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November 21, 2003

U.S. Nuclear Regulatory Commission
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NEF: #03-002

Subject: Louisiana Energy Services Gas Centrifuge Uranium Enrichment Facility
Response to NRC Request for Information
NRC Docket No. 70-3103

NRC Letter dated March 25, 2003, "Request for Additional Information on the Louisiana Energy Services Quality Assurance Program Description, Revision 0, Dated November 26, 2002," transmitted a Request for Additional Information (RAI) resulting from the NRC's technical review of the Louisiana Energy Services (LES) Quality Assurance Program Description (QAPD) submitted to the NRC by letter dated November 26, 2002. This RAI reflects the additional information or clarification identified by the NRC that is needed to determine the acceptability of the QAPD for the design, construction, operation, and decommissioning of the gas centrifuge uranium enrichment facility to be proposed by LES. LES's responses to the questions in the RAI are provided below, including a reiteration of the NRC questions for completeness.

As a result of responses to the NRC requests for additional information or clarification, we have revised the original QAPD and this new version is transmitted as part of this response to the NRC RAI as requested in the March 25, 2003, NRC letter. In order to incorporate the requested level of detail and specificity, the QAPD has been extensively revised. Accordingly, we consider the version of the QAPD included here to be revision 0, and therefore no revision bars are indicated in the margin.

Contrary to our understanding from the September 5, 2002, meeting between LES and NRC, we now understand that the acceptability of the QAPD cannot be determined for the full scope of the proposed activities until the Integrated Safety Analysis Summary and the description and commitments to the interfacing management measures have been submitted in the facility license application and reviewed by the NRC. While the NRC states in its March 25, 2003, letter that NRC in-office review of the QAPD implementation and supporting QA procedures may also be scheduled as part of the review process, we request a meeting with the NRC to discuss this aspect.

LES Response to the NRC RAI

NRC Request: QAPD Introduction, Sections 1 and 2
1. Please identify the specific LES QAPD commitments or exceptions to the 18 Basic and Supplementary Requirements of NQA-1 for IROFS. Also, explain the QAPD references to NQA-1 as guidelines, not commitments.

Response: The statement in the "Introduction" section of the original QAPD that "...the criteria in 10 CFR Part 50, Appendix B, are implemented following the guidelines of the American Society of Mechanical Engineers (ASME) Quality Assurance (QA) standard NQA-1-1994, "Quality Assurance

NMSS01

Program Requirements for Nuclear Facilities," as revised by the ASME NQA-1a-1995-Addenda," was intended to establish our documented commitment to the provisions of NQA-1-1994 and the 1995 addenda as applied to the design, construction, operation, and decommissioning of the proposed gas centrifuge uranium enrichment plant, including the Items Relied on For Safety (IROFS). Since no exceptions were taken to the provision of NQA-1-1994 or the 1995 addenda, no exceptions were identified. Nonetheless, the QAPD has been revised to identify the commitment to each specific provision of the NQA-1-1994 and the 1995 addenda and as in the original QAPD, no exceptions are taken and therefore none are identified. To ensure clarity, the following table is provided to show which section of the QAPD contains the commitment to specific provisions of the NQA-1-1994 and the 1995 addenda.

Criterion	ASME NQA-1 Commitment
1	Basic Requirement 1 and Supplement 1S-1 of NQA-1-1994
2	Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3 and 2S-4 of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda of NQA-1-1994
3	Basic Requirement 3 and Supplement 3S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda of NQA-1-1994, Part II ASME NQA-1-1994 Subpart Part 2.7, as revised by NQA-1a-1995 Addenda of NQA-1-1994 and ASME NQA-1-1994, Part I
4	Basic Requirement 4 and Supplement 4S-1 of NQA-1-1994
5	Basic Requirement 5 of NQA-1-1994 Part I
6	Basic Requirement 6 and Supplement 6S-1 of NQA-1-1994
7	Basic Requirement 7 and Supplement 7S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda of NQA-1-1994
8	Basic Requirement 8 and Supplement 8S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda
9	Basic Requirement 9 and Supplement 9S-1 of NQA-1994 Part I
10	Basic Requirement 10 and Supplement 10S-1 of NQA-1-1994 Part I
11	Basic Requirement 11 and Supplement 11S-1and 11S-2 of NQA-1-1994 Part I.
12	Basic Requirement 12 and Supplement 12S-1 of NQA-1-1994 Part I
13	Basic Requirement 13 and Supplement 13S-1 of NQA-1-1994 Part I
14	Basic Requirement 14 of NQA-1-1994 Part I
15	Basic Requirement 15 and Supplement 15S-1 of NQA-1-1994 Part 1
16	Basic Requirement 16 of NQA-1-1994 Part 1
17	Basic Requirement 17 and Supplement 17S-1 of NQA-1-1994 Part I
18	Basic Requirement 18 and Supplements 18S-1 and 2S-3 of NQA-1-1994 Part I as revised by NQA-1a-1995

Just as the provisions of an NRC Regulatory Guide are guidelines that an applicant or license commits or takes an exception to, the provisions of NQA-1-1994 and the 19995 addenda are guidelines that applicants like LES or licensees commit or take exception to as documented in their QAPDs.

NRC Request: 2a. Describe clearly how the design engineering, construction, safety, and QA functions and organizations report and interface within LES, and how activities are controlled by the QAPD.

Response: The description of how the design engineering, construction, safety, and QA functions and how organizations report and interface with LES provided in the original QAPD have been expanded and clarified. The revised QAPD now delineates the following specific subsections:

- Corporate Organization and Functions
- Design and Construction Organization and Functions
- Operating Organization and Functions
- QA Organization and Functions
- Organizational Interfaces

Descriptions of how activities are controlled by the QAPD and included in each of the above subsections as well as the subsections covering "Delegation of Work," "Resolution of Disputes," and " Worker Responsibilities."

NRC Request: 2b. Explain the LES organization, its external interfaces, including major subcontractors or delegated responsibilities, and to whom the various QA functions report during construction, startup testing and operations, including design control/configuration management, inspection, quality control, procurement, receipt inspection, and document and records control. Since construction, startup testing and operations may be concurrent as the facility is completed in phases, this should include how the controls are applied.

Response: The information provided in the original QAPD explaining the LES organization has been amplified. The revised QAPD now delineates and explains the interfaces between LES and the centrifuge technology provider Urenco Ltd, the architect/engineer and contractors who perform the initial site evaluation, safety and environmental analyses and construction. The revised QAPD contains an expanded discussion of the reporting relationship between the QA functions during the design and construction phases and the startup testing and operations phases. Within this reporting relationship the responsibilities for design control/configuration management, inspection, quality control, procurement, receipt inspection, and document and records control are clearly delineated. The revised QAPD clarifies the QA organization responsibilities for applying specific QA controls.

NRC Request: 2c. Clearly identify the responsibilities, functions, and interfaces of the QA Director and the QA Manager and, on Page A5, the "QA Managers."

Response: The responsibilities and functions of the LES QA Director and the LES QA Manager identified in the original QAPD have been clarified in the revised QAPD as has the interface of these two management positions. Specifically, the LES Corporate QA Director is responsible for the managing the LES QA Program during the design and construction phases, including specific technical support and verification activities. During the transition from construction to operations, an LES plant QA Manager will be added to the LES QA organization, but report to the Plant Manager. The QA Manager has specific responsibilities covering startup testing, operations and ultimately decommissioning. Upon completion of construction, the technical support and verification activities carried out under the LES QA Director will move under the

responsibility of the LES plant QA Manager and the LES QA Director will continue to have governance and oversight responsibilities with respect to the plant QA Manager's organization.

Rather than discuss the contract design and construction organizations' QA Managers separately as in the original QAPD, their responsibilities, functions, and interfaces have been subsumed into the description of the QA organization in the revised QAPD. The revised QAPD delineates the LES corporate QA Directors responsibilities relative to the contract design organizations' QA Managers.

NRC Request: 2d. Explain what is, and who is in charge of, the "QA organization," and clarify the requirements of the various QAPD sections that refer to the QA Director, QA Manager and QA organization.

Response: The description of the QA organization and the roles of the corporate QA Director and plant QA Manager as described in the response to requests 2b and 2c above have been clarified in Section 1 "Organization," Subsection "QA Organization and Function," of the revised QAPD.

NRC Request: 2e. Please clarify how the appropriate authority, access to work areas, and organizational independence of the QA organization and QA management is assured through all facility phases under the proposed LES organization.

Response: The description in the original QAPD of how the appropriate authority, access to work areas, and independence of the QA organization and its management is assured through all facility phases and has been clarified in the revised QAPD, Section 1, Subsection "QA Organization and Functions."

NRC Request: 2f. Identify and explain the functions and responsibilities of the QA organization responsible for review and oversight of the Integrated Safety Analysis process, the structures, systems, and component (SSC) IROFS Quality Levels categorization process and determinations, for establishing the QA controls to provide adequate assurance of IROFS performance, and for verification of the design bases.

Response: The discussion in the original QAPD of the functions and responsibilities of the QA Organization with respect to the review and oversight of the Integrated Safety Analysis (ISA) process, the quality level categorization process and determination of Items Relied On For Safety (IROFS), covering structures, systems and components (SSC) and activities, the establishment of controls to provide adequate assurance of the performance of the IROFS, and the program for verifying and maintaining the facility design bases has been expanded and clarified in the revised QAPD. This discussion is provided in Section 1, Subsection "QA Organization and Functions," and Section 2, "QA Program," Subsection "Identification and Application of QA Controls."

NRC Request: 3a. Clarify the process, criteria and methods for determining QA Levels for all SSCs and for application of QA controls to IROFS.

Response: The process, criteria, and methods for determining QA Levels for all SSC and the application of QA controls to IROFS has been clarified in Sections "Introduction," 1, "Organization," and 2, "QA Program." As described in these sections, the application of QA controls is not "graded." The QA Program described in this QAPD will be applied to QA Level 1 items. IROFS and any items which are determined, by a proceduralized evaluation process that includes review and concurrence by the QA organization, to affect the function of IROFS will be specified as QA Level 1 items. Accordingly, the design, procurement, operation, maintenance, replacement, and corrective actions applied to IROFS and items determined to affect the function of IROFS will be in accordance with the QAPD.

As described in the "Introduction" and Section 2, "QA Program," of the QAPD, the criteria for determining QA Level 2 SSC are those SSC that are not IROFS, provide support of normal operations of the facility and do not affect the functions of the IROFS. The criteria for determining QA Level 3 SSC are those SSC that are not IROFS, affect the function of IROFS, and are not SSC to which QA Level 2 requirements are applied. These criteria and the process and methods of determining the QA Levels of SSC, including the review and concurrence by the QA organization, will be documented in procedures.

NRC Request: 3b. Also, describe the QA controls that assure that QA Level 2 or 3 SSCs do not affect the functions of IROFS.

Response: The description of QA controls that assure that QA Level 2 or 3 SSC do not affect the functions of IROFS is provided in Section 2, "QA Program," of the QAPD. The process for determining the IROFS and the items that affect the functions of the IROFS, including the QA Program elements applied to this process, is the Integrated Safety Analysis (ISA) and is described in SAR Chapter 3, "Integrated Safety Analysis Summary". This process will be proceduralized as will the process for determining the application of QA Levels 2 and 3 to SSC. This procedure will include the steps to be taken to determine whether QA Level 2 or 3 SSC affect the functions of IROFS and this procedure will be reviewed by the QA organization. The QA organization will also perform oversight assessments of the implementation of this procedure as part of its responsibility.

NRC Request: 3c. Please explain how the QAPD elements or Quality Level requirements would be applied to SSCs that serve other regulatory or safety functions, such as radiation monitors and criticality alarms, which may not be categorized as IROFS.

Response: The method by which requirements would be applied to SSC that serve other regulatory or safety functions (i.e., QA Level 2 requirements) would be applied to SSC is described in QAPD Chapter 2, "QA Program," and Chapter 20, "Quality Assurance Program for QA Level 2 Activities." These requirements are implemented by LES and LES contractors through the use of approved QA programs and procedures. Accordingly, the requirements of Chapter 20 would be applied to QA Level 2 SSC.

NRC Request: 3d. Explain how the categorical statement in the QAPD Introduction section that a QA program meeting International Standards Organization

(ISO) 9000 "is acceptable for QA Level 1 applications" is appropriate for activities, suppliers, or services that have not yet been selected or had their QA programs audited or evaluated. These consensus standards may be appropriate for a particular activity or procurement, however, this should be based on an appropriate evaluation of the supplier's programs for the scope and the activity, product, or service. The specific ISO 9000 standard(s) intended should be identified also.

Response: The original QAPD stated in the "Introduction" that "...a QA program that meets the requirements of the International Organization for Standardization ISO 9000 is acceptable for QA Level 2 applications," (emphasis added). This statement has been clarified in the "Introduction," and Section 2, "QA Program," to include the qualification that an ISO 9000 QA program may be acceptable provided it complies with the LES QAPD requirements and the proposed QA program is reviewed and accepted by the LES QA Director. Accordingly, the specific ISO 9000 standard(s) will be identified as part of that review and acceptance process.

NRC Request: 4a. Clarify that the QAPD design control commitments include Basic Requirement 1and Supplement 1S-1of NQA-1.

Response: The specific commitment to Basic Requirement 3, "Design Control," and Supplement 3S-1, "Supplementary Requirements for Design Control," of NQA-1-1994 is stated in the Section 3, "Design Control," of the revised QAPD. The commitment to Basic Requirement 1 and Supplement 1S-1 is reflected in Section 1 "Organization".

NRC Request: 4b. Clarify that the QAPD, Section 3, Design Control, fourth paragraph commitments for computer programs that are design output includes NQA-1, Part II, Subpart 2.7, "QA Requirements for Computer Software For Nuclear Facility Applications." Please also clarify that the QAPD commitments include NQA-1, Part II, Subpart 2.7, for all computer software that is used to produce or manipulate data that is used directly in the design, analysis and operation of SSCs relied on for safety.

Response: Section 3, "Design Control," of the QAPD has been revised to include the specific commitment to NQA-1-1994, Part II, Subpart 2.7, "QA Requirements for Computer Software for Nuclear Facility Applications," as modified by Subpart 2.7 of the NQA-1a-1995 Addenda. Section 3, "Design Control," has also been revised to state explicitly that these commitments apply to computer software that is used to produce or manipulate data that is used directly in the design, analysis, and operation of SSC relied on for safety.

NRC Request: 4c. Confirm that all deficiencies that are discovered, during the design process or subsequent design-related activities that affect the design of SSCs are also included in the controls identified in the QAPD, Section 15, "Nonconforming Materials, Parts, or Components," and Section 16, "Corrective Action," or address the adequacy of exceptions or other specific controls.

Response: Section 3, "Design Control," has been revised to clarify that deficiencies discovered during the design process or subsequent design related activities that affect the design of SSC will be entered into the Corrective

Action Program described in QAPD Section 16, "Corrective Action." Any SSC affected by these design deficiencies will be controlled in accordance with the process for handling nonconforming items as described in QAPD Section 15, "Nonconforming Items."

NRC Request: 4d. No NRC Request 4d) was provided.

NRC Request: 4e. Describe the measures to be provided during the facility operational phase to ensure responsible personnel are made aware of design changes and modifications that may affect the performance of their duties. This description should include appropriate references to the design, configuration management, QA, maintenance, and operations organizational entities.

Response: The description of the measures provided during the facility operational phase to ensure responsible personnel and organizations are made aware of design changes and modifications that may affect the performance of their duties in the original QAPD has been expanded and includes appropriate references to the design, configuration management, QA, maintenance, and operations organizations.

NRC Request: 5a. Delete the statement regarding services or materials which cannot meet the 10 CFR 21 reporting requirements, since this is a regulatory requirement for the entity that dedicates the item or service for nuclear application.

Response: The statement regarding services and materials which cannot meet the 10 CFR 21, "Reporting of Defects and Nonconformances," reporting requirements has been deleted in the revised QAPD.

NRC Request: 5b. Delete reference to the Electric Power Research Institute and Nuclear Construction Issues Group, "Guidelines for Utilization of Commercial Grade Items in Nuclear Safety Related Application."

Response: The reference to the Electric Power Research Institute Nuclear Construction Issues Group document, "Guidelines for Utilization of Commercial Grade Items in Nuclear Safety Related Application," has been deleted in the revised QAPD.

NRC Request: 5c. Identify a commitment to apply the 10 CFR Part 21 requirements for dedication of items or services for 10 CFR 50 applications or describe the LES alternate commitments including controls to provide assurance of the relied upon functions of the IROFS and any basic component for the facility.

Response: A commitment to apply the 10 CFR 21 requirements for dedication of items or services for which 10 CFR 50, Appendix B or 10 CFR 70, "Special Nuclear Material," requirements apply has been restated in the revised QAPD.

