GEHitachiUELAPEm Resource

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Subject: QAPD submittal for NRC approval
Attachments: Submittal of QAPD for review and approval 09223010 scan for NRC.pdf; GLE_QAPD-R2.pdf

<<Submittal of QAPD for review and approval 09223010 scan for NRC.pdf>> <<GLE_QAPD-R2.pdf>> The attached documents were submitted to the NRC last week. Please let me know if you have any questions or comments. Thanks.

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September 23, 2010

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U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Subject: **SUBMITTAL OF GLOBAL LASER ENRICHMENT QUALITY ASSURANCE PROGRAM DESCRIPTION, REVISION 2**

Dear Mr. Smith:

GE-Hitachi Global Laser Enrichment LLC (GLE) hereby submits Revision 2 of the GLE Quality Assurance Program Description for NRC review and approval. Based on recent discussions with your staff, GLE understands that this document will be referenced as part of the safety basis for NRC's licensing determination, and therefore needs to be submitted for NRC review and approval, rather than information only as it has previously been submitted. Please note that Section 20 of this document will be revised to make the document change process consistent with the process described in the GLE License Application. If there are any questions regarding this letter and its contents, please do not hesitate to contact me at 910-819-4799 or at Julie.Olivier@ge.com.

Sincerely,

Julie Olivier
GLE Licensing Manager

Enclosure: GLE Quality Assurance Program Description, Revision 2

HITACHI

Global Laser Enrichment

NEDE-33451
Rev 2
Class I
March 2010

QUALITY ASSURANCE PROGRAM DESCRIPTION

FOR THE

GE-HITACHI GLOBAL LASER ENRICHMENT LLC COMMERCIAL FACILITY

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QUALITY ASSURANCE PROGRAM DESCRIPTION
FOR THE
GE-HITACHI GLOBAL LASER ENRICHMENT LLC
COMMERCIAL FACILITY

Revision 2

Reviewed by:

Lon E. Paulson, GLE EHS Manager (Acting) — Date: 3/19/2010

David W. Hamilton, Quality Assurance Manager — Date: 3/19/10

Kenneth R. Givens, GLE Projects Manager — Date: 3/19/2010

Tom Owens, Engineering Manager — Date: 3/19/2010

Approved by:

Tammy G. Orr, President/CEO of GLE — Date: 3/19/2010

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REVISION LOG

Rev.	Effective Date	Affected Chapters/Pages	Revision Description
0	01/26/2009	ALL	Initial revision.
1	04/02/2009	Pg 3	Revision to the organization chart.
2	03/19/2010	ALL	Incorporate RAIs responses submitted to the NRC via MFN-09-802 dated 12/28/2009 and MFN-10-036 dated 02/01/2010.

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FIGURES

Figure 1. Global Laser Enrichment Project Design and Construction Phase Organization Chart. 33

ACRONYMS

ANSI – American National Standards Institute

ASME – American Society of Mechanical Engineers

Assessment – Used to determine the effectiveness of activities in achieving applicant-specified objectives that provide reasonable assurance of the continued availability and reliability of items relied on for safety (IROFS). [NUREG-1520]

ASTM – American Society for Testing and Materials

Audit – Used to monitor compliance with regulatory requirements and license commitments. [NUREG-1520] A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with self-assessment, surveillance, and inspection activities performed for the purpose of process control or product acceptance. [ANSI NQA-1-1989]

Available and Reliable to Perform Their Function When Needed – Based on the analyzed, credible conditions in the integrated safety analysis (ISA), items relied on for safety (IROFS) will perform their intended safety function when needed, and management measures will be implemented that ensure compliance with the performance requirements of 10 CFR 70.61, considering factors such as necessary maintenance, operating limits, common-cause failures, and the likelihood and consequences of failure or degradation of the times and measures. [10 CFR 70.4]

Basic Component – A structure, system, or component (SSC) designated as an item relied on for safety (IROFS), or part thereof that affects the IROFS function, that is directly procured by the licensee of a facility or activity subject to the regulations in 10 CFR 70 and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the U.S. Nuclear Regulatory Commission (NRC) would create a substantial safety hazard (i.e., exceed the performance requirements of 10 CFR 70.61). In all cases, basic components include IROFS-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, whether these services are performed by the component supplier or others.

