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U.S Nuclear Regulatory Commission
Document Control Desk
Office of Nuclear Material Safety and Safeguards
11555 Rockville Pike
Rockville, MD 20852

Louisiana Energy Services, LLC
National Enrichment Facility
NRC Docket No. 70-3103

Subject: RAI response on NEF License Amendment Request LAR-09-02,
Organizational Change affecting the Quality Assurance Program Description

Reference 1) National Enrichment Facility License Amendment Request LAR-09-02,
Organizational Change affecting the Quality Assurance Program
Description, January 23, 2008
2) Letter from NRC to LES, Louisiana Energy Services Request for
Additional Information on Quality Assurance Program Description
License Amendment Request, April 2, 2009

On January 23, 2008, LES submitted a License Amendment Request making organizational changes to the reporting structure of the Quality Assurance Department (Ref. 1). On April 2, 2009, LES received a Request for Additional Information (RAI) from the NRC. Attached as Enclosure 1 are our responses to the RAIs.

As a result of our responses changes to the markups submitted in reference 1 are necessary. Attached as Enclosure 2 are the marked up changes to the Quality Assurance Program Description and the Safety Analysis Report. Changes to the Fundamental Nuclear Material Control Plan, as submitted in reference 1, were not needed.

If you have any questions, please contact Stephen Cowne, Director of Quality and Regulatory Affairs at 575.394.5253.

Respectfully,

Jerome A. Reed for
Gregory OD Smith
Chief Operating Officer and Chief Nuclear Officer

Enclosures: 1) LES Responses to NRC RAI on the QA organizational
amendment
2) Marked up version of the Quality Assurance Program Description and
Safety Analysis Report

NM5501
2009

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Enclosure 1
LES Responses to NRC RAI on the QA organizational amendment

1. QAPD, Section 1, QA Organization and Functions. p. A5

The Louisiana Energy Services Quality Assurance Program Description (QAPD) amendment request shifts responsibilities from the Quality Assurance (QA) Manager to the Quality and Regulatory Affairs Director (QRAD). This responsibility shift should not include stop work authority. Revise the appropriate sections of the QAPD and organizational structure to ensure that the QA Manager has sufficient independence for all issues affecting quality, specifically stop work authority.

Under American Society of Mechanical Engineers (ASME) NQA-1 programs, the authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components need to be clearly delineated in writing. These activities include both performing functions of attaining quality objectives and the QA functions. The QA functions are those of: (1) assuring that an appropriate QA program is established and effectively executed; and (2) verifying, such as checking, auditing, and inspecting, that activities affecting the safety-related functions have been correctly performed. The persons and organizations performing QA functions need to have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and verify implementation of solutions. The persons and organizations performing QA functions need to report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations are provided.

LES Response: The QAPD and SAR organizational structure has been revised to ensure that the QA Manager has sufficient independence for all issues affecting quality and specifically for stop work authority. Enclosure 2 provides the revised mark ups.

2. SAR, Chapter 2, Figure 2.2-1, p. 2.5-2

Clarify in the organizational chart depicted in Figure 2.1-1, how lines of authority and organizational freedom are maintained between the QA Manager, QRAD, and the Chief Operating Officer and Chief Nuclear Officer.

Under ASME NQA-1, the QA functions are those of: (1) assuring that an appropriate QA program is established and effectively executed; and (2) verifying such as checking, auditing and inspecting, that activities affecting the safety-related functions have been correctly performed. The persons and organizations performing QA functions need to have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and verify implementation of solutions. The persons and organizations performing QA functions need to report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations are provided.

LES Response: The Chief Operating Officer and Chief Nuclear Officer is ultimately responsible for the design, construction, commissioning and operation of the facility. The Quality Manager is being provided a reporting relationship for specific stop work authority, as described in the response to RAI #1 above, in addition to a relationship with

the Chief Operating Officer and Chief Nuclear Officer for quality concerns with the Performance Assessment & Feedback organization. The Performance Assessment & Feedback organization is responsible for the corrective action program and reports to the same manager as the Quality Assurance organization. Providing a relationship to the Chief Operating Officer and Chief Nuclear Officer ensures the Quality Assurance Manager has sufficient independence for all issues affecting quality including the corrective action program.

3. QAPD, Section 1

Clarify the QA organizational responsibilities for “management” and “implementation” of the QA program. The organizational role and responsibilities described in various sections of the QAPD of the QRAD and QA Manager are unclear.

Under an ASME NQA-1 program, the authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components need to be clearly delineated in writing. These activities include both performing functions of attaining quality objectives and the QA functions. The QA functions are those of: (1) assuring that an appropriate QA program is established and effectively executed; and (2) verifying such as checking, auditing and inspecting, that activities affecting the safety-related functions have been correctly performed. The persons and organizations performing QA functions need to have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and verify implementation of solutions. The persons and organizations performing QA functions need to report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations are provided.

LES Response: As submitted, the QAPD stated that the Quality and Regulatory Affairs Director was responsible for the management of the Quality Assurance Program; the QAPD also stated that the Quality Assurance Manager was responsible for managing the Quality Assurance Program. The QAPD has been revised to show that the Quality Assurance Manager is responsible for managing the Quality Assurance Program. Enclosure 2 provides the revised mark ups.

4. SAR, Section 11.8, p. 11.8-2, and QAPD Section 1, pp. A-3 and A-11

QA Level 2 requirements identified in the SAR Section 11.8, on page 11.8.2, and in the QAPD on pages A3 and A-11 are inconsistent with QAPD Level 2 descriptions. Clarify the review and acceptance responsibilities of the QA Manager and Quality and Regulatory Affairs Director for QA Level 2 requirements.

Additionally, clarify the two review and approval processes for contractor QA programs and the Urenco QA program approved for design, manufacture, and delivery of centrifuges. Explain how QA functions ensure that sufficient authority and organizational freedom is maintained to identify quality problems; to initiate, recommend, or provide solutions; and verify implementation of solutions.

Under an ASME NQA-1 program, the authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems and components needs to be clearly delineated in writing. These activities include both performing functions of

attaining quality objectives and the QA functions. The QA functions are those of: (1) assuring that an appropriate QA program is established and effectively executed; and (2) verifying such as checking, auditing and inspecting, that activities affecting the safety-related functions have been correctly performed. The persons and organizations performing QA functions need to have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and verify implementation of solutions. The persons and organizations performing QA functions need to report to a management level, so that the required authority and organizational freedom, including sufficient independence, from cost and schedule, when opposed to safety considerations are provided.

LES Response: As submitted, the SAR stated that the Quality and Regulatory Affairs Director must review and accept QA Level 2 programs and the QAPD stated that the Quality Assurance Manager must review and accept QA Level 2 programs. This has been changed in the markups to clearly state that the Quality Assurance Manager is responsible for the review and acceptance of QL-2 programs. Enclosure 2 provides the revised mark ups.

Furthermore, Section 20 of the QAPD stated that an ISO 9000 series QA Program is acceptable as a QA Level 2 program and has been changed to be consistent with the statement made earlier in the QAPD that the program may be acceptable provided that it complies with the QAPD requirements.

For both Urenco and other contractor QA programs a determination would be made as to what are the appropriate management measures necessary to assure LES that there is reasonable assurance that the goods and services provided will be, and or perform, as expected. The reference to Urenco, in the case of QAPD, Section 1, is to provide a description of the scope of responsibilities in the construction and outfitting of the NEF. Urenco is divided into several daughter companies which provide different components and services. In such cases, individual company QA programs would be reviewed and determination of adequacy performed based upon the goods or services provided.

