Enclosure 3
Page changes to the Quality Assurance Program Description showing changes made under Revision 19

LES

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SAFETY ANALYSIS REPORT
APPENDIX A

QUALITY ASSURANCE PROGRAM DESCRIPTION

REVISION 19

LES building and operating the National Enrichment Facility providing energy independence for America
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Summary of Changes for Revision 18		
Issue / Date	**Change**	**Description of Change**
18a 02-02-09	n/a	No additional textual changes were made as part of Issue 18a. The document version change is necessary since changes to the SAR have been made and the QAPD is Appendix A of the SAR.
18b 02-09-09	n/a	No additional textual changes were made as part of Issue 18b. The document version change is necessary since changes to the SAR have been made and the QAPD is Appendix A of the SAR.
18c 02-23-09	LBDCR-09-0018 02-06-09	Provide an alternate sole IROFS for DBE No CC Package
19 02-27-09	LBDCR-09-0025 02-24-09	Clarify the QA Level 2 requirements No CC package
	n/a	Submittal to NRC for non substantial changes previously approved by LES

INTRODUCTION

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

The LES QA Program described herein covers design, construction (including pre-operational testing), operation (including testing), maintenance and modification, and decommissioning of the facility. This Quality Assurance Program Description (QAPD) describes the requirements to be applied to those structures, systems and components, and activities that have been designated Quality Assurance (QA) Level 1 and QA Level 1 Graded. LBDCR-09-0018

QA Level 1 is applied exclusively to items relied on for safety (IROFS), any items which are determined to ~~affect the function of the IROFS~~be essential for the function of an IROFS, and to items required to satisfy regulatory requirements for which QA Level 1 requirements are applied. LBDCR-09-0018 The development of the IROFS list is a product of the Integrated Safety Analysis (ISA) 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 sections of this QAPD are applied to IROFS, any SSC and administrative controls which are determined to ~~affect the functions of the IROFS~~be essential for the function of an IROFS and items required to satisfy regulatory requirements for which QA Level 1 requirements are applied. LBDCR-09-0018 Application of the QAPD requirements is part of the configuration management system and will be performed in accordance with documented procedures. The LES QA organization reviews and concurs with the selection of the IROFS and the application of QA requirements to the IROFS, any items which are determined to ~~affect the functions of the~~be essential for the function of an IROFS and items required to satisfy regulatory requirements for which QA Level 1 requirements are applied.

The QA Level 1 Graded program is provided in Section 21, Quality Assurance Program for QA Level 1 Graded. QA Level 1 Graded is applied only to IROFS27e 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. LBDCR-09-0018

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. LES 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 to protect the public and worker, and to minimize 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 and do not affect the functions of the IROFS. 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 ~~three~~four levels defined as follows: LBDCR-09-0018

QA LEVEL 1 REQUIREMENTS

The QA Level 1 Program shall conform to the criteria established in 10 CFR 50, Appendix B. These criteria shall be met by commitments to follow the guidelines of ASME NQA-1-1994, including supplements as revised by the ASME NQA-1a-1995 Addenda. The QA Level 1 QA program shall be applied to those structures, systems, components, and administrative controls that have been determined to be IROFS, items that are essential to~~affect~~ the functions of the IROFS, and to items required to satisfy regulatory requirements for which QA Level 1 requirements are applied. LBDCR-09-0018

QA LEVEL 1 GRADED REQUIREMENTS

The QA Level 1 Graded QA 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 Graded program applies to: LBDCR-09-0018

Separation Building Modules (SBMs) with the exception of slab on grade or supports for internally housed QA Level 1 IROFS that are required to perform a safety function for a seismic event.

QA LEVEL 2 REQUIREMENTS

The QA Level 2 program is an owner defined QA program that uses the ASME NQA 1 standard as guidance to identify and manage SSCs and activities that do not meet the requirements for inclusion in the QA Level 1 or QA Level 1 Graded program, but have ~~attributes~~elements or characteristics that warrant control under a quality program more detailed than the QA Level 3 program. General QA Level 2 requirements are described in Section 20, Quality Assurance Program for QA Level 2. For contractors, the QA Level 2 program shall be described in documents that must be approved by LES or be described in approved LES documents. The QA Level 2 program shall be applied to Owner designated structures, systems, components, and activities. An International Organization for Standardization (ISO) 9000 series QA program may be acceptable for QA Level 2 applications provided it complies with applicable LES QAPD requirements and the contractor's QAPD is reviewed and accepted by the LES QA Director. LBDCR-09-0018 LBDCR-09-0018

QA LEVEL 3 REQUIREMENTS

The QA Level 3 program is defined as standard commercial practice. A documented QA Level 3 program is not required. QA Level 3 governs all activities not designated as QA Level 1, ~~or~~ QA Level 2, or QA Level 1 Graded. LBDCR-09-0018