CEO – Chief Executive Officer

CFPM – Commercial Facility Project Manager

CFR – Code of Federal Regulations

Commercial Grade Item – A structure, system, or component (SSC), or part thereof that affects its IROFS function, which 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 defect or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified.)

Configuration Management (CM) – A management measure that provides oversight and control of design information, safety information, and records of modifications (both temporary and permanent) that might impact the ability of items relied on for safety (IROFS) to perform their functions when needed. [10 CFR 70.4]

Contractor Personnel – Persons who are not GLE/GEH/GNF employees or active pensioners. Contract Workers have been contracted to provide a service or activity. [P&P 20-21]

Corrective Action – A measure taken to rectify significant conditions adverse to quality and to preclude repetition. [ANSI/ASME NQA-1]

CM – Configuration Management

Critical Characteristics – Those important to 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. [10 CFR 21.3]

Decommission – To remove a facility or site safety from service and reduce residual radioactivity to a level that permits: (1) release of the property for unrestricted use and termination of the license; or (2) release of the property under restricted conditions and termination of the license. [10 CFR 70.4]

Dedication Process – An acceptance process undertaken to provide reasonable assurance that a commercial-grade item or service to be used as a basic component will perform its intended item relied on for safety (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 50, Appendix B. The process is considered complete when the item is designated for use as a basic component.

Dedicating Entity – 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 10 CFR 21.21(c), is responsible for identifying and evaluating deviations, reporting defects and failure to comply for the dedicated item, and maintaining auditable records of the dedication process. In cases where the Licensee applies the commercial-grade item procurement strategy and performs the dedication process, the Licensee would assume full responsibility as the dedicating entity.

EHS – Environmental, Health, and Safety

GLE – GE-Hitachi Global Laser Enrichment LLC

GLE Commercial Facility – The structures, systems, and components that comprise the GLE Site infrastructure established to support the enrichment processing and support operations. The GLE Commercial Facility includes the Operations Building, multiple administrative and support buildings or areas, a parking lot, retention basins, cylinder storage pads, and connecting roadways. A cleared security buffer surrounds the entire GLE Commercial Facility and defines both the Restricted Area and the Protected Area of the facility.

Integrated Safety Analysis (ISA) – A systematic analysis to identify facility and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the items relied on for safety (IROFS). As used here, integrated means joint consideration of, and protection from, all relevant hazards, including radiological, nuclear criticality, fire, and chemical. However, with respect to compliance with the regulations of this part, the NRC requirement is limited to consideration of the effects of all relevant hazards on radiological safety, prevention of nuclear criticality accidents, or chemical hazards directly associated with NRC licensed radioactive material. An ISA can be performed process by process, but all processes must be integrated, and process interactions considered. [10 CFR 70.4]

Integrated Safety Analysis Summary (ISAS) – A document or documents submitted with the license application, license amendment application, license renewal application, or pursuant to 10 CFR 70.62(c)(3)(ii) that provides a synopsis of the results of the integrated safety analysis and contains the information specified in 10 CFR 70.65(b). The ISAS can be submitted as one document for the entire facility, or as multiple documents that cover all portions and processes of the facility. [10 CFR 70.4]

IROFS – Items Relied on for Safety

IROFS Boundary Definition Package – Documents that contain the physical descriptions and parameters of structures, systems, and components (SSCs) used to meet the performance requirements of 10 CFR 70.61. IROFS boundary definition packages are also prepared for administrative procedures or worker actions, which are defined as IROFS. The boundary packages identify the specific functions to be performed by an IROFS and identify any items that may affect the function of the IROFS. The boundary packages also identify the facility areas in which the IROFS is used, design and functional attributes, management measures, any open items, and supporting documentation (i.e., P&IDs, schematics, etc.). Open items that affect the reliability and/or effectiveness of the IROFS should be closed prior to the NRC Operational Readiness Review (ORR). The open items section should identify open items associated with the IROFS during the NRC License review and describe how the open items were resolved. [NUREG-1520]