NRC Request: 6a. In QAPD Section 4.0, "Procurement Document Control," and Section 7.0, "Control of Purchased Material, Equipment, and Services," as well as Section 1.0, " Organization," clarify the project and QA management responsibilities for preparing and controlling an approved suppliers list, supplier selection, procurement document preparation and approval, bid

evaluation, review of supplier-generated documents, acceptability of items in-work, delivered items and services (activities), resolution of supplier nonconformance and procurement and supplier records.

Response: The responsibilities of the line and QA organizations for preparing and controlling an approved suppliers list, supplier selection, procurement document preparation and approval, bid evaluation, review of supplier-generated documents, acceptability of items in-work, delivered items and services, resolution of supplier nonconformances, and procurement and supplier records have been clarified in Sections 1, "Organization," 4, "Procurement Document Control," and 7, "Control of Purchased Material, Equipment, and Services," of the revised QAPD.

NRC Request: 6b. Also, describe QA, design engineering, and procurement organization interfaces and interactions for controlling these activities, particularly the processes for controlling changes, supplier-generated nonconformance, and for assuring that items under Quality Level 2 and 3 requirements do not affect IROFS.

Response: The description of the QA, design engineering, and procurement organization interfaces and interactions for controlling the activities specified in response to NRC Request 6a) above is clarified in the revised QAPD sections cited in the response to NRC Request 6a). As described in revised QAPD Section 2, "QA Program," the process for identifying IROFS and items that affect the functions of IROFS, including organizational interfaces and interactions, ensures that QA Level 2 and 3 items do not affect IROFS.

NRC Request: 7. QAPD Section 5, "Instructions, Procedures, and Drawings," states that procedures are reviewed by knowledgeable personnel. Please identify the scope and function of the QA organization in this area. Clarify whether the QA organization does review or approve all QA implementing procedures, and procedures affecting IROFS or quality-affecting activities, and identify the basis and process for procedure review.

Response: As described in revised QAPD Sections 1, "Organization," 5, "Instructions, Procedures, and Drawings," and 6, "Document Control," the scope and function of the QA organization in the review and approval of QA procedures and the other administrative and implementing procedures, including the role of QA in the review of procedures affecting IROFS or quality-affecting activities, is clarified. The bases and processes for procedure reviews are also provided in those QAPD sections.

NRC Request: 8a. QAPD Section 6.0, "Document Control," does not address the requirements of NQA-1, supplement 6S-1, nor identify the types of documents controlled, and the LES document control methods and system are not described. Please clarify and address the commitments and requirements for document control, including types of documents controlled, responsibilities, and document review and change controls.

Response: The revised QAPD Section 6, "Document Control," has been expanded to address explicitly the provisions of NQA-1-1994, Basic Requirement 6, "Document Control," and Supplement 6S-1, "Supplementary Requirements for Document Control." The description provided in the

original QAPD of the types of documents controlled has been expanded in the revised QAPD as have the descriptions of the document control methods, system, responsibilities, and document review and change controls.

NRC Request: 8b. Describe the LES document control system or features, such as a master list or equivalent. Clarify whether a master list or equivalent, updated and distributed to predetermined personnel in a timely manner, has been established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents.

Response: The appropriate descriptions in the original QAPD have been restated and expanded in the revised QAPD. This includes a discussion of the master controlled document list and the process for ensuring that document recipients and copyholders are made aware of the current document revision in a timely manner.

NRC Request: 9. Please address commitments to NQA-1, Supplement 9S-1, requirements in Section 2 for process control, Sections 3.1.1 and 3.2.2 for equipment qualification and controls, Section 3.3 for records, and Section 3.4 for special processes not covered by existing codes and standards.

Response: Section 9, "Control of Special Process," of the original QAPD has been expanded in the revised QAPD, and explicitly addresses the provisions of NQA-1-1994, Supplement 9S-1, "Supplementary Requirements for Control of Processes," Sections 2, "Process Control," and 3, "Special Processes," Subsections 3.1-1, 3.1-2, 3.3, "Records," and 3.4, "Special Requirements."

NRC Request: 10a. Clarify that inspection personnel do not report directly to the immediate supervisors, who are responsible for performing the work being inspected, as stated in NQA-1 Supplement 10S-1, Section 3.1.

Response: Section 10, "Inspection," of the original QAPD has been reworded in the revised QAPD to contain the explicit statement regarding the reporting relationship of inspection personnel.

NRC Request: 10b. Specify a commitment that, where sampling is used to verify acceptability of a group of items, the sampling procedure shall be based on recognized standard practices, as stated in NQA-1, Supplement 10S-1, Section 5.2, or provide alternate bases with justification.

Response: A commitment to use sampling procedures based on recognized standard practices where sampling is used to verify acceptability of a group of items is included in the revised QAPD, Section 10.

NRC Request: 11a. QAPD Section 11, "Test Control," does not address requirements for computer program testing, nor does it contain, or commit to, the requirements of Supplement 11S-2. Please identify the LES QAPD commitments and requirements for computer software that is used to produce or manipulate data that is used directly in the determination, categorization, design, analysis, and operation of IROFS.

Response: The discussion of computer program testing contained in Section 3, "Design Control," of the original QAPD has been expanded and included in Sections 3 and 11, "Test Control," of the revised QAPD, along with an explicit commitment to NQA-1-1994, Supplement 11S-2, "Supplementary Requirements for Computer Program Testing." The commitments and requirements for software that is used to produce or manipulate data that is used directly in the determination, categorization, design, analysis, and operation of IROFS are included in Section 3, the subsection entitled, "Computer Software Controls."

NRC Request: 11b. Please clarify the Section 11 requirements for LES engineering and QA personnel for monitoring or oversight of supplier tests, and identify organizational responsibilities and the procedural controls to assure the test adequacy.

Response: Section 11 of the revised QAPD clarifies the requirements for the LES Engineering and Contracts Manager and the QA Director to monitor or provide oversight of supplier tests. The identification of organizational responsibilities and procedural controls to assure the test adequacy in the original QAPD has been expanded in the revised QAPD.

NRC Request: 12a. Please clarify that control of measuring and test equipment is a commitment for design activities, where applicable, and the construction phase.

Response: Section 12, "Control of Measuring and Test Equipment," has been clarified in the revised QAPD to state that measurement and test equipment (M&TE) controls will be used for activities affecting quality, including design activities where applicable, construction, operation, and decommissioning.

NRC Request: 12b. Clarify that the QAPD controls assure verification of the acceptability of items previously inspected or tested when equipment is found to be out of calibration.

Response: The verification of the acceptability of items previously inspected or tested when M&TE is found to be out of calibration has been restated in Section 11 of the revised QAPD.

NRC Request: 13. Please clarify that the QAPD commitments to the NQA 1 requirements including 13S-1, Sections 3.3 and 3.4, for special handling and lifting tools and equipment.

Response: Section 13, "Handling, Storage, and Shipping," of the revised QAPD includes an explicit commitment to NQA-1-1994, Basic Requirement 13, "Handling, Storage, and Shipping," and Supplement 13S-1, "Supplementary Requirements for Handling, Storage, and Shipping," including Sections 3.3, "Tools and Equipment," and 3.4, "Operators."

NRC Request: 14a. State that the requirements of Section 15 apply to activities and services as well as materials, parts, or components, or identify alternative methods or controls.

Response: In the original QAPD, the provisions of NQA-1-1994, Basic Requirement 15, "Control of Nonconforming Items," and Supplement 15S-1,

"Supplementary Requirements for the Control of Nonconforming Items," were applied to materials, parts, or components in Section 15, "Nonconforming Items." Section 16, "Corrective Action," described the application of the Corrective Action Program to nonconformances, which included nonconforming activities and services. Section 15 of the revised QAPD has been changed to state explicitly that the control of nonconforming activities and services is described in Section 16.

NRC Request: 14b. Identify the QAPD commitment, or exceptions, to all of the requirements of NQA-1, Supplement 15S-1, Sections 4.4 and 4.5, for disposition and rework activities.

Response: Section 15 of the revised QAPD includes an explicit statement of commitment to NQA-1-1994, Supplement 15S-1, including Subsections 4.4, "Disposition," and 4.5, "Repaired or Reworked Items."

NRC Request: 14c. Clarify the responsibilities for nonconforming items, including the QA organization responsibilities and involvement, and explain the following Section 15 statements:

1. "LES or its representative had the responsibility for resolutions and approval of the ultimate disposition of nonconforming item reports....."
2. "The QA Director or QA Manager is responsible for assuring that the proper organizations are assigned responsibility for resolution."
3. "All organizational groups within their areas have authority to disposition nonconforming items."

Response: The responsibilities for nonconforming items, including the QA organization responsibilities and involvement have been clarified in Section 15 of the revised QAPD. This clarification covers the responsibilities discussed in the three statements from the original QAPD specified in the NRC request and these statements have been deleted.

NRC Request: 15. NQA-1 Basic Requirement 16, "Corrective Action," states that "Conditions adverse to quality shall be identified promptly and corrected as soon as practical." These NQA-1 commitments are not explicitly addressed in the LES QAPD. Please confirm the QAPD commitment to these requirements or address the basis for other QAPD corrective action commitments.

Response: Section 16, "Corrective Action," of the revised QAPD has been changed to restate explicitly the requirement to promptly identify conditions adverse to quality and correct these adverse conditions as soon as practical.

NRC Request: 16. Please clarify the requirements for retention, receipt, storage, retrieval, and disposition of records, including records administration, a records system, generation of records, record validation, distribution, identification, and classification. This clarification should include the commitments to Supplement 17S-1 and identify any exceptions or alternative approaches to that supplement.

Response: Section 17, "Quality Assurance Records," of the revised QAPD includes an expanded discussion of the QA records management system and its relationship with management measures. Section 17 now includes an explicit statement of commitment to NQA-1-1994, Basic Requirement 17, "Quality Assurance Records," and its Supplement 17S-1, "Supplementary Requirements for Quality Assurance Records," which includes the provisions for retention, receipt, storage, retrieval, and disposition of QA records, including records administration, a records system, generation of records, record validation, distribution, identification, and classification.

NRC Request: 17a. Clarify the basis and criteria for determining the audit scope and frequency in selecting and scheduling internal and supplier audit activities for the various QA, safety and management activities, for suppliers and for construction, testing and operation of IROFS.

Response: The description of the basis and criteria for determining the audit scope and frequency in selecting and scheduling internal and supplier (i.e., external) audit activities has been clarified in Section 18, "Audits," of the revised QAPD.

NRC Request: 17b. Please identify the qualification requirements for auditor and lead auditor training and qualifications.

Response: An explicit commitment to the provisions of NQA-1-1994, Basic Requirement 2, "Quality Assurance Program," Supplement 2S-3, "Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel," is stated in Section 2 of the revised QAPD. Section 18, "Audits," of the revised QAPD references this commitment with respect to auditor and lead auditor training and qualification requirements.

NRC Request: 17c. Identify the QAPD commitments to the requirements of NQA-1, Supplement 18-S1, and identify any exceptions or alternative approaches.

Response Section 18, "Audits," of the revised QAPD includes an explicit commitment to NQA-1-1994, Basic Requirement 18, "Audits," and Supplement 18S-1, "Supplementary Requirements for Audits".

NRC Request: 18. Please clarify QAPD Section 19, "Provisions for Changes," to clearly identify the provisions for continuing QA, including notification of the NRC of changes in the implementation of the QA program from that described in the QAPD. The QAPD should include appropriate provisions for the resubmittal of the QAPD, based on reorganizations, revised activities, lessons learned, changes to applicable regulations, and other QA changes, both prior to approval of a license and after. Clarification is particularly needed for changes in the QAPD commitments that address 10 CFR Part 70.61 through 70.64 requirements, including QA Level requirements, and SSC/IROFS classification.

Response: Section 19, "Provisions for Change," of the revised QAPD clarifies the basis for changes to the QAPD, submittal of the revised QAPD to the

NRC, and the need for prior NRC review and approval when changes to QAPD commitments are proposed.

If you have any questions or need additional information, please contact me at 630-657-2813.

Respectfully,

R. M. Krich
Vice President
Licensing, Safety and Nuclear Engineering

Attachment

cc: T. C. Johnson, NRC Project Manager
Derrith Watchman-Moore, Deputy Secretary, New Mexico Environmental Department

Louisiana Energy Services

Quality Assurance Program Description

Design, Construction, Operations and Decommissioning Phases

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Figure A1 LES Corporate, Design and Construction Organization
Figure A2 LES National Enrichment Facility Operating Organization

INTRODUCTION

Louisiana Energy Services (LES) maintains full responsibility for ensuring that the enrichment facility is designed, constructed, operated, and decommissioned in conformance with applicable regulatory requirements, specified design requirements, applicable industry standards and good engineering practices in a manner to protect the health and safety of the employees and the public. To this end, the LES Quality Assurance Program conforms to the criteria established in Title 10 of the Code of Federal Regulations (10 CFR) 50, Appendix B, "Quality Assurance Criteria For Nuclear Power Plants and Fuel Reprocessing Plants." The criteria in 10 CFR 50, Appendix B, are met by LES's commitment to follow the guidelines of the American Society of Mechanical Engineers (ASME) Quality Assurance (QA) standard NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities," including supplements as revised by the ASME NQA-1a-1995 Addenda.

The LES QA Program described herein covers design, construction (including pre-operational testing), operation (including testing), maintenance and modification, and decommissioning of the facility. This Quality Assurance Program Description (QAPD) describes the requirements to be applied to those structures, systems and components, and activities that have been designated Quality Assurance (QA) Level 1.

QA Level 1 is applied exclusively to items relied on for safety (IROFS) and any items which are determined to affect the function of the IROFS. The development of the IROFS list is a product of the Integrated Safety Analysis (ISA) process. Chapter 3 "Integrated Safety Analysis Summary" of the LES Safety Analysis Report (SAR) provides the methodology utilized to establish the IROFS list. IROFS are comprised of specific structures, systems and components (SSC) and administrative controls. All sections of this QAPD are applied to IROFS and any SSC and administrative controls which are determined to affect the functions of the IROFS. Application of the QAPD requirements is part of the configuration management system and will be performed in accordance with documented procedures. The LES QA organization reviews and concurs with the selection of the IROFS and the application of QA requirements to the IROFS and any items which are determined to affect the functions of the IROFS.

The QA Level 2 program description is provided in Section 20, "Quality Assurance Program for QA Level 2 Activities" of this QAPD. These requirements are implemented by LES and LES contractors through the use of approved QA programs and procedures. The Owner defined QA Level 2 SSCs and their associated activities i.e., those SSCs that are not IROFS, provide support of normal operations of the facility, and do not affect the functions of the IROFS (e.g., occupational exposure, radioactive waste management) and SSCs that minimize public, worker, and environmental risks (e.g., physical interaction protection, certain radiation monitors and criticality alarms) are evaluated against the requirements in Section 20, "Quality Assurance Program for QA Level 2 Activities" of this QAPD. This evaluation identifies which QA controls are needed to ensure these SSC meet their intended functions and do not affect the functions of the IROFS. This evaluation may also include nuclear industry precedent in the application of augmented QA requirements.

Three QA Levels have been established and apply throughout the life of the facility from licensing and siting through design, construction, operation, and decommissioning. The three levels are defined as follows.

QA LEVEL 1 REQUIREMENTS

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

QA LEVEL 2 REQUIREMENTS

The QA Level 2 program is an owner-defined QA program that uses the ASME NQA-1 standard 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 applicable LES QAPD requirements and the QAPD is 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.

As described in Section 19 "Provisions for Change," subsequent changes to the LES QA Program shall be incorporated in this QAPD. Any changes that reduce the commitments in the approved QAPD will be submitted to the NRC for review and approval prior to implementation.

SECTION 1 ORGANIZATION

The elements of the LES QA Program described in this section and associated QA procedures implement the requirements of Criterion 1, "Organization," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 1 and Supplement 1S-1 of NQA-1-1994.

LES employees and contractor employees representing LES have full responsibility to ensure that the facility is designed, constructed, operated, and decommissioned in a manner to protect the health and safety of the public. This responsibility begins with initial design and continues throughout the life of the facility. The LES QA Program is designed to ensure that the necessary quality requirements for structures, systems, components and work activities are met. This objective is attained by ensuring that the organizational structure and the responsibility assignments are such that (a) quality is achieved and maintained by those who have been assigned responsibility for performing work and, (b) quality achievement is verified by persons or organizations not directly responsible for performing the work.

CORPORATE ORGANIZATION AND FUNCTIONS

LES is the owner and operator of the enrichment facility. LES is a registered limited partnership formed to provide uranium enrichment services for commercial nuclear power plants. LES is responsible for the design, construction, operation and decommissioning of the enrichment facility in accordance with its QA Program. The President of LES reports to the LES Management Committee. The committee is composed of representatives from the general partners of LES.