For Urenco, the Quality Assurance Group of the Enrichment Technology Company (ETC) provided oversight of all other divisions and vendors. The head of ETC QA reports directly to the president of Urenco. Additionally, a division of the Central Technology Group of Urenco called Technical Controlling (TC) acts as the client advocate in issues of design and manufacturing of "Black Box" items where the client is not allowed access. In such cases, TC acts on behalf of the client to ensure that license requirements, design and operating parameters are preserved. The head of Technical Controlling reports to the Chief Executive Officer of ETC and to the Client (LES). In all cases, the reporting lines of communication are sufficiently high authority to ensure that quality is preserved through independence and the organizational freedom to identify quality issues and that issues receive the proper attention to effect resolution.

Enclosure 2

Marked up pages of the Quality Assurance Program Description and
Safety Analysis Report



SAFETY ANALYSIS REPORT
LAR-09-02

2.1 ORGANIZATIONAL STRUCTURE

The LES organizational structure is described in the following sections. The organizational structure indicates the lines of communication and management control of activities associated with the design, construction, operation, and decommissioning of the facility.

2.1.1 Corporate Functions, Responsibilities, and Authorities

LES is a registered limited liability company formed solely to provide uranium enrichment services for commercial nuclear power plants. The LES company organization and management structure is described in Chapter 1, Section 1.2, Institutional Information.

LES has presented to Lea County, New Mexico a proposal to develop the NEF. Lea County would issue its Industrial Revenue Bond (National Enrichment Facility Project) Series 2004 in the maximum aggregate principal amount of \$1,800,000,000 to accomplish the acquisition, construction and installation of the project pursuant to the County Industrial Revenue Bond Act, Chapter 4, Article 59 NMSA 1978 Compilation, as amended. The Project is comprised of the land, buildings, and equipment.

Under the Act, Lea County is authorized to acquire industrial revenue projects to be located within Lea County but outside the boundaries of any incorporated municipality for the purpose of promoting industry and trade by inducing manufacturing, industrial and commercial enterprises to locate or expand in the State of New Mexico, and for promoting a sound and proper balance in the State of New Mexico between agriculture, commerce, and industry. Lea County will lease the project to LES, and LES will be responsible for the construction and operation of the facility. Upon expiration of the Bond after 30 years, LES will purchase the project.

The County has no power under the Act to operate the project as a business or otherwise or to use or acquire the project property for any purpose, except as lessor thereof under the terms of the lease.

In the exercise of any remedies provided in the lease, the County shall not take any action at law or in equity that could result in the Issuer obtaining possession of the project property or operating the project as a business or otherwise.

LES is responsible for the design, quality assurance, construction, operation, and decommissioning of the enrichment facility. The President of LES reports to the LES Board of Managers as described in Section 1.2.

The President receives policy direction from the LES Board of Managers. Reporting to the President is the Chief Operating Officer & Chief Nuclear Officer. The Vice President - Engineering, Vice President - Operations, Vice President - Construction and the Quality & Regulatory Affairs Director all report to the Chief Operating Officer & Chief Nuclear Officer. The Quality Assurance Director reports to the Quality & Regulatory Affairs Director for functional day to day activities and has a direct line of communication to the Chief Operating Officer & Chief Nuclear Officer ~~and the President for all quality related activities~~ stop work authority. The Health, Safety & Environment Manager and Programs Manager both report to the Plant Support Director which reports to the Vice President of Operations. The HS&E Manager and Programs Manager both have a direct line of communication to the Chief Operating Officer & Chief Nuclear Officer for all matters concerning safety during operations, design and construction.

2.2 KEY MANAGEMENT POSITIONS

This section describes the functional positions responsible for managing the operation of the facility. The facility is staffed at sufficient levels prior to operation to allow for training, procedure development, and other pre-operational activities.

The responsibilities, authorities and lines of communication for each key management position are provided in this section. Responsible managers have the authority to delegate tasks to other individuals; however, the responsible manager retains the ultimate responsibility and accountability for implementing the applicable requirements. Management responsibilities, supervisory responsibilities, and the criticality safety engineering staff responsibilities related to nuclear criticality safety are in accordance with ANSI/ANS-8.19, Administrative Practices for Nuclear Criticality Safety.

The LES Corporate Organization and lines of communication are shown in Figure 2.1-1.

2.2.1 Operating Organization

The functions and responsibilities of key facility management are described in the following paragraphs. Additional detailed responsibilities related to nuclear criticality safety for key management positions and remaining supervisory and criticality safety staff are in accordance with ANSI/ANS-8.19. Some position titles have been changed to better reflect the actual responsibilities of the position. Similarly, some operating functions have been assigned to different managers to better reflect the operating organization presently used at Urenco and U. S. nuclear facilities.

A. Chief Operating Officer & Chief Nuclear Officer

The Chief Operating Officer & Chief Nuclear Officer reports to the President and is a critical member of the leadership team for LES, with the ultimate responsibility for the design, construction, commissioning and operations of the facility. The Chief Operating Officer & Chief Nuclear Officer is ultimately responsible for completion and safe operation of the NEF by managing the overall project.

B. Vice President - Operations

The Vice President - Operations reports to the Chief Operating Officer & Chief Nuclear Officer and is responsible for ensuring the facility complies with all applicable regulatory requirements. The Vice President - Operations is the Plant Manager. The Plant Manager has direct responsibility for operation of the facility in a safe, reliable and efficient manner. The Plant Manager is responsible for proper selection of staff for all key positions including positions on the Safety Review Committee. The Plant Manager is responsible for the protection of the facility staff and the general public from radiation and chemical exposure and/or any other consequences of an accident at the facility and also bears the responsibility for compliance with the facility license.

C. Quality Assurance ~~Director~~Manager

The Quality Assurance ~~Director~~Manager reports to the Quality & Regulatory Affairs Director and has overall responsibility for ~~development, the~~ management and implementation of the LES QA Program.

2.2 Key Management Positions

The facility line managers and their staff who are responsible for performing quality-affecting work are responsible for ensuring implementation of and compliance with the QA Program. The QA Director-Manager position maintains an reporting relationship independence from other management positions at the facility. Since the QA Manger reports to the Quality & Regulatory Affairs Director whom is responsible for Performance Assessment and Feedback, the QA Manager has by having a direct line of communication to relationship with the Chief Operating Officer and Chief Nuclear Officer as well as the President for matters affecting quality for quality concerns with Performance Assessment and Feedback. This ensures the QA Director-Manager has access to any manager for sufficient independence for all issues affecting quality. In addition the QA Manager has a reporting relationship with the Chief Operating Officer and Chief Nuclear Officer for adequate stop work authority.

D. Health, Safety, and Environment Manager

The Health, Safety, and Environment (HS&E) Manager reports to the Plant Support Director and has the responsibility for assuring safety at the facility through activities including HS&E activities associated with nuclear criticality safety, industrial safety, chemical safety, environmental compliance, and environmental compliance. The HS&E Manager works with the other facility managers to ensure consistent interpretations of HS&E requirements, performs independent reviews, and supports facility and operations change control reviews.

This position has a line of communications to the Chief Operating Officer and Chief Nuclear Officer to ensure objective HS&E audit, review, and control activities are maintained. The HS&E Manager has the authority to shut down operations if they appear to be unsafe, and must consult with the Chief Operating Officer and Chief Nuclear Officer with respect to restart of shutdown operations after the deficiency, or unsatisfactory condition, has been resolved.

