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DEC 13 2013

LES-13-00166-NRC

Attn: Document Control Desk
Director
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

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

Subject: Quality Assurance Program Description (QAPD) Update

In accordance with Section 19 of its Quality Assurance Program Description (QAPD), Louisiana Energy Services, LLC (dba "UUSA") is required to submit non-substantive changes to the QAPD to the NRC within 30 days of implementation of such changes.

The page changes to the QAPD are provided in Enclosure 1. Revision bars, strikethroughs and underlines were utilized, and these changes are referenced to License Basis Document Change Request (LBDCR), LBDCR-13-0042. A complete copy of the QAPD with changes incorporated is provided in Enclosure 2.

Should there be any questions regarding this submittal, please contact Timothy Knowles, UUSA Licensing and Performance Assessment Manager, at 575-394-6212.

Respectfully,

Jay Laughlin
Chief Nuclear Officer and Head of Operations

Enclosures: 1) Marked up Pages of the (QAPD) Showing the Changes Made in LBDCR-13-0042
2) Complete Copy of the (QAPD), Revision 34c

Q004

CC: (with enclosures)

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ENCLOSURE 1

Marked-up Pages of the (QAPD)
Showing the Changes Made in LBDCR-13-0042

SECTION 16 CORRECTIVE ACTION

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

Conditions adverse to quality, safety, and security including activities and services shall be identified promptly and corrected as soon as practical. For significant conditions adverse to quality, safety, and security the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality, safety, and security shall be documented and reported to appropriate levels of management. Follow-up action shall be taken to verify implementation of the corrective action. Significant conditions adverse to quality, safety, and security shall be tracked and evaluated so that adverse trends can be identified and appropriate corrective action can be taken. LBDCR-13-0042

Procedure(s) shall be established to implement a corrective action program (CAP) which includes the following elements:

- Prompt identification and correction of conditions adverse to quality, safety, and security;
- Classifying identified problems as conditions adverse to quality or significant conditions adverse to quality, safety, and security as a minimum; LBDCR-13-0042
- Evaluating significant conditions adverse to quality for reportability to the NRC (when required) under 10 CFR 21, Reporting of Defects and Noncompliance, or other applicable reporting requirements and reporting such conditions when warranted;
- Stopping work, if applicable;
- Determining the cause and corrective actions to preclude recurrence for significant conditions adverse to quality, safety, and security and
- Verifying the implementation of corrective actions taken for significant conditions adverse to quality, safety, and security. LBDCR-13-0042

IDENTIFYING AND CLASSIFYING CONDITIONS ADVERSE TO QUALITY

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

- Conditions adverse to quality
- Significant conditions adverse to quality

Conditions adverse to quality are defined as items such as failures, malfunctions, deficiencies, deviations, defective material and equipment and nonconformances directly associated with a QL-1 or QL-2 (all inclusive) item or service. Conditions adverse to quality shall be documented and reported to the appropriate levels of management.

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

Significant conditions adverse to quality are defined as:

- A deficiency that would seriously impact a QL-1 (inclusive) item, activity or service from meeting or performing its intended function or output of assuring public health and safety;
- A deficiency in QL-1 (inclusive) design that has been approved for fabrication or construction where the design deviates extensively from design criteria and bases;
- A deficiency in the fabrication or construction of, or significant damage to, QL-1 (inclusive) structures, systems or components that require extensive evaluation, re-design or repair in order to establish the adequacy of the structure, system or component to perform its intended function of assuring public health and safety;
- A deviation from QL-1 (inclusive) performance specifications that shall require extensive evaluation, re-design, or repair to establish the adequacy of the structure, system or component to perform its intended function;
- A significant error in a QL-1 (inclusive) computer program used to support activities affecting quality after it has been released for use;
- A deficiency, repetitive in nature, related to a QL-1 or QL-2 (inclusive), activity, service or item subject to the LES QAPD; and
- A condition that, if left uncorrected, has the potential to have a serious negative impact on QL-1 or QL-2 (inclusive) activities, services or items subject to the LES QAPD controls.

If a supplier or subtier supplier discovers a defect or noncompliance which the supplier evaluates as a substantial safety hazard, then the supplier shall be required to report the item under 10 CFR 21, Reporting of Defects and Noncompliance, and notify LES in writing. If the supplier or subtier supplier is unable to determine if the defect/non compliance is a substantial safety hazard then the supplier or subtier supplier is required to report the item to LES for determination of reportability. In accordance with the CAP, significant conditions adverse to quality shall be evaluated for a stop work condition to determine if stopping work is warranted. If a stop work condition is identified, management shall issue stop work in accordance with the applicable procedure. Upon completion of action(s) to return the related significant condition adverse to quality to compliance, management shall take appropriate action to lift and close (in part or total) the stop work order.

IDENTIFIYING AND CLASSIFYING CONDITIONS ADVERSE TO SAFETY AND SECURITY

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

- Conditions adverse to safety and security
- Significant condition adverse to safety and security

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Conditions adverse to safety and security are defined as items such as failures, malfunctions, deficiencies, deviations, defective material and equipment and nonconformance's directly associated with safety and security. Conditions adverse to safety and security shall be documented and reported to the appropriate levels of management.

In accordance with the CAP, responsible management shall investigate and fully identify the condition and document the results. Responsible management shall then utilize investigation results to determine and document corrective action (including remedial action and if

appropriate, actions to prevent recurrence). Responsible management shall complete remedial action and document completion of actions in a timely manner.

Significant conditions adverse to safety and security may include the following:

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- trend of multiple conditions adverse to safety or security
- deficiencies in design, manufacturing , construction, testing, or process requiring substantial rework, repair, or replacement
- damage to a structure, system, component, or facility requiring substantial repairs
- a non-conservative error detected in a computer program or design input after it has been implemented or released for use;
- repeated failure to implement a portion of an approved procedure

FOLLOW-UP ACTION

The procedure(s) establishing the CAP shall include a requirement for management to take follow-up action to verify implementation of corrective action taken to address significant conditions adverse to quality, safety, and security. The QA organization shall be responsible for conducting periodic audits of these follow-up actions in accordance with Section 18 of the QAPD.

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Significant Conditions adverse to quality, safety, and security shall be reported to the QA organization for tracking. Responsible management shall then determine the root cause, and corrective action (including remedial action and actions to prevent recurrence) based on investigation results. Concurrence from QA organization shall be obtained to ensure that QA requirements are satisfied. The QA organization will verify implementation of corrective actions.

TRENDING

Procedures shall include requirements and organizational responsibility for trending which will include conditions adverse to quality, safety, and security, and significant conditions adverse to quality, safety, and security ~~as well as adverse conditions to safety and security~~. Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse ~~quality~~ trends. Identified adverse trends shall be handled in accordance with the CAP and reported to the appropriate management.

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ENCLOSURE 2

Complete Copy of the (QAPD),
Revision 34c

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SAFETY ANALYSIS REPORT APPENDIX A

QUALITY ASSURANCE PROGRAM DESCRIPTION

Revision 34c

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Summary of Changes for Revision 34		
Issue / Date	**Change**	**Description of Change**
34a 9-9-2013	LBDCR-13-0025 9-3-2013	Significant Condition Adverse to Quality definition is being further clarified in response to RAI IN-13-00058-NRC CC-CA-2012-0001; 70.72 = NA
	NA	Submittal to NRC for non substantial changes previously approved by LES
34b 10-9-2013	LBDCR-13-0033 9-30-2013	Additional clarification of terms - Significant Condition Adverse to Quality definition is being further clarified in response to RAI IN-13-00058-NRC
	NA	Submittal to NRC for non substantial changes previously approved by LES
34c 12-13-2013	LBDCR-13-0042 12-11-2013	Update QAPD Section 16 to include guidance contained in NUREG-2154. This change adds Safety and Security related events to tracking and trending to the corrective action section. CC-LS-2013-0006; 70.72 = 2013-0601
	NA	Submittal to NRC for non substantial changes previously approved by LES

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INTRODUCTION

Louisiana Energy Services (LES) maintains full responsibility for ensuring that the enrichment facility is designed, constructed, operated, and decommissioned in conformance with applicable regulatory requirements, specified design requirements, applicable industry standards and good engineering practices in a manner to protect the health and safety of the employees and the public. To this end, the LES Quality Assurance Program conforms to the criteria established in Title 10 of the Code of Federal Regulations 10 CFR 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants. The program also satisfies the requirements of Title 10 of the Code of Federal Regulations, Part 71, Subpart H, Quality Assurance for Packaging and Transportation of Radioactive Material. The criteria in 10 CFR 50, Appendix B and 10 CFR 71 Subpart H, are met by LES's commitment to follow the guidelines of the American Society of Mechanical Engineers (ASME) Quality Assurance (QA) standard NQA-1-1994, Quality Assurance Program Requirements for Nuclear Facilities, including supplements as revised by the ASME NQA-1a-1995 Addenda. See Section 4 Procurement Document Control for specific LES exemptions to 10 CFR 21.3 for the definitions of "commercial grade item", "basic component", "critical characteristics", "dedicating entity", and "dedication".

The LES QA Program described herein covers design, construction (including pre-operational testing), operation (including testing), maintenance and modification, and decommissioning of the facility. This Quality Assurance Program Description (QAPD) describes the requirements to be applied to those structures, systems and components (SSC's), and activities that have been designated Quality Assurance (QA) Level 1, QA Level 1 Graded, QA Level 1-Fire Protection (QL-1F), and QA Level 2. The QA Levels and applicable requirements of the QAPD are defined in Section 2, Quality Assurance Program.

As described in Section 19, Provisions for Change, subsequent changes to the LES QA Program that shall be incorporated in this QAPD. Any changes 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 assessment of the applicability of the QAPD to an activity and continues through the termination of the license. The LES QAPD has been established to ensure that the necessary quality requirements are applied appropriately to designated structures, systems, components and work activities. This objective is achieved by ensuring that the organizational structure and the associated responsibilities for quality activities are defined. The responsibilities ensure quality is achieved and maintained by those assigned individuals and 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 Managers as described in Section 1.2 of the SAR. The President is responsible for all design, construction and the operation of the facility.

The 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 Head of Compliance has overall responsibility for development 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 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. Architect/engineering (A/E) firms are contracted and/or design is performed by LES and under the responsibility of the Vice President Site Projects 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 Vice President Site Projects is responsible for managing the associated activities as described in Section 2.1.2, *Project Organization*, of the SAR. Figure 2.1-2 of the SAR shows that the Vice President Site Projects is responsible for managing the construction work and contracts, design and engineering up to and through construction turnover and final acceptance. Final acceptance is performed by the Head of Operations, Head of Technical Services or Head of Compliance depending on which structure, system or components are included as part of the turnover within their respective responsibilities. Upon final acceptance, the responsibility for site Design Authority also transfers from Head of Project Engineering to the Head of Technical Services. The Procurement Director is responsible for coordinating procurements using qualified contractors or LES personnel to support both project construction and operations needs. Contractor QA Programs will be reviewed by the LES QA organization and must be approved by the LES QA 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 QAPD approved by the LES QA Manager or under the LES QAPD. In addition, URENCO is supplying the technical assistance and consultation for the facility in accordance with the applicable requirements of the LES QAPD.

