



11.8 OTHER QA ELEMENTS

The QA Program and its supporting manuals, procedures and instructions are applicable to items and activities designated as QA Level 1 and 2.

The QA Director is responsible for developing and revising the QA Program and assuring it is in compliance with applicable regulations, codes and standards. The QA Director approves the supporting manuals, procedures, and revisions for their respective scope of responsibility.

The QA Program specifies mandatory requirements for performing activities affecting quality and is set forth in procedures which are distributed on a controlled basis to organizations and individuals responsible for quality. Revisions to these procedures are also distributed on a controlled basis. Applicable portions of the QA Program are documented, approved and implemented prior to undertaking an activity.

A management assessment of the QA program is performed at least six months prior to scheduled receipt of licensed material on the site. Items identified as needing completion or modification are entered into the CAP and corrective action completed before scheduled receipt of licensed material. LES Management monitors the QA program prior to this initial management assessment through project review meetings and annual assessments. This management assessment along with integrated schedules and program review meetings ensure that the QA program is in place and effective prior to receiving licensed material.

The LES QA program for design, construction, and preoperational testing continues simultaneously with the QA program for the operational phase while construction activities are in progress.

Anyone may propose changes to the QA Program supporting manuals and procedures. When reviewed by the QA Director and found acceptable and compatible with applicable requirements, guidelines and LES policy, the changes may be implemented. The QA Program and supporting manuals and procedures are reviewed periodically to ensure they are in compliance with applicable regulations, codes, and standards. New or revised regulations, codes, and standards are reviewed for incorporation into the QA Program and supporting manuals and procedures as necessary.

Personnel performing activities covered by the QA program shall perform work in accordance with approved procedures, and must demonstrate suitable proficiency in their assigned tasks. Formal training programs are established for quality assurance policies, requirements, procedures, and methods. Ongoing training is provided to ensure continuing proficiency as procedural requirements change. New employees are required to attend a QA indoctrination class on authority, organization, policies, manuals, and procedures.

Additional formal training is conducted in specific topics such as NRC regulations and guidance, procedures, auditing, and applicable codes and standards. Supplemental training is performed as required. On-the-job training is performed by the employee's supervisor in QA area-specific procedures and requirements. Training records are maintained for each person performing quality-related job functions.

The LES President assesses the scope, status, adequacy and regulatory compliance of the QA Program through regular meetings and correspondence with the Plant Manager and the LES

QA organization. Additionally, LES QA, through the QA Director, periodically informs the LES President and Plant Manager of quality concerns that need management resolution.

LES participates in the planning and scheduling for system turnover as construction is completed. Prior to system turnover, written procedures are developed for control of the transfer of systems, structures, components and associated documentation. The procedures include checklists, marked drawings, documentation lists, system status, and receipt control.

Major work activities contracted by LES shall be identified and controlled. Principal contractors shall be required to comply with the applicable portions of 10 CFR 50, Appendix B (CFR, 2003b), as determined by LES. The performance of contracted activities shall be formally evaluated by LES commensurate with the importance of the activities to safety.

Facility components and processes are assigned a QA level based on their safety significance. Each component will receive a classification of QA Level 1, QA Level 2, or QA Level 3 that applies throughout the life of the facility and is based on the following definitions:

QA Level 1 Requirements

The QA Level 1 Program shall conform to the criteria established in 10 CFR 50, Appendix B (CFR, 2003b). These criteria shall be met by commitments to follow the guidelines of ASME NQA-1-1994 (ASME, 1994), including supplements as revised by the ASME NQA-1a-1995 Addenda (ASME, 1995) as specified in the QA Program Description. The QA Level 1 QA program shall be applied to those structures, systems, components, and administrative controls that have been determined to be IROFS, items that affect the functions of the IROFS, and items required to satisfy regulatory requirements for which QA Level 1 requirements are applied.

QA Level 2 Requirements

The QA Level 2 program is an owner-defined QA program that uses the ASME NQA-1-1994 standard (ASME, 1994), including supplements as revised by the ASME NQA-1a-1995 Addenda (ASME, 1995) as guidance. General QA Level 2 requirements are described in Section 20, "Quality Assurance Program for QA Level 2 Activities". For contractors, the QA Level 2 program shall be described in documents that must be approved by LES. The QA Level 2 program shall be applied to Owner designated structures, systems, components, and activities. An International Organization for Standardization (ISO) 9000 series QA program may be acceptable for QA Level 2 applications provided it complies with LES Quality Assurance Program Description requirements. The QA program manual must be reviewed and accepted by the LES QA Director.

QA Level 3 Requirements

The QA Level 3 program is defined as standard commercial practice. A documented QA Level 3 program is not required. QA Level 3 governs all activities not designated as QA Level 1 or QA Level 2.

Appendix A, "LES Quality Assurance Program Description" of this chapter provides additional details and commitments to other QA elements that will be implemented to support the Management Measures described in this chapter.