SECTION 1 ORGANIZATION

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

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

CORPORATE ORGANIZATION AND FUNCTIONS

LES is the owner and operator of the enrichment facility. LES is a registered limited liability company formed to provide uranium enrichment services for commercial nuclear power plants. LES is responsible for the design, construction, operation and decommissioning of the enrichment facility in accordance with its QA Program. The President of LES reports to the LES Board of Managers as described in Section 1.2 of the SAR. LBDCR-09-0018

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

DESIGN AND CONSTRUCTION ORGANIZATION AND FUNCTIONS

LES has contracted Urenco, the owner of the enrichment technology and operator of enrichment facilities in Europe, to prepare the reference design for the facility. An architect/engineering (A/E) firm was contracted and is under the responsibility of the Vice President - Engineering, Chief Operating Officer and Chief Nuclear Officer, or President to further specify structures and systems of the facility, and ensure the reference design meets all applicable U.S. codes and standards. A contractor specializing in site evaluations was contracted to perform the site selection evaluation. A nuclear consulting company was contracted to conduct the site characterization, perform the Integrated Safety Analysis and to support development of the license application including the Environmental Report.

During the design and construction phases, preparation of design and construction documents and construction itself are contracted to qualified contractors. The Chief Operating Officer and Chief Nuclear Officer is responsible for managing the associated activities as described in Section 2.1.2, *Design and Construction Organization*, of the SAR. Figure 2.1-1 of the SAR, shows that the Chief Operating Officer and Chief Nuclear Officer is assisted by the Vice

- QA technical reviews of procurement documents
- Review and concurrence of changes to the identified IROFS, items that ~~could affect~~are essential to the functions of IROFS, and items required to satisfy regulatory requirements for which QA Level 1 or QA Level 1 Graded requirements are applied LBDCR-09-0018
- Oversight of the Corrective Action and Nonconformance Processes
- Maintain the LES Approved Suppliers List (ASL)
- Administer the Auditor and Lead Auditor Certification Process
- QA reviews of project documents
- Approval of contractor QA Programs
- Oversight of contractor QA Programs Implementation
- Oversight of the quality of design and construction, including but not limited to the ISA process and the resultant selection of IROFS
- Oversight of document and records control

- QA Verification
  - Audits, surveillances and assessments
  - Contractor/supplier evaluations
  - Contractor nonconformances
  - Equipment/Vendor Shop Inspections
  - Witness vendor acceptance testing

The following additional QA Director responsibilities are included for start up testing and operations:

- QA Technical Support
  - Quality Engineering support of startup organization
  - Oversight of startup activities
  - QA selected reviews and oversight of programs developed for operations, including but not limited to the ISA process, the identification of IROFS and items that ~~affect~~are essential to the performance of IROFS and any changes thereto, the controls for assuring IROFS performance and verifying and maintaining the facility design basis. LBDCR-09-0018
  - QA selected reviews and oversight of operations including maintenance and testing and modification procedures
  - Review and concurrence of changes to the identified IROFS, items that ~~could affect~~are essential to the functions of IROFS, and items required to satisfy regulatory requirements for which QA Level 1 or QA Level 1 Graded requirements are applied LBDCR-09-0018
  - QA Oversight of operations procedure implementation
  - Quality Control (QC) Inspection certification process
- QC Inspections

- Receipt Inspections of QA Level 1 items
- Applicable discipline inspections of modifications to QA Level 1 components

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

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

ORGANIZATIONAL INTERFACES

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

DELEGATION OF WORK

The delegation of work between LES and contractors is identified in applicable plans, contracts and implementing procedures. In all cases of delegation, LES retains the overall responsibility for all work performed under the direction of LES. All LES QA Level 1, QA Level 1 Graded, 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.

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

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

IDENTIFICATION AND APPLICATION OF QA CONTROLS

QA Level 1 is applied exclusively to IROFS, any items which are determined to ~~affect~~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 ~~affect~~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 ~~affect the~~be essential to the functions of the IROFS and items required to satisfy regulatory requirements for which QA Level 1 requirements are applied. LBDCR-09-0018 LBDCR-09-0018

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 Graded program applies to: LBDCR-09-0018

Separation Building Modules (SBMs) with the exception of slab on grade or supports for internally housed QA Level 1 IROFS that are required to perform a safety function for a seismic event. LBDCR-09-0018

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 ~~and do not affect the functions of the IROFS~~. 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. LBDCR-09-0018

The QA program is established at the very earliest aspects of the project. It is comprised of ~~three~~four levels defined as follow: LBDCR-09-0018