The LES President establishes the basic policies of the QA Program. These policies are described in this QA Program, are transmitted to all levels of management, and are implemented through approved procedures. The LES QA Director has overall responsibility for development, management and implementation of the LES QA Program during all phases of the enrichment facility. As part of this responsibility, the QA Director is responsible for ensuring that contractor QA Programs meet all applicable requirements of the LES QA Program. LES management is continually involved in activities affecting quality and QA requirements.

Reporting to the President are the Engineering and Contracts Manager, Corporate Communications Manager, Chief Financial Officer (CFO), Quality Assurance Director, Chief Operating Officer (COO) and the Health, Safety and Environment Director. Figure A1, "LES Corporate Organization," shows the levels of authority and lines of communications for activities affecting quality.

DESIGN AND CONSTRUCTION ORGANIZATION AND FUNCTIONS

As the owner of the enrichment technology and operator of the enrichment facilities in Europe, LES, under the responsibility of the Engineering and Contracts Manager or President acting in that capacity has contracted Urenco Limited to prepare the reference design for the facility. An architect/engineering (A/E) firm has been contracted and is under the responsibility of the Engineering and Contracts Manager or President to further specify structures and systems of the facility, and ensure the reference design meets all applicable U.S. codes and standards. A consultant specializing in site evaluations has been contracted and is under the responsibility of the Engineering and Contracts Manager or President to perform the site selection evaluation. A nuclear consulting company has been contracted and is under the responsibility of the Engineering and Contracts Manager or President to conduct the site characterization, perform

the Integrated Safety Analysis and to support development of the license application including the Environmental Report.

During the design and construction phases, preparation of design and construction documents and construction itself are contracted to qualified contractors. The Engineering and Contracts Manager is responsible for managing the design, construction, startup, including pre-operational testing and procurement activities during these phases. Contractor QA Programs will be reviewed by the LES QA organization and must be approved by the LES QA Director before work can start as described in Section 4, "Procurement Document Control," and Section 7, "Control of Purchased Material, Equipment and Services". Urenco will design, manufacture and deliver to the site the centrifuges necessary for the facility under a QA Program approved by the LES QA Director or under the LES QA Program. In addition, Urenco is supplying the technical assistance and consultation for the facility in accordance with the applicable requirements of the LES QA Program. As shown in Figure A1, "LES Corporate, Design and Construction Organization," the Engineering and Contracts Manager is responsible for managing the work and contracts with the Technology Supplier (i.e.,Urenco) and a select group of Project Managers. These Project Managers will be responsible for the areas of Procurement, Construction, Engineering, Project Engineering, Project Controls and Start up.

QA Procedures will be developed by the Engineering and Contracts organization to implement this QAPD in the Engineering and Contracts area.

OPERATING ORGANIZATION AND FUNCTIONS

The operating organization is shown in Figure A2, "National Enrichment Facility Operating Organization". The Plant Manager reports to the COO and is responsible for the overall operation and administration of the enrichment facility. The Plant Manager is also responsible for ensuring the facility complies with all applicable regulatory requirements including the requirements of this QAPD. In the discharge of these responsibilities, the Plant Manager directs the activities of the following groups.

- Health, Safety and Environment
- Operations
- Uranium Management
- Technical Services
- Human Resources
- Quality Assurance

Procedures will be developed by the respective operations organizations to implement the requirements of this QAPD. Specific details of organizational responsibilities and job descriptions are provided in the LES Safety Analysis Report.

QA ORGANIZATION AND FUNCTIONS

The LES QA organization during the design and construction phases will be headed by the LES QA Director. The LES QA Director reports directly to the LES President and is vested with the authority, access to work areas, and organizational independence to ensure that the requirements of this QAPD are properly implemented.

The LES QA Director is responsible for managing the LES QA Program that includes the following activities:

- QA Technical Support
  - Maintain the LES QAPD
  - Maintain QA procedures
  - QA technical reviews of procurement documents
  - Review and concurrence of changes to the identified IROFS and items that could affect the functions of IROFS
  - Administer the Corrective Action and Nonconformance Processes
  - Maintain the LES Approved Suppliers List (ASL)
  - Administer the Auditor and Lead Auditor Certification Process
  - QA reviews of project documents
  - Approval of contractor QA Programs
  - Oversight of contractor QA Programs Implementation
  - Oversight of the quality of design and construction, including but not limited to the ISA process and the resultant selection of IROFS.
  - Oversight of document and records control
- QA Verification
  - Audits, surveillances and assessments
  - Contractor/supplier evaluations
  - Contractor nonconformances
  - Equipment/ Vendor Shop Inspections
  - Witness vendor acceptance testing

During the transition from construction to operations, when startup testing and plant operations may be concurrent as the facility is completed in phases, a plant QA Manager will be added to the LES QA Organization. During this transition period as well as during operations, the plant QA Manager will report to the Plant Manager. However, the plant QA Manager has the authority and responsibility to contact the LES President, through the QA Director, with any QA concerns during startup and plant operations. After construction has been completed on the facility the corporate functions reporting the LES QA Director, i.e., QA Technical Support and QA Verification; will transition to the plant QA Manager. During the operations and decommissioning phases, the LES QA Director will advise the LES President on quality-related matters and continue to have governance and oversight responsibilities with respect to the QA organization headed by the plant QA Manager. The following additional QA Manager responsibilities are included for start up testing and operations:

- QA Technical Support
  - Quality Engineering support of startup organization
  - Oversight of startup activities
  - QA selected reviews and oversight of programs developed for operations, including but not limited to the ISA process, the identification of IROFS and items that affect the performance of IROFS and any changes thereto, the controls for assuring IROFS performance and verifying and maintaining the facility design basis.
  - QA selected reviews and oversight of operations including maintenance and testing and modification procedures
  - Review and concurrence of changes to the identified IROFS and items that could affect the functions of IROFS
  - QA Oversight of operations procedure implementation
  - Quality Control (QC) Inspection certification process
- QC Inspections
  - Receipt Inspections of QA Level 1 items
  - Applicable discipline inspections of modifications to QA Level 1 components

Accordingly, during the transition from construction to operations, the operations phase, and the decommissioning phase, the management of the QA organization and the QA staff have the responsibility to make quality assurance decisions and have sufficient authority, access to work areas, and organizational freedom to:

- Identify quality problems
- Initiate and recommend solutions to quality problems through designated channels
- Verify implementation of solutions
- Assure that further processing, delivery, installation, or use of items is controlled until proper disposition of nonconformances, deficiencies or unsatisfactory conditions has occurred
- Have direct access to highest levels of management
- Be sufficiently independent from cost and schedule considerations and have stop-work authority.

ORGANIZATIONAL INTERFACES

The organizational interfaces between LES, contractors, and project applicable regulatory agencies are identified in the appropriate plans, contracts and implementing procedures. These documents contain the appropriate protocols, applicable roles, responsibilities and approval authorities for the specific topics for which they apply. LES design interfaces shall be identified and procedurally controlled. Design efforts shall be coordinated among interfacing organizations as detailed in LES procedures. Interface controls shall include the assignment of responsibility and the establishment of implementing documents among interfacing design organizations for the review, approval, release, distribution and revision of documents involving design interfaces. LES design information transmitted across interfaces shall be documented and procedurally controlled. LES transmittals of design information and/or documents shall reflect the status of the transmitted information and documents. Incomplete designs that require further evaluation, review or approval shall be identified. When it is necessary to initially

transmit the design information orally or by other informal means, design information shall be promptly confirmed through a controlled implementing document.

DELEGATION OF WORK

The delegation of work between LES and contractors is identified in applicable plans, contracts and implementing procedures. In all cases of delegation, LES retains the overall responsibility for all work performed under the direction of LES. All LES QA Level 1 work activities shall meet the requirements of this QAPD. Responsible managers have the authority to delegate tasks to another qualified individual within their organization provided the designated individual possesses the required qualifications and these qualifications are documented. All delegations shall be in writing. The responsible manager retains the ultimate responsibility and accountability for implementing the applicable requirements.

RESOLUTION OF DISPUTES

Disputes involving differences of opinion on quality matters or issues are brought to the attention of line management, and if not resolved by the individual's manager, are elevated progressively to the QA Director. If satisfactory resolution cannot be obtained at that level, the matter is then elevated to the LES President for final resolution.

WORKER RESPONSIBILITIES

Each employee has an obligation to identify concerns using the corrective action process with respect to work within their scope of responsibility whenever the health and safety of our workers, the public, or the environment is involved or when continued work will produce results that are not in compliance with the LES QA Program. This process is controlled by an LES procedure, which applies across the entire project/facility. The authorities and responsibilities for stopping work, the criteria and documentation required to process the stop work and the actions required before work may resume are detailed in an LES procedure. This process ensures that safety related activities are controlled until the deficiency, or unsatisfactory condition, has been resolved. Worker responsibilities are further discussed in Section 16, "Corrective Action."

SECTION 2 QA PROGRAM

The elements of the LES QA Program described in this section and associated QA procedures implement the requirements of Criterion 2, "Quality Assurance Program," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3 and 2S-4 of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda of NQA-1-1994.

PROGRAM BASIS

The LES Quality Assurance Program complies with 10CFR50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," and applies to all levels of the organization, including contractors, who perform QA Level 1 activities. Part I and selected sections of Part II of ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," as revised by NQA-1a-1995 Addenda are used in conjunction with 10 CFR 50, Appendix B and provide additional detailed quality assurance guidelines which are committed to in this QAPD. The LES QAPD describes LES's overall compliance with 10CFR50, Appendix B and commitments to ASME NQA-1. This document states LES policies, assigns responsibilities and specifies requirements governing implementation of the QA Program to the design, construction, operation and decommissioning of the LES enrichment facility. All 18 criteria of 10 CFR 50, Appendix B have been addressed to identify the scope of QA Program applied to the LES enrichment facility. QA requirements will also apply to contractors as delineated in procurement documents controlled under Section 4, "Procurement Document Control," of this QAPD. The necessary management measures to control the quality of subcontracted activities for the LES design, procurement, and installation and testing of QA Level 1 components and activities have been established in this QAPD. The QAPD will be reviewed for needed revisions as described in Section 19, "Provisions For Change."

Specific processes and controls, which implement the provisions of 10 CFR 50, Appendix B and the commitment to ASME NQA-1-1994, as specified in this QAPD are delineated in procedures. Development, review, approval and training on procedures shall be performed prior to performance of the activities controlled by the procedures.

The QA Program provides for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The LES QA Program provides for special controls, processes, test equipment, tools and skills to attain the required quality and verification of quality. QA requirements contained in this QAPD are also invoked on LES contractors for their contracted scope of work.

When work cannot be accomplished as specified in implementing QA procedures, or accomplishment of such work would result in an adverse condition, work is stopped until proper corrective action is taken. If procedures cannot be used as written, then work is stopped until the procedures are changed. Requirements for stop work are further discussed in Section 16, "Corrective Action."

Flowdown of QA Requirements to Contractors and Suppliers

QA requirements for QA Level 1 activities are imposed on LES contractors and suppliers

through the respective procurement documents for the particular scope of work being contracted. Determination of the specific QA requirements, supplier evaluations, and proposal/bid evaluations are in accordance with the requirements of Section 4, "Procurement Document Control," and Section 7, "Control of Purchased Material, Equipment and Services," of this document. Applicable QA Program elements required for the particular scope of work are identified in procurement documents. Potential contractors/suppliers are required to submit their QA Programs to the LES QA organization for review in accordance with the request for proposal/procurement specification. The LES QA organization performs an audit at the contractor's/supplier's facility of their QA program and its implementation verifying that the contractor's/supplier's QA program meets the requirements established in the request for proposal/procurement specification. If the audit is acceptable then the contractor/supplier is added to the LES ASL and a contract between LES and the contractor/supplier may be issued. For procured items, LES may also require that the LES QA organization perform source inspections or witness tests at the supplier's facility prior to shipment if the equipment/component warrants inspection due to its safety significance and/or complexity. Such requirements are also identified in the procurement documents and/or contract.

Construction contractors for LES QA Program controlled construction activities are required to be placed on the ASL prior to contract award. Construction contractors are required to perform the QA activities required by their QA program including audits of their own activities as well as any required quality control (QC) inspections. The LES QA organization will provide oversight of these contractors in the form of audits and surveillances verifying that each contractor is properly implementing its QA program as approved by LES QA. Contractually contractors will be required to promptly correct LES identified deficiencies and noncomformances.

IDENTIFICATION AND APPLICATION OF QA CONTROLS

QA Level 1 is applied exclusively to IROFS and any items which are determined to affect the function of the IROFS. Since the development of the IROFS list is a product of the ISA process, the applicable QA Level 1 requirements are also applied to this process. Chapter 3 "Integrated Safety Analysis Summary" of the LES Safety Analysis Report (SAR) provides the methodology utilized to establish the IROFS list. IROFS are comprised of specific structures, systems and components (SSC) and administrative controls. All applicable sections of this QAPD are applied to IROFS and any SSC and administrative controls which are determined to affect the functions of the IROFS. Application of the QAPD requirements is part of the configuration management program used to verify and maintain the facility design bases and will be performed in accordance with documented procedures. Accordingly, as described in Section 1 "Organization," the QA organization is responsible for selected reviews and oversight of these processes and programs. In particular, the LES QA organization reviews and concurs with the selection of the IROFS and the application of QA requirements to the IROFS and any items which are determined to affect the functions of the IROFS.

The QA Level 2 program description is provided in Section 20, "Quality Assurance Program for QA Level 2 Activities" of this QAPD. These requirements are implemented by LES and LES contractors through the use of approved QA programs and procedures. The Owner defined QA Level 2 SSCs and their associated activities i.e., those SSCs that are not IROFS, provide support of normal operations of the facility, and do not affect the functions of the IROFS (e.g., occupational exposure, radioactive waste management) and SSCs that minimize public, worker, and environmental risks (e.g., physical interaction protection, certain radiation monitors and criticality alarms) are evaluated against the requirements in section 20 of this QAPD. This

evaluation identifies which QA controls are needed to ensure these SSCs meet their intended functions and do not affect the functions of the IROFS. This evaluation may also include nuclear industry precedent in the application of augmented QA requirements.

Three QA Levels have been established and apply throughout the life of the facility from licensing and siting through design, construction, testing, startup, operation, maintenance, modification, and decommissioning. The three levels are defined as follows.

QA LEVEL 1 REQUIREMENTS

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

QA LEVEL 2 REQUIREMENTS

The QA Level 2 program is an owner-defined QA program that uses the ASME NQA-1 standard 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 QAPD requirements and the QAPD is 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.

QUALITY ASSURANCE TRAINING

LES employees who perform QA Level 1 activities receive LES QA Indoctrination Training. This training includes general criteria, including introduction to applicable codes, standards, QA Procedures, QA Program elements and job responsibilities and authorities. LES personnel assigned to perform QA Level 1 activities are also required to complete training in the specific LES QA procedures needed to perform their job roles and responsibilities as assigned by their supervisor. Detailed QA training is provided on the LES QA Program and job specific QA procedures prior to an employee beginning QA Level 1 work. Supervision is responsible for ensuring that personnel performing work under their supervision are appropriately trained.

The Human Resources Manager is responsible for coordinating QA training activities for LES.Human Resources serves as a centralized training support service for supervision in coordinating training and maintaining QA training records. This responsibility is carried out as support for line management. LES supervisory personnel are responsible for determining the type and extent of the training to be provided to an individual, and ensuring that the training is properly documented for personnel performing QA Level 1 activities. Retraining, when applicable, shall occur in order to maintain proficiency or when changes to work methods, technology, or job responsibilities occur. Such retraining is also documented.

MANAGEMENT ASSESSMENTS

The LES President is responsibility for ensuring that management assessments are conducted annually to determine if the LES QA Program is effective. Recommendations are provided to the LES President for action. Functional Managers and the QA Director conduct assessments annually of QA activities under their control. The managers report the results to the LES President for review. The results of these assessments are reviewed by senior management to determine the adequacy of implementation of the LES QA Program and to direct any needed changes for program improvements.

QUALIFICATION/CERTIFICATION OF INSPECTION AND TEST PERSONNEL

Inspection and test personnel performing QA Level 1 activities shall be certified in accordance with NQA-1-1994 Part I Supplement 2S-1, *Supplementary Requirements for the Qualification of Inspection and Test Personnel.*

QUALIFICATION/CERTIFICATION OF NONDESTRUCTIVE EXAMINATION (NDE) PERSONNEL

Nondestructive Examination (NDE) personnel performing QA Level 1 activities shall be certified in accordance with NQA-1a-1995 Part 1 Supplement 2S-2, *Supplementary Requirements for the Qualification of Nondestructive Examination Personnel and American Society of Nondestructive Testing (ASNT) Recommended Practice No. SNT-TC-1A, Personnel Qualification and Certification in Nondestructive Testing*, December 1988 Edition. Qualification/certification records meeting the requirements of Supplement 2S-2 shall be established and maintained as QA records.