OPERATING ORGANIZATION AND FUNCTIONS

- The operating organization is shown in Figure 2.1-2 of the SAR, LES National Enrichment Facility Operating Organization. The Head of Operations, Head of Technical Services, and Head of Compliance, functioning as the Chief Nuclear Officer, are 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.

Procedures are developed by designated organizations to implement the requirements of the QAPD. Organizational responsibilities are provided within Section 2 of the National Enrichment Facility (NEF) Safety Analysis Report.

QA ORGANIZATION AND FUNCTIONS

The LES QA organization has been established to verify the effectiveness of the implementation of quality activities during the design, construction, testing, operations, and decommissioning phases of the enrichment facility. The QA organization is headed by the LES QA Manager.

The LES QA Manager reports to the Head of Compliance. The QA Manager is specifically provided stop work authority at the Chief Nuclear Officer and President level for Quality Assurance issues. As described in Chapter 2 of the SAR, the Head of Operations and the Chief Nuclear Officer are responsible for operations activities and is thus a high enough level to authorize a stop work. In addition, the President is ultimately responsible for all procurement quality, construction and design. The QA Manager has a direct relationship with the President for quality concerns. This ensures the QA Manager has sufficient independence for all issues affecting quality.

The LES QA Manager has been assigned by the President to maintain the LES QAPD. The QA Manager is responsible for providing technical support, independent audits, verifications and independent inspections. These responsibilities are defined in approved procedures controlled under the QAPD. These responsibilities are applicable during construction, testing, operation and decommissioning phases of the enrichment facility. The QA organization is sufficiently independent from cost and schedule considerations and has stop work authority. The QA organization also has sufficient authority, access to work areas and organizational freedom to perform quality activities such as:

- Identifying quality problems
- Initiating and recommending solutions to quality problems through designated channels
- Verifying implementation of solutions
- Assuring that further processing, delivery, installation, or use of items is controlled until proper disposition of nonconformances, deficiencies or unsatisfactory conditions has occurred

ORGANIZATIONAL INTERFACES

The organizational interfaces within LES, between the LES organization and 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, QA Level 1 Graded, QA Level 1F, QA Level 2AC, QA Level 2 and QA Level 3 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 through the LES management trough resolution. If satisfactory resolution cannot be obtained then the matter is elevated to the Chief Nuclear Officer or President for final resolution.

WORKER RESPONSIBILITIES

Every individual has an obligation to identify concerns using the corrective action process described in Section 16 of the QAPD whenever the health and safety of our workers, the public, or the environment could be compromised or QAPD requirements are not satisfied. This process is controlled by an LES procedure, which applies across the entire project/facility. The authorities and responsibilities and process for stopping work are defined in an LES procedure. This process control 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

The elements of the LES QA Program described in this section and associated QA procedures implement the requirements of Criterion 2, Quality Assurance Program, of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3 and 2S-4 of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda of NQA-1-1994. See Section 4 Procurement Document Control for specific LES exemptions to 10 CFR 21.3 for the definitions of "commercial grade item", "basic component", "critical characteristics", "dedicating entity", and "dedication".

PROGRAM BASIS

The LES QAPD complies with 10 CFR 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants, and applies to all levels of the organization, including contractors, who perform QA Level 1 activities. The program also satisfies the requirements of Title 10 of the Code of Federal Regulations, Part 71, Subpart H, Quality Assurance for Packaging and Transportation of Radioactive Material. Part I and selected sections of Part II of ASME NQA-1-1994, Quality Assurance Requirements for Nuclear Facility Applications, as revised by NQA-1a-1995 Addenda are used in conjunction with 10 CFR 50, Appendix B and provide additional detailed quality assurance guidelines which are committed to in this QAPD. The LES QAPD describes LES' overall compliance with 10 CFR 50, Appendix B and 10 CFR 71, Subpart H, and commitments to ASME NQA 1. This document defines the LES policies, assigns responsibilities and specifies requirements governing implementation of the QAPD to the design, construction, operation and decommissioning of the LES enrichment facility. The 18 criteria of 10 CFR 50, Appendix B have been addressed within the QAPD to identify the applicability of QA requirements to the LES enrichment facility. QA requirements also apply to contractors performing quality activities as delineated in procurement documents controlled under Section 4, Procurement Document Control. The necessary management measures to control the quality of subcontracted activities for the LES design, procurement, and installation and testing of QA Level 1 components and activities have been established in this QAPD. The QAPD will be periodically reviewed as described in Section 19, Provisions For Change. Exceptions to these commitments will be defined as an attachment to the QAPD.

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

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

When work cannot be accomplished as specified in implementing QA procedures, or accomplishment of such work would result in an adverse condition, work is stopped until proper corrective action is taken as described in Section 16, Corrective Action.

Flowdown of QA Requirements to Contractors and Suppliers

QA requirements for QA Level 1 activities are imposed on LES contractors and suppliers through the respective procurement documents for the particular scope of work being contracted. Determination of the specific QA requirements, supplier evaluations, and proposal/bid evaluations are in accordance with the requirements of Section 4, Procurement Document Control, and Section 7, Control of Purchased Material, Equipment and Services, of this document. Applicable QAPD elements required for the particular scope of work are identified in procurement documents.

IDENTIFICATION AND APPLICATION OF QA CONTROLS

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

The QA Level 1 Graded program description is provided in Section 21, Quality Assurance Program for QA Level 1 Graded. The QA Level 1 Graded program applies exclusively to IROFS27e structures. IROFS27e structures whose failure has been analyzed to result in consequences that exceed the 10 CFR 70.61 performance requirements. The QA Level 1 Graded program applies to:

- Separation Building Modules (SBMs 1001 and 1003 (including associated UF_6 Handling Areas), Interconnecting Corridor, and all UF_6 Handling Areas for SBMs beyond SBM-1003 with the exception of QA Level 1 slab-on-grade and supports for internally housed QA Level 1 IROFS that are required to perform a safety function for a seismic event.
- Cylinder Receipt and Dispatch Building (CRDB) superstructure with the exception of the Bunkered Area structure which is designated QL-1. The non-bunkered area foundation is designated QL-1G; slab on grade is designated QL-3.
- Interconnecting Corridor (ICC). The ICC slab on grade is designated QL-3.

The QL-1F Program is a graded quality assurance program that applies exclusively to fire protection features designated as IROFS. Such IROFS designated fire protection features are those whose failure has been analyzed to result in consequences that exceed the 10 CFR 70.61

performance requirements. The QL-1F program is applied to design, procurement, and other activities as described in Section 23. The QL-1F Program applies to:

- Any fire protection features designated as IROFS.

The QA Level 2AC (QL-2AC) program description is provided in Section 22, Quality Assurance Program for QA Level 2AC of this QAPD. QA Level 2AC is applied to Administrative Control IROFS Support Equipment for Administrative Control IROFS. The QA Level 2AC Administrative Control IROFS Support Equipment activities shall be identified in applicable QA procedures, implementing documents, and documents specifying quality requirements or prescribing activities affecting quality. These requirements are implemented by LES and LES contractors through the use of approved QA programs and procedures.

The QA Level 2 program description is provided in Section 20, Quality Assurance Program for QA Level 2 of this QAPD. These requirements are implemented by LES and LES contractors through the use of approved QA programs and procedures. The Owner defined QA Level 2 SSCs and their associated activities i.e., those SSCs that are not IROFS, provide support of normal operations of the facility, and do not affect the functions of the IROFS and SSCs that minimize public, worker, and environmental risks are evaluated against the requirements in Section 20, of this QAPD. This evaluation identifies which QA controls are needed to ensure these SSCs meet their intended functions. This 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 five 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 program shall be applied to those structures, systems, components, and administrative controls that have been determined to be IROFS (except IROFS27e to which QA Level 1 Graded applies and fire protection features designated as IROFS to which QL-1F applies), items that are essential to the functions of the IROFS, and to items required to satisfy regulatory requirements for which QA Level 1 requirements are applied.

QA LEVEL 1 GRADED REQUIREMENTS

The QA Level 1 Graded program applies exclusively to IROFS27e structures. IROFS27e structures are structures whose failure has been analyzed to result in consequences that exceed the 10 CFR 70.61 performance requirements. The QA Level 1 Graded program is applied to design, procurement, construction and other activities as described in Section 21. The QA Level 1 Graded program applies to:

- Separation Building Modules (SBM-1001 and SBM-1003), Interconnecting Corridor, and all UF_6 Handling Areas for SBMs beyond SBM-1003 with the exception of QA Level 1

slab on grade or supports for internally housed QA Level 1 IROFS that are required to perform a safety function for a seismic event.

- Cylinder Receipt and Dispatch Building (CRDB) superstructure with the exception of the Bunkered Area structure which is designated QL-1. The non-bunkered area foundation is designated QL-1G; slab on grade is designated QL-3.

- Interconnecting Corridor (ICC). The ICC slab on grade is designated QL-3.

QA LEVEL 1 FIRE PROTECTION REQUIREMENTS[1]

The QL-1F Program applies exclusively to fire protection features designated as IROFS. Such IROFS designated fire protection features are those whose failure has been analyzed to result in consequences that exceed the 10 CFR 70.61 performance requirements. The QL-1F Program is applied to design, procurement, and other activities as described in Section 23.

QA LEVEL 2AC REQUIREMENTS

Administrative Control IROFS are safety functions provided by human actions as discussed in NUREG-1520,

> *In 10 CFR Part 70, an administrative control is an IROFS if it is the human action necessary to meet safety performance requirements, and it is supported by management measures (training, quality assurance, procedures, etc.) that ensures the action will be taken if needed.*

Administrative Control IROFS Support Equipment are not "items which are determined to be essential to the function of the IROFS." Administrative Control IROFS Support Equipment is used by the worker to perform the actions of the Administrative Control IROFS. This equipment is not essential to a passive or active engineered safety feature that must operate without any human interaction.

The QA Level 2AC Program is applied to Administrative Control IROFS Support Equipment Components. The worker utilizes Administrative Control IROFS Support Equipment to perform the human action of the administrative control. This equipment is specified in Table 3.4-1 of the Safety Analysis Report. In addition, the QL requirements applicable for this equipment are specified in Section 22 of this QAPD.

Any removal of the management measure designed to provide assurance of the Administrative Control IROFS Support Equipment used by the worker, or removal of the Administrative Control IROFS Support Equipment quality requirements from the Administrative Control IROFS Boundary, would be considered a reduction in commitment and require regulatory approval prior to implementation. Current application of management measures to this Administrative Control IROFS Support Equipment and/or attributes is defined in the administrative control IROFS Boundary Definition Documents.

General QA Level 2AC requirements are described in Section 22, Quality Assurance Program for QA Level 2AC. An International Organization for Standardization (ISO) 9000 series QA program may be acceptable for QA Level 2AC applications provided it complies with applicable LES QAPD requirements and the contractor's QAPD is reviewed and accepted by the LES QA Manager.

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, QA Level 1 Graded, or QA Level 1F (or QL-1F), or QA Level 2AC program, but have elements or characteristics that may 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 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, QA Level 1 Graded, QA Level 1F, QA Level 2AC, or QA Level 2.