E. Operations Director

The Operations Director reports to the Plant Manager and has the responsibility for Shift Operations, Operations Support, Logistics Services, and Chemistry Services. This includes such activities as ensuring the correct and safe operation of UF₆ processes, proper handling of UF₆, and the identification and mitigation of any off normal operating conditions, UF₆ cylinder management (including transportation licensing), directing the scheduling of enrichment operations to ensure smooth production, ensuring proper material and equipment are available for the facility, developing and maintaining production schedules and procedures for enrichment services, ensuring that cylinders of uranium hexafluoride are received and routed correctly at the facility, all transportation licensing and plant and environmental analysis. In the event of the absence of the Plant Manager, the Operations Director may assume the responsibilities and authorities of the Plant Manager.

F. Technical Services Director

The Technical Services Director reports to the Plant Manager and is the NEF Design Authority during operations with responsibility for providing technical support to the facility during the operations phase. NEF Design Authority responsibilities include approving design standards and design criteria, preparing and reviewing the NEF Functional Specification, leading the development and resolution of key technical issues, approving changes to the NEF approved design, and establishing processes for design and configuration control. During the operations phase this also includes technical support for facility modifications (including administration of the configuration management system), design and systems engineering support for operations

2.2 Key Management Positions

and maintenance, facility management (facility maintenance, warehouse management, and outsourced maintenance supervision), and contamination control (decontamination and waste treatment). The Technical Services Director is also responsible for records management. In the event of the absence of the Plant Manager, the Technical Services Director may assume the responsibilities and authorities of the Plant Manager.

G. Plant Support Director

The Plant Support Director reports to the Plant Manager and has the responsibility for emergency planning, ensuring training is provided for facility employees as well as implementation of the Radiation Protection Program, Environmental Compliance Program and Criticality Safety Program. In doing so he is ensuring proper contamination control and nuclear criticality safety protection. The Plant Support Director is also responsible for the fire protection program, industrial safety, chemical safety and material accountability program. The Plant Support Director, in coordination with the Communications and Community Affairs Director, has the responsibility for providing information about the facility and LES to the public and media, including ensuring that the public and media receive accurate and up-to-date information during an abnormal event at the facility. In the event of the absence of the Plant Manager, the Plant Support Director may assume the responsibilities and authorities of the Plant Manager.

H. Commissioning & Plant Control Director

The Commissioning & Plant Control Director reports to the Plant Manager and has the responsibility for the implementation of major facility modifications and acceptance of the facility during commissioning. The Commissioning & Plant Control Director is also responsible for scheduling and project financial controls.

I. Performance Assessment and Feedback Manager

The Performance Assessment and Feedback Manager reports to the Quality & Regulatory Affairs Director and has the responsibility for organizational performance metrics, and implementing the Corrective Action Program (CAP), Nonconformance Process and Industry Experience Program.

J. Quality Assurance Inspectors

The Quality Assurance Inspectors report to the Quality Assurance ~~Director~~ Manager (via a designated supervisory position, if applicable) and have the responsibility for performing inspections related to the implementation of the LES QA Program.

K. Quality Assurance Auditors

The Quality Assurance Auditors report to the Quality Assurance ~~Director~~ Manager (via a designated supervisory position, if applicable) and have the responsibility for performing audits related to the implementation of the LES QA Program.

L. Quality Assurance Technical Support

The Quality Assurance Technical Support personnel report to the Quality Assurance ~~Director~~ Manager (via a designated supervisory position, if applicable) and have the responsibility for providing technical support related to the implementation of the LES QA Program.

2.2 Key Management Positions

DD. Information Services Manager

The Information Services Manager reports to the Facilities Manager and has the responsibility for adequately controlling documents at the facility.

EE. Training Manager

The Training Manager reports to the Plant Support Director and has the responsibility for conducting training and maintaining training records for personnel at the facility.

FF. Procurement Director

The Procurement Director reports to the Chief Financial Officer and has the responsibility for ensuring spare parts and other materials needed for operation of the facility are ordered, received, inspected and stored properly. For quality and technical matters the Procurement Director reports to the Chief Operating Officer & Chief Nuclear Officer.

GG. Deputy Director of Operations

The Deputy Director of Operations reports to the Director of Operations and assists the Director of Operations and has the responsibility for Shift Operations, Operations Support, Logistics Services, and Chemistry Services. This includes such activities as ensuring the correct and safe operation of UF₆ processes, proper handling of UF₆, and the identification and mitigation of any off normal operating conditions, UF₆ cylinder management (including transportation licensing), directing the scheduling of enrichment operations to ensure smooth production, ensuring proper material and equipment are available for the facility, developing and maintaining production schedules and procedures for enrichment services, ensuring that cylinders of uranium hexafluoride are received and routed correctly at the facility, all transportation licensing and plant and environmental analysis.

HH. Quality & Regulatory Affairs Director

The Quality and Regulatory Affairs Director reports to the Chief Operating Officer and Chief Nuclear Officer and has responsibility for the direction of Quality Assurance, Performance Assessment and Feedback (including the Corrective Action Program) and Licensing activities (including the Industry Experience Program). The Quality & Regulatory Affairs Director has overall responsibility for the development of the LES QA Program. The Quality and Regulatory Affairs Director has responsibility for coordinating facility activities to evaluate and assist the LES organizations in maintaining compliance with applicable Nuclear Regulatory Commission (NRC) requirements.

II. Facilities Manager

The Facilities Manager reports to the Technical Services Director and is responsible for adequately controlling documents at the facility.

2.2.2 Shift Crew Composition

The minimum operating shift crew consists of a Shift Manager (or Deputy Shift Manager in the absence of the Shift Manager), one Control Room operator, one Radiation Protection

2.2 Key Management Positions

2.2.4 Personnel Qualification Requirements

The minimum qualification requirements for the facility functions that are directly responsible for its safe operation shall be as outlined below consistent with NUREG-1520. This includes the facility manager (Plant Manager), Operations Manager, Shift Managers, and managers for various safety and environmental disciplines. The nuclear experience of each individual shall be determined to be acceptable by the ~~Plant Manager~~ Chief Operating Officer and Chief Nuclear Officer. "Responsible nuclear experience" for these positions shall include (a) responsibility for and contributions towards support of facility(s) in the nuclear fuel cycle (e.g., design, construction, operation, and/or decommissioning), and (b) experience with chemical materials and/or processes. Relevant work experience of at least five years, in addition to the minimum experience requirements specified in this section, may be substituted for educational Bachelor's degree requirements. The ~~Chief Operating Officer and Chief Nuclear Officer~~ Plant Manager may approve different experience requirements for key positions. Approval of different requirements shall be done in writing and only on a case-by-case basis.

The assignment of individuals to the Manager positions reporting directly to the Plant Manager, and to positions on the SRC, shall be approved by the Plant Manager. Assignments to all other staff positions shall be made within the normal administrative practices of the facility.

The actual qualifications of the individuals assigned to the key facility positions described in Section 2.2.1, Operating Organization will be maintained in the employee personnel files or other appropriate file at the facility. Development and maintenance of qualification records and training programs are the responsibility of the Training Manager.

A. Chief Operating Officer & Chief Nuclear Officer

The President of LES, based on the individual's experience, proven ability in management of large scale facilities, and overall leadership qualities, appoints the Chief Operating Officer & Chief Nuclear Officer.