QUALITY ASSURANCE AUDIT PERSONNEL

Audit personnel performing QA Level 1 activities shall be certified in accordance with NQA-1a-1995 Part 1 Supplement 2S-3 *Supplemental Requirements for the Qualification of Quality Assurance Program Audit Personnel.*

QUALITY ASSURANCE PROGRAM STATUS REPORTING TO MANAGEMENT

Management is regularly informed by the LES QA organization of adverse trends and lessons learned as a result of reviews conducted on audit reports, surveillance reports, corrective action reports, management assessments, etc. Corrective action is initiated as necessary.

SECTION 3 DESIGN CONTROL

The elements of the LES Program described in this section and associated procedures implement the requirements of Criterion 3, "Design Control," of 10 CFR 50, Appendix B, and the commitment to Basic Requirements 3 and Supplement 3S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda of NQA-1-1994. The LES QA Program also implements the commitment to Part II of NQA-1-1994 Subpart Part 2.7, *Quality Assurance Requirements of Computer Software for Nuclear Facility Applications,* as revised by NQA-1a-1995 Addenda of NQA-1-1994. These commitments also apply to computer software that is used to produce or manipulate data that is used directly in the design, analysis and operation of structures, systems and components relied on for safety. Part I, Supplement 11S-2, *Supplementary Requirements for Computer Program Testing,* requirements for computer software qualification and use are also implemented by the LES QA Program.

Measures are established in procedures to assure that applicable requirements are correctly translated into design documents. Design inputs are specified on a timely basis to support LES milestones. Controls are established for the selection and suitability of application of materials, parts, equipment and processes that are essential to the functions of structures, systems and components. Design interfaces to ensure completeness and efficiency of design are established in applicable procedures. Procedures detail the controls for design input, design process, design verification, design changes and approval. These procedures include appropriate quantitative and/or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished. LES design documents are prepared, reviewed, and approved by qualified individuals. Design is verified by one or more of the following verification methods: design reviews, alternate calculations or qualification tests. Design changes are governed by control measures commensurate with those applied to the original design. The design process and design verification practices and procedures shall be reviewed and modified, as necessary, when a significant design change is required because of an incorrect design. These and any other design deficiencies discovered during the design process on subsequent design related activities that affect the design of SSC shall be entered into the Corrective Action Program (CAP) according to Section 16, "Corrective Action". If these deficiencies cause constructed or partially constructed items (systems, structures or components) to be deficient, the affected items shall be controlled in accordance with Section 15, "Nonconforming Items." Configuration management is maintained in accordance with the applicable procedure and the applicable procedures controlling changes to the various types of design documents.

DESIGN INPUT CONTROL

Applicable design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes and standards) shall be controlled by the LES Engineering and Contracts Manager according to the following requirements:

- Design inputs shall be identified and documented, and their selection reviewed and approved.
- Design inputs shall be specified and approved in a manner to support the schedule. Design inputs shall provide the necessary details to permit design to be carried out in a manner that provides a consistent basis for making design decisions, accomplishing design verification and evaluating design changes.

- Changes from approved design inputs and reasons for the changes shall be identified, approved, documented and controlled.
- Design inputs based on assumptions that require re-verification shall be identified and controlled by the appropriate procedures.

DESIGN PROCESS

The LES design process shall be controlled by the Engineering and Contracts Manager according to the following requirements:

- LES design work shall be prescribed and documented on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner and to permit verification that the design meets requirements.
- Design documents shall be adequate to support design, construction and operation.
- Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.
- Changes from specified standards, including the reasons for the change, shall be identified, approved, documented and controlled.
- Design methods, materials, parts, equipment and processes that are essential to the function of the structure, system, or component shall be selected and reviewed for and suitability of application.
- Applicable information derived from experience as set forth in reports or other documentation, shall be made available to cognizant design personnel.
- Final design documents (i.e., approved design output documents and approved changes thereto) shall be sufficiently detailed as to purpose, method, assumptions, design input, references and units such that a person technically qualified in the subject/engineering discipline can understand the documents and verify their adequacy without recourse to the originator of the design document.
- Procedural controls for identifying sub-assemblies or components on final design documents that are part of the item being designed shall be established. When a commercial grade item is modified and/or tested to new requirements that are more restrictive than the supplier's published product description, the component part shall be traceable to documentation noting that it is different from the originally approved commercial grade item.
- LES design drawings, specifications or other design output documents shall contain appropriate inspection, examination and testing acceptance criteria.

<u>DESIGN ANALYSIS</u>

LES design analyses shall be planned, controlled and documented. Design analysis documents shall be legible, in a form suitable for reproduction, filing and retrieval, and under configuration management control. LES design calculations shall be identifiable by subject (including structure, system or component to which the calculation applies), originator, reviewer and date, or by other designators in order that approved calculations are retrievable.

Computer software used to perform design analyses shall be developed and/or qualified, and used according to the provisions of ASME NQA-1-1994, Part II, Subpart 2.7 as revised by NQA-1a-1995 Addenda and Supplement 11S-2. Computer software developed and/or qualified under the LES or its contractor QA programs may also be used to perform design analyses for

LES, provided that the LES QA organization confirms these contractor QA programs meet the provisions NQA-1-1994, Part I, Supplement 11S-2 and NQA-1-1994 Part II, Subpart 2.7 as revised by NQA-1a-1995 addenda.

Computer programs may be utilized for design analysis without individual verification of the program for each application provided:

- The computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and
- The encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.

Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on the above.

LES design analyses documentation shall include:

- Definition of the objective of the analyses,
- Definition of design inputs and their sources,
- Results of literature searches or other applicable background data,
- Identification of assumptions and designation of those that must be verified as the design proceeds,
- Identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of reference to computer program verification and the bases (or reference thereto) supporting application of the computer program to the specific physical problem,
- Review and approval.

DESIGN VERIFICATION

The following design control requirements shall be applied to verify the adequacy of LES design:

- LES design verification is required for design documents, and shall be performed using one or a combination of the design review, alternate calculations and/or qualification testing methods.
- The particular design verification method used shall be documented.
- Results of design verification shall be documented and shall include the identification of the verifier(s).
- Competent individuals or groups, other than those, who performed the original design (but may be from the same organization), shall perform design verification. If necessary, this verification may be performed by the originator's supervisor provided that the engineering supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or the supervisor is the only individual in the organization competent to perform the verification.

LES design verification shall be performed in a timely manner at appropriate times during the design process. Verification shall be performed before release for procurement, manufacture or

construction, or release to another organization for use in other design work. In some cases (such as when insufficient data exists) it may be necessary to release unverified designs to other engineering organizations or disciplines to support schedule requirements. Unverified portions of the design shall be clearly identified and procedurally controlled. In all cases, design verification shall be completed before relying on the item or computer program to perform its function. The extent of design verification required shall be a function of the importance to safety, complexity of design, degree of standardization, state of the art and similarity with previously proven designs.

LES use of previously standardized designs shall be controlled according to the following requirements:

- The applicability of standardized or previously proven designs shall be verified with respect to meeting pertinent design inputs for each application.
- Known problems affecting standard or previously proven designs and their effects on other features shall be considered.
- The "Americanization" of previously proven European designs shall be documented in accordance with the applicable QA procedure.
- The original design and associated verification measures shall be adequately documented and referenced in the files for subsequent application of the design.
- Changes in previously verified designs shall require re-verification. Such verifications shall include the evaluation of the effects of those changes on the overall previously verified design and on any design analyses upon which the design is based.

DESIGN VERIFICATION METHODS

Acceptable verification methods include, but are not limited to, any one of the following or a combination of the following:

- Design Reviews
- Alternate Calculations
- Qualification Testing

DESIGN REVIEWS

Design reviews are critical reviews to provide assurance that the final design is correct and satisfactory. The following items shall be addressed, as applicable during the review:

- Were the design inputs correctly selected and incorporated into the design?
- Are assumptions necessary to perform the design activity adequately described, reasonable and, where necessary, re-verified?
- Was an appropriate design method used?
- Is the design output is reasonable compared to the applicable design inputs?
- Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures and instructions?

ALTERNATE CALCULATIONS

The appropriateness of assumptions, input data, and the computer program or other calculation methods used, shall be evaluated and the results shall be checked through the use of alternate

calculation methods to verify the correctness of the original calculations or analyses.

QUALIFICATION TESTS

If design adequacy is to be verified by qualification testing, the tests shall be identified, procedurally controlled and documented according to the following:

- The test configuration shall be defined and documented.
- Testing shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse design conditions.
- If the tests verify only specific design features, then the other features of the design shall be verified by other means.
- Test results shall be documented and evaluated to ensure that test requirements have been met.
- If qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, then the modification shall be documented and the item modified and re-tested or otherwise verified to ensure satisfactory performance.
- Scaling laws shall be established, verified and documented when tests are being performed on models or mockups.
- The results of model test work shall be subject to error analysis, where applicable, before using the results in final design work.

DESIGN CHANGE CONTROL

Design changes during the initial design phase and the operational phase shall be controlled according to the following requirements:

- Changes to final designs, field changes, modifications to the operating facility and nonconforming items dispositioned as "use-as-is" or "repair," as described in Section 15, "Nonconforming Items," and shall have documented justification for use and are subject to the same design control measures and reviews as those applied to the original design.
- Design control measures for changes shall include provisions to ensure that the design analyses for the item are still valid.
- Changes shall be reviewed and approved by the affected groups or organizations that reviewed and approved the original design documents, with the following clarifications:
    - o If the organization that originally was responsible for approving a particular design document is no longer responsible, then a new responsible organization shall be designated.
    - o The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.
- The interface between the design organization responsible for finalizing a design change and other organizations either involved in the review of the change, such as the QA and configuration management organizations, and those affected by the change, such as the operations and maintenance organizations, described in the next subsection, "Design

Interface Control," shall be maintained.

- The design process and design verification practices and procedures shall be reviewed and modified, as necessary, when a significant design change is required because of an incorrect design. These design deficiencies shall be documented according to Section 16.0, "Corrective Actions". If these deficiencies cause constructed or partially constructed items (systems, structures or components) to be deficient, the affected items shall be controlled in accordance with Section 15, "Nonconforming Items".
- When a design change is approved other than revision to the affected design documents, field changes shall be incorporated into affected design documents when such incorporation is appropriate.

DESIGN INTERFACE CONTROL

LES design interfaces shall be identified and procedurally controlled. Design efforts shall be coordinated among interfacing organizations as detailed in LES procedures. Interface controls shall include the assignment of responsibility and the establishment of procedures among interfacing design organizations for the review, approval, release, distribution and revision of documents involving design interfaces. LES design information transmitted across interfaces shall be documented and procedurally controlled. LES transmittals of design information and/or documents shall reflect the status of the transmitted information and documents. Incomplete designs that require further evaluation, review or approval shall be identified. When it is necessary to initially transmit the design information orally or by other informal means, design information shall be promptly confirmed through a controlled document.

During the operational phase, the Plant Manager is responsible for ensuring the facility complies with all applicable regulatory requirements including the requirements of this QA Program. In the discharge of these responsibilities, the Plant Manager directs the activities of the Technical Services, which includes Engineering and Maintenance, and Operations. Procedures for controlling the interfaces and configuration management ensure that changes and modifications are properly managed and disseminated to those responsible personnel or organizations whose duties may be affected by the design change or modification and do not adversely impact the safe operation of the plant.

COMPUTER SOFTWARE CONTROLS

If LES uses software to produce or manipulate data that is used directly in the design, analysis and operation of structures, systems, and components relied on for safety, the provisions provided in Part II ASME NQA-1-1994 Subpart Part 2.7, *Quality Assurance Requirements of Computer Software for Nuclear Facility Applications,* as revised by NQA-1a-1995 Addenda of NQA-1-1994 and ASME NQA-1-1994, Part I, Supplement 11S-2, *Supplementary Requirements for Computer Program Testing* shall apply. Procedures will be developed to implement of these provisions as applicable.

DOCUMENTATION AND RECORDS

Design documentation which provide evidence that the design and design verification were performed in accordance with this QAPD shall be collected and maintained in accordance with the requirements of Section 17 "Quality Assurance Records". The documentation shall include not only final design documents such as drawings, specifications and revision thereto but also documentation which identifies the important steps, including sources of design inputs that support the final design.

SECTION 4 PROCUREMENT DOCUMENT CONTROL

The elements of the LES QA Program described in this section and associated procedures implement the requirements of Criterion 4, "Procurement Document Control," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 4 and Supplement 4S-1 of NQA-1-1994.

LES procurements shall be issued only to those suppliers that have been evaluated and qualified as acceptable for the particular scope of material, equipment and services to be procured. The material, equipment and services shall be procured from approved suppliers by procurement documents, approved by the LES President and QA Director or their qualified designees. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. Procurement documents shall require suppliers to have a quality assurance program consistent with the applicable requirements of 10 CFR 50 Appendix B and this QAPD. The requirements of 10 CFR 21 "Reporting of Defects and Nonconformance" are invoked during design, construction, testing and operations of QA Level 1 procurement or dedication of items and services including the dedication of items or services used to satisfy the requirements of 10 CFR 50, Appendix B or 10 CFR 70 "Domestic Licensing of Special Nuclear Material".

Procurement Document Content

LES procurement documents issued for QA Level 1 items or services shall include the following provisions, as applicable to the procured material, equipment or service:

- Statement of the scope of work to be performed by the supplier.
- Technical requirements including:
  - o Design bases, identified or referenced in the procurement documents.
  - o Specific documents (such as drawings, codes, standards, regulations, procedures or instructions) describing the technical requirements of the material, equipment or services to be furnished, shall be specified along with their revision level or change status.
  - o Tests, inspections or acceptance requirements that LES will use to monitor and evaluate the performance of the supplier shall be specified.
- Quality Assurance Program requirements including:
  - o A requirement for the supplier to have a documented quality assurance program that implements applicable requirements of 10 CFR 50, Appendix B and this QAPD in place before the initiation of work. The extent of the quality assurance program shall depend on the scope, nature or complexity of the material, equipment or service to be procured. The supplier shall also incorporate the appropriate requirements into any subtier supplier issued procurement documents.
  - o A requirement invoking NRC reporting requirements of 10 CFR 21 for QA Level 1 procurements.
- Right of access to supplier, including subtier, facilities and records for inspection or audit by LES, or other designee authorized by LES.
- Provisions for establishing witness/inspection hold points beyond which work cannot proceed by the supplier without LES QA Director authorization. The LES Engineering and

Contracts Manager may also establish hold points indicating work that cannot proceed without authorization by the Engineering and Contracts Manager.

- Documentation required to be submitted to LES for information, review or acceptance shall be identified along with a document submittal schedule. Record retention times, disposition requirements and record maintenance responsibilities shall be identified for documentation that will become quality assurance records.
- Requirements for the supplier to report to LES in writing adverse quality conditions resulting in work stoppages and nonconformances. LES approval of partial and full work releases and disposition of nonconformances is required.
- Identification of any spare and replacement parts or assemblies and the appropriate delineation of technical and quality assurance data required for ordering these parts or assemblies. Commercial Grade procurements shall also be identified in procurement documents.

Procurement Document Review and Approval

Procurement document reviews shall be performed and documented before issuing the procurement documents to the supplier. A review of the procurement documents and any changes thereto shall be made to verify that documents include all applicable requirements specified under "*Procurement Document Content*" above and contain appropriate provisions to ensure that material, equipment or services will meet the governing requirements. Reviews shall be performed and documented to provide objective evidence of satisfactory accomplishment of such review prior to contract award. Changes made as a result of the bid evaluation or precontract negotiations shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed prior to contract award. This review shall include the following considerations: 1) appropriate requirements specified in "Procurement Document Content" above, 2) a determination of any additional or modified design criteria, and 3) an analysis of exceptions or changes requested by the supplier and a determination on the impacts such changes may have on the intent of the procurement documents or quality of the item or service to be provided shall be performed by the LES organization initiating the procurement. Personnel who have access to pertinent information and have an adequate understanding of the requirements and scope of the procurement shall perform reviews of the procurement documents. Reviewers shall include representatives from the Engineering and Contracts and QA organizations. The QA review shall assure compliance to quality assurance requirements.

Procurement Document Change

Changes to the scope of work, technical requirements, quality assurance program requirements, right of access, documentation requirements, work stoppage and nonconformance, hold points and lists of spare and replacement parts delineated in procurement documents, shall be subject to the same degree of control as used in the preparation of the original procurement document.

SECTION 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

The elements of the LES QA Program described in this section and associated procedures implement the requirements of Criterion 5, "Instructions, Procedures, and Drawings," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 5 of NQA-1-1994 Part I.