Any removal of the management measures designed to provide assurance of other equipment attributes, identified in Table 3.4-1 of the SAR, that are used by the worker would be considered a reduction in commitment and require regulatory approval prior to implementation.

QUALITY ASSURANCE TRAINING

Personnel who are assigned to perform QA Level 1 activities receive LES QA Indoctrination Training. This training includes general criteria, such as an introduction to applicable codes, standards, QA Procedures, QAPD elements and job responsibilities and authorities. Personnel assigned to perform QA Level 1, QA Level 1 Graded, or QA Level 1F 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 QAPD and job specific QA procedures prior to an employee beginning QA Level 1, QA Level 1 Graded, or QA Level 1F 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 for those individuals required to take the training.

The Training Manager provides the support function for coordinating this QA training. Plant Support provides centralized training support 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, QA Level 1 Graded, and QA Level 1F activities. Retraining is performed and documented, when applicable, shall occur in order to maintain proficiency or when changes to work methods, technology, or job responsibilities occur.

MANAGEMENT ASSESSMENTS

The Head of Compliance is responsible for ensuring that management assessments are conducted annually to determine if the LES QA Program is effective. Audits conducted in accordance with QAPD Section 18 may be used to fulfill this annual Assessment requirement. Recommendations are provided to the Chief Nuclear Officer and President for action.

Functional Managers and the QA Manger conduct assessments annually of QA activities under their control. The managers report the results to the Head of Operations, Head of Technical Services or Head of Compliance for review and assignments as appropriate, and to the Chief Nuclear Officer or 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, QA Level 1 Graded, QA Level 1F, and QA Level 2AC 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, QA Level 1 Graded, QA Level 1F, or QA Level 2AC 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 (2006 Edition for Ultrasonic Thickness Testing and Mass Spectrometer (Helium) Leak Test). 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 or QA Level 1 Graded, or QA Level 1F 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.

QUALITY ASSURANCE PROGRAM STATUS REPORTING TO MANAGEMENT

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

SECTION 3 DESIGN CONTROL

The elements of the LES QA Program described in this section and associated procedures implement the requirements of Criterion 3, Design Control, of 10 CFR 50, Appendix B, and the commitment to Basic Requirements 3 and Supplement 3S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda of NQA-1-1994. See Section 4 Procurement Document Control for specific LES exemptions to 10 CFR 21.3 for the definitions of "commercial grade item", "basic component", "critical characteristics", "dedicating entity", and "dedication". The LES QA Program also implements the commitment to Part II of NQA-1-1994 Subpart Part 2.7, Quality Assurance Requirements of Computer Software for Nuclear Facility Applications, as revised by NQA-1a-1995 Addenda of NQA-1-1994. These commitments also apply to computer software that is used to produce or manipulate data that is used directly in the design, analysis and operation of structures, systems and components relied on for safety. Part I, Supplement 11S-2, Supplementary Requirements for Computer Program Testing, requirements for computer software qualification and use are also implemented by the LES QA Program.

The quality classification of NRC Licensed Transportation Packages may not be revised using the LES Design Control process. These modifications must be made by the NRC Certificate Holder. The Certificate Holder is responsible for design and licensing controls for these components under the provisions of an NRC General License for Radioactive Material Transportation Packages under 10 CFR 71.

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

DESIGN INPUT CONTROL

Applicable design inputs (such as design basis, conceptual design reports, performance requirements, regulatory requirements, codes and standards) shall be controlled by the LES – Design Authority according to the following requirements:

- Design inputs shall be identified and documented, and their selection reviewed and approved.
- Design inputs shall be specified and approved in a manner to support the schedule. Design inputs shall provide the necessary details to permit design to be carried out in a manner that provides a consistent basis for making design decisions, accomplishing design verification and evaluating design changes.
- Changes from approved design inputs and reasons for the changes shall be identified, approved, documented and controlled.
- Design inputs based on assumptions that require re-verification shall be identified and controlled by the appropriate procedures.

DESIGN PROCESS

The LES design process shall be controlled by the Design Authority according to the following requirements:

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

DESIGN ANALYSIS

LES design analyses shall be planned, controlled and documented. Design analysis documents shall be legible, in a form suitable for reproduction, filing and retrieval, and under configuration management control. LES design calculations shall be identifiable by subject (including

structure, system or component to which the calculation applies), originator, reviewer and date, or by other designators in order that approved calculations are retrievable.

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

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

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

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

LES design analyses documentation shall include:

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

DESIGN VERIFICATION

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

- LES design verification is required for design documents, and shall be performed using one or a combination of the design review, alternate calculations and/or qualification testing methods.
- The particular design verification method used shall be documented.
- Results of design verification shall be documented and shall include the identification of the verifier(s).

- Competent individuals or groups, other than those who performed the original design (but may be from the same organization), shall perform design verification. If necessary, this verification may be performed by the originator's supervisor provided that the engineering supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or the supervisor is the only individual in the organization competent to perform the verification.

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

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

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

DESIGN VERIFICATION METHODS

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

- Design Reviews
- Alternate Calculations
- Qualification Testing

DESIGN REVIEWS

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

- Were the design inputs correctly selected and incorporated into the design?
- Are assumptions necessary to perform the design activity adequately described, reasonable and, where necessary, re-verified?

- Was an appropriate design method used?
- Is the design output reasonable compared to the applicable design inputs?
- Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures and instructions?

ALTERNATE CALCULATIONS

The appropriateness of assumptions, input data, and the computer program or other calculation methods used, shall be evaluated and the results shall be checked through the use of alternate calculation methods to verify the correctness of the original calculations or analyses.

QUALIFICATION TESTS

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

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

DESIGN CHANGE CONTROL

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

- Changes to final designs, field changes, modifications to the operating facility and nonconforming items dispositioned as "use-as-is" or "repair," as described in Section 15, Nonconforming Items, and shall have documented justification for use and are subject to the same design control measures and reviews as those applied to the original design.
- Design control measures for changes shall include provisions to determine that the design analyses for the item are still valid.
- Changes shall be reviewed and approved by the affected groups or organizations that reviewed and approved the original design documents, with the following clarifications:

  - If the organization that originally was responsible for approving a particular design document is no longer responsible, then a new responsible organization shall be designated.
  - The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design
- The interface between the design organization responsible for finalizing a design change and other organizations either involved in the review of the change, such as the QA and configuration management organizations, and those affected by the change, such as the operations and maintenance organizations, described in the next subsection, Design Interface Control, shall be maintained.
- The design process and design verification practices and procedures shall be reviewed and modified, as necessary, when a significant design change is required because of an incorrect design. These design deficiencies shall be documented according to Section 16.0, Corrective Actions. If these deficiencies cause constructed or partially constructed items (systems, structures or components) to be deficient, the affected items shall be controlled in accordance with Section 15, Nonconforming Items.
- When a design change is approved other than revision to the affected design documents, field changes shall be incorporated into affected design documents when such incorporation is appropriate.

DESIGN INTERFACE CONTROL

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

During the operational phase that begins after final acceptance, the Head of Operations, Head of Technical Services, and Head of Compliance are responsible for ensuring the facility complies with all applicable regulatory requirements including the requirements of this QA Program. Responsibility as the site Design Authority transfers from the Head of Project Engineering to the Head of Technical Services concurrent with final acceptance. In the discharge of these responsibilities, the Head of Operations, Head of Technical Services, and Head of Compliance direct the activities of their respective organizations. Procedures for controlling the interfaces and configuration management ensure that changes and modifications are properly managed and disseminated to those responsible personnel or organizations whose duties may be affected by the design change or modification and do not adversely impact the safe operation of the plant. The Vice President of Regulatory Affairs directs the activities of Performance Assessment including the implementation of the Corrective Actions Program.

COMPUTER SOFTWARE CONTROLS

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

DOCUMENTATION AND RECORDS

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

SECTION 4 PROCUREMENT DOCUMENT CONTROL

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

LES quality related 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 in accordance with procedures. The material, equipment and services shall be procured from approved suppliers utilizing procurement documents, approved in accordance with procedures controlled under the QAPD. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in procurement documents for 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 in accordance with approved procedures.

LES is exempted from the definitions of "commercial grade item", "basic component", "critical characteristics", "dedicating entity", and "dedication" in 10 CFR 21.3, as replaced by the following:

Commercial grade item: A commercial grade item means a structure, system or component, or part thereof that affects its Items Relied on for Safety (IROFS) function that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

As described above, some NEF components are designed and specified by vendors such as ETC. Where such components are designated as Items Relied On For Safety (IROFS), LES will commercially dedicate the items using one or more acceptance methods to verify the critical characteristics related to the IROFS function of the item. Inspections, tests and special process verifications performed by the vendor may be credited for control of critical characteristics on the basis of a commercial grade survey performed in accordance with approved procedures.

Basic component: A basic component means a structure, system, or component, or part thereof that affects their IROFS function, that is directly procured by the licensee or activity subject to the regulations in part 70 and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission would create a substantial safety hazard (i.e., exceed performance requirements of 10 CFR 70.6 1). In all cases, basic components includes IROFS-related design, analysis, inspection, testing, fabrication, replacement parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

When applied to fire protection systems procured for facilities and other activities licensed under 10 CFR Part 70 of the chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard. For fire protection systems designated as items relied on for safety, a basic component may be directly procured from a commercial entity by a Part 70 licensee if (1) the system, structure or component is manufactured to an established, acceptable national code or standard that included some independent product endorsements based on qualification testing or periodic testing of selected characteristics of the component and (2) the acceptability of the item's manufacture, testing, and/or certification has been reviewed and verified by the licensee prior to use as a basic component. Once the acceptability of the item has been verified by URENCO USA (UUSA) and the item has been designated for use as a basic component, the licensee accepts responsibility for Part 21 reporting.

Critical characteristics: Critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended IROFS function.

Dedication: Dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended IROFS function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR 50, Appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, Appendix B. The process is considered complete when the item is designated for use as a basic component.

Dedicating entity: Dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to Section 21.21 (c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process. In cases where LES applies the commercial grade item procurement strategy and performs the dedication process, LES would assume full responsibility as the dedicating entity.

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 as described in approved procedures controlled under the QAPD:

- 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 sub-tier supplier issued quality related 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 Manager authorization. The Procurement Director may also establish hold points indicating work that cannot proceed without authorization by the Procurement Director.
- Provisions for 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.
- Provisions for requiring the suppliers to report to LES in writing adverse quality conditions resulting in work stoppages and nonconformances. Requirements for LES approval of partial and full work releases and disposition of nonconformances will be defined.
- Provisions for identifying 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 content for QA Level 1-Graded or QA Level 1F items or services shall be in accordance with Section 21.4 or Section 23.4, respectively.

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. Procedures controlled under the QAPD shall ensure the provisions of NQA-1-1994, Supplement 4S-1 are addressed. 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 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/or 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 items such as procedures, drawings and specifications. Work controlling procedures may also utilize approved checklists, travelers or other means to assure process requirements are met including prerequisite requirements prior to starting work. Procedures provide a consistent method for process performance and documentation of completion as well as ensure specified safety and environmental conditions are maintained.

