptable if, in addition to addressing the acceptance criteria in Section 11.7.4.3.1 above,
- a. The application indicates that audit personnel have no direct responsibility for the items they audit.
 - b. The application indicates that audits are led by appropriately qualified and certified audit personnel from the QA organization.
 - c. The application indicates that audit team membership may include personnel (not necessarily from the QA organization) having technical expertise in the areas being audited.
 - d. The application indicates that both 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 that these audits provide a comprehensive independent verification and evaluation of procedures and activities affecting the quality of items relied on for safety.
 - e. The application indicates that auditing organizations schedule and conduct appropriate follow-up to ensure timely and effective corrective action.
 - f. The application indicates that audit reports are issued to appropriate management on a timely basis.
 - g. The application indicates that reports on the status of corrective actions for audit-findings are issued periodically to appropriate management.
 - h. The application indicates that internal audits address compliance with selected operating limits during facility operation.
3. Assessments: The description of assessments should be acceptable if, in addition to addressing the acceptance criteria in Section 11.7.4.3.1 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.

4. Applicant's Provisions for Continuing Assurance: The applicant's provisions for continuing audits and assessments should be acceptable if the application indicates that 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.

11.7.5 REVIEW PROCEDURES

11.7.5.1 Acceptance Review

The primary reviewer should evaluate the application to determine whether it addresses the "Areas of Review" discussed in Section 11.7.3, above. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation.

11.7.5.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with Section 11.7.5.1, above, the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 11.7.4. The review 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 and the design of items 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's audit and assessment commitments are consistent with other sections of the submittal. The secondary reviewer is also responsible for integrating the audit and assessment input into the Safety Evaluation Report (SER).

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.

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 11.7.4. The staff or applicant may also propose license conditions to ensure audits and assessments meet the acceptance criteria. 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.

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When the safety evaluation is complete, the primary staff reviewer, with assistance from the other reviewers, should prepare the audits and assessments input for the SER as described in Section 11.7.6 using the acceptance criteria from Section 11.7.4.

11.7.6 EVALUATION FINDINGS

The staff's evaluation should verify that the license application provides sufficient information to satisfy the regulatory requirements of Part 70, as revised (as listed in SRP Section 11.7.4.1), and that the regulatory acceptance criteria in Section 11.7.4.3 have been appropriately considered in satisfying the 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:*

1. *the applicant has adequately described its system of audits and assessments and*
2. *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.*

11.7.7 REFERENCE

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.