Activities affecting quality shall be prescribed by and conducted in accordance with approved procedures and other implementing documents (drawings, specifications, etc.) appropriate to the circumstances. Generally, four types of procedures are used by LES to ensure that activities are carried out in compliance with the requirements of this QAPD and in a safe manner. These include administrative, operating, maintenance and emergency procedures. Administrative procedures would include areas such as engineering procurement, etc. Administrative procedures are the higher level procedures that prescribe the implementation of the requirements provided in this QAPD. Operating and maintenance procedures are utilized to implement the QA program during the start up, operation, and testing of the facility. During the design and construction phases, procedures are reviewed and approved by the affected organizations with review and oversight by the QA organization. Those procedures that delineate the responsibilities and functions of the QA organization, the QA procedures, are approved by the LES QA Director to ensure compliance with QAPD. During operations, the LES Plant QA Manager and Plant Manager have responsibility to review and approve the procedures that cover activities under their organizational purview that relate to the QAPD and the safe operation of the plant. Procedures approved by the Plant Manager will be subject to selected review and oversight by the QA organization.

TYPES OF DOCUMENTS

The type of document to be used to perform work shall be appropriate to the nature and circumstances of the work being performed. Documents include procedures, drawings and specifications. Work controlling procedures may also utilize approved checklists, travelers or other means to assure process requirements are met including prerequisite requirements prior to starting work. Procedures provide a consistent method for process performance and documentation of completion as well as ensure specified safety and environmental conditions are maintained.

CONTENT OF DOCUMENTS

Documents shall include or reference the following information as appropriate to the work to be performed:

- Responsibilities of the organizations affected by the document,
- Quality, technical and regulatory requirements,
- A sequential description of the work to be performed including controls for altering the sequence of required inspections, tests and other operations,
- Quantitative or qualitative acceptance criteria sufficient for determining that prescribed activities have been satisfactorily accomplished,
- Prerequisites, limits, precautions, process parameters and environmental conditions,
- Quality verification points and hold points,
- Methods for demonstrating that the work was performed as required,

- Identification of the lifetime or nonpermanent quality assurance records generated by the implementing document, and
- Identification of associated QA Levels as appropriate.

REVIEW, APPROVAL, AND CONTROL OF DOCUMENTS

Procedures and implementing documents shall be controlled according to the requirements of Section 6, "Document Control" of this document. Procedures and implementing documents shall be reviewed and approved as described in this section and in Section 6.

SECTION 6 DOCUMENT CONTROL

The elements of the LES QA Program described in this section and associated procedures implement the requirements of Criterion 6, "Document Control," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 6 and Supplement 6S-1 of NQA-1-1994.

Procedures are established which control the preparation, issuance and changes of documents that specify quality requirements or prescribe activities affecting quality. Measures are established to ensure that documents, including revisions are adequately reviewed, approved, and released for use by authorized personnel. Controlled documents are transmitted to the appropriate locations where the prescribed activity is being performed. Superceded documents are destroyed or retained only when they have been properly marked.

TYPES OF DOCUMENTS

QA procedures, other administrative procedures and implementing documents and documents specifying quality requirements or prescribing activities affecting quality shall be controlled in accordance with this section. LES documents controlled under the LES QA Program will be specified by procedures and include, but are not limited to, procedures, design requirements document, design basis documents, engineering specifications, instructions, drawings, calculations, procurement documents, and documents that need to be controlled due to being input to other LES design documents or used for construction and operations affecting quality.

PREPARING AND REVIEWING DOCUMENTS

The document control system shall ensure that the identification of documents to be controlled and their specified distribution are preceduralized. The system shall further ensure that the responsibility for preparing, reviewing, approving and issuing documents shall be assigned by procedure to the appropriate LES functional area manager. Implementing documents and documents specifying quality requirements or prescribing activities affecting quality, shall be reviewed in accordance with applicable procedures for adequacy, correctness and completeness and by the QA organization as specified by procedure, prior to approval and issuance. The organizational position(s) responsible for approving the document(s) for release shall be identified in the applicable procedures.

CONTROLLING THE DISTRIBUTION AND USE OF DOCUMENTS

Documents needing to be placed under the document control system are transmitted to the Document Control organization with the distribution list for document holders. The Document Control organization shall enter the document into the Document Control electronic database and master list of controlled documents, assign document control numbers, complete transmittal forms and distribute the documents and transmittal form to the document holders. Document holders shall acknowledge receipt on the transmittal and send the acknowledgement to the Document Control organization. The up-to-date master listing of controlled documents will be made continuously available to document holders to verify that they have the current revisions. The document control process will be audited in accordance with the requirements of Section 18, "QA Audits," to verify implementation effectiveness.

CHANGES TO DOCUMENTS

Changes to documents other than minor changes shall be reviewed for adequacy, correctness and completeness, prior to approval and issuance. Major changes shall be reviewed and

approved by the same organization that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to the applicable background data or information upon which to base their approval. A temporary procedure change that does not change the intent of the procedure may be made at the work location by responsible management. The applicable procedure shall control the process, documentation and approval of the temporary changes.

MINOR CHANGES

Minor changes such as inconsequential editorial corrections may be made to documents without being subject to the review and approval of the requirements specified above. The applicable procedure shall define the organizational positions authorized and criteria acceptable for making minor changes.

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

The elements of the LES QA Program described in this section and associated procedures implement the requirements of Criterion 7, "Control of Purchased Material, Equipment and Services," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 7 and Supplement 7S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda of NQA-1-1994.

LES procurement of material, equipment and services is controlled to assure conformance with specified requirements. These controls include requirements for pre-award evaluations of suppliers' QA programs, annual evaluations, periodic audits/source inspections and surveillance. Suppliers with a LES approved QA program are placed on the LES ASL prior to award of contract. Source inspections and surveillances, evaluation of objective evidence of quality furnished by the supplier, maintaining the ASL, as well as, examination of received items and services are the responsibility of LES QA organization and are performed, as necessary, upon delivery or completion to ensure requirements specified in procurement documents are met. Supplier evaluations, annual evaluations, audits, surveillances, source inspections and receipt inspections shall be documented.

PROCUREMENT PLANNING

LES procurements shall be planned and documented to ensure a systematic approach to the procurement process exists and supports the schedule. Procurement planning shall:

- Identify procurement methods and organizational responsibilities, including what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished.
- Identify and document the sequence of actions and milestones needed to effectively complete the procurement.
- Provide for the integration of the following activities:
  - o Procurement document preparation, review and change control according to the requirements of Section 4, Procurement Document Control
  - o Selection of procurement sources, proposal/bid evaluation and award
  - o LES evaluation of supplier performance
  - o LES verifications including any hold and witness point notifications
  - o Control of nonconformances
  - o Corrective action
  - o Acceptance of the material, equipment or service
  - o Identification of quality assurance records to be provided to LES.
- Be accomplished as early as possible, and no later than at the start of those procurement activities that are required to be controlled to assure interface compatibility and a uniform approach to the procurement process.
- Be performed relative to the level of importance, complexity and quantity of the item or service being procured and the supplier's quality performance.

- Include the involvement of the LES QA organization to ensure that the QA requirements have been properly identified.

SOURCE EVALUATION AND SELECTION

Supplier selection shall be based on an evaluation, performed before the contract and/or purchase order is awarded, of the supplier's capability to provide items or services in accordance with procurement document (technical and quality) requirements. The functional area needing the procurement shall request that the LES QA organization evaluate the potential supplier for placement on the LES ASL. Responsibilities and measures for evaluating and selecting procurement sources are detailed in the applicable QA procedure and include one or more of the following methods for evaluating potential suppliers:

- Evaluation of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use. The supplier's history shall reflect current capability.
- Evaluation of supplier's current quality assurance records supported by any documented qualitative and quantitative information which can be objectively evaluated.
- Evaluation of the supplier's technical and quality capability based on an evaluation of supplier facilities, personnel and quality assurance program implementation.

The results of procurement source evaluation and selection shall be documented in accordance with the applicable QA procedure.

PROPOSAL/BID EVALUATION

For proposals and bids, technically qualified personnel from the QA and Engineering and Contracts or other affected/involved organizations shall perform an evaluation to determine if the proposal/bid meets procurement document requirements. As a minimum, this evaluation shall review the following subjects consistent with the importance, complexity and quantity of items or services being procured:

- Technical considerations
- QA program requirements
- Supplier personnel qualifications
- Supplier production capability and past performance
- Alternatives and exceptions

Before the contract is awarded, the LES QA Director or Engineering and Contracts Manager, or other affected/involved organization manager shall resolve, or obtain commitments to resolve, unacceptable quality conditions identified during the proposal/bid evaluation. Supplier quality assurance programs shall be evaluated by the QA organization before contract placement, and any deficiencies that would affect quality shall be corrected before starting work subject to these requirements. Supplier QA programs shall be accepted by the LES QA Director before the supplier starts work.

SUPPLIER PERFORMANCE EVALUATION

The LES Engineering and Contracts Manager in coordination with the QA Director shall establish measures to routinely interface with the supplier and to verify supplier performance. The measures shall include:

- Establishing an understanding between LES and the supplier of the requirements and specifications identified in procurement documents.
- Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements.
- Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement requirements.
- Identifying and processing necessary change information.
- Establishing the method to be used to document information exchanges between LES and supplier.
- Establishing the extent of source surveillance and inspection.

The extent of LES verifications shall be a function of the relative importance, complexity/quantity of items or services being procured and the supplier's quality performance. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the activities of the suppliers. LES verifications shall be conducted as early as practical and shall not relieve the supplier of the responsibility for the verification of quality achievement. Verifications shall include supplier audits, surveillances or source inspections (or combinations) used as a method of evaluating the supplier's performance, and evaluation of purchaser's documentation to aid in the determination of the effectiveness of the supplier's quality assurance program. Records, including source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions shall be maintained in accordance with the requirements of Section 17, "Quality Assurance Records."

CONTROL OF SUPPLIER GENERATED DOCUMENTS

Supplier generated documents shall be controlled, processed and accepted by LES in accordance with the requirements established in the applicable QA procedures. Measures shall be implemented to ensure that the submittal of supplier generated documents is accomplished in accordance with the procurement document requirements. These measures shall also provide for the acquisition, processing and recorded evaluation of technical, inspection and test data compared against the acceptance criteria.

CONTROL OF CHANGES IN ITEMS OR SERVICES

LES shall establish contractual controls with suppliers to ensure that changes in procurement documents are controlled and documented in accordance with this QAPD.

ACCEPTANCE OF ITEMS OR SERVICES

Methods for accepting supplier furnished material, equipment or services shall include one or more of the following, as appropriate to the items or services being procured:

- Evaluating the supplier certificate of conformance,
- Performing one or a combination of source verification, receiving inspection or post-installation test,

- Technical verification of the data produced (services only),
- Surveillance or audit of the activities (services only),
- Review of objective evidence for conformance to procurement requirements (services only).

The supplier shall verify that furnished material, equipment or services comply with LES's procurement requirements before offering the material, equipment or services for acceptance and shall provide to LES objective evidence that material, equipment or services conform to procurement documents. Where required by code, regulations or contract provisions, documentary evidence that items conform to procurement documents shall be available at the site prior to installation or use.

CERTIFICATE OF CONFORMANCE

When a certificate of conformance is used to accept material, equipment or service:

- The certificate shall identify the purchased material, equipment or service to the specific procurement document.
- The certificate shall identify the specific procurement requirements met by the purchased material, equipment or service. The procurement requirements identified shall include any approved changes, waivers or deviations applicable to the material, equipment or service.
- The certificate shall identify any procurement requirements that have not been met together with an explanation and the means for resolving nonconformances.
- The certificate shall be signed and dated or otherwise authenticated by an individual who is responsible for the supplier's quality assurance function and whose responsibilities and position are described in the supplier's quality assurance program.
- The certification process, including the implementing documents to be followed in filling out a certificate and the administrative implementing documents for review and approval of the certificates, shall be described in the supplier's quality assurance program.
- Measures shall be identified to verify the validity of supplier certificates and the effectiveness of the certification process (such as by audit of the supplier or by an independent inspection or test of the item). Verifications shall be conducted by LES at intervals commensurate with the past quality performance of the supplier.

SOURCE VERIFICATION

LES may accept material, equipment or service by monitoring, witnessing or observing activities performed by the supplier. This method of acceptance is called source verification. Source verification shall be implemented consistent with the supplier's planned inspections, examinations or tests at predetermined points and performed at intervals consistent with the importance and complexity of the item. Documented evidence of acceptance of source verified material, equipment or services shall be furnished to the receiving destination of the item, to LES, and to the supplier. Personnel qualified in accordance with the applicable requirements for the material, equipment or service being procured shall perform source verification.

RECEIVING INSPECTION

When receiving inspection is used to accept an item:

- The inspection shall consider any source verifications/audits and the demonstrated quality performance of the supplier.

- The inspection shall be performed in accordance with established inspection procedures.
- The inspection shall verify, as applicable, proper configuration; identification; dimensional, physical and other characteristics; freedom from shipping damage; and cleanliness.
- The inspection shall be planned and executed according to the requirements of Section 10 "Inspections".
- Receiving inspection shall be coordinated with a review for adequacy and completeness of any required supplier documentation submittals.

POST-INSTALLATION TESTING

When post-installation testing is used as a method of acceptance, the LES Engineering and Contracts Manager or the affected/involved LES organization manager and the supplier shall mutually establish test requirements and acceptance documentation.

CONTROL OF SUPPLIER NONCONFORMANCES

The LES Engineering and Contracts organization and the supplier shall establish and document the process for disposition of items that do not meet procurement document requirements. The supplier shall evaluate nonconforming items according to the applicable requirements of Section 15, "Nonconforming Items" and submit a report of nonconformance to LES Engineering and Contracts organization including supplier recommended disposition (for example, use-as-is or repair) and technical justification. Reports of nonconformances to procurement document requirements, or documents approved by LES, shall be submitted to LES Engineering and Contracts organization for approval of the recommended disposition whenever one of the following conditions exists:

- Technical or material requirements are violated.
- A requirement in supplier documents, which have been approved by LES, is violated.
- The nonconformance cannot be corrected by continuation of the original manufacturing process or by re-work.
- The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

LES Engineering and Contracts organization shall disposition the supplier's recommendation and verify implementation of the disposition. LES will maintain records of the supplier-submitted nonconformances.

COMMERCIAL GRADE ITEMS

Where the design utilizes commercial grade material and/or equipment, the following requirements are an acceptable alternate to other requirements of this Section:

- The commercial grade material/equipment is identified in an approved design output document. An alternate commercial grade material/ equipment may be applied, provided there is verification that the alternate commercial grade material/equipment will perform the intended function and will meet design requirements applicable to both the replaced material/equipment and its application.
- Supplier evaluation and selection, where determined necessary by the LES based on complexity and importance to safety, shall be in accordance with "*Source Evaluation and Selection*" section of this document.

- Commercial grade items shall be identified in the purchase order by the manufacturer's published product description (e.g., catalog number).
- One or a combination of the following methods shall be utilized to provide reasonable assurance that the item meets the acceptance criteria for the characteristics identified to be verified for acceptance:
  - special test(s) or inspection (s) or both;
  - commercial grade survey of the supplier;
  - source verification;
  - acceptable supplier/item performance records.
- Prior to acceptance of a commercial grade item, LES QA organization shall determine that:
  - damage was not sustained during shipment;
  - the item received has satisfied the specified acceptance criteria;
  - inspection and/or testing is accomplished, as required, to assure conformance with critical characteristics; and
  - documentation, as applicable to the item, was received and is acceptable.

APPROVED SUPPLIER LIST

The LES Quality Assurance Director is responsible for the development and maintenance of the LES ASL. The ASL contains those suppliers with acceptable QA Programs that have been evaluated and accepted by the LES QA in accordance with approved procedures. The LES QA organization shall perform and document an evaluation of each supplier every 12 months. Satisfactory results will allow the supplier to remain on the ASL. Additionally, suppliers will be evaluated by means of an audit at least triennially, if initial approval was by audit or survey. Suppliers that have unacceptable evaluations or that have not had a procurement placed with them in three years will be removed from the ASL.

SECTION 8 IDENTIFICATION AND CONTROL MATERIALS, PARTS AND COMPONENTS

The elements of the LES QA Program described in this section and associated procedures implement the requirements of Criterion 8, "Identification and Control of Materials, Parts and Components," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 8 and Supplement 8S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda.

The controls necessary to ensure that only correct and accepted items are used or installed will be required by the appropriate QA procedure. Identification requirements for materials, parts and components are stated in design specifications, drawings, and procurement documents. Specific identification requirements are as follows.