CONTENT OF DOCUMENTS

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

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

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

REVIEW, APPROVAL, AND CONTROL OF DOCUMENTS

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

SECTION 6 DOCUMENT CONTROL

The elements of the LES QA Program described in this section and associated procedures implement the requirements of Criterion 6, Document Control, of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 6 and Supplement 6S-1 of NQA-1-1994. See Section 4 Procurement Document Control for specific LES exemptions to 10 CFR 21.3 for the definitions of "commercial grade item", "basic component", "critical characteristics", "dedicating entity", and "dedication".

Procedures are established which control the preparation, issuance and changes of documents that specify quality requirements or prescribe activities affecting quality. Measures are established to ensure that documents, including revisions are adequately reviewed, approved, and released for use by authorized personnel. Controlled documents are transmitted to the appropriate locations where the prescribed activity is being performed in accordance with administrative procedures controlled under the QAPD.

TYPES OF DOCUMENTS

Designated procedures which implement QAPD requirements shall be controlled in accordance with this section. Other LES documents will also be controlled in accordance with approved procedures including, but not limited to, procedures, design requirements documents, and basis of design documents that need to be controlled due to being input to other LES design documents or used for construction and operations affecting quality.

PREPARING AND REVIEWING DOCUMENTS

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

CONTROLLING THE DISTRIBUTION AND USE OF DOCUMENTS

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

CHANGES TO DOCUMENTS

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

MINOR CHANGES

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

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

The elements of the LES QA Program described in this section and associated procedures implement the requirements of Criterion 7, Control of Purchased Material, Equipment and Services, of 10 CFR 50, Appendix B, and the commitment to Basic Requirement 7 and Supplement 7S-1 of NQA-1-1994 Part I as revised by NQA-1a-1995 Addenda of NQA-1-1994. See Section 4 Procurement Document Control for specific LES exemptions to 10 CFR 21.3 for the definitions of "commercial grade item", "basic component", "critical characteristics", "dedicating entity", and "dedication".

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

PROCUREMENT PLANNING

LES procurements shall be planned and documented to ensure a systematic approach to the procurement process exists and supports the schedule. Procurement planning shall be performed in accordance with Supplement 7S-1 Section 2 of NQA-1-1994 as defined in approved procedures controlled under the QAPD. Procurement planning shall be accomplished as early as possible, but no later than at the start of those procurement activities that are required to be controlled to assure interface compatibility and a uniform approach to the procurement process.

These actions will be performed relative to the level of importance, complexity and quantity of the item or service being procured and the supplier's quality performance.

Procurement planning shall 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 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 Manager before the supplier starts work.

SUPPLIER PERFORMANCE EVALUATION

The LES Procurement Director in coordination with the QA 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.

ACCEPTANCE OF ITEMS OR SERVICES

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

- Evaluating the supplier certificate of conformance,
- Performing one or a combination of source verification, receiving inspection or post-installation test,
- Technical verification of the data produced (services only),
- Surveillance or audit of the activities (services only),
- Review of objective evidence for conformance to procurement requirements (services only).

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

CERTIFICATE OF CONFORMANCE

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

- The certificate shall identify the purchased material, equipment or service to the specific procurement document.
- The certificate shall identify the specific procurement requirements met by the purchased material, equipment or service. The procurement requirements identified shall include any approved changes, waivers or deviations applicable to the material, equipment or service.

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

SOURCE VERIFICATION

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

RECEIVING INSPECTION

When receiving inspection is used to accept an item:

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

POST-INSTALLATION TESTING

When post-installation testing is used as a method of acceptance the affected/involved LES organization manager and the supplier, when possible, shall mutually establish test requirements and acceptance documentation. The LES –Design Authority is ultimately responsible for ensuring appropriate test requirements and acceptance documentation are established.

CONTROL OF SUPPLIER NONCONFORMANCES

The LES Procurement organization (or its agents during Construction) and the supplier shall establish and document the process for disposition of items that do not meet procurement

document requirements. The supplier shall evaluate nonconforming items according to the applicable requirements of Section 15, Nonconforming Items and submit a report of nonconformance to LES Procurement organization including supplier recommended disposition (for example, use-as-is or repair) and technical justification. Reports of nonconformances to procurement document requirements, or documents approved by LES, shall be submitted to LES Engineering organization for approval of the recommended disposition whenever one of the following conditions exists:

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

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.

COMMERCIAL GRADE CALIBRATION SERVICES

When purchasing commercial grade calibration services from domestic calibration laboratories accredited by a nationally recognized accrediting body, the following conditions shall be satisfied:

- A technical evaluation shall be performed by LES Engineering for the specific M&TE being calibrated to identify any additional technical requirements that need to be included in the purchase order (e.g. tolerances, accuracies, ranges, specific industry standards to be used).
- Minimum critical characteristics to include in the purchase order shall include: use of ISO 17025 accredited quality program, technical requirements identified in the technical evaluation, as-found calibration data when calibrated items are found to be out-of – tolerance, and identification of the laboratory equipment and standards used.
- The accrediting body shall be a NRC recognized agency, such as, the National Voluntary Laboratory Accreditation Program (NVLAP), the American Association for Laboratory Accreditation (A2LA) or ACLASS Accreditation Services (ACLASS). These agencies are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).
- The scope of the accreditation covers the contracted calibration service.

In lieu of performing an audit or commercial grade survey of the calibration service, a documented review of the supplier's accreditation shall be performed by LES QA to ensure the accreditation was performed by a NRC recognized agency to ANSI/ISO/IEC 17025 and the published scope of accreditation covers the needed measurement parameters, ranges and uncertainties.

See Section 4 Procurement Document Control for specific LES exemptions to 10 CFR 21.3 for the definitions of "commercial grade item", "basic component", "critical characteristics", "dedicating entity", and "dedication".

APPROVED SUPPLIER LIST

The LES Quality Assurance 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 annual evaluation of each supplier. 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 will be removed from the ASL or restrictions added to address noted concerns.

SECTION 8 IDENTIFICATION AND CONTROL MATERIALS, PARTS AND COMPONENTS

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

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

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

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

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

SECTION 9 CONTROL OF SPECIAL PROCESSES

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

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

SPECIAL PROCESSES

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

PERSONNEL, IMPLEMENTING DOCUMENTS, AND EQUIPMENT QUALIFICATIONS

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

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

QUALIFICATION OF NONDESTRUCTIVE EXAMINATION PERSONNEL

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

DOCUMENTATION

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

SECTION 10 INSPECTION

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

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

INSPECTION PLANNING

Inspection planning shall be performed and documented in accordance with approved procedures controlled under the QAPD, which satisfy NQA-1 requirements.

SELECTING INSPECTION PERSONNEL TO PERFORM INSPECTION

The individual who performs an inspection to verify conformance of an item to specified acceptance criteria shall be qualified to perform the assigned inspection tasks in accordance with the requirements of Section 2, QA Program. Data recorders, equipment operators or other inspection team members who are supervised by a qualified inspector shall not be required to be a qualified inspector. Verification of conformance shall be by a qualified person. Inspections shall be performed by personnel other than those who performed or directly supervised the work being inspected. Inspection personnel shall not report directly to the immediate supervisors who are responsible for performing the work being inspected.

INSPECTION HOLD POINTS

When mandatory hold points are used to control work that shall not proceed without the specific consent of the organization responsible for the hold point, the specific hold points shall be indicated in implementing documents. Consent to waive specified hold points shall be documented and approved before continuing work beyond the designated hold point.

STATISTICAL SAMPLING

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

IN-PROCESS INSPECTIONS AND MONITORING

Items shall be inspected when necessary to verify quality in accordance with approved procedures controlled under the QAPD, which satisfy NQA-1 requirements.

FINAL INSPECTION

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

ACCEPTING ITEMS

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

INSERVICE INSPECTION

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

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

INSPECTION DOCUMENTATION

Inspection documentation shall identify:

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

SECTION 11 TEST CONTROL

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

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

TEST REQUIREMENTS

Test requirements and acceptance criteria shall be developed and controlled in accordance with approved procedures which satisfy NQA-1 requirements.

TEST PROCEDURES

Test procedures shall include:

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

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 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.

TEST DOCUMENTATION

Test documentation shall include:

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

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

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

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

CALIBRATION

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

DOCUMENTING THE USE OF M&TE

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

OUT OF CALIBRATION M&TE

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

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

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

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

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

LOST M&TE

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

HANDLING AND STORAGE

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

COMMERCIAL DEVICES

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

M&TE DOCUMENTATION

M&TE calibration documentation shall include the following information:

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

SECTION 13 HANDLING, STORAGE, AND SHIPPING

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

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

CONTROLS

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

SPECIAL EQUIPMENT, TOOLS AND ENVIRONMENTS

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

MARKING AND LABELING

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

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

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

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

Procedures shall provide management controls for installation, testing or repair of structures, system and components. Documents generated utilizing these procedures shall contain controls, such as, hold points, activity checklists, and in many cases, step-by-step signoffs which indicate the status of fabrication, installation, inspections, and test. This system is used to prevent inadvertent use of nonconforming items or bypassing of inspections and tests and prevent inadvertent operation.

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

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

Controls shall be established for changing the sequence of inspections, tests, and other activities which require the same controls as the original review and approval.

SECTION 15 NONCONFORMING ITEMS

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

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

DOCUMENTING AND EVALUATING NONCONFORMING ITEMS

A process shall be developed to document, provide notification, evaluate, review and approve nonconforming items. The review shall also include determining the need for additional corrective actions according to the requirements of Section 16, Corrective Action. In addition, organizations affected by the nonconformance shall be notified. Recommended dispositions shall be evaluated and approved in accordance with procedures. Personnel performing evaluations of recommended dispositions shall have demonstrated competence in the specific area they are evaluating, an adequate understanding of the requirements and access to pertinent background information. The responsibility and authority for reviewing, evaluating, approving the disposition and closing nonconformances shall be specified in procedures. QA can initiate, recommend, or provide solutions via designated channels. QA will periodically audit the process in accordance with Section 18 of the QAPD to verify effective implementation and that actions being taken to disposition nonconforming items are acceptable. QA will also verify during audits, that procedures are in place to control the installation and use of nonconforming items until an acceptable solution has been provided. Further processing, delivery, installation or use of a nonconforming item shall be controlled pending the evaluation and approval of the disposition by authorized personnel.

IDENTIFYING NONCONFORMING ITEMS

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

SEGREGATING NONCONFORMING ITEMS

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

DISPOSITION OF NONCONFORMING ITEMS

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

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

TRENDING

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

SECTION 16 CORRECTIVE ACTION

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

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

Procedure(s) shall be established to implement a corrective action program (CAP) which includes the following elements:

- Prompt identification and correction of conditions adverse to quality, safety, and security;
- Classifying identified problems as conditions adverse to quality or significant conditions adverse to quality, safety, and security as a minimum;
- Evaluating significant conditions adverse to quality for reportability to the NRC (when required) under 10 CFR 21, Reporting of Defects and Noncompliance, or other applicable reporting requirements and reporting such conditions when warranted;
- Stopping work, if applicable;
- Determining the cause and corrective actions to preclude recurrence for significant conditions adverse to quality, safety, and security and
- Verifying the implementation of corrective actions taken for significant conditions adverse to quality, safety, and security.