ISA – Integrated Safety Analysis

ISA Baseline Documents – Includes technical reports, Process Hazard Analyses, Quantitative Risk Analyses (QRAs), calculations, drawings, white papers, IROFS Boundary Definition Packages, and memos or notes to file that capture the ISA. [NEDE-33480]

Items Relied on for Safety (IROFS) – Structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in 10 CFR 70.61 or to mitigate their potential consequences. This does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as IROFS. [10 CFR 70.4]

LA – License Application

M&TE – Materials and Testing Equipment

Management Measures – The functions performed by the licensee, generally on a continuing basis, that are applied to items relied on for safety (IROFS), to ensure the items are available and reliable to perform their functions when needed. Management measures include Configuration Management, Maintenance, Training and Qualifications, Procedures, Audits and Assessments, Incident Investigations, Records Management, and other Quality Assurance elements. [10 CFR 70.4]

NQA – Nuclear Quality Assurance

NRC – U.S. Nuclear Regulatory Commission

Policy – A document that contains “rules,” that is identifies requirements that must be met and provides top-level descriptions of what is expected. Policies do not contain specific instructions for how the requirements are to be met.

Procedure – A document that specifies or describes how an activity is to be performed. Procedures may include methods to be employed, equipment or materials to be used, and sequences of operations. Procedures may also interface activities among different company organizations, groups, divisions, etc. [ANSI N45.2.10-1973]

Procurement Document – Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase. [ANSI/ASME NQA-1]

QA – Quality Assurance

QAPD – Quality Assurance Program Description

QL – Quality Level

Qualification (Personnel) – The characteristics or abilities gained through education, training, or experience as measured against established requirements, such as standards or tests, which qualify an individual to perform a required function. [ANSI/ASME NQA-1]

SSC – Structures, Systems, and Components

UF_6 – Uranium Hexafluoride

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1. INTRODUCTION

GE-Hitachi Global Laser Enrichment LLC (GLE) maintains full responsibility for ensuring the GLE Commercial 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 workers and the public. Application of the program is mandatory for items (structures, systems, components [SSCs], equipment, and activities) identified as items relied on for safety (IROFS) in accordance with 10 Code of Federal Regulations (CFR) 70.4, *Definitions (Ref. 1)*, 10 CFR 70.61, *Performance Requirements (Ref. 2)*, 10 CFR 70.64, *Requirements for New Facilities or New Processes at Existing Facilities (Ref. 3)*, and 10 CFR 21, *Reporting of Defects and Noncompliance (Ref. 4)*.

The GLE Quality Assurance (QA) Program covers design, construction (including preoperational testing), operation (including testing), maintenance, modification, and decommissioning of the facility. This Quality Assurance Program Description (QAPD) describes the requirements applied to those SSCs and activities designated as Quality Level (QL)-1 or QL-2. The QLs are described in Section 3, Quality Assurance Program.

2. ORGANIZATION

GLE maintains overall responsibility for design, construction, operation, maintenance, modification, testing, and decommissioning of the GLE Commercial Facility. The organization of the GLE Project is shown in Figure 1. Listed below is a description of project personnel and key positions within the GLE organization as related to QA.

2.1 Global Laser Enrichment President and Chief Executive Officer

The GLE President and Chief Executive Officer (CEO) establishes the basic policies of the QA Program. The policies described in this QAPD are transmitted to all levels of management, and implemented through approved written polices, plans, and procedures.

The GLE President and CEO shall have, as a minimum, a bachelor's degree (or equivalent) and five years of related experience.

2.2 Quality Assurance and Infrastructure Program Manager

The QA and Infrastructure Program Manager reports to the GLE President and CEO and is responsible for establishing and maintaining the QA, Document Control, and Records Management Programs. The QA and Infrastructure Program Manager has the authority, access to work areas, and organizational independence to ensure the requirements of this QAPD are properly implemented. The QA and Infrastructure Program Manager has the authority to stop work based on quality concerns. This authority to stop work, and the process to resume stopped work, is documented in approved policies, plans, and/or procedures.