- Identification markings, when used shall be applied using materials and methods which provide a clear and legible identification and do not detrimentally affect the function or service life of the item. Markings shall be transferred to each part of an item when subdivided and shall not be obliterated or hidden by surface treatments or coatings unless other means of identification are substituted.
- When required by specifications or codes and standards, identification of material or equipment with traceability to the corresponding mill test reports, certifications and other required documentation is maintained throughout fabrication, erection, installation, or use.
- Sufficient precautions shall be taken to preclude identifying materials in a manner that degrades the function or quality of the item being identified.

Control of material, parts and components is governed by approved procedures. Specific control requirements include the following.

- Identification of nonconforming or rejected materials, parts or components to ensure that they are not inadvertently used.
- Verification of correct identification of materials (including consumable materials or items with a limited shelf life), parts, and components shall be required to prevent the use of incorrect or defective items.
- Receipt inspection to ensure that materials, parts or components are properly identified and that supporting documentation is available as required by procurement specifications.
- Maintaining and replacement of markings and identification records due to damage during handling, aging or environmental exposure.

SECTION 9 CONTROL OF SPECIAL PROCESSES

The elements of the LES QA Program described in this section and associated procedures implement the requirements of Criterion 9, "Control of Special Processes," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 9 and Supplement 9S-1 of NQA-1994 Part I.

Processes affecting the quality of items or services shall be controlled by written procedures using drawings, checklists, travelers or other appropriate means. These means shall ensure that the process parameters are controlled and that specified environmental conditions are maintained. Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

SPECIAL PROCESSES

Special processes that control or verify quality shall be controlled according to the requirements of this section whether or not they are covered by existing codes and standards, or whether or not the quality requirements specified for an item exceed those of existing codes or standards.

PERSONNEL, IMPLEMENTING DOCUMENTS, AND EQUIPMENT QUALIFICATIONS

Implementing LES documents shall be used to ensure that process parameters are controlled and that the specified environmental conditions are maintained. Each special process shall be performed in accordance with appropriate implementing documents and these implementing documents shall include or reference:

- The responsibility of the organization performing the special process to adhere to the approved procedures and processes,
- Qualification requirements for personnel, implementing documents and equipment,
- Conditions necessary for accomplishment of the special process. These conditions shall include proper equipment, controlled parameters of the process and calibration requirements, and/or
- Requirements of applicable codes and standards, including acceptance criteria for the special process.

QUALIFICATION OF NONDESTRUCTIVE EXAMINATION PERSONNEL

Personnel who have been qualified and certified in accordance with Section 2.0, "QA Program," of this QAPD shall perform nondestructive examinations required for the LES work activities.

DOCUMENTATION

Records shall be maintained as appropriate in accordance with Section 17," Quality Assurance Records," for currently qualified personnel, processes and equipment of each special process.

SECTION 10 INSPECTION

The elements of the LES QA Program described in this section and associated procedures implement the requirements of Criterion 10, "Inspection," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 10 and Supplement 10S-1 of NQA-1-1994 Part I.

Inspections required to verify conformance of an item or activity to specified requirements are planned and executed. Characteristics to be inspected and inspection methods to be employed are specified in procedures. Inspection results are documented. Persons other than those who performed or directly supervised the work being inspected shall perform inspection for acceptance. Inspection requirements and acceptance criteria shall include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization. Inspection activities are documented and controlled by instructions, procedures, drawings, checklists, travelers or other appropriate means.

INSPECTION PLANNING

Inspection planning shall be performed, documented and include:

- Identification of each work operation where inspection is necessary to ensure quality and implementing documents that shall be used to perform the inspections;
- Identification of the characteristics to be inspected and the identification of when, during the work process, inspections are to be performed;
- Identification of inspection or process monitoring methods to be employed;
- The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements;
- Identification of the functional qualification level (category or class) of personnel performing inspections;
- Identification of acceptance criteria;
- Methods to record objective evidence of inspection results; and
- Selection and identification of the measuring and test equipment to be used to perform the inspection.

SELECTING INSPECTION PERSONNEL TO PERFORM INSPECTION

The individual who performs an inspection to verify conformance of an item to specified acceptance criteria shall be qualified to perform the assigned inspection tasks in accordance with the requirements of Section 2.0, "QA Program." Data recorders, equipment operators or other inspection team members who are supervised by a qualified inspector shall not be required to be a qualified inspector. Verification of conformance shall be by a qualified person. Inspections shall be performed by personnel other than those who performed or directly supervised the work being inspected. Inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected.

INSPECTION HOLD POINTS

When mandatory hold points are used to control work that shall not proceed without the specific consent of the organization placing the hold point, the specific hold points shall be indicated in

implementing documents. Consent to waive specified hold points shall be documented and approved before continuing work beyond the designated hold point.

STATISTICAL SAMPLING

When statistical sampling is used to verify the acceptability of a group of items, the statistical sampling method used shall be based on recognized standard practices and these practices shall be implemented through applicable approved procedures.

IN-PROCESS INSPECTIONS AND MONITORING

Items shall be inspected when necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment and personnel shall be provided. Inspection and process monitoring shall be conducted when control is inadequate with only one method. A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to ensure that the specified requirements for control of the process and the quality of the item are met throughout the duration of the process. Controls shall be established and documented for the coordination and sequencing of inspections and monitoring at established inspection points during successive stages of the process or construction.

FINAL INSPECTION

Finished items shall be inspected for completeness, markings, calibration, adjustments, protection from damage or other characteristics as required in order to verify the quality and conformance of the item to specified requirements. Documentation not previously examined shall be examined for adequacy and completeness. The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements. Final inspections shall include a review of the results and resolution of any nonconformances identified by earlier inspections. Modifications, repairs or replacements of items performed subsequent to final inspection shall require re-inspection or retest, as appropriate, to verify acceptability.

ACCEPTING ITEMS

The acceptance of an item shall be documented and approved by qualified and authorized personnel. The inspection status of an item shall be identified according to Section 14, "Inspection, Test and Operating Status."

INSERVICE INSPECTION

Inservice inspection or surveillance of structures, systems, or components shall be planned and implemented by or for the LES Operating organization. Procedures shall control the inspections to verify that the characteristics of the item remain with the specified limits. The inspection procedure shall include the following, as appropriate:

- Evaluations of performance capabilities of essential emergency and safety systems and equipment,
- Verification of calibration and integrity of instruments and instrument systems, and
- Verification of maintenance.

INSPECTION DOCUMENTATION

Inspection documentation shall identify:

- The item inspected, date of inspection, the name of the inspector who documented, evaluated and determined acceptability;
- Name of data recorder, as applicable and type of observation or method of inspection;
- The inspection criteria, sampling plan or reference documents (including revision levels) used to determine acceptance;
- Results or acceptability of characteristics inspected;
- Measuring and test equipment used during the inspection including the identification number and the most recent calibration date; and
- Reference to information on actions taken in connection with nonconformances, as applicable.

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SECTION 11 TEST CONTROL

The elements of the LES QA Program described in this section and associated procedures implement the requirements of Criterion 11, "Test Control," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 11 and Supplement 11S-1 of NQA-1-1994 Part I. The commitment to the provisions in Supplement 11S-2, "Supplementary Requirements for Computer Program Testing" is addressed in Section 3, "Design Control".

Tests required to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service are planned and executed. Characteristics to be tested and test methods to be employed are specified. Test results are documented and their conformance with acceptance criteria is evaluated. Tests required to collect data, such as for siting or design input, shall be planned, executed, documented and evaluated.

TEST REQUIREMENTS

Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests are controlled. Test requirements and acceptance criteria are based upon specified requirements contained in applicable design or other pertinent technical documents.

TEST PROCEDURES

Test procedures shall include:

- Test objectives and the identification of any implementing documents to be developed to control and perform tests as appropriate;
- Identification of items to be tested, test requirements and acceptance limits, including required levels of precision and accuracy;
- Identification of test methods to be employed and instructions for performing the test;
- Test prerequisites that address calibrated instrumentation, appropriate and adequate test equipment/instrumentation, trained personnel, condition of test equipment and the item to be tested, suitably controlled environmental conditions and provisions for data acquisition;
- Mandatory hold points and methods to record data and results;
- Provisions for ensuring that prerequisites for the given test have been met;
- Selection and identification of the measuring and test equipment to be used to perform the test to ensure that the equipment is of the proper type, range, accuracy, and tolerance to accomplish the intended function; and
- Identification of the functional qualification level of personnel performing tests.

PERFORMING TESTS

Tests shall be performed in accordance with procedures that address the following requirements as applicable:

- Provisions for determining when a test is required, describing how tests are performed, and ensuring that testing is conducted by trained and appropriately qualified personnel.
- Include or reference test objectives and provisions for ensuring that prerequisites for the given test have been met, adequate calibrated instrumentation is available and used, necessary monitoring is performed and suitable environmental conditions are maintained.
- Test requirements and acceptance criteria provided or approved by the organization responsible for the design of the item to be tested, unless otherwise designated.
- Test requirements and acceptance criteria based upon specified requirements contained in applicable design or other pertinent technical documents.
- Potential sources of uncertainty and error. Test parameters affected by potential sources of uncertainty and error shall be identified and controlled.

MONITORING AND OVERSIGHT OF SUPPLIER TEST

The LES Engineering and Contracts Manager in coordination with the QA Director shall establish measures to routinely interface with the supplier and to verify supplier performance. LES may accept material, equipment or service by monitoring, witnessing or observing activities performed by the supplier. This method of acceptance is called source verification. Source verification shall be implemented consistent with the supplier's planned inspections, examinations or tests at predetermined points and performed at intervals consistent with the importance and complexity of the item. Documented evidence of acceptance of source verified material, equipment or services shall be furnished to the receiving destination of the item, to LES, and to the supplier. Personnel qualified in accordance with the applicable requirements for the material, equipment or service being procured shall perform source verification.

USE OF OTHER TESTING DOCUMENTS

Other testing documents (e.g., American Society for Testing and Materials (ASTM)) specifications, supplier manuals or other related documents containing acceptance criteria may be used instead of preparing special test procedures. If used, the information shall be incorporated by reference in the approved test procedure. Implementing documents shall include adequate supplemental instructions as required to ensure the required quality of the testing work.

TEST RESULTS

Test results shall be documented and their conformance with acceptance criteria shall be evaluated by a qualified individual within the responsible organization to ensure that test requirements have been satisfied.

TEST DOCUMENTATION

Test documentation shall include:

- Item or work product tested, date of test, names of tester and data recorders, type of observation and method of testing;
- Identification of test criteria or reference documents used to determine acceptance;
- Results and acceptability of the test;
- Actions taken in connection with any nonconformances or deviations noted;
- Name of the person evaluating the test results; and

- Identification of the measuring and test equipment (M&TE) used during the test.

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

The elements of the LES QA Program described in this section and associated procedures implement the requirements of Criterion 12, "Control of Measuring and Test Equipment ,"of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 12 and Supplement 12S-1 of NQA-1-1994 Part I.

This section establishes LES control for tools, gages, instruments and other measuring and test equipment (M&TE) used for activities affecting quality, including design activities where applicable, construction, operation and decommissioning. M&TE is controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits. Selection of M&TE shall be controlled to ensure that such items are of proper type, range, accuracy, and tolerance to accomplish the functions of determining conformance to specified requirements.

CALIBRATION

M&TE shall be calibrated, adjusted and maintained at prescribed intervals or, prior to use, against reference calibration standards having traceability to nationally recognized standards. If no nationally recognized standards or physical constants exist, the basis for calibration shall be documented. Calibration standards shall have a greater accuracy than the required accuracy of the M&TE being calibrated. If calibration standards with a greater accuracy than required of the M&TE being calibrated do not exist or are unavailable, calibration standards with accuracy equal to the required calibration accuracy may be used, provided they are shown to be adequate for the requirements. The basis for the calibration acceptance shall be documented and authorized by responsible management as defined in applicable procedures. The level of management authorized to perform this function shall be identified. The method and interval of calibration for each device shall be defined, based on the type of equipment, stability characteristics, required accuracy, intended use and other conditions affecting measurement control. For M&TE used in one- time-only applications, the calibration shall be performed both before and after use. A calibration shall be performed when the accuracy of calibrated M&TE is suspect. Calibrated M&TE shall be labeled, tagged, or otherwise suitably marked or documented to indicate due date or interval of the next calibration and uniquely identified to provide traceability to its calibration data.

DOCUMENTING THE USE OF M&TE

The use of M&TE shall be documented. As appropriate to equipment use and its calibration schedule, the documentation shall identify the processes monitored, data collected or items inspected or tested since the last calibration.

OUT OF CALIBRATION M&TE

M&TE shall be considered to be out-of-calibration and not be used until calibrated if any of the following conditions exist:

- The calibration due date or interval has passed without re-calibration.
- The device produces results known or suspected to be in error.

- Out-of-Calibration M&TE shall be controlled. The controls shall include the following requirements:
  - Out-of-Calibration M&TE shall be tagged, segregated or otherwise controlled to prevent use until they have been recalibrated.

When M&TE is found out-of-calibration, the validity of results obtained using that equipment since its last valid calibration shall be evaluated to verify the acceptability of previously collected data, processes monitored, or items previously inspected or tested. The evaluation shall be documented.

If any M&TE is consistently found out-of-calibration during the re-calibration process, it shall be repaired or replaced.

LOST M&TE

When M&TE is lost, the validity of results obtained using that equipment since its last valid calibration shall be evaluated to determine acceptability of previously collected data, processes monitored or items previously inspected or tested. The evaluation shall be documented.

HANDLING AND STORAGE

M&TE shall be properly handled and stored to maintain accuracy.

COMMERCIAL DEVICES

Calibration and control shall not be required for rulers, tape measures, levels and other normal commercial equipment that provides adequate accuracy.

M&TE DOCUMENTATION

M&TE calibration documentation shall include the following information:

- Identification of the measuring or test equipment calibrated;
- Traceability to the calibration standard used for calibration;
- Calibration data;
- Identification of the individual performing the calibration;
- Identification of the date of calibration and the re-calibration due date or interval, as appropriate;
- Results of the calibration and statement of acceptability;
- Reference to any actions taken in connection with out-of-calibration or nonconforming M&TE including evaluation results, as appropriate; and
- Identification of the implementing document used in performing the calibration.

SECTION 13 HANDLING, STORAGE, AND SHIPPING

The elements of the LES QA Program described in this section and associated procedures implement the requirements of Criterion 13, "Handling, Storage and Shipping," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 13 and Supplement 13S-1 of NQA-1-1994 Part I.

Handling, storage, cleaning, packaging, shipping and preservation of items are controlled in accordance with requirements of this section to prevent damage or loss and to minimize deterioration.

CONTROLS

Handling, storage, cleaning, packaging, shipping and preservation of items shall be conducted in accordance with established work and inspection implementing procedures, shipping instructions or other specified documents. For critical, sensitive, perishable or high-value articles, specific instructions for handling, storage, cleaning, packaging, shipping and preservation shall be prepared and used.

SPECIAL EQUIPMENT, TOOLS AND ENVIRONMENTS

If required for particular items, special equipment (i.e., containers, shock absorbers and accelerometers) and special protective environments (i.e., inert gas and specific moisture/temperature levels) shall be specified and provided. If special equipment and environments are used, provisions shall be made for their verification. Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested at specified time intervals and in accordance with procedures to verify that the tools and equipment are adequately maintained. Operators of special handling and lifting equipment shall be experienced or trained in the use the equipment.

MARKING AND LABELING

Measures shall be established for marking and labeling for the packaging, shipping, handling and storage of items as necessary to adequately identify, maintain and preserve the item. Markings and labels shall indicate the presence of special environments or the need for special controls if necessary.

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

The elements of the LES QA Program described in this section and associated procedures implement the requirements of Criterion 14, "Inspection, Test and Operating Status," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 14 of NQA-1-1994 Part I.

This section establishes requirements for LES to identify the status of inspection and test activities. Status is indicated either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used or operated. Status is maintained through indicators (i.e., physical location and tags, markings, shop travelers, stamps, inspection records or other suitable means). The authority for application and removal of tags, markings, labels and stamps are specified. Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility (i.e., tagging valves and switches) to prevent inadvertent operation.

Process control procedures, test and inspection procedures, nonconforming item control procedures, installation records, and checklists are used as applicable to control the installation of structures, system and components. These documents contain hold points, activity checklists, and in many cases, step-by-step signoffs which indicate the status of fabrication, installation, inspections, and test. This system is used to prevent inadvertent use of nonconforming items or bypassing of inspections and tests and prevent inadvertent operation.

During operation, in order to ensure that equipment status is clearly evident, and to prevent inadvertent operation, the LES QA Program requires structures, systems and components that are inoperable to be identified as such. This identification may be by means of tags, labels, stamps or other suitable methods. When tags, labels, or stamps are utilized for the identification of equipment status, the issuance and removal thereof is documented to ensure proper control of such identification measures. Also, procedures require that the operability of an item removed from operation for maintenance or testing be verified prior to returning the item to normal service.