QA LEVEL 1 REQUIREMENTS

The QA Level 1 Program shall conform to the criteria established in 10 CFR 50, Appendix B. These criteria shall be met by commitments to follow the guidelines of ASME NQA-1-1994, including supplements as revised by the ASME NQA-1a-1995 Addenda. The QA Level 1 QA program shall be applied to those structures, systems, components, and administrative controls that have been determined to be IROFS, items that ~~affect~~are essential to the functions of the IROFS, and to items required to satisfy regulatory requirements for which QA Level 1 requirements are applied. LBDCR-09-0018

QA LEVEL 1 GRADED

The QA Level 1 Graded QA 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 Graded program applies to: LBDCR-09-0018

- Separation Building Modules (SBMs) with the exception of slab on grade or supports for internally housed QA Level 1 IROFS that are required to perform a safety function for a seismic event.

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 or QA Level Graded program, but have ~~attributes~~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 LBDCR-09-0018

structures, systems, components, and activities. An International Organization for Standardization (ISO) 9000 series QA program may be acceptable for QA Level 2 applications provided it complies with applicable LES QAPD requirements and the contractor's QAPD is reviewed and accepted by the LES QA Director. The QA Level 2 SSCs which support normal operations shall be identified in applicable QA procedures and implementing documents and documents specifying quality requirements or prescribing activities affecting quality.

QA LEVEL 3 REQUIREMENTS

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

QUALITY ASSURANCE TRAINING

LES employees who perform QA Level 1 activities receive LES QA Indoctrination Training. This training includes general criteria, including introduction to applicable codes, standards, QA Procedures, QA Program elements and job responsibilities and authorities. LES personnel assigned to perform QA Level 1 and QA Level 1 Graded activities are also required to complete training in the specific LES QA procedures needed to perform their job roles and responsibilities as assigned by their supervisor. Detailed QA training is provided on the LES QA Program and job specific QA procedures prior to an employee beginning QA Level 1 and QA Level 1 Graded work. Supervision is responsible for ensuring that personnel performing work under their supervision are appropriately trained. LES will also include a version of QA Indoctrination Training as part of the general employee training given to all full-time employees. LBDCR-09-0018 LBDCR-09-0018

The Training Manager is responsible for coordinating QA training activities for LES. Support Services serves as a centralized training support service for supervision in coordinating training and maintaining QA training records. This responsibility is carried out as support for line management. LES supervisory personnel are responsible for determining the type and extent of the training to be provided to an individual, and ensuring that the training is properly documented for personnel performing QA Level 1 and QA Level 1 Graded activities. Retraining, when applicable, shall occur in order to maintain proficiency or when changes to work methods, technology, or job responsibilities occur. Such retraining is also documented LBDCR-09-0018

MANAGEMENT ASSESSMENTS

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

QUALIFICATION/CERTIFICATION OF INSPECTION AND TEST PERSONNEL

Inspection and test personnel performing QA Level 1 and QA Level 1 Graded 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. LBDCR-09-0018

QUALIFICATION/CERTIFICATION OF NONDESTRUCTIVE EXAMINATION (NDE) PERSONNEL

Nondestructive Examination (NDE) personnel performing QA Level 1 or QA Level 1 Graded activities shall be certified in accordance with LES procedures that meet the requirements of NQA-1a-1995 Part 1 Supplement 2S-2, Supplementary Requirements for the Qualification of Nondestructive Examination Personnel and American Society of Nondestructive Testing (ASNT) Recommended Practice No. SNT-TC-1A, Personnel Qualification and Certification in Nondestructive Testing, December 1988 Edition. Qualification/certification records meeting the requirements of Supplement 2S-2 shall be established and maintained as QA records. LBDCR-09-0018

QUALITY ASSURANCE AUDIT PERSONNEL

Audit personnel performing QA Level 1 or QA Level 1 Graded 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. LBDCR-09-0018

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.

- Provisions for establishing witness/inspection hold points beyond which work cannot proceed by the supplier without LES QA Director authorization. The Procurement Director may also establish hold points indicating work that cannot proceed without authorization by the Procurement Director.
- Documentation required to be submitted to LES for information; review or acceptance shall be identified along with a document submittal schedule. Record retention times, disposition requirements and record maintenance responsibilities shall be identified for documentation that will become quality assurance records.
- Requirements for the supplier to report to LES in writing adverse quality conditions resulting in work stoppages and nonconformances. LES approval of partial and full work releases and disposition of nonconformances is required.
- Identification of any spare and replacement parts or assemblies and the appropriate delineation of technical and quality assurance data required for ordering these parts or assemblies. Commercial Grade procurements shall also be identified in procurement documents.