IDENTIFYING AND CLASSIFYING CONDITIONS ADVERSE TO QUALITY

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

- Conditions adverse to quality
- Significant conditions adverse to quality

Conditions adverse to quality are defined as items such as failures, malfunctions, deficiencies, deviations, defective material and equipment and nonconformances directly associated with a QL-1 or QL-2 (all inclusive) item or service. Conditions adverse to quality shall be documented and reported to the appropriate levels of management.

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

Significant conditions adverse to quality are defined as:

- A deficiency that would seriously impact a QL-1 (inclusive) item, activity or service from meeting or performing its intended function or output of assuring public health and safety;
- A deficiency in QL-1 (inclusive) design that has been approved for fabrication or construction where the design deviates extensively from design criteria and bases;
- A deficiency in the fabrication or construction of, or significant damage to, QL-1 (inclusive) structures, systems or components that require extensive evaluation, re-design or repair in order to establish the adequacy of the structure, system or component to perform its intended function of assuring public health and safety;
- A deviation from QL-1 (inclusive) performance specifications that shall require extensive evaluation, re-design, or repair to establish the adequacy of the structure, system or component to perform its intended function;
- A significant error in a QL-1 (inclusive) computer program used to support activities affecting quality after it has been released for use;
- A deficiency, repetitive in nature, related to a QL-1 or QL-2 (inclusive), activity, service or item subject to the LES QAPD; and
- A condition that, if left uncorrected, has the potential to have a serious negative impact on QL-1 or QL-2 (inclusive) activities, services or items subject to the LES QAPD controls.

If a supplier or subtier supplier discovers a defect or noncompliance which the supplier evaluates as a substantial safety hazard, then the supplier shall be required to report the item under 10 CFR 21, Reporting of Defects and Noncompliance, and notify LES in writing. If the supplier or subtier supplier is unable to determine if the defect/non compliance is a substantial safety hazard then the supplier or subtier supplier is required to report the item to LES for determination of reportability. In accordance with the CAP, significant conditions adverse to quality shall be evaluated for a stop work condition to determine if stopping work is warranted. If a stop work condition is identified, management shall issue stop work in accordance with the applicable procedure. Upon completion of action(s) to return the related significant condition adverse to quality to compliance, management shall take appropriate action to lift and close (in part or total) the stop work order.

IDENTIFIYING AND CLASSIFYING CONDITIONS ADVERSE TO SAFETY AND SECURITY

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

- Conditions adverse to safety and security
- Significant condition adverse to safety and security

Conditions adverse to safety and security are defined as items such as failures, malfunctions, deficiencies, deviations, defective material and equipment and nonconformance's directly associated with safety and security. Conditions adverse to safety and security shall be documented and reported to the appropriate levels of management.

In accordance with the CAP, responsible management shall investigate and fully identify the condition and document the results. Responsible management shall then utilize investigation results to determine and document corrective action (including remedial action and if

appropriate, actions to prevent recurrence). Responsible management shall complete remedial action and document completion of actions in a timely manner.

Significant conditions adverse to safety and security may include the following:

- trend of multiple conditions adverse to safety or security
- deficiencies in design, manufacturing , construction, testing, or process requiring substantial rework, repair, or replacement
- damage to a structure, system, component, or facility requiring substantial repairs
- a non-conservative error detected in a computer program or design input after it has been implemented or released for use;
- repeated failure to implement a portion of an approved procedure

FOLLOW-UP ACTION

The procedure(s) establishing the CAP shall include a requirement for management to take follow-up action to verify implementation of corrective action taken to address significant conditions adverse to quality, safety, and security. The QA organization shall be responsible for conducting periodic audits of these follow-up actions in accordance with Section 18 of the QAPD.

Significant Conditions adverse to quality, safety, and security shall be reported to the QA organization for tracking. Responsible management shall then determine the root cause, and corrective action (including remedial action and actions to prevent recurrence) based on investigation results. Concurrence from QA organization shall be obtained to ensure that QA requirements are satisfied. The QA organization will verify implementation of corrective actions.

TRENDING

Procedures shall include requirements and organizational responsibility for trending which will include conditions adverse to quality, safety, and security, and significant conditions adverse to quality, safety, and security. Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse trends. Identified adverse trends shall be handled in accordance with the CAP and reported to the appropriate management.

SECTION 17 QUALITY ASSURANCE RECORDS

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

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

RECORD MANAGEMENT SYSTEM

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

GENERATION, CLASSIFICATION AND RETENTION OF QA RECORDS

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

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

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

Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements of the LES QA Program but need not be retained for the life of the item because they do not meet the criteria for lifetime records. The retention period for nonpermanent records shall be documented in the applicable procedure.

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

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

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

RECEIVING, STORING, SAFEKEEPING AND PRESERVING QA RECORDS

A process shall be provided within approved procedures, which provides the requirements for receiving, storing, safekeeping and preserving QA records as defined within Supplement 17S-1 of NQA-1-1994 Part 1. In addition, the storage process for electronic QA records shall be provided within approved procedures requiring both media and compatible processing systems which ensure a retrievable and legible format for the entire retention period of the record. Responsibilities for implementing the processes shall be defined.

LES RECORDS CENTERS

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

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

- Records shall be temporarily stored in a container or facility with a fire rating of one (1) hour. The temporary storage container or facility shall bear an Underwriters' Laboratories label

(UL) (or equivalent) certifying one (1) hour fire protection, or be certified by a person competent in the technical field of fire protection.

- The maximum time limit for keeping records in temporary storage shall be specified by implementing procedures consistent with the nature or scope of work.

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

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

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

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

RETRIEVING AND DISPOSITIONING QA RECORDS

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

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

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

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

RETENTION OF QA RECORDS

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

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

CORRECTING INFORMATION IN QA RECORDS

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

REPLACING LOST OR DAMAGED QA RECORDS

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

ELECTRONIC RECORDS

Electronic records may be generated using several different methods, which may include electronic data, electronic mail and records resulting from the conversion from one media type to another. A process shall be provided within approved procedures which provide the requirements for electronic records authorization by electronic signatures, electronic approvals, or any other means that ensures traceability to a specific individual or organization of authorization with an associated date. The authentication information must be identified on the media or contained within or linked to the document itself.

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 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 Manager and has the organizational independence and authority to execute an effective audit process to meet all requirements of the QAPD. 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. For Construction Phase activities, internal audits of LES QA Level 1, QA Level 1 Graded, QA Level 1F, and QA Level 2AC activities shall be conducted on an annual basis or at least once during the life of the activity, whichever is shorter. For Operational Phase activities, internal audits shall be conducted on a biennial basis. Exceptions to these audit frequencies are those audit intervals defined by codes or regulations as committed to by the facility license and applicable to specific functional areas. Regularly scheduled internal audits shall be supplemented by additional audits of specific subjects when necessary to provide an adequate determination of the effectiveness of the QAPD. Internal audits to determine QAPD 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 QAPD applicable to LES workscope. These evaluations should include an assessment of the effectiveness of the applicable and active elements of the QAPD based upon previous audit results and corrective actions, nonconformance reports, identified trends, and significant organizational changes. Audits maybe supplemented by QA Surveillances conducted in accordance with approved procedures to ensure that QA is providing sufficient oversight of important QAPD activities. These surveillances are performed by the QA organization.

Audits shall be performed at the intervals designated herein for each audit area. Schedules shall be based on the month in which the audit starts. A maximum extension not to exceed 90 days for internal and external audits shall be allowed. When an audit interval extension greater than one month is used, the next audit for that particular audit area will be scheduled from the month

the original audit started. The provision for audit start date extension shall also apply supplier audits, surveys and evaluations.

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 Manager shall select and assign auditors who are independent of any direct responsibility for performing the work being audited and are capable of auditing the audit scope. 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 assigned to supervise the team, organize and direct the audit, prepare and coordinate issuance of the audit report and evaluate responses. Technical personnel may be used to assist in assessing the adequacy of technical processes based on their experience and expertise. 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 personnel shall be trained and qualified according to the requirements of Section 2, Quality Assurance Program.

PERFORMING AUDITS

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

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

REPORTING AUDIT RESULTS

The audit report shall be prepared and signed by the lead auditor 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 the 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 QAPD elements audited.
- A description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.
- A requested date for response by the audited organization.

RESPONDING TO AUDITS

Management of the audited organization or activity shall investigate adverse audit findings in a timely manner; determine and schedule corrective action, including measures to prevent recurrence, as applicable, according to the requirements of Section 16 Corrective Action.

EVALUATING AUDIT RESPONSES AND FOLLOW-UP ACTION

The LES QA organization is responsible for evaluating responses to audit findings and for follow-up action to verify the corrective action is accomplished 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 Manager confirms and documents applicable QAPD requirements have been met and the individual has been certified in accordance with the QA procedure on auditor qualification and certification.

SECTION 19 PROVISIONS FOR CHANGE

The LES QAPD is kept current as the design, construction, operation, (including maintenance and modification) and decommissioning activities progress. Appropriate changes to the QAPD are made based on any of the following:

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

Changes to the LES QAPD that do not reduce NRC license commitments, shall be incorporated in this QAPD and submitted to the NRC within 30 days of implementation. Any changes that reduce commitments in the approved QAPD, including those commitments that address the safety program and integrated safety analysis regulatory requirements, as well as the QA Level requirements in this QAPD, will be submitted to the NRC for review and approval prior to implementation.

10 CFR 21 APPLICABILITY FOR SUPPORT EQUIPMENT

QA Level 2AC Support Equipment is included in the Administrative Control IROFS boundary. Support Equipment is identified in SAR Table 3.4-1. This is equipment the worker may rely upon to take action with a level of quality commensurate with its importance to the worker's safety function. If the equipments failure to function does not represent a *substantial safety hazard* as defined in 10 CFR 21.3, then 10 CFR Part 21 requirements do not apply.

> Substantial safety hazard *means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC (under part 70 of this chapter).*

The loss of this Support Equipment must not represent a loss of a specified safety function of the IROFS. The safety function must be the worker action portion of the Administrative Control IROFS. If such Support Equipment should fail to function, then other available equipment and sufficient time to evaluate and take actions must be available to the worker. Additionally, the use of this equipment must be a precursor for the worker to take action to meet the safety performance requirements of the administrative control. Failure of this equipment would generally result in the failure of a precursor action and the evolution would be terminated before an accident could occur. For example, UF_6 should not be introduced into an empty cylinder (IROFS16a), the filling of a cylinder should be terminated (IROFS38), feed flow should be secured to the assay (IROFSC22).

SAR Table 3.4-1 identifies Support Equipment. Support Equipment meets QA Level 2AC requirement. The addition of Support Equipment to the Administrative Control IROFS boundary and use of management measures serve to enhance plant safety and worker response to postulated accident sequences in the Integrated Safety Analysis. Instrumentation or operated Support Equipment associated with Administrative Control IROFS must not have a failure that could result in a consequence which meets the criteria of a *substantial safety hazard*; otherwise, 10 CFR Part 21 would apply to Support Equipment.

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 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 Manager.