Measures taken by QA personnel, during the performance of required inspection and quality control activities, to identify equipment status are controlled by the QA organization independent of measures taken to identify and control equipment status by LES.

Changing the sequence of inspections, tests, and other activities involving safety requires the same controls as the original review and approval.

SECTION 15 NONCONFORMING ITEMS

The elements of the LES QA Program described in this section and associated QA procedures implement the requirements of Criterion 15, "Nonconforming Items," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 15 and Supplement 15S-1 of NQA-1-1994 Part 1.

This section provides the process for controlling items that do not conform to specified requirements. For the purposes of this QAPD, items referenced to in this section means materials, parts, or components. The control of nonconforming activities and services is described in Section 16, "Corrective Action." These items are controlled to prevent inadvertent installation or use. The controls provide for identification, documentation, evaluation, segregation when practical, disposition of nonconforming items and for notification to affected organizations.

DOCUMENTING AND EVALUATING NONCONFORMING ITEMS

Nonconformance documentation shall clearly identify and describe the characteristics that do not conform to specified criteria. Nonconformance documentation shall be reviewed by the responsible affected organization and recommended dispositions of nonconforming items shall be proposed in accordance with procedures. The review shall include determining the need for additional corrective actions according to the requirements of Section 16, "Corrective Action." In addition, organizations affected by the nonconformance shall be notified. Recommended dispositions shall be evaluated and approved in accordance with procedures. Personnel performing evaluations of recommended dispositions shall have demonstrated competence in the specific area they are evaluating, an adequate understanding of the requirements and access to pertinent background information. The responsibility and authority for reviewing, evaluating, approving the disposition and closing nonconformances shall be specified in procedures. The LES QA Organization is responsible for administering the Nonconformance Process. QA can initiate, recommend, or provide solutions via designated channels. QA will verify the implementation of the corrective actions and QA will assure that procedures are in place to control the installation and use of nonconformances until an acceptable solution has been provided. Further processing, delivery, installation or use of a nonconforming item shall be controlled pending the evaluation and approval of the disposition by authorized personnel.

IDENTIFYING NONCONFORMING ITEMS

Employees of LES and LES contractors have a procedural obligation to identify and document nonconformances. Nonconforming items shall be identified by marking, tagging or other methods that do not adversely affect their end use. The identification shall be legible and easily recognizable. If the identification of a nonconforming item is not practical, the container, package or segregated storage area, as appropriate, shall be identified.

SEGREGATING NONCONFORMING ITEMS

Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. If segregation is impractical or impossible due to physical conditions, then other precautions shall be employed to preclude inadvertent use.

DISPOSITION OF NONCONFORMING ITEMS

The disposition, such as "use-as-is," "reject," "repair," or "rework," of nonconforming items shall be identified and documented. The technical justification for the acceptability of a nonconforming item that has been dispositioned "repair" or "use-as-is" shall be documented.

Items that do not meet original design requirements that are dispositioned "use-as-is" or "repair" shall be subject to design control measures commensurate with those applied to the original design. If changes to the specifying document are required to reflect the as-built condition, the disposition shall require action to change the specifying document to reflect the accepted nonconformance. Any document or record change required by the disposition of the nonconformance shall be identified in the nonconformance documentation; and, when each document or record is changed, the justification for the change shall identify the nonconformance documentation. The disposition of an item to be reworked, or repaired shall contain a requirement to reexamine (inspect, test, or nondestructive examination) the item to verify acceptability. Repaired or reworked items shall be reexamined in accordance with applicable procedures using the original process and acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

TRENDING

Nonconformance documentation shall be periodically analyzed by the LES QA organization to identify adverse quality trends in accordance with Section 16, "Corrective Action."

SECTION 16 CORRECTIVE ACTION

The elements of the LES QA Program described in this section and associated QA procedures implement the requirements of Criterion 16, "Corrective Action," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 16 of NQA-1-1994 Part 1.

Conditions adverse to quality including activities and services shall be identified promptly and corrected as soon as practical. For significant conditions adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Follow-up action shall be taken to verify implementation of the corrective action. Significant conditions adverse to quality shall be tracked and evaluated so that adverse trends can be identified and appropriate corrective action can be taken.

Procedure(s) shall be issued to establish the CAP which includes the following processes, including closure:

- Prompt identification and correction of conditions adverse to quality;
- Evaluating significant conditions adverse to quality for reportability to the NRC (when required) under 10 CFR 21 "Reporting of Defects and Nonconformance," or other applicable reporting requirements and reporting such conditions when warranted;
- Stopping work, if applicable;
- Determining root cause and corrective actions to preclude recurrence for significant conditions adverse to quality; and
- Follow-up actions to verify implementation of corrective actions taken for significant conditions adverse to quality.

IDENTIFYING AND CLASSIFYING CONDITIONS ADVERSE TO QUALITY

Conditions adverse to quality shall be classified in one of two categories in regard to their significance, and corrective actions shall be taken accordingly. The two categories of significance include:

- Conditions adverse to quality
- Significant conditions adverse to quality

Conditions adverse to quality are defined as failures, malfunctions, deficiencies, deviations, defective material and equipment and nonconformances. Conditions adverse to quality shall be documented and reported to the appropriate levels of management.

Responsible management shall investigate and fully identify the condition and document the results. Responsible management shall then utilize investigation results to determine and document corrective action (including remedial action and if appropriate, actions to prevent recurrence). Responsible management shall complete remedial action and document completion of actions in a timely manner.

Significant conditions adverse to quality are defined as:

- A deficiency that would seriously impact an item, activity or service from meeting or performing its intended function or output of assuring public health and safety;

- A deficiency in design that has been approved for fabrication or construction where the design deviates extensively from design criteria and bases;
- A deficiency in the fabrication or construction of, or significant damage to, structures, systems or components that require extensive evaluation, re-design or repair in order to establish the adequacy of the structure, system or component to perform its intended function of assuring public health and safety;
- A deviation from performance specifications that shall require extensive evaluation, re-design, or repair to establish the adequacy of the structure, system or component to perform its intended function;
- A significant error in a computer program used to support activities affecting quality after it has been released for use;
- A deficiency, repetitive in nature, related to an activity or item subject to the LES QA Program; and
- A condition that, if left uncorrected, has the potential to have a serious negative impact on activities or items subject to the LES QA Program controls.

If a supplier or subtier supplier discovers a defect or noncompliance which the supplier evaluates as a substantial safety hazard, then the supplier shall be required to report the item under 10 CFR 21 "Reporting of Defects and Nonconformance," and notify the LES in writing. If the supplier or subtier supplier is unable to determine if the defect/non compliance is a substantial safety hazard then the supplier or subtier supplier is required to report the item to LES for determination of reportability.

Significant conditions adverse to quality shall be evaluated for a stop work condition to determine if stopping work is warranted. If a stop work condition is identified, management shall issue stop work in accordance with the applicable procedure. Upon resolution of the related significant condition adverse to quality, management shall take appropriate action to lift and close (in part or total) the stop work order.

FOLLOW-UP ACTION

The procedure(s) establishing the Corrective Action Program shall include a requirement for management to take follow-up action to verify implementation of corrective action taken to address significant conditions adverse to quality. The QA organization shall be responsible for conducting periodic assessments of these follow-up actions.

TRENDING

The procedure(s) establishing the CAP shall assign organizational responsibility for trending significant conditions adverse to quality and the criteria for determining trends. Reports of significant conditions adverse to quality shall be evaluated to identify adverse quality trends and help identify root causes. Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends. Identified adverse trends shall be handled in accordance with the CAP described here and reported to the appropriate management.

SECTION 17 QUALITY ASSURANCE RECORDS

The elements of the LES QA Program described in this section and associated QA procedures implement the requirements of Criterion 17, "Quality Assurance Records," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 17 and Supplement 17S-1 of NQA-1-1994 Part I.

A QA record is any completed record that furnishes documentary evidence of the quality of items and/or activities affecting quality. Records may include specially processed records such as radiographs, photographs, negatives, microforms and magnetic/electronic media. LES completed QA records that furnish documentary evidence of quality shall be specified, prepared and maintained in accordance with applicable regulatory requirements and applicable procedures. QA Records shall be legible, identifiable, retrievable, and shall be protected against damage, deterioration and loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance and disposition shall be established and documented in procedures. Retention periods for the various types of records generated under the LES QA Program shall be specified as Lifetime or Nonpermanent according to the criteria provided in this Section. The term "records" used throughout this section is to be interpreted as "Quality Assurance Record," unless otherwise specified.

RECORD MANAGEMENT SYSTEM

LES shall establish a record management system and LES Records Center at the earliest practicable time consistent with the schedule for accomplishing work activities and in compliance with the requirements of this QAPD. The QA records management system shall be defined, implemented and enforced in accordance with written procedures, instructions or other documentation. Records shall be distributed, handled, and controlled in accordance with written procedures.

GENERATION, CLASSIFICATION AND RETENTION OF QA RECORDS

Applicable LES design specifications, procurement documents, test procedures, operational procedures or other documents and procedures shall specify the records to be generated, supplied or maintained. Documents that are designated to become records shall be legible, accurate and completed appropriate to the work accomplished. LES records shall be classified for retention purposes as lifetime records or nonpermanent records in accordance with the criteria provided below.

- Lifetime records are those that meet one or more of the following criteria:
  - Those which would be of significant value in demonstrating capability for safe operation;
  - Those which would be of significant value in maintaining, reworking, repairing, replacing or modifying an item;
  - Those which would be of significant value in determining the cause of an accident or malfunction of an item; and/or
  - Those which provide required baseline data for in-service inspections.

Lifetime records are required to be maintained for the life of the particular item while it is installed in the facility or stored for future use.

Nonpermanent records are those required to show evidence that an activity was performed in

accordance with the applicable requirements of the LES QA Program but need not be retained for the life of the item because they do not meet the criteria for lifetime records. The retention period for nonpermanent records shall be documented in the applicable procedure.

Procedures shall identify those documents that will become QA records. The individual using the procedure is responsible for ensuring the QA records required by the procedure are submitted to the LES Records Center. Documents that may become records shall be maintained and processed in a prudent manner to avoid unnecessary delay and/or expense in retrieving the record when the record is needed to support other work.

Individuals creating records shall ensure the records are legible, accurate and complete, and shall protect them from damage, deterioration or loss during the time the records are in their possession.

Documents shall be considered valid records only if authenticated (i.e., stamped, initialed or signed and dated complete by authorized personnel). If the nature of the record precludes stamping or signing, then other means of authentication by authorized personnel is permitted. This may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization. QA records may be originals or copies. LES contractors shall submit to the LES Records Center those records being temporarily stored by them in accordance with contractual requirements. The timing of the submittal shall be as records become completed, or as items are released for shipment, or as prescribed by QA procedures and procurement documents. Records shall be controlled and submitted to the records management system in accordance with implementing procedures.

RECEIVING QA RECORDS

Each organization responsible for receiving records shall provide protection from damage or loss during the time that the records are in their possession. A receipt control system shall be established by the organization to include the following:

- A method for designating the required records;
- A method for identifying records received;
- Procedures for receipt and inspection of incoming records; and
- A method for submittal of completed records to the storage facility without unnecessary delay; and
- Capability to provide current and accurate status of records during the receipt process.

Records shall be indexed to ensure retrievability. Records and/or indexing systems shall provide sufficient information to permit identification between the record and the item or activity to which it applies. The indexing system shall include:

- The location of the records within the records management system;
- Identification of the item or related activity to which the records pertain; and
- The retention classification of the record.

STORING, SAFEKEEPING, AND PRESERVING QA RECORDS

Records shall be stored and preserved in the LES Records Center in accordance with a procedure that includes the following:

- Assignment of responsibility for enforcing the requirements of the procedure;
- A description of the storage facility;
- A description of the filing system to be used;
- A method for verifying that the records received are in agreement with the transmittal document;
- A method for verifying that the records are those designated and the records are legible and complete;
- A description of rules governing control of the records, including access, retrieval and removal;
- A method for maintaining control of and accountability for records removed from the storage facility;
- A method for filing supplemental information and disposition of superseded records;
- A method for precluding entry of unauthorized personnel into the storage area to guard against larceny and vandalism; and
- A method for providing for replacement, restoration or substitution of lost or damaged records.

Storage methods shall be approved by the organization responsible for storage to preclude deterioration of records in accordance with the following:

- Provisions shall be made in the storage arrangement to prevent damage from moisture, temperature and pressure.
- Approved filing methods shall require records to be firmly attached in binders, or placed in folders or envelopes, for storage in steel file cabinets or on shelving in containers appropriate for the record medium being stored.
- The storage arrangement shall provide adequate protection of special processed records (e.g., radiographs, photographs, negatives, microform and magnetic media) to prevent damage from humidity, temperature, excessive light, electromagnetic fields or stacking, consistent with the type of record being stored.

LES RECORDS CENTERS

Originating organizations shall store records in temporary storage while active and required for use; subsequently the records shall be transmitted for permanent storage in accordance with the requirements of this Section and associated procedures.

LES organizations shall provide for temporary storage of records during processing, review or use, until turnover to the LES Records Center for disposition, according to implementing procedures and the following requirements:

- Records shall be temporarily stored in a container or facility with a fire rating of one (1) hour. The temporary storage container or facility shall bear an Underwriters' Laboratories label (UL) (or equivalent) certifying one (1) hour fire protection, or be certified by a person competent in the technical field of fire protection.
- The maximum time limit for keeping records in temporary storage shall be specified by implementing procedures consistent with the nature or scope of work.

LES QA records permanent storage shall either invoke the alternate single storage facility

provision of Section 4.4.2 and/or the dual facilities provision of Section 4.4.4 of Supplement 17S-1 of NQA-1-1994. With either provision used, the LES Records Center shall be constructed and maintained in a manner that minimizes the risk of damage or destruction from the following:

- Natural disasters (i.e., winds, floods or fires);
- Environmental conditions (i.e., high and low temperatures and humidity); and
- Infestation of insects, mold or rodents.

If the alternate single storage facility provision is used, then LES records shall be stored in the LES Records Center in two (2) hour fire rated Class B file containers meeting the requirements of National Fire Protection Association (NFPA) 232-1986 or NFPA 232AM-1986 or both.

If the dual storage facility provision is used for hard copies, then LES records shall be stored with one copy in the LES Records Center and the second copy stored in facility that is sufficiently remote from the Records Center to eliminate the chance of exposure to a simultaneous hazard. If the dual storage facilities provision is used via scanned documents into an electronic records management system, then a back-up tape shall be periodically made of the electronic records management system and its contents and the tape shall be stored in temporary storage devise in a fire-proof safe. This process invokes the dual storage provision as one copy resides on the records management system computer and a second copy of the total records system resides in a remote location with temporary storage being used for records entered in the interim.

RETRIEVING AND DISPOSITIONING QA RECORDS

The records management system shall provide for retrieval of records in accordance with planned retrieval times based upon the designated record type. Access to records storage facilities shall be controlled. A list shall be maintained designating personnel who are permitted access to the records at the LES Records Center.

Records maintained by a supplier at its facility or other location shall be accessible to the purchaser or designated alternate. The supplier's records shall not be disposed of until contractual requirements are satisfied.

Records accumulated at various locations prior to transfer shall be made accessible to LES directly or through the procuring organization. The record-keeper shall inventory the submittals, acknowledge receipt and process these records in accordance with this QAPD. Various regulatory agencies have requirements concerning records that are within the scope of this Section. The most stringent requirements should be used in determining the final disposition. The supplier's nonpermanent records shall not be disposed of until the applicable conditions listed below are satisfied.

- Items are released for shipment, a Code Data Report is signed, or a Code Symbol stamp is affixed.
- Regulatory requirements are satisfied.
- Operational status permits.
- Warranty consideration is satisfied.
- Purchaser's requirements are satisfied.

RETENTION OF QA RECORDS

Lifetime records shall be retained and preserved for the operating life of the particular item while it is installed in the plant or stored for future use. Nonpermanent records shall not be disposed of until the following conditions are met:

- Regulatory requirements are satisfied;
- Facility status allows document disposal; and
- LES QAPD requirements are satisfied

CORRECTING INFORMATION IN QA RECORDS

Corrections shall include the identification of the person authorized to make the correction and the date the correction was made. Corrections to records shall be performed in accordance with implementing procedures, which provide for appropriate review or approval of the corrections, by the originating organization.

REPLACING LOST OR DAMAGED QA RECORDS

Replacement, restoration or substitution of lost or damaged records shall be performed in accordance with implementing procedures, which provide for appropriate review or approval by the originating organization and any additional information associated with the replacement.