Procurement Document content for QA Level 1-Graded items or services shall be in accordance with Section 21.4. LBDCR-09-0018

Procurement Document Review and Approval

Procurement document reviews shall be performed and documented before issuing the procurement documents to the supplier. A review of the procurement documents and any changes thereto shall be made to verify that documents include all applicable requirements specified under Section 4, Procurement Document Content, above and contain appropriate provisions to ensure that material, equipment or services will meet the governing requirements. Reviews shall be performed and documented to provide objective evidence of satisfactory accomplishment of such review prior to contract award. Changes made as a result of the bid evaluation or precontract negotiations shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed prior to contract award. This review shall include the following considerations: 1) appropriate requirements specified in Procurement Document Content above, 2) a determination of any additional or modified design criteria, and 3) an analysis of exceptions or changes requested by the supplier and a determination on the impacts such changes may have on the intent of the procurement documents or quality of the item or service to be provided shall be performed by the LES organization initiating the procurement. Personnel who have access to pertinent information and have an adequate understanding of the requirements and scope of the procurement shall perform reviews of the procurement documents. Reviewers shall include representatives from the Procurement and QA organizations. The QA review shall assure compliance to quality assurance requirements.

Procurement Document Change

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

SECTION 18 AUDITS

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

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

AUDIT SCHEDULES

Internal or external audits shall be scheduled in a manner to provide coverage, consistency and coordination with ongoing work, and at a frequency commensurate with the status and importance of the work. Internal or external audits shall be scheduled to begin as early in the life of the work as practical and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work. As a minimum, internal audits of LES QA Level 1 and QA Level 1 Graded activities shall be at least once per year or at least once during the life of the activity, whichever is shorter. Regularly scheduled internal audits shall be supplemented by additional audits of specific subjects when necessary to provide an adequate assessment of compliance or effectiveness. Internal audits to determine quality assurance program effectiveness shall be performed on selected work products. The audit schedule shall be developed annually and revised as necessary to ensure that coverage is maintained current. Frequency of audits should be based upon evaluation of all applicable and active elements of the LES QAPD applicable to LES workscope. These evaluations should include an assessment of the effectiveness of the applicable and active elements of the LES QAPD based upon previous audit results and corrective actions, nonconformance reports, identified trends, and significant organizational changes. LBDCR-09-0018

AUDIT PLANS

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

AUDIT TEAMS

The LES QA Director shall select and assign auditors who are independent of any direct responsibility for performing the work being audited. Audit personnel shall have sufficient

SECTION 20 QUALITY ASSURANCE PROGRAM FOR QA LEVEL 2

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

An International Organization for Standardization (ISO) 9000 series QA program is acceptable for QA Level 2 applications provided it complies with LES QAPD requirements and the ISO program is reviewed and approved by the LES QA Director.

QA Level 2 program activities are those activities that do not meet the requirements for inclusion in the QA Level 1 or QA Level 1 Graded program, but have ~~attributes~~elements or characteristics that may warrant control under a quality program more detailed than the QA Level 3 program. QA Level 2 requirements ~~are~~ may be applied to activities and SSCs for the following reasons: LBDCR-09-0018 LBDCR-09-0025

- 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,

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 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. LBDCR-09-0018

- 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: LBDCR-09-0018

  - 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 Director 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 Director, 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.

LBDCR-09-0018

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. LBDCR-09-0018

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. LBDCR-09-0018

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. LBDCR-09-0018

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. LBDCR-09-0018

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

LBDCR-09-0018

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.

LBDCR-09-0018

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. LBDCR-09-0018

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. LBDCR-09-0018
- Right of access to supplier, including subtier, facilities and records for inspection or audit by LES, or other designee authorized by LES.
- Provisions for establishing witness/inspection hold points beyond which work cannot proceed by the supplier without LES QA Director authorization. The 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. LBDCR-09-0018
- 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: LBDCR-09-0018

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. LBDCR-09-0018

SECTION 21.5 INSTRUCTIONS, PROCSDURES, 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. LBDCR-09-0018

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.

LBDCR-09-0018

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.

LBDCR-09-0018

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:

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- 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.

LBDCR-09-0018

- 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.

LBDCR-09-0018

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.

LBDCR-09-0018

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.

LBDCR-09-0018

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.

LBDCR-09-0018

SECTION 21.12 CONTROL OF MEASURING AND TEST EQUIPMENT

LBDCR-09-0018

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. LBDCR-09-0018

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. LBDCR-09-0018

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.

LBDCR-09-0018

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.

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SECTION 21.16 CORRESCTIVE 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.

LBDCR-09-0018

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.

LBDCR-09-0018

SECTION 21.18 AUDITS

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

LBDCR-09-0018

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.

LBDCR-09-0018