This appointment by the President of LES reflects confidence in the individual's ability as an effective programs and business manager. The Chief Operating Officer & Chief Nuclear Officer shall have, as a minimum, a bachelor's degree (or equivalent) and at least ten years related experience and/or training, or twenty years of related experience.

B. Vice President - Operations

The Chief Operating Officer & Chief Nuclear Officer, based on the individual's experience, proven ability in management of large-scale facilities, proven knowledge of regulatory and QA requirements, and overall leadership qualities, appoints the Vice President - Operations.

The Vice President – Operations is the Plant Manager, who is the overall manager of the facility. The Plant Manager shall be knowledgeable of the enrichment process, enrichment process controls and ancillary processes, criticality safety control, chemical safety, industrial safety, and radiation protection program concepts as they apply to the overall safety of a nuclear facility. The Plant Manager shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and ten years of responsible nuclear experience.

2.2 Key Management Positions

C. Quality Assurance ~~Director~~Manager

The Quality Assurance ~~Director~~Manager shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and at least six years of responsible nuclear experience in the implementation of a quality assurance program. The QA ~~Director~~Manager shall have at least four years experience in a QA organization at a nuclear facility.

D. Health, Safety, and Environment Manager

The Health, Safety, and Environment (HS&E) Manager shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and at least five years of responsible nuclear experience in HS&E or related disciplines. The HS&E Manager shall also have at least one year of direct experience in the administration of nuclear criticality safety evaluations and analyses.

E. Operations Director

The Operations Director shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and four years of responsible nuclear experience.

F. Shift Operations Manager

The Shift Operations Manager shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and four years of responsible nuclear experience.

G. Technical Services Director

The Technical Services Director shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and four years of responsible nuclear experience.

H. Plant Support Director

The Plant Support Director shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and four years of responsible nuclear experience.

I. Emergency Preparedness Manager

The Emergency Preparedness Manager shall have a bachelor's degree (or equivalent) and a minimum of six years of experience in the implementation and supervision of emergency plans and procedures, at least three of which must be at a nuclear facility. No credit for academic training may be taken toward fulfilling this experience requirement.

J. Programs Manager

The Programs Manager shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and at least five years of responsible nuclear experience in HS&E, nuclear safety or related disciplines.

2.2 Key Management Positions

Y. Fire Protection Officer

The Fire Protection Officer shall have bachelor's degree (or equivalent) and shall be trained in the field of fire protection and have practical day-to-day experience at nuclear facilities.

Z. Information Services Manager

The Information Services Manager shall have a minimum of three years of appropriate, responsible experience in implementing and supervising a document control program.

AA. Performance Assessment and Feedback Manager

The Performance Assessment and Feedback Manager shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and four years of responsible nuclear experience.

BB. Procurement Director

The Procurement Director shall have, as a minimum, a bachelor's degree (or equivalent) and have a minimum of three years of appropriate, responsible experience in implementing and supervising a procurement program.

CC. Deputy Director of Operations

The Deputy Director of Operations shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and four years of responsible nuclear experience.

DD. Quality & Regulatory Affairs Director

The Quality & Regulatory Affairs Director shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and have a minimum of six years of appropriate, responsible nuclear experience of which at least four years are in a Quality and Regulatory Affairs organization.

EE. Facilities Manager

The Facilities Manager shall have a minimum of four years of appropriate, responsible experience.

2.3 Administration

2.3.5.3 Facility Operating Organization

The facility operating organization shall provide, as part of the normal duties of supervisory personnel, timely and continuing monitoring of operating activities to assist the Plant Manager in keeping abreast of general facility conditions and to verify that the day-to-day operating activities are conducted safely and in accordance with applicable administrative controls.

These continuing monitoring activities are considered to be an integral part of the routine supervisory function and are important to the safety of the facility operation.

2.3.5.4 Audited Organizations

Audited organizations shall assure that deficiencies identified are corrected in a timely manner.

Audited organizations shall transmit a response to each audit report within the time period specified in the audit. For each identified deficiency, the response shall identify the corrective action taken or to be taken. For each identified deficiency, the response shall also address whether or not the deficiency is considered to be indicative of other problems (e.g., a specific audit finding may indicate a generic problem) and the corrective action taken or to be taken for any such problems determined.

Copies of audit reports and responses are maintained in accordance with the records management system.

2.3.6 Incident Investigations

The Corrective Action Program (CAP) is described in detail in Section 11.6. Each event is considered in terms of its requirements for reporting in accordance with regulations and is evaluated to determine the level of investigation required. These evaluations and investigations are conducted in accordance with approved CAP procedures. The depth of the investigation depends upon the severity of the incident in terms of the levels of uranium released and/or the degree of potential for exposure of workers, the public or the environment.

2.3.7 Employee Concerns

Employees who feel that safety or quality is being compromised have the right and responsibility to initiate the "stop work" process in accordance with the applicable project or facility procedures to ensure the work environment is placed in a safe condition.

Employees also have access to various resources to ensure their safety or quality concerns are addressed, including:

- line management or other facility management (e.g., Performance Assessment and Feedback Management, Plant Manager, HS&E Manager, Programs Manager, QA-Quality and Regulatory Affairs Director)
- the facility safety organization (i.e., any of the safety engineers or managers)
- NRC's requirements under 10 CFR 19, Notices, Instructions and Reports to Workers: Inspection and Investigations (CFR, 2003a)

2.3 Administration

- LES CAP - a simple mechanism available for use by any person at the NEF site for reporting unusual events and potentially unsafe conditions or activities.

2.3.8 Records Management

Procedures are established which control the preparation and issuance of documents such as manuals, instructions, drawings, procedures, specifications, and supplier-supplied documents, including any changes thereto. Measures are established to ensure documents, including revisions, are adequately reviewed, approved, and released for use by authorized personnel.

Document control procedures require documents to be transmitted and received in a timely manner at appropriate locations including the location where the prescribed activity is to be performed. Controlled copies of these documents and their revisions are distributed to and used by the persons performing the activity.

Superseded documents are destroyed or are retained only when they have been properly labeled. Indexes of current documents are maintained and controlled.

The QA Program assigns responsibility for verifying QA record retention to the QA ~~Director~~ Manager. Applicable design specifications, procurement documents, or other documents specify the QA records to be generated by, supplied to, or held, in accordance with approved procedures. QA records are not considered valid until they are authenticated and dated by authorized personnel.

Additional details on the records management program are provided in Chapter 11, Management Measures.

2.3.9 Written Agreements with Offsite Emergency Resources

The plans for coping with emergencies at the facility are presented in detail in the Emergency Plan. The Emergency Plan includes a description of the facility emergency response organization and interfaces with off-site EROs. Written agreements between the facility and off-site EROs, including the local fire department, the local law enforcement agency, ambulance/rescue units, and medical services and facilities have been established.

Coordination with participating government agencies (State, Counties) is vital to the safety and health of plant personnel and the general public. The principal state and local agencies/organizations having responsibilities for radiological or other hazardous material emergencies for the facility are:

- A. New Mexico Department of Public Safety, Office of Emergency Management
- B. Eunice Emergency Response Services
- C. Hobbs Emergency Response Services

Details of the interfaces with these agencies are provided in Section 4 of the Emergency Plan.