SECTION 18 AUDITS

The elements of the LES QA Program described in this section and associated QA procedures implement the requirements of Criterion 18, "Audits," of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 18 and Supplement 18S-1 of NQA-1-1994 Part 1.

In accordance with the description of the QA organization during the various phases of design, construction, and operation provided in Section 1, "Organization," the LES QA Director or QA Manager shall verify LES compliance with all aspects of the LES QA Program and determine QA Program effectiveness by ensuring that planned and scheduled audits are conducted. Elements that have been selected for audit shall be evaluated against specified requirements. An auditing function reports to the LES QA Director/QA Manager and has the organizational independence and authority to execute an effective audit process to meet all requirements of the QA Program. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. LES audits are performed in accordance with written procedures or checklists by appropriately trained and qualified personnel who do not have direct responsibility for performing the activities being audited. Audit results are documented and provided to the appropriate management for review and corrective action as applicable. Follow-up actions are taken where indicated.

AUDIT SCHEDULES

Internal or external audits shall be scheduled in a manner to provide coverage, consistency and coordination with ongoing work, and at a frequency commensurate with the status and importance of the work. Internal or external audits shall be scheduled to begin as early in the life of the work as practical and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work. As a minimum, internal audits of LES QA Level 1 activities shall be at least once per year or at least once during the life of the activity, whichever is shorter. Regularly scheduled internal audits shall be supplemented by additional audits of specific subjects when necessary to provide an adequate assessment of compliance or effectiveness. Internal audits to determine quality assurance program effectiveness shall be performed on selected work products. The audit schedule shall be developed annually and revised as necessary to ensure that coverage is maintained current. Frequency of audits should be based upon evaluation of all applicable and active elements of the LES QAPD applicable to LES workscope. These evaluations should include an assessment of the effectiveness of the applicable and active elements of the LES QAPD based upon previous audit results and corrective actions, nonconformance reports, identified trends, and significant organizational changes.

AUDIT PLANS

A documented audit plan shall developed for each audit. This plan shall identify the audit scope, requirements for performing the audit, type of audit personnel needed, work to be audited, organizations to be notified, applicable documents, audit schedule, and implementing documents or checklists to be used.

AUDIT TEAMS

The LES QA Director or QA Manager shall select and assign auditors who are independent of any direct responsibility for performing the work being audited. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. The audit team shall include one or more auditors comprised of representatives from the LES QA organization and any applicable technical organizations. A lead auditor shall be appointed to supervise the team, organize and direct the audit, prepare and coordinate issuance of the audit report and evaluate responses. Technical specialists may be used to assist in assessing the adequacy of technical processes. Before commencing the audit, the lead auditor shall ensure the personnel assigned to the audit team are prepared and collectively have experience and/or training commensurate with the scope, complexity or special nature of the work to be audited. Lead auditors, auditors and technical specialists shall be trained and qualified according to the requirements of Section 2, "Quality Assurance Program."

PERFORMING AUDITS

The LES QA Director or QA Manager shall provide written notification of a planned audit to the affected organizations at a reasonable time before the audit is to be performed. The notification should include all relevant information pertaining to the audit, such as schedule, scope and names of audit lead and team members, if known. In addition, the audit team leader shall ensure the following is performed.

- The audit team shall be adequately prepared before starting the audit.
- Audits shall be performed in accordance with written procedures or checklists.
- Elements that have been selected for the audit shall be evaluated against specified requirements.
- Objective evidence shall be examined to the depth necessary to determine if the selected elements are being implemented effectively.
- Audit results shall be documented by auditing personnel, and reported to/reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.
- Identified audit findings shall be documented and the audited organization shall correct the findings according to the requirements of Section 16, "Corrective Action." Minor audit findings can be corrected during the conduct of the audit.

REPORTING AUDIT RESULTS

The audit report shall be prepared and signed by the audit team leader and issued to the management of the audited organization in a timely manner after completion of the audit.

The audit report shall include the following information:

- A description of the audit scope.
- Identification of the auditors.
- Identification of persons contacted during the audit.
- A summary of audit results and the documents reviewed, persons interviewed and the specific results of the reviews and interviews (i.e., a summary of the checklist contents).

- Statement as to the effectiveness of the implementation of the QA Program elements audited.
- A description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.
- A requested date for response by the audited organization.

RESPONDING TO AUDITS

Management of the audited organization or activity shall:

- Investigate adverse audit findings in a timely manner;
- Determine and schedule corrective action, including measures to prevent recurrence;
- Prior to or by the requested response date, notify the LES QA Director in writing of the actions taken or scheduled, according to the requirements of Section 16 "Corrective Action."

EVALUATING AUDIT RESPONSES

The LES QA Director or QA Manager is responsible for evaluating audit responses.

FOLLOW-UP ACTION

Follow-up action shall be taken by the LES QA Director to verify that:

- Corrective actions are completed as scheduled according to the requirements of Section 16 "Corrective Action."

RECORDS

- Audit records include audit plans and audit reports.
- Written replies and the record of completion of any required corrective actions.

These documents are QA records and shall be submitted to the LES Records Center for retention according to the requirements of Section 17, "Quality Assurance Records."

NON-LES AUDITOR QUALIFICATIONS

Non-LES certified auditors may be used to perform audits and surveillances provided the LES QA Director or QA Manager confirms and documents applicable QAPD requirements have been met and the individual has been certified in accordance with the QA procedure on auditor qualification and certification.

SECTION 19 PROVISIONS FOR CHANGE

This QAPD is reviewed and revised as necessary to reflect any changes that occur during the design, construction, operation, including maintenance and modifications, and decommissioning phases. In addition, this QAPD is revised when corrective actions, regulatory, organizational, or work scope changes warrant changes to the LES QA Program. The LES QAPD is maintained current through design, construction, operation and decommissioning of the facility. The LES QAPD is kept current as the design, construction, operation, and decommissioning activities progress, and appropriate changes are made based on any of the following:

- Lessons learned from audit and assessment findings,
- Program improvements identified from analysis of trends, and
- Changes due to regulations, commitments, reorganizations, revised project schedule, or program improvements from continuous review of assessment results and process improvement initiatives.

Changes to the LES QA Program shall be incorporated in this QAPD and submitted to the NRC within 30 days of implementation prior to and after NRC issuance of the License. Any changes that reduce commitments in the approved QAPD, including those commitments that address the safety program and integrated safety analysis regulatory requirements, as well as the QA Level requirements in this QAPD, will be submitted to the NRC for review and approval prior to implementation.

SECTION 20 QUALITY ASSURANCE PROGRAM FOR QA LEVEL 2 ACTIVITIES

This section outlines the owner defined 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 is acceptable for QA Level 2 applications provided it complies with LES QAPD requirements and the ISO program is reviewed and approved by the LES QA Director.

Requirements for QA Level 2 are defined below. QA Level 2 requirements shall not be applied to IROFS or items that may affect the functions of the IROFS.

ORGANIZATION

The organization, lines of responsibility and authority are clearly established and documented.

PERSONNEL QUALIFICATIONS

Measures are established to provide for indoctrination and training of personnel to ensure suitable proficiency is achieved and maintained. Where specific qualifications are required by codes and standards, measures shall be taken to document the qualifications.

PROCEDURES

Work activities are performed in accordance with written procedures. Procedures shall contain the appropriate criteria for determining that prescribed activities have been satisfactorily accomplished.

DOCUMENT CONTROL

Procedures are established to ensure that appropriate documents are properly initiated, changed, and controlled to prevent use of incorrect or superseded documents.

DESIGN CONTROL

The design shall be defined, controlled, and verified. Applicable design inputs shall be appropriately specified on a timely basis and correctly translated into design documents. Design interfaces are identified and controlled. Design adequacy is verified by persons independent of those who performed the design. Design changes are governed by control measures commensurate with those applied to the original design. Design of systems, structures or components may be verified by the development and service testing of hardware similar to the equipment to be used in the facility. Installation and use of this type of equipment requires approval of LES management.

CONTROL OF PURCHASED ITEMS AND SERVICES

Measures are established to ensure conformance with the specified requirements. Measures are established to ensure suppliers of materials, equipment, or services are capable of supplying these items to the quality specified in the procurement documents. This may be done by evaluation and approval of the supplier's products and facilities or audits of the supplier's

quality program.

CONTROL OF PROCESSES, MEASURING AND TEST EQUIPMENT

Processes affecting quality of items or services are controlled. Special processes such as welding, heat treating, and nondestructive examination shall be performed by certified personnel using certified procedures in accordance with specified requirements. To maintain accuracy within specified limits, the LES QA Program requires that devices (e.g., tools, gauges, instruments), and measuring and test equipment including process-related instrumentation and controls that are used in activities affecting the quality of items, are properly controlled, calibrated, and adjusted at specified periods in accordance with written procedures.

INSPECTIONS

Inspections required to verify conformance of an item or activity to specified requirements are planned and executed. Characteristics to be inspected and inspection methods to be employed are specified. Inspection results are documented. Inspections for acceptance are performed by persons other than those who performed the work being inspected.

NONCONFORMANCES AND CORRECTIVE ACTION

Measures are established so conditions adverse to required quality are promptly identified and corrected. Controls are established to prevent inadvertent installation or use of items that do not conform to specified requirements.

RECORDS

Records that furnish documentary evidence of quality are specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. Records are protected against damage, deterioration, and loss. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition are established and documented.

AUDITS AND ASSESSMENTS

Measures are established to verify compliance with the LES QA Program and to determine its effectiveness. The results are documented and reported to and reviewed by responsible management. Follow-up action shall be taken where indicated.

FIGURES

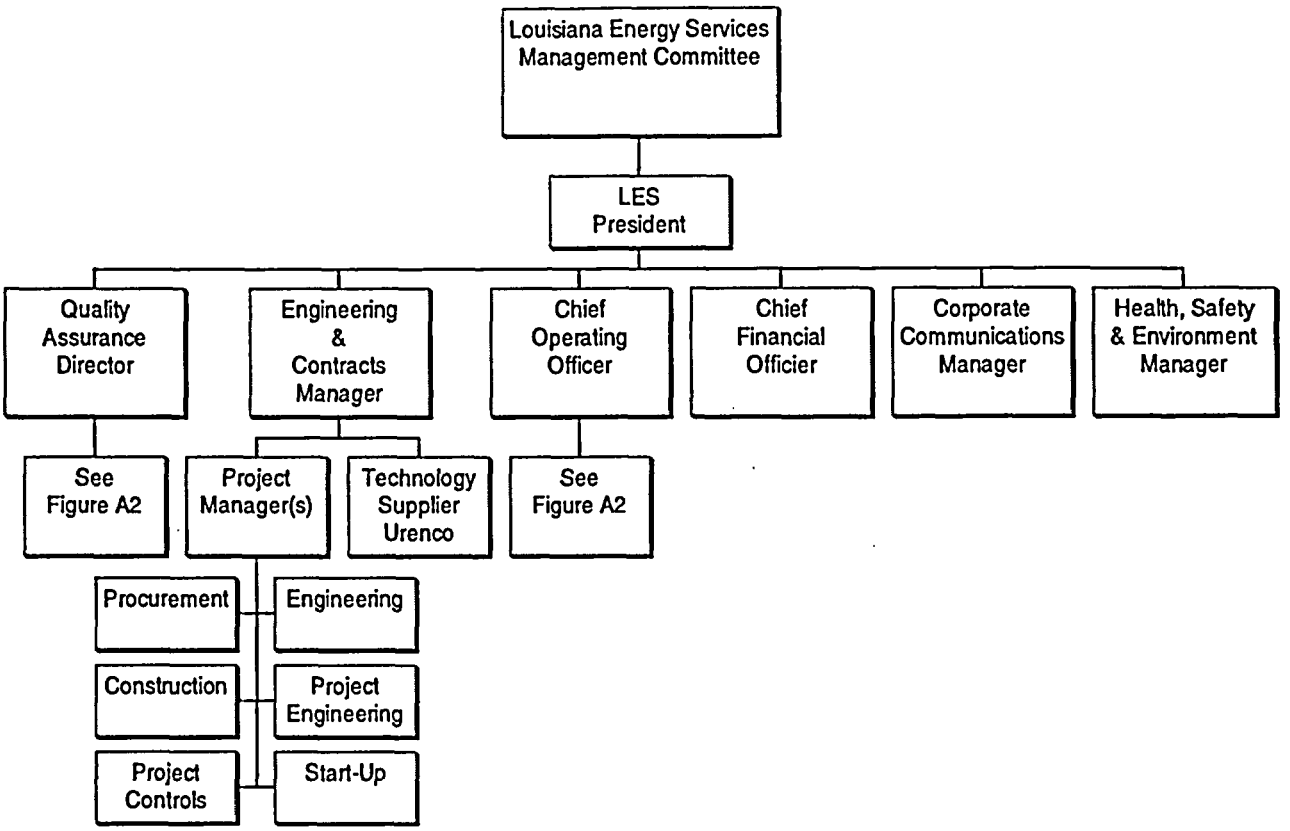

Figure A1 LES Corporate, Design and Construction Organization

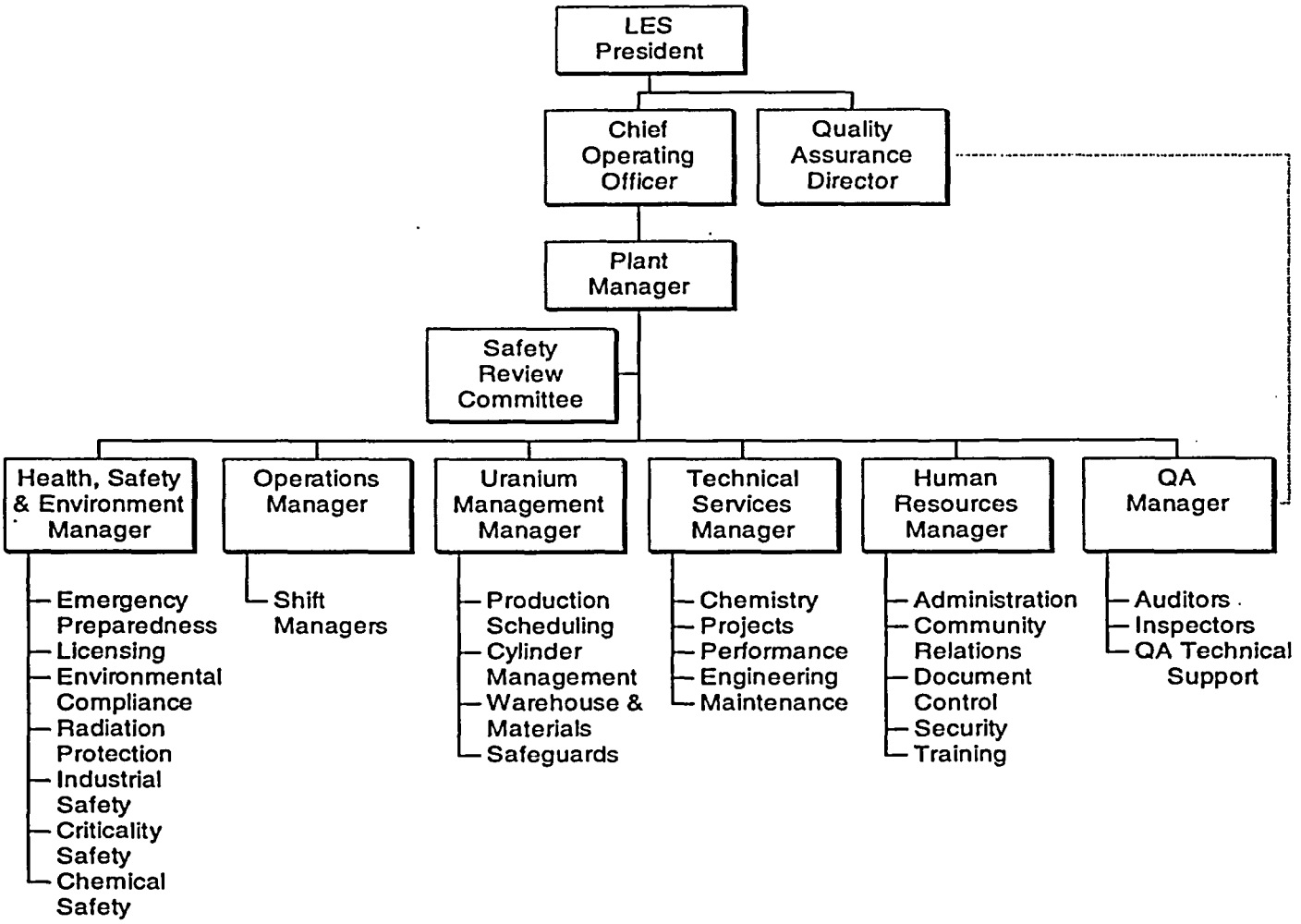

Figure A2 LES National Enrichment Facility Operating Organization