QA Level 2 program activities are those activities that do not meet the requirements for inclusion in the QA Level 1, QA Level 1 Graded, QA Level 1F, or QA Level 2AC program, but have elements or characteristics that may warrant control under a quality program more detailed than the QA Level 3 program. QA Level 2 requirements may be 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 UF_6, 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 similar to the equipment to be used in the facility. Installation and use of this type of equipment requires approval of LES management.

CONTROL OF PURCHASED ITEMS AND SERVICES

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

CONTROL OF PROCESSES, MEASURING AND TEST EQUIPMENT

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

INSPECTIONS

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

NONCONFORMANCES AND CORRECTIVE ACTION

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

RECORDS

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

AUDITS AND ASSESSMENTS

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

SECTION 21 QUALITY ASSURANCE PROGRAM FOR QUALITY ASSURANCE LEVEL 1- GRADED (QL-1G)

This section outlines the requirements for QL-1G Program. This section applies only to IROFS27e structures. The requirements of this section are intended to provide reasonable assurance that IROFS27e structure will perform their intended function by fulfilling the appropriate design, procurement, fabrication, and construction requirements necessary to demonstrate this functionality. IROFS27e structure(s) are those structures whose failure during a seismic, tornado or other extreme loading condition, could result in consequences that exceed the 10 CFR 70.61 performance requirements.

The QL-1G Program is based upon the following:

- Management measure shall be identified, for IROFS27e in IROFS Boundary Definition Documents in accordance with LES procedures.
- Critical elements of the IROFS27e structure for performance, construction and fabrication will be defined during the design phase. Appropriate requirements will be implemented to ensure that the final "as-built" structure(s) include these critical elements and are controlled through the design, procurement, and construction phases.
- The IROFS27e design for the building structural system shall be performed under an LES approved QA Level 1 Program.
- The IROFS27e structural design shall be based on design basis loading conditions defined within the LES licensing documents to withstand extreme environmental loads without consequences in excess of 10 CFR 70.61. The design loads shall be defined within an approved LES Specification Document which included design, procurement, construction, and fabrication requirements to assure that critical elements are identified and controlled during the design, procurement, and construction of the IROFS27e structure.
- Procurement controls of materials and services shall be in accordance with design requirements. Supplementary testing of materials by approved testing facilities, which provide satisfactory evidence of compliance with design requirements, may be used in lieu of procurement from approved venders.
- Construction activities shall be performed in accordance with documented work instructions. QC Hold Points shall be identified for inspection of critical elements. Such inspections will be subject to the full requirements applied to QC Hold Points under to QA Level 1 Program.
- A Project Quality Assurance Plan (PQAP) shall be prepared to implement the QL Level 1 Graded Program as defined below:
  - The PQAP shall provide a documented basis describing how those responsible for the IROFS27e structure design, procurement and fabrication and construction meet the requirements of the QL-1G Program as defined below. The PQAP shall be approved by the LES QA Manager prior to implementation of the procurement, fabrication and construction phases of the IROFS27e structure.
  - The PQAP format will follow the same outline as the QL-1G Program provided below, which is consistent with the requirements necessary for ensuring reasonable assurance of quality. The final PQAP, approved by the LES QA Manager, will identify specific provisions performed under each of the headings below to assure that critical elements defined during the design phases are controlled to provide reasonable assurance that the "as-built" IROFS27e structure will perform its function.

SECTION 21.1 ORGANIZATION

The roles, responsibilities and organizational interfaces to assure that those responsible for the IROFS27e structure design, procurement and fabrication and construction meet the requirements of the QL-1G Program shall be identified. The responsibility begins with the establishment of a QA Program at the very earliest aspect of the project.

Persons or organizations responsible for verification that a quality assurance program has been established and verified that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to:

(a) Identify quality problems:

(b) Initiate, recommend, or provide solutions to quality problems through designated channels:

(c) Verify implementation of solutions:

(d) Assure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

Such persons or organizations shall have direct access to responsible management at a level where appropriate action can be affected. Such persons or organizations shall report to a management level such that required authority and organization freedom are provided, including sufficient independence from cost and schedule considerations.

SECTION 21.2 QUALITY ASSURANCE PROGRAM

A documented quality assurance program shall be implemented and maintained in accordance with this section. The program shall identify the activities and items to which it applies. The establishment of the program shall include consideration of the technical aspects of the activities affecting quality. The program shall provide control over activities affecting quality to an extent consistent with their importance.

The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.

The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The program shall provide for any special process controls, test equipment, tools, and skills to attain the required quality and for verification of quality.

The program shall provide for indoctrination and training, as necessary, of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained.

LES shall regularly assess the adequacy of that part of the program for which QL-1G contractors are responsible and shall assure its effective implementation.

SECTION 21.3 DESIGN CONTROL

DESIGN INPUT CONTROL, DESIGN PROCESS, DESIGN VERIFICATION, DESIGN VERIFICATION METHODS, DESIGN CHANGE CONTROL, DESIGN INTERFACE CONTROL, COMPUTER SOFTWARE CONTROLS, DOCUMENTATION AND RECORDS

Design Control shall be in accordance with Section 3 of the QAPD.

The QA Level 1 design analysis and imposition of design basis loading conditions in specifications provide assurance that the IROFS27e structures will perform their intended function.

The requirements of this section apply to the critical elements for IROFS27e structures. The Quality Level of other aspects of the IROFS27e building package shall be identified in the PQAP.

The specification(s) for IROFS27e structures shall identify the applicable codes and standards for the performance of the detailed structural design. In addition, the specifications shall require the application of design basis loading conditions including: Design Basis Earthquake, Tornado Winds, Extreme Snow Loading and Rainfall Loadings associated with the postulated maximum precipitation (PMP) event.

SECTION 21.4 PROCUREMENT DOCUMENT CONTROL

LES procurements for laboratory testing services shall be issued only to those suppliers that have been evaluated and qualified as acceptable for the particular scope services to be procured.

Procurements of QL-1G materials, equipment and services may be procured from unevaluated suppliers provided that applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in procurement documents.

Testing by approved independent laboratories may be used in lieu of requiring Certified Material Test reports (CMTRs) from approved vendors or as a method of verifying compliance with design requirements for QL-1G materials obtained from commercial vendors.

LES procurement documents issued for QL-1G items or services shall include the following provisions.

- Statement of the scope of work to be performed by the supplier.
- Technical requirements including LES Specification(s) for IROFS27e which define minimum requirements for the materials provided and the level of documentation required. The LES Specifications will define the QL-1G Program requirements as follows;
  - Design bases, identified or referenced in the procurement documents.
  - Specific documents (such as drawings, codes, standards, regulations, procedure 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.
  - Test, inspections or acceptance requirements that LES will use to monitor and evaluate the performance of the supplier shall be specified.
- 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 Manager authorization. The Procurement Director may also establish hold points including 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 QA records.
- Requirements for the supplier to report the LES, in writing, of adverse quality conditions resulting in work stoppages and nonconformances. LES approval of nonconformances dispositioned as "Repair" or "Use As Is" is required. LES approved of partial and full work released prior to disposition of nonconformances resulting in work stoppages 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 be identified in procurement documents.

Procurement Document Review and Approval

A review of the procurement documents and any changes thereto shall be made to verify that documents include all applicable requirements specified and contain appropriate provisions to ensure that material, equipment or services will meet the procurement requirements. Reviews shall be performed and documented to provide objective evidence of satisfactory accomplishment of such review. Changes made as a result of the bid evaluation or pre-contract negotiations shall be incorporated into the procurement documents. Reviews shall include the following considerations:

1) Appropriate requirements are specified in the procurement specifications and supporting documents.
2) Supplies initiated exceptions and/or changes in the procurement document for QL-1G items and/or services shall be reviewed and approved by the LES technical representative and approved by LES QA Department.
3) 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, as appropriate.

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.

The requirements of 10 CFR 21, Reporting of Defects and Noncompliance, shall be the responsibility of LES for QL-1G procurements from unapproved vendors.

SECTION 21.5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Instructions and procedures, developed in support of QL-1G implementation for IROFS27e shall be of a type appropriate to the circumstances. These documents shall include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactory accomplished.

Critical elements of IROFS27e will be incorporated in a manner that provides assurance of compliance to required specifications including dimensional and physical performance criteria. e.g., spatial orientations, fastener torque, weld certifications, etc.

Drawings shall be developed in accordance with QL-1 requirements of Sections 3 and 4 of the QAPD.

The PQAP will document the specific project requirements for instructions, procedures, and drawing.

SECTION 21.6 DOCUMENT CONTROL

Documents that furnish documentary evidence of quality of critical elements are specified, prepared, and maintained. Documents shall be legible, identifiable, and retrievable. Documents are protected against damage, deterioration, and loss. Requirements and responsibilities for document transmittal, distribution, retention, maintenance, and disposition are established and documented within the PQAP.

SECTION 21.7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

Measures are established to ensure conformance with the procurement specifications and documents. Measures are established to ensure suppliers of material, equipment, or services are capable of supplying these items to the Quality Level specified in the procurement documents. This may be done by evaluation and approval of the supplier's products and facilities or audits of the supplier's quality program or by independent testing by an approved testing laboratory.

LES Engineering shall define critical elements applicable to the components and material furnished for the IROFS27e structures.

SECTION 21.8 IDENTIFICATION AND CONTROL MATERIALS, PARTS AND COMPONENTS

The controls necessary to ensure that only correct and accepted items are used or installed will be required and specified in the PQAP, including requirements for identification of materials, parts and components. Specific identification requirements which should be considered are as follows:

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

Specific control requirements shall include documented processes for the following:

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

The requirements for IROFS27e structures will include provisions for segregated and controlled laydown areas for the IROFS27e structural elements and bolting utilized to connect the structural elements. Storage requirements shall be in accordance with supplies requirements for QL-1G components.

Steel frame manufacture's standard marking and identification practices will be reviewed for adequacy in supporting construction activities by the contractor(s) performing the erection activity.

SECTION 21.9 CONTROL OF SPECIAL PROCESSES

Control of Special Processes shall be in accordance with Section 9 of the QAPD.

SECTION 21.10 INSPECTION

Inspections required to verify conformance of an item or activity to specify critical elements are planned and executed. Characteristics to be inspected and inspection methods to be employed are defined within the PQAP or installation procedures.

Critical elements of the IROFS27e structures that warrant inspection during construction and installation activities shall be documented in the implementing work plans as QC Hold Points requiring verification by trained and qualified Quality Control personnel (or approved designee). The inspections performed to verify critical elements for QL-1G IROFS27e Structures are treated as QA Level 1 inspection hold points.

QC Hold Points shall be identified within the supporting design documents and/or enumerated within the PQAP.

SECTION 21.11 TEST CONTROL

Test Control for the QL-1G Program shall be in accordance with the requirements of Section 11 of the QAPD.

SECTION 21.12 CONTROL OF MEASURING AND TEST EQUIPMENT

Control of Measuring And Test Equipment for the QL-1G Program shall be in accordance with the requirements of Section 12 of the QAPD.

SECTION 21.13 HANDLING, STORAGE, AND SHIPPING

Items and components determined to be critical to the IROFS27e performance shall be defined within the PQAP.