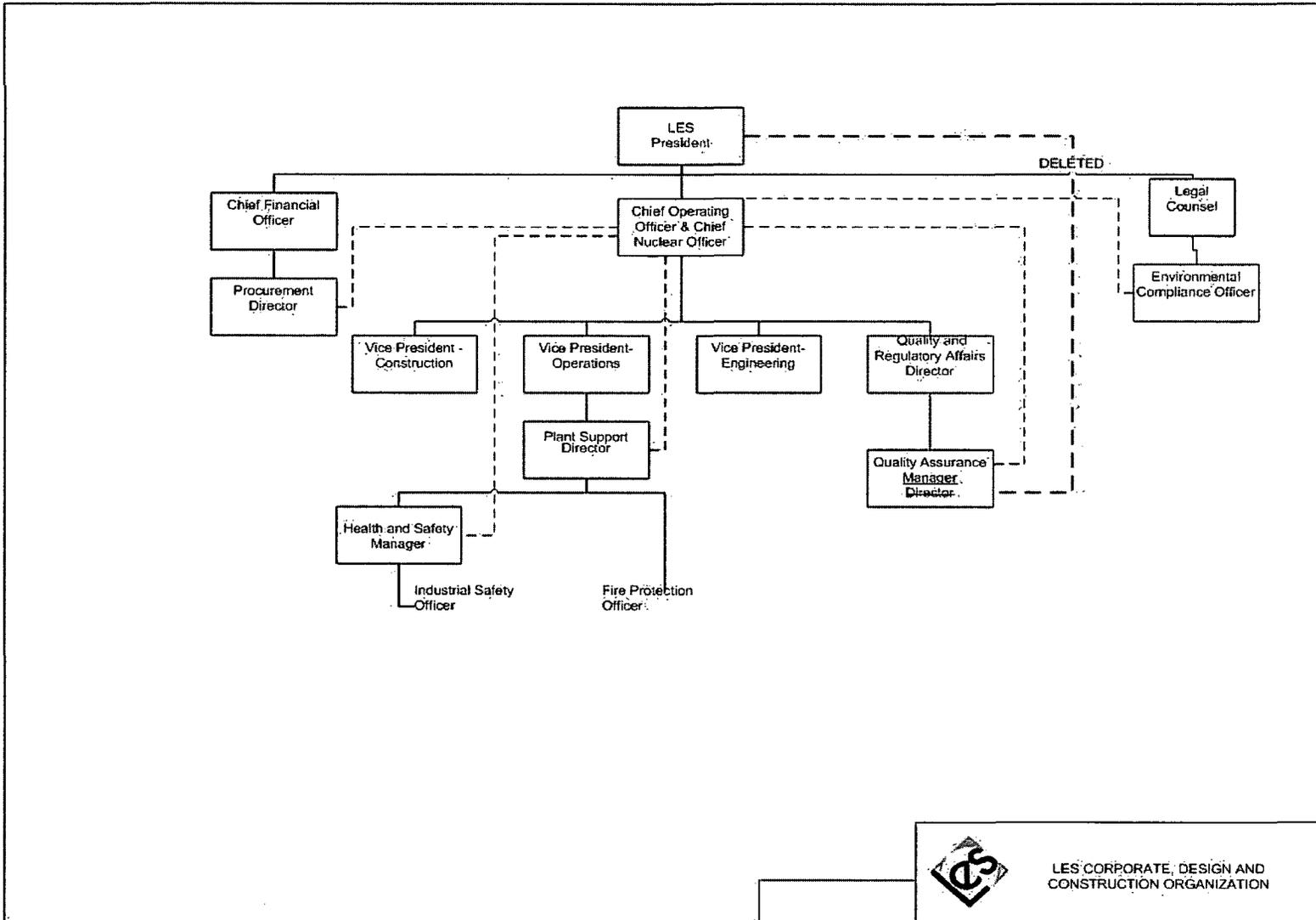


Figure 2.1-1 LES Corporate, Design and Construction Organization

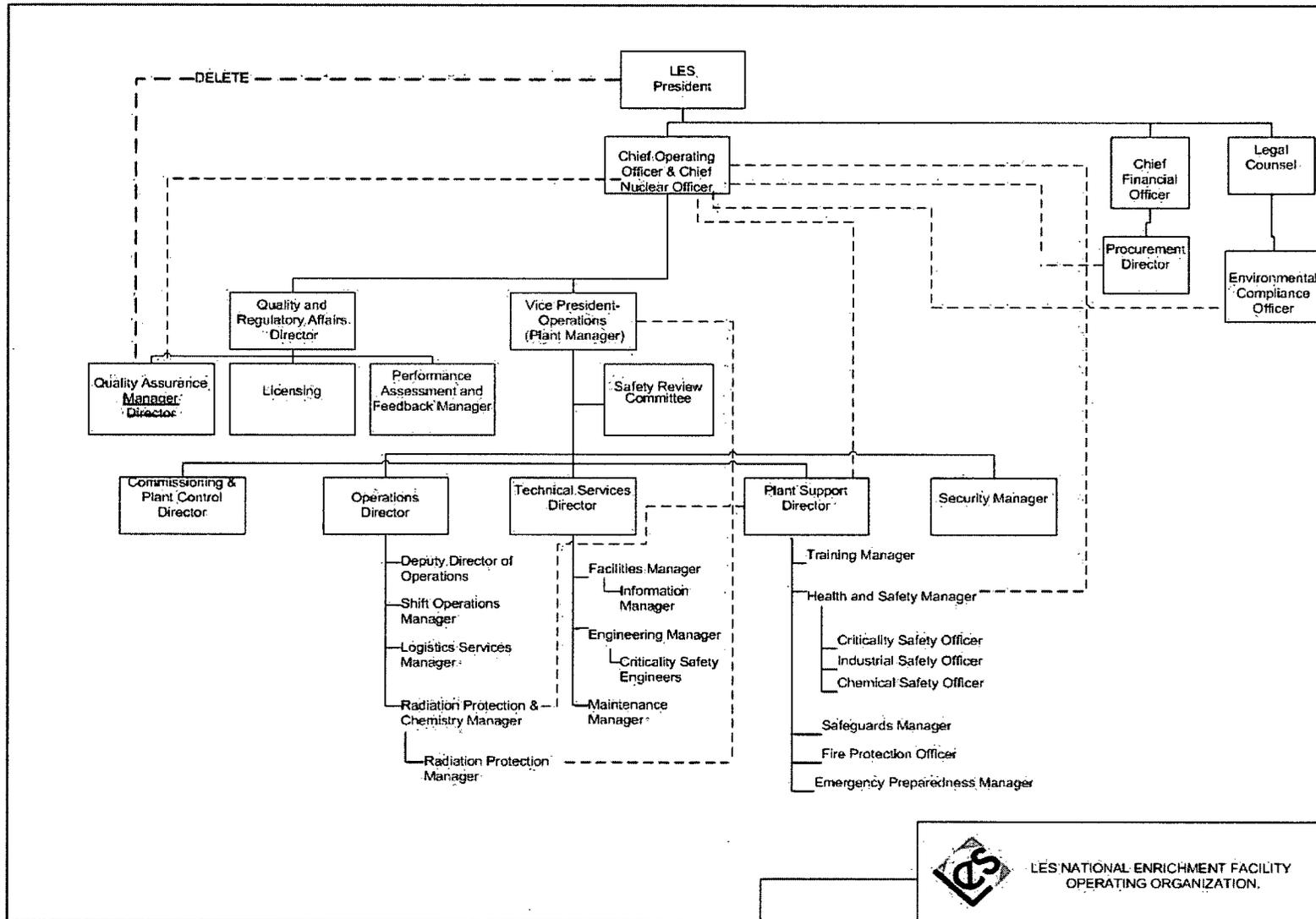


Figure 2.1-2 LES National Enrichment Facility Operating Organization

11.1 CONFIGURATION MANAGEMENT (CM)

This section describes the configuration management program for the NEF. Configuration management for the NEF is implemented through requirements of the QA Program and associated procedures.

The ~~LES President~~ Chief Operating Officer and Chief Nuclear Officer is the executive responsible for quality assurance and is the highest level of management responsible for LES's QA policies, goals, and objectives. The ~~LES Board of Managers~~ Chief Operating Officer and Chief Nuclear Officer receives policy direction from the ~~LES Board of Managers~~ President. The LES organization during the design, construction and operation phases, including QA, is presented in Chapter 2, Organization and Administration.

11.1.1 Configuration Management Policy

Configuration management is provided throughout facility design, construction, testing, and operation. Configuration management provides the means to establish and maintain a technical baseline for the facility based on clearly defined requirements. During design and construction, the Vice President - Engineering has responsibility for configuration management through engineering established design control process. Selected documentation, including the integrated safety analysis (ISA), is controlled under the configuration management system in accordance with procedures associated with design control, document control, and records management. Design changes undergo formal review, including interdisciplinary reviews as appropriate, in accordance with these procedures. This interdisciplinary review includes as a minimum the review for ISA impacts.

Configuration management provides the means to establish and maintain the essential features of the design basis of IROFS, including the ISA. As the project progresses from design and construction to operation, configuration management is maintained by the Engineering organization as the overall focus of activities changes. Procedures will define the turnover process and responsibilities since construction will continue on new work modules during operations.

During the design phase of the project, configuration management is based on the design control provisions and associated procedural controls over design documents to establish and maintain the technical baseline. Design documents, including the ISA, that provide design input, design analysis, or design results specifically for IROFS are identified with the appropriate QA level. These design documents undergo interdisciplinary review during the initial issue and during each subsequent revision. During the construction phase of the project, changes to drawings and specifications issued for construction, procurement, or fabrication are systematically reviewed and verified, evaluated for impact, including impact to the ISA, and approved prior to implementation. Proper implementation is verified and reflected in the design basis documentation.

11.1 Configuration Management (CM)

The design bases are documented in the Functional Specification and Licensing Bases Documents. The NEF is designed and built to the NEF Licensing Code of Record identified in the Integrated Safety Analysis Summary.

Design requirements are derived from the design bases identified above. Design requirements are documented in design requirement documents i.e. calculations, safety analysis, design criteria, engineering drawings, system descriptions, technical documents, and specifications. The design requirements and basis of design documents are controlled under the design control provisions of the configuration management program as described above and are subject to the same change control as analysis, specifications, and drawings.

IROFS, any items that affect the function of the IROFS, and, in general, items required to satisfy regulatory requirements are designated as QA Level 1. The associated design documents are subject to interdisciplinary reviews and design verification. Analyses constituting the integrated safety analysis of the design bases are subject to the same requirements. Changes to the design are evaluated to ensure consistency with the design bases. Computer codes used in the design of IROFS are also subject to these design control measures, with additional requirements as appropriate for software control, verification, and validation.

IROFS are listed in the Integrated Safety Analysis Summary. This list will be augmented and maintained current as appropriate as IROFS are identified in more detail during detailed design.

A qualified individual who specifies and includes the appropriate codes, standards, and licensing commitments within the design documents prepares each design document, such as a calculation, specification, procedure, or drawing. This individual also notes any deviations or changes from such standards within the design documentation package. Each design document is then checked by another individual qualified in the same discipline and is reviewed for concept and conformity with the design inputs. These design inputs are in sufficient detail to permit verification of the document. The manager having overall responsibility for the design function approves the document. The Engineering Manager documents the entire review process in accordance with approved procedures. These procedures include provisions to assure that appropriate quality standards are specified in design documents, including quantitative or qualitative acceptance criteria. The QA ~~Director~~ Manager conducts audits on the design control process using independent technically qualified individuals to augment the QA audit team.

During the check and review, emphasis is placed on assuring conformance with applicable codes, standards and license application design commitments. The individuals in engineering assigned to perform the check and review of a document have full and independent authority to withhold approval until questions concerning the work have been resolved. Design reviews, alternative calculations, or qualification testing accomplishes verification of design. The bases for a design, such as analytical models, theories, examples, tables, codes and computer programs must be referenced in the design document and their application verified during check and review. Model tests, when required to prove the adequacy of a concept or a design, are reviewed and approved by the responsible qualified individual. Testing used for design verification shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. The tests used for design verification must meet all the design requirements.

Qualified individuals other than those who performed the design but may be from the same organization perform design verification. Verification may be performed by the supervisor of the

11.1 Configuration Management (CM)

individual performing the design, provided this need is documented, approved in advance by the supervisor's management, and the 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, provided the supervisor is the only individual in the organization competent to perform the verification. The verification by a supervisor of their own design constraints, design input, or design work would only occur in rare instances. This would occur only when the supervisor is the only individual in the organization competent to perform the verification. These instances are authorized and documented in writing on a case-by-case basis.

Independent design verification shall be accomplished before the design document (or information contained therein) is used by other organizations for design work or to support other activities such as procurement, construction, or installation. When this is not practical due to time constraints, the unverified portion of the document is identified and controlled. In all cases, the design verification shall be completed before relying on the item to perform its function or installation becomes irreversible. Any changes to the design and procurement documents, including field changes, must be reviewed, checked and approved commensurate with the original approval requirements.

After design documents have been properly prepared, checked, reviewed, and approved by the appropriate parties, the responsible engineer sends the document to document control for distribution. When required, each recipient of a design document verifies receipt of such document to the document control center.

The document control center, after verification of distribution to a recipient, maintains the required documentation in its files.

When deficiencies are identified which affect the design of IROFS, such deficiencies are documented and resolved in accordance with approved CAP procedures. In accordance with the CAP the report is forwarded for appropriate review to the responsible manager, who coordinates further review of the problem and revises all design documents affected by the deficiency as necessary. Where required, the responsible manager forwards the report to the engineers in other areas, who coordinate necessary revisions to their affected documents

Design interfaces are maintained by communication among the principals. Methods by which this is accomplished include the following:

- A. Design documents are reviewed by the responsible engineer or authorized representative. As appropriate, subsequent review or waiver of review by the other area engineers is documented.
- B. Project review meetings are scheduled and held to coordinate design, procurement, construction and pre-operational testing of the facility. These meetings provide a primary working interface among the principal organizations.
- C. Reports of nonconformances are transmitted and controlled by procedures. As required by the nonconformance procedure, the QA ~~Director~~ Manager or designee approves resolution of nonconformances.

During the operational phase, measures are provided to ensure responsible facility personnel are made aware of design changes and modifications that may affect the performance of their duties.

Corrective actions following issuance of the audit and/or assessment report require compliance with the CAP procedure. Audit reports are required to contain an effectiveness evaluation and statement for each of the applicable QA program elements reviewed during the audit. The audit/assessment is closed with the proper documentation as required by the applicable audit and assessment procedure. The QA organization will conduct follow-up audits or assessments to verify that corrective actions were taken in a timely manner. In addition, future assessments will include a review to evaluate if corrective actions have been effective.