Handling, storage, cleaning, packaging, shipping and preservation of items are controlled in accordance with requirements of engineering or work control documents, shipping instructions or other specified documents, as applicable, to prevent damage or loss and to minimize deterioration.

SPECIAL EQUIPMENT, TOOLS AND ENVIRONMENTS

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

MARKING AND LABELING

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

SECTION 21.14 INSPECTION, TEST, AND OPERATING STATUS

Controls for the Inspection, Test and Operating Status for the QI-1G Program shall be in accordance with the requirements of Section 14 of the QAPD.

SECTION 21.15 NONCONFORMING ITEMS

Controls for the Nonconforming Items for the QI-1G Program shall be in accordance with the requirements of Section 15 of the QAPD.

Contractor(s) performing work of IROFS27e structure(s) shall utilize the LES processes for identification and control on nonconforming items. The PQAP shall include specific instructions concerning the interface between contractor(s) procedures and program and the applicable LES procedures to assure that the QA Level 1 Program requirements, as they pertain to nonconforming items, are implemented.

SECTION 21.16 CORRECTIVE ACTION

Corrective Action requirements for the QL-1G Program shall be in accordance with the requirements of Section 16 of the QAPD.

Contractor(s) performing work on IROFS27e structure(s) shall utilize the LES processes for identification and resolution of adverse conditions. The PQAP shall include specific instructions concerning the interface between contactor(s) procedures and program and the applicable LES procedures to assure that the QA Level 1 Program requirements, as they pertain to corrective actions, are implemented.

SECTION 21.17 QUALITY ASSURANCE RECORDS

Requirements for the identification, generation and control of Quality Assurance Records for the QL-1G Program shall be in accordance with the requirements of Section 17 of the QAPD.

SECTION 21.18 AUDITS

Auditing requirements for the QL-1G Program shall be in accordance with the requirements of Section 18 of the QAPD.

LES shall be responsible for the auditing requirements of Contractor(s) performing work on IROFS27e structure(s).

SECTION 21.19 PROVISIONS FOR CHANGE

Changes to the QL-1G Program shall be in accordance with Section 19 of the QAPD.

SECTION 22 QUALITY ASSURANCE PROGRAM FOR QUALITY ASSURANCE LEVEL 2AC

This section outlines the requirements for the QL-2AC Program. This section applies only to QL-2AC components. The requirements of this section are intended to provide reasonable assurance that QL-2AC components will fulfill their intended function, e.g., accurate and reliable indication or valve closure. The QL-2AC Program is based upon the following:

Management measures will be identified for QL-2AC components in accordance with LES procedures.

Activities for QL-2AC components, to ensure reliability and accuracy, include initial calibration and periodic in service calibration checks.

QA Level 2AC program activities are those activities that do not meet the requirements for inclusion in the QA Level 1 or QA Level 1 Graded. QA Level 2 AC apply to the Administrative Control IROFS Support Equipment identified in Table 3.4-1 of the Safety Analysis Report.

SECTION 22.1 ORGANIZATION

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

SECTION 22.2 QUALITY ASSURANCE PROGRAM

The program will provide for indoctrination and training, as necessary, of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained.

LES will assess the adequacy of that part of the program for which QL-2AC applies to assure its effective implementation.

SECTION 22.3 DESIGN CONTROL, DESIGN DOCUMENTATION AND RECORDS

LES will specify applicable design requirements for QL-2AC components. QL-2AC components will be identified in applicable design documents.

SECTION 22.4 PROCUREMENT

Quality Level 2AC procurements shall be conducted in accordance with the UUSA requirements for Quality Level 3 procurements. The QL-3 procurement process is described in Procurement Department procedures. The process includes requirements for: formal interfaces between UUSA and the supplier, identification of specific terms and conditions, procurement planning, complete and accurate description of needs, reviews and approvals by knowledgeable and responsible individuals, technical and quality requirements, verification of technical adequacy and completeness, design review, change review and approval, identification of deviations by suppliers, methods of acceptance, procurement package closure and documentation.

SECTION 22.5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

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 and to the level of detail necessary. Work activities are performed in accordance with written procedures. Procedures will contain the actions, acceptance criteria, and methods for evaluation to ensure prescribed activities have been satisfactorily accomplished.

SECTION 22.6 DOCUMENT CONTROL

Documents that furnish documentary evidence of quality of critical elements are specified, prepared, and maintained. Documents will be legible, identifiable, and retrievable. Documents are protected against damage, deterioration, and loss. Requirements and responsibilities for document transmittal, distribution, retention, maintenance, and disposition are established. Requirements for the identification, generation, and control of Quality Assurance Documents for the QL-2AC components will be in accordance with the requirements of Section 6 of the QAPD.

SECTION 22.7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

Measures are established to ensure conformance with procurement specifications and documents.

LES will define critical elements applicable to the components and material.

SECTION 22.8 IDENTIFICATION AND CONTROL MATERIALS, PARTS AND COMPONENTS

The controls necessary to ensure that only correct and accepted items are used or installed will be required and specified in implementing procedures, including requirements for identification of materials, parts and components.

SECTION 22.9 CONTROL OF SPECIAL PROCESSES

This section is not applicable to QL-2AC components.

SECTION 22.10 INSPECTION

Inspections required to verify conformance of an item or activity to specified requirements are planned and executed. Characteristics to be inspected and inspection methods to be employed are specified. Inspection results are documented.

SECTION 22.11 TEST CONTROL

Procedures will provide management controls for testing of QL-2AC components. Documents generated utilizing these procedures will contain controls such as hold points, activity checklists, and in many cases, step-by-step sign-offs which indicate the status of testing.

SECTION 22.12 CONTROL OF MEASURING AND TEST EQUIPMENT

Processes affecting quality of items or services are controlled. To maintain accuracy within specified limits, the LES QA Program requires that devices (e.g., tools, gauges, instruments), and measuring and test equipment, including process-related instrumentation and controls that are used in activities affecting the quality of items, are properly controlled, calibrated, and adjusted at specified periods in accordance with written procedures.

For calibration of components that have Material Control and Accounting calibration requirements imposed on them, the MC&A calibration is considered equivalent.

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

CALIBRATION

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

DOCUMENTING THE USE OF M&TE

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

OUT OF CALIBRATION M&TE

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

- The calibration due date or interval has passed without re-calibration.

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

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

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

LOST M&TE

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

HANDLING AND STORAGE

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

COMMERCIAL DEVICES

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

M&TE DOCUMENTATION

M&TE calibration documentation shall include the following information:

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

SECTION 22.13 HANDLING, STORAGE, AND SHIPPING

Handling, storage, cleaning, packaging, shipping and preservation of QL-2AC components is controlled in accordance with requirements of work control documents, shipping instructions or other specified documents, as applicable, to prevent damage or loss and to minimize deterioration.

Measures will be established for marking and labeling for the packaging, shipping, handling and storage of items, as necessary, to adequately identify, maintain and preserve QL-2AC components. Markings and labels will indicate the presence of special environments or the need for special controls, if necessary.

SECTION 22.14 INSPECTION, TEST, AND OPERATING STATUS

This section establishes requirements for LES to identify the status of inspection and test activities associated with QL-2AC components. Status is indicated either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used or operated. Status is maintained through indicators (i.e., physical location and tags, markings, shop travelers, stamps, inspection records or other suitable means). The authority for application and removal of tags, markings, labels and stamps are specified. Status indicators will also provide for indicating the operating status of systems and components of the facility (i.e., tagging valves and switches) to prevent inadvertent operation.

Procedures will provide management controls for installation, testing or repair of QL-2AC components. Documents generated utilizing these procedures will contain controls, such as, hold points, activity checklists, and in many cases, step-by-step signoffs which indicate the status of installation, inspections, and tests. This system is used to prevent inadvertent use of nonconforming items or bypassing of inspections and tests and prevent inadvertent operation.

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

Controls will be established for changing the sequence of inspections, tests, and other activities which require the same controls as the original review and approval.

SECTION 22.15 NONCONFORMING ITEMS

Controls for the Nonconforming Items for the QL-2AC components will be in accordance with the requirements of Section 15 of the QAPD.

SECTION 22.16 CORRECTIVE ACTION

Corrective Action requirements for the QL-2AC components will be in accordance with the requirements of Section 16 of the QAPD.

SECTION 22.17 QUALITY ASSURANCE RECORDS

Requirements for the identification, generation and control of Quality Assurance Records for the QL-2AC components will be in accordance with the requirements of Section 17 of the QAPD.

SECTION 22.18 AUDITS

Auditing requirements for the QL-2AC components will be in accordance with the requirements of Section 18 of the QAPD.

SECTION 22.19 PROVISIONS FOR CHANGE

Any removal of management measures designed to provide assurance of the Administrative Control IROFS Support Equipment used by the worker, or removal of the Administrative Control IROFS Support Equipment quality requirements, would be considered a reduction in commitment and require regulatory approval prior to implementation.

SECTION 23 QUALITY ASSURANCE PROGRAM FOR QUALITY ASSURANCE LEVEL 1- FIRE PROTECTION (QL-1F)

This section outlines the requirements for the graded QL-1F Program. This section applies only to fire protection features designated as Items Relied On For Safety (IROFS). The requirements of this section are intended to provide reasonable assurance that such a designated IROFS will perform its intended function by fulfilling the appropriate design, procurement, fabrication, and construction requirements necessary to demonstrate this functionality. Such IROFS are those fire protection features (e.g., designated structural fire barriers, isolation systems, fire detection and suppression, and fire prevention measures) whose failure during a fire could result in consequences that exceed the 10 CFR 70.61 performance requirements.

When applied to fire protection systems procured for facilities and other activities licensed under 10 CFR Part 70 of the chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard. For fire protection systems designated as items relied on for safety, a basic component may be directly procured from a commercial entity by a Part 70 licensee if (1) the system, structure or component is manufactured to an established, acceptable national code or standard that includes some independent product endorsements based on qualification testing or periodic testing of selected characteristics of the component and (2) the acceptability of the item's manufacture, testing, and/or certification has been reviewed and verified by the licensee prior to use as a basic component. Once the acceptability of the item has been verified by UUSA and the item has been designated for use a basic component, the licensee accepts responsibility for Part 21 reporting.

As modified, this definition of a basic component provides suitable guidance for the procurement of fire protection IROFS and the supporting quality verification activities that will be performed by LES. The revised definition will allow LES to credit a supplier's certification (e.g., Underwriters Laboratory [UL] or Factory Mutual [FM] as a means of establishing the supplier's performance history and capability to supply basic components. It is recognized, however, that a supplier's certification alone is not suitable to establish the supplier's capability to supply basic components; LES will still perform a review and /or verification of the item's acceptability through independent measures, such as through receipt inspection activities, independent technical reviews, or other suitable measures. Therefore, the revised definition of basic component presents a suitable approach for establishing the requisite quality of fire protection basic components through: (1) procurement from certified suppliers and the use of licensed, qualified contractors who commit to meet accepted fire protection Codes and Standards, and (2) verification of the item's acceptability by LES.