11.5.4 Qualifications and Responsibilities for Audits and Assessments

The QA ~~Director~~ Manager initiates audits. The responsible Lead Auditor and QA ~~Director~~ Manager determine the scope of each audit. The QA ~~Director~~ Manager may initiate special audits or expand the scope of audits. The Lead Auditor directs the audit team in developing checklists, instructions, or plans and performing the audit. The audit shall be conducted in accordance with the checklists, but the scope may be expanded by the audit team during the audit. The audit team consists of one or more auditors.

Auditors and lead auditors are responsible for performing audits in accordance with the applicable QA procedures. Auditors and lead auditors hold certifications as required by the QA Program. Additional details can be found in Appendix A of this chapter. Before being certified under the LES QA Program, auditors must complete training on the following topics:

- LES QA Program
- Audit fundamentals, including audit scheduling, planning, performance, reporting, and follow-up action involved in conducting audits
- Objectives and techniques of performing audits
- On-the-job training.

Certification of auditors and lead auditors is based on the QA ~~Director's~~ Manager's evaluation of education, experience, professional qualifications, leadership, sound judgment, maturity, analytical ability, tenacity, and past performance and completion of QA training courses. A lead auditor must also have participated in a minimum of five QA audits or audit equivalent within a period of time not to exceed three years prior to the date of certification. Audit equivalents include assessments, pre-award evaluations or comprehensive surveillances (provided the prospective lead auditor took part in the planning, checklist development, performance, and reporting of the audit equivalent activities). One audit must be a nuclear-related QA audit or audit equivalent within the year prior to certification.

Personnel performing assessments do not require certification, but they are required to complete QA orientation training, as well as training on the assessment process. The nuclear criticality safety assessments are performed under the direction of the criticality safety staff. Personnel performing these assessments do not report to the production organization and have no direct responsibility for the function or area being assessed.

Appendix A, Section 18 "Audits" of this chapter provides additional details regarding the QA Audit program requirements.

11.6 Incident Investigations and Corrective Action Process

the ISA Summary will be modified to include evaluation of the risk associated with accidents of the type actually experienced.

LES will develop CAP procedures for conducting an incident investigation, and the procedures will contain the following elements:

1. A documented plan for investigating an abnormal event.
2. A description of the functions, qualifications, and/or responsibilities of the manager who would lead the investigative team and those of the other team members; the scope of the team's authority and responsibilities; and assurance of cooperation of management.
3. Assurance of the team's authority to obtain all the information considered necessary and its independence from responsibility for or to the functional area involved in the incident under investigation.
4. Retention of documentation relating to abnormal events for two years or for the life of the operation, whichever is longer.
5. Guidance for personnel conducting the investigation on how to apply a reasonable, systematic, structured approach to determine the specific or generic root cause(s) and generic implications of the problem.
6. Requirements to make available original investigation reports to the NRC on request.
7. A system for monitoring the completion of appropriate corrective actions.

11.6.2 Corrective Action Process

The LES QA Program identifies the responsibilities and provides authority for those individuals involved in quality activities to identify any condition adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective materials and equipment, and non-conformances. These individuals identify and document conditions adverse to quality, analyze and determine how the conditions can be corrected or resolved, and take such steps as necessary to implement corrective actions in accordance with documented procedures.

The QA Program requires regularly scheduled audits and assessments to ensure that needed corrective actions are identified. LES employees have the authority and responsibility to initiate the corrective action process if they discover deficiencies. The QA Program contains procedures for identifying, reporting, resolving, documenting, and analyzing conditions adverse to quality. Reports of conditions adverse to quality are analyzed to identify trends in quality performance. Significant conditions adverse to quality and significant trends are reported to senior management in accordance with CAP procedures.

Follow-up action is taken by the QA ~~Director~~ Manager to verify proper and timely implementation of corrective action.

Significant conditions adverse to quality, the cause of the conditions and the corrective action taken to preclude repetition are documented and reported to management for review and assessment in accordance with CAP procedures.

Appendix A, Section 16 "Corrective Action" of this chapter provides additional details regarding the CAP requirements.

11.8 OTHER QA ELEMENTS

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

The QA-Quality and Regulatory Affairs Director is responsible for developing and revising the QA Program and assuring it is in compliance with applicable regulations, codes and standards.

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

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

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

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

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

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

11.8 Other QA Elements

The Chief Operating Officer and Chief Nuclear Officer~~LES President~~ assesses the scope, status, adequacy and regulatory compliance of the QA Program through regular meetings and correspondence with the Plant Manager and the LES QA organization. Additionally, LES QA, through the QA Quality and Regulatory Affairs Director, periodically informs the LES Chief Operating Officer and Chief Nuclear Officer~~President~~ and Plant Manager of quality concerns that need management resolution.

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

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

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

QA Level 1 Requirements

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

QA Level 2 Requirements

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

QA Level 3 Requirements

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

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



**SAFETY ANALYSIS REPORT
APPENDIX A**

**QUALITY ASSURANCE
PROGRAM DESCRIPTION**

LAR-09-02

The QA program is established at the very earliest aspects of the project. It is comprised of three levels 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, items that affect the functions of the IROFS, and to items required to satisfy regulatory requirements for which QA Level 1 requirements are applied.

QA LEVEL 2 REQUIREMENTS

The QA Level 2 program is an owner defined QA program that uses the ASME NQA 1 standard as guidance to identify and manage SSCs and activities that do not meet the requirements for inclusion in the QA Level 1 program, but have attributes or characteristics that warrant control under a quality program more detailed than the QA Level 3 program. General QA Level 2 requirements are described in Section 20, Quality Assurance Program for QA Level 2. 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 contractor's QAPD is reviewed and accepted by the LES QA ~~Director~~Manager.

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 change to the LES QA Program shall be incorporated in this QAPD. Any change that reduce the commitments in the approved QAPD will be submitted to the Nuclear Regulatory Commission (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 the establishment of the QA program at the very earliest aspects of the project 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 liability company 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 Board of Manager as described in Section 1.2 of the SAR. The Chief Operating Officer and Chief Nuclear Officer reports to the President and is responsible for all design, construction and the operation of the facility. The LES President, Chief Operating Officer and Chief Nuclear Officer 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 Quality and Regulatory Affairs Director has overall responsibility for development, and management and implementation of the LES QA Program during all phases of the enrichment facility. The Quality Assurance Manager is responsible for the implementation and management of the LES QA Program. As part of this responsibility, the QA Director Manager 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.

DESIGN AND CONSTRUCTION ORGANIZATION AND FUNCTIONS

LES has contracted Urenco, the owner of the enrichment technology and operator of enrichment facilities in Europe, to prepare the reference design for the facility. An architect/engineering (A/E) firm was contracted and is under the responsibility of the Vice President - Engineering, Chief Operating Officer and Chief Nuclear Officer, 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 contractor specializing in site evaluations was contracted to perform the site selection evaluation. A nuclear consulting company was contracted 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 Chief Operating Officer and Chief Nuclear Officer is responsible for managing the associated activities as described in

Section 2.1.2, *Design and Construction Organization*, of the SAR. Figure 2.1-1 of the SAR, shows that the Chief Operating Officer and Chief Nuclear Officer is assisted by the Vice President of Construction who is responsible for managing the construction work and contracts, the Vice President – Engineering who is responsible for design and engineering related construction issues, the Commissioning and Plant Control Director who is responsible for scheduling and project financial controls and the Procurement Director who is responsible for coordinating procurements using qualified contractors or LES Operations personnel to support project construction needs. Contractor QA Programs will be reviewed by the LES QA organization and must be approved by the LES QA ~~Director~~ Manager 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~~ Manager 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.