Fire protection features shall be procured, constructed, and installed with appropriate UL/FM fire ratings and/or ASTM tested designs, as applicable. These systems shall meet the applicable requirements of the International Fire Code (IFC), the International Building Code (IBC), and the National Fire Protection Association (NFPA) in accordance with the NEF Code of Record, in Table 3.0-1 of the Integrated Safety Analysis Summary. Fire rated features that are not specifically tested as identified in UL, ASTM, or NFPA are to be evaluated to be equivalent in performance to a nationally recognized fire standard.

For engineered fire protection IROFS, items manufactured, procured, and installed in accordance with industry standards (e.g., NFPA, UL) that include independent product assessments by a nationally recognized testing laboratory, certified by state authorities, can be used to assure component performance.

Because some IROFS involve elements of fire protection (e.g., designated fire barriers, smoke detection, and control of combustibles), specifically defined portions of the Quality Assurance Program are invoked for fire protection to ensure that required fire protection attributed attributes are adequately provided and maintained. In the context of the application of the QA Program to fire protection, only the subset of fire protection (e.g., designated structures, systems, components, procedures, etc) related to IROFS is included.

The elements of the QA Program invoked for fire protection features designated as IROFS are described in the following Sections 23.1 through 23.19.

For engineered fire protection IROFS, items manufactured, procured, and installed in accordance with industry standards (e.g., NFPA, UL) that include independent product assessments by a nationally recognized testing laboratory, certified by state authorities, can be used to assure component performance.

The QL-1F Program is based upon the following:

- Management measures shall be identified for fire protection features designated as IROFS in IROFS Boundary Definition Documents in accordance with LES procedures.

- Critical elements of these IROFS for performance, construction, fabrication, or implementation will be defined during the design phase. Appropriate requirements will be implemented to ensure that the final "as-built" structure(s) include these critical elements and are controlled through the design, procurement, construction, and operations phases.

- Procurement controls of materials and services shall be in accordance with design requirements.

SECTION 23.1 ORGANIZATION

The Organization requirements for the QL-1F Program shall be in accordance with Section 1 of the QAPD.

SECTION 23.2 QUALITY ASSURANCE PROGRAM

The QA Program for the QL-1F Program shall be in accordance with the requirements of Section 2 of the QAPD.

SECTION 23.3 DESIGN CONTROL

Design Control for the QL-1F Program shall be in accordance with the requirements of Section 3 of the QAPD.

SECTION 23.4 PROCUREMENT DOCUMENT CONTROL

Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in procurement documents for items and services.

Basic components for use in QL-1F will be procured as QL-3 with the procurement document stipulating the requirement for the material to meet one or more applicable fire protection industry standards. Section 7.6 of the Safety Analysis Report provides a listing of the applicable fire protection standards.

Procurement Document Content

LES procurement documents issued for QA Level 1F (QL-1F) items or services shall include the following provisions, as applicable to the procured material, equipment or service as described in approved procedures controlled under the QAPD:

- Statement of the scope of work to be performed by the supplier.
- For materials, the supplier chosen will be an Authorized and/or Certified supplier for the standard used to certify the material *(i.e. UL, FM). For vendors who are not the manufacturers of the items, i.e., the vendor is not involved in any aspect of the manufacturing or certification of the material but is a supplier of the materials, then the Supplier must ensure all materials provided are accompanied by documentation that the products were manufactured to nationally recognized standard (i.e., ASTM, NFPA) which includes independent product endorsements based on qualification testing.
- For Services, the contractor will be on the LES Approved Suppliers List or will work under the direct control and oversight of the LES Quality Assurance Program.
- 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.
    - Test, inspections or acceptance requirements that LES will use to monitor and evaluate the performance of the supplier shall be specified. Since Certificates of Conformance or Certified Material Test Reports are not provided with QL-3 procurements, as an alternative means to provide reasonable assurance that the materials being sought comply with an industry recognized fire protection standard, one or more of the following actions can be taken:
        - Vendor is to ensure the material will contain a UL, FM or other test certification symbol on the product (e.g., on a caulking tube).
        - Vendor is to package the material to be received such that a nationally recognized standard, (e.g., ASTM, ANSI, SAE, etc.,

code) is identifiable on the package (e.g., if screws, bolts or sheet metal are involved), which includes independent product endorsements based on qualification testing.

Quality Assurance Program requirements including:

- 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 point beyond which work cannot proceed by the supplier without LES QA Manager authorization. The Procurement Director may also establish hold points indicating work that cannot proceed without authorization by the Procurement Director.

- Provisions for 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.

- Provisions for identifying spare and replacement parts or assemblies and the appropriate delineation of technical and quality assurance data required for ordering these parts or assemblies.

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 23.4, Procurement Document Content, above and contain appropriate provisions to ensure that material, equipment or services will meet the governing requirements.

Reviewers shall include representatives from the Procurement and QA organizations. The QA review shall assure compliance with quality assurance requirements.

Procurement Document Change

Changes to the scope of work, technical requirements, quality assurance program requirements, right of access, and list 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 23.5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

The Instructions, Procedures, and Drawings for the QL-1F Program shall be in accordance with the requirements of Section 5 of the QAPD.

SECTION 23.6 DOCUMENT CONTROL

Document Control for the QL-1F Program shall be in accordance with the requirements of Section 6 of the QAPD.

SECTION 23.7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

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

Section4, Procurement Document Control provides specific LES exemptions to 10 CFR 21.3 for the definitions of "commercial grade item", "basic components", "critical characteristics", "dedicating entity", and "dedication".

PROCUREMENT PLANNING

LES procurements shall be planned and documented to ensure a systematic approach to the procurement process exists and supports the schedule. Procurement planning shall be performed in accordance with Supplement 7S-1 Section2 of NQA-1-1994 as defined in approved procedures controlled under the QAPD. Procurement planning shall be accomplished as early as possible, but no later than at the start of those procurement activities that are required to be controlled to assure interface compatibility and a uniform approach to the procurement process.

These actions will be performed relative to the level of importance, complexity and quantity of the item or service being procured and the supplier's quality performance.

Procurement planning shall include the involvement of the LES QA organization to ensure that the QA requirements have been properly identified.

For materials, the Suppler chosen will be an authorized and/or Certified supplier for the standard used to certify the material (i.e. UL, FM).

For services, the contractor will be on the LES Approved Suppliers List or will work under the direct control and oversight of the LES Quality Assurance Program.

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.

Typically, QL-1 F material procurements are from vendors who are not the manufacturers of the items (distributors), that is, the vendor is not involved in any aspect of the manufacturing or certification of the material. Thus, evaluation of QL-1 F vendors for material will not be as stringent as QL-1 or QL-2 purchases. The evaluations performed of QL-1F suppliers should include: Evaluation of QL-1F suppliers should include:

- The evaluation of QL-1F supplier's history for providing an identical or similar product.
- Review of financial rating of the supplier (e.g. Dunn and Bradstreet rating report)
- Verification that the vendor (for services performed on site) is licensed to do business in the state of New Mexico.

Evaluations performed on the QL-1F vendors will be documented in the purchase order file.

PROPOSAL/BID EVALUATION

For proposals and bids, technically qualified personnel from the 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 capabilities and past performance
- Alternatives and exceptions

Before the contract is awarded, the 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 PERFORMANCE EVALUATION

The LES Procurement Director shall establish measures to routinely interface with the supplier and to verify supplier performance. The measures shall include:

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

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

CONTROL OF CHANGES IN ITEMS OR SERVICES

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

ACCEPTANCE OF ITEMS OR SERVICES

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

- Evaluating the supplier certificate of conformance,
- Performing one or a combination of receiving inspection or post-installation test,
- Technical verification of the data produced (services only),
- Review of objective evidence for conformance to procurement requirements (services only).

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

RECEIVING INSPECTION

When receiving inspection is used to accept an item:

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

POST-INSTALLATION TESTING

When post-installation testing is used as a method of acceptance the affected/involved LES organization manager and the supplier, when possible, shall mutually establish test requirements and acceptance documentation. The LES –

Design Authority is ultimately responsible for ensuring appropriate test requirements and acceptance documentation are established."

SECTION 23.8 IDENTIFICATION AND CONTROL MATERIALS, PARTS AND COMPONENTS

Basic components for use in QL-1F will be procured as QL-3 with the procurement document stipulating the requirement for the material to meet one or more applicable fire protection industry standards.

The controls necessary to ensure that only correct QL-1F items are used or installed will be required by the appropriate QA procedure. Identification requirements for materials, parts and components are stated in design specifications, drawings, and procurement documents. Specific identification requirements are as follows.

- Identification markings, when used shall be applied using materials and methods which provide a clear and legible identification and do not detrimentally affect the function or service life of the item. Markings shall not be obliterated or hidden by surface treatments or coatings unless other means of identification are substituted.
- Documentation is maintained throughout fabrication, erection, installation, or use.
- Sufficient precautions shall be taken to preclude identifying materials in a manner that degrades the function or quality of the item being identified.

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

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

SECTION 23.9 CONTROL OF SPECIAL PROCESSES

Control of Special Processes shall be in accordance with Section 9 of the QAPD.

SECTION 23.10 INSPECTION

Inspection requirements for the QL-1F Program shall be in accordance with Section 10 of the QAPD.

SECTION 23.11 TEST CONTROL

Following installation, modification, repair, or replacement of fire protection equipment, material or components, sufficient testing is performed to demonstrate satisfactory in-service performance pursuant to the specified design criteria. This testing is in accordance with the requirements of Section 11 of the QAPD. Written test procedures are prepared by the responsible engineer group and incorporate the requirements and acceptance limits contain in the applicable design documents. Third party testing, if necessary, will be performed in accordance with the requirements of Section 11 of the QAPD.

SECTION 23.12 CONTROL OF MEASURING AND TEST EQUIPMENT

Control of measuring and test equipment shall be in accordance with the requirements of Section 12 of the QAPD.

SECTION 23.13 HANDLING, STORAGE, AND SHIPPING

Handling, Storage, and Shipping requirements for the QL-1F Program shall be in accordance with Section 13 of the QAPD.

SECTION 23.14 INSPECTION, TEST, AND OPERATING STATUS

Inspection, Test, and Operating Status requirements for the QL-1F Program shall be in accordance with Section 14 of the QAPD.

SECTION 23.15 NONCONFORMING ITEMS

Controls for the Nonconforming Items for the QL-1F Program shall be in accordance with the requirements of Section 15 of the QAPD.

SECTION 23.16 CORRECTIVE ACTION

Corrective Action requirements for the QL-1F Program shall be in accordance with the requirements of Section 16 of the QAPD.

SECTION 23.17 QUALITY ASSURANCE RECORDS

Requirements for the identification, generation and control of records for the QL-1F Program shall be in accordance with the requirements of Section 17 of the QAPD.

SECTION 23.18 AUDITS

Auditing requirements for the QL-1F Program shall be in accordance with the requirements of Section 18 of the QAPD. In addition, the audit team shall include a fire protection engineer. The fire protection engineer, can be a licensee employee, but should be an outside independent fire protection consultant every third year. This audit team approach will ensure that the technical requirements as well as the QA requirements are adequately assessed.

SECTION 23.19 PROVISIONS FOR CHANGE

Changes to the QL-1F Program shall be in accordance with Section 19 of the QAPD.