QA Procedures will be developed by the Vice President - Engineering, Vice President - Construction, Commissioning and Plant Control Director and the Procurement Director organizations to implement this QAPD in the project management area.

OPERATING ORGANIZATION AND FUNCTIONS

- The operating organization is shown in Figure 2.1-2 of the SAR, LES National Enrichment Facility Operating Organization. The Plant Manager is responsible for ensuring the facility complies with all applicable regulatory requirements including the requirements of this QAPD. Section 2.1.3, *Operating Organization*, of the SAR describes the reporting chain, responsibilities and activities directed by the Plant Manager.

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 National Enrichment Facility (NEF) Safety Analysis Report.

QA ORGANIZATION AND FUNCTIONS

The LES QA organization during the design, construction, operations, and decommissioning phases will be headed by the LES QA ~~Director~~ Manager. The LES QA ~~Director~~ Manager reports to the Quality & Regulatory Affairs Director, ~~for day to day activities but has a direct line of communications with the LES President and~~ The QA Manager is specifically provided stop work authority at the Chief Operating Officer & Chief Nuclear Officer level for Quality Assurance issues. for the ability to stop work. With this line of communication to the Chief Operating Officer and Chief Nuclear Officer and the President, the QA Director has the authority, access to work areas, and organizational independence to ensure that the requirements of this QAPD are properly implemented. As described in Chapter 2 of the SAR, the ~~President and Chief Operating Officer & Chief Nuclear Officer are~~ is responsible for construction, design and operations activities and are thus a high enough level to authorize a stop work. In addition, the Chief Operating Officer and Chief Nuclear Officer is responsible for all procurement quality and technical functions. Since the QA Manager reports to the Quality and Regulatory Affairs Director whom is responsible for Performance Assessment and Feedback, The QA Manager has a direct relationship with the Chief Operating Officer and Chief Nuclear Officer for quality concerns with Performance Assessment and Feedback. This ensures the QA Manager has sufficient independence for all issues affecting quality.

Section 1 Organization

The LES QA ~~Director~~Manager 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, items that could affect the functions of IROFS, and items required to satisfy regulatory requirements for which QA Level 1 requirements are applied
 - Oversight of 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

The following additional QA ~~Director~~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

Section 1 Organization

- Review and concurrence of changes to the identified IROFS, items that could affect the functions of IROFS, and items required to satisfy regulatory requirements for which QA Level 1 requirements are applied
- 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 at the Chief Operating Officer and Chief Nuclear Officer level.

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~~ Quality and Regulatory Affairs Director. If satisfactory resolution cannot be obtained at that level, the matter is then elevated to the ~~President and/or~~ Chief Operating Officer & Chief Nuclear Officer 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 provides a mechanism by which activities may be controlled until the deficiency, or unsatisfactory condition, has been resolved. Worker responsibilities are further discussed in Section 16, Corrective Action.

Section 2 Quality Assurance Program

evaluation may also include nuclear industry precedent in the application of augmented QA requirements. The QA Level 2 SSCs which support normal operations shall be identified in applicable QA procedures and implementing documents and documents specifying quality requirements or prescribing activities affecting quality.

The QA program is established at the very earliest aspects of the project. It is comprised of three levels defined as follow:

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, items that affect the functions of the IROFS, and to items required to satisfy regulatory requirements for which QA Level 1 requirements are applied.

QA LEVEL 2 REQUIREMENTS

The QA Level 2 program is an LES defined QA program that uses the ASME NQA 1 standard as guidance to identify and manage activities that do not meet the requirements for inclusion in the QA Level 1 program, but have attributes or characteristics that warrant control under a quality program more detailed than the QA Level 3 program. General QA Level 2 requirements are described in Section 20, Quality Assurance Program for QA Level 2. For contractors, the QA Level 2 program shall be applied to LES 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 contractor's QAPD is reviewed and accepted by the LES QA ~~Director~~ Manager. The QA Level 2 SSCs which support normal operations shall be identified in applicable QA procedures and implementing documents and documents specifying quality requirements or prescribing activities affecting quality.

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. LES

will also include a version of QA Indoctrination Training as part of the general employee training given to all full-time employees.

The Training Manager is responsible for coordinating QA training activities for LES. Support Services 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 and~~ Chief Operating Officer & Chief Nuclear Officer ~~are~~ is responsible for ensuring that management assessments are conducted annually to determine if the LES QA Program is effective. Recommendations are provided to the Chief Operating Officer & Chief Nuclear Officer ~~and LES President~~ for action. Functional Managers and the QA ~~Director~~ Manager conduct assessments annually of QA activities under their control. The managers report the results to the Chief Operating Officer & Chief Nuclear Officer ~~and 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 LES procedures that meet the requirements of 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 LES procedures that meet the requirements of 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 LES procedures that meet the requirements of NQA-1a-1995 Part 1 Supplement 2S-3 Supplemental Requirements for the Qualification of Quality Assurance Program Audit Personnel.

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~~ Chief Operating Officer and Chief Nuclear Officer and QA ~~Director-Manager~~ 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 Noncompliance, 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. LES will also apply the requirements of 10 CFR 21 where appropriate, regardless of QA level.

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:
 - Design bases, identified or referenced in the procurement documents.
 - 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.
 - 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:
 - 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.
 - 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/Manager authorization. The Procurement Director may also establish hold points indicating work that cannot proceed without authorization by the Procurement Director.
- 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 Section 4, 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 Procurement 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, as applicable. Those procedures that delineate the responsibilities and functions of the QA organization, the QA procedures, are approved by the LES QA ~~Director~~ Manager to ensure compliance with QAPD. During construction and operations, the LES FAMs have responsibility to review and approve the procedures that cover activities under their organizational purview. Approved procedures will be subject to QA audits and surveillance.

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

- 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 Procurement 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~~Manager or Procurement Director, 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~~Manager before the supplier starts work.

SUPPLIER PERFORMANCE EVALUATION

The LES Procurement Director in coordination with the QA Director~~Manager~~ 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.

The LES Procurement organization shall ensure disposition of the supplier's recommendation and shall ensure verification of the 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~~ Manager 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.

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 Procurement Director in coordination with the QA ~~Director~~ Manager 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 assure that test requirements have been satisfied.

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~~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~~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 be 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~~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~~ 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.

Section 18 Audits

- 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~~Manager in writing of the actions taken or scheduled, according to the requirements of Section 16 Corrective Action.

EVALUATING AUDIT RESPONSES

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

FOLLOW-UP ACTION

Follow-up action shall be taken by the LES QA ~~Director~~Manager 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~~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 20 QUALITY ASSURANCE PROGRAM FOR QA LEVEL 2

This section outlines LES defined Quality Assurance Program for QA Level 2 requirements. For contractors, the QA Level 2 program shall be described in documents that must be approved by LES.

An International Organization for Standardization (ISO) 9000 series QA program ~~is~~ may be 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~~ Manager.

QA Level 2 program activities are those activities that do not meet the requirements for inclusion in the QA Level 1 program, but have attributes or characteristics that warrant control under a quality program more detailed than the QA Level 3 program. QA Level 2 requirements are applied to activities and SSCs for the following reasons:

- To minimize the adverse consequences of radiation to the worker, public and the environment after initiation of accidents involving licensed material or their byproducts.
- To minimize the adverse consequences of hazardous chemicals produced from licensed material, such as UF₆, to the worker, public and the environment after initiation of releases or accidents.
- Other items/processes that management decides are a good practice.

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