The QA and Infrastructure Program Manager shall have, as a minimum, a bachelor's degree in an engineering or scientific field and four years of nuclear supervisory experience in the implementation of a QA Program. The QA and Infrastructure Program Manager shall have at least two years experience in a QA Organization at a nuclear facility.

2.3 Operations Manager

The Operations Manager reports to the GLE President and CEO and has the responsibility for providing operational specifications into design documents and establishing processes and procedures for activities including, but not limited to, operation of uranium hexafluoride (UF_6) processes, proper handling of UF_6, and the identification and mitigation of off-normal operating conditions.

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

2.4 Engineering Manager

The Engineering Manager reports to the GLE President and CEO. The Engineering Manager is responsible for developing the conceptual design for the GLE Commercial Facility, to include, but not limited to, development of design requirements, design bases, and design criteria for the enrichment process and supporting systems.

The Engineering Manager shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and a minimum of five years of related nuclear experience in implementing and supervising a nuclear engineering program.

2.5 Global Laser Enrichment Projects Manager

The GLE Projects Manager reports to the GLE President and CEO. The GLE Projects Manager is responsible for managing the design, construction, initial startup, and procurement activities. In addition to managing contracts, the GLE Projects Manager also manages a group of Project Managers and the Project Controls Manager. The Project Managers are responsible for Procurement, Construction, Engineering, Project Engineering, Project Controls, and Startup.

The GLE Projects Manager shall have, as a minimum, a bachelor’s degree (or equivalent) in an engineering or scientific field, five years of nuclear experience, and three years of supervisory or management experience.

2.6 Security Manager

The Security Manager reports to the GLE President and CEO. The Security Manager is responsible for, but not limited to, establishing and maintaining the GLE Security Program; providing physical security for the GLE Site and facilities; protecting classified matter; obtaining facility clearances for facility personnel; and providing advice and counsel to managers regarding security.

The Security Manager shall have, as a minimum, a bachelor’s degree (or equivalent) in a related field and two year of related experience; or a high school diploma with eight years of related experience.

2.7 Global Laser Enrichment Environmental, Health, and Safety Manager

The GLE Environmental, Health, and Safety (EHS) Manager reports to the GLE President and CEO and is responsible for Environmental Protection, Industrial Safety, Material Control and Accounting (MC&A), Fire Safety, Nuclear Criticality Safety (NCS), and Radiological Protection.

The GLE EHS Manager works with the other facility managers to ensure consistent interpretations of EHS requirements, performs independent reviews, and supports facility and operations change control reviews. This position is independent from other management positions at the facility to ensure objective EHS audit, review, and control activities. The EHS Manager has the authority to issue stop work orders and must be consulted prior to resumption of stopped work. Changes to the facility or to activities of personnel that require prior U.S. Nuclear Regulatory Commission (NRC) approval are reviewed and approved by the EHS Manager or designee.

The GLE EHS Manager shall have, as a minimum, a bachelor's degree (or equivalent) in an engineering or scientific field and five years of management experience in assignments involving regulatory activities. The manager of the GLE EHS function shall have experience in the understanding and management of NCS, Environmental Protection, and Industrial Safety programs.

2.8 Procurement Manager

The Procurement Manager reports operationally to the GLE President and CEO and reports functionally to the GE Hitachi Global Supply Chain General Manager. The Procurement Manager is responsible for procurement and providing procurement material control services, to include, but not limited to, supplier qualification coordination, purchasing, and contracting. The Procurement Manager is also responsible for supply strategy and development of qualified long-lead-time and complex-system suppliers.

The Procurement Manager shall have, as a minimum, a bachelor's degree and seven years of experience in engineering, program/project management, supply chain management, or manufacturing. The Procurement Manager shall have experience in the understanding and management of the assigned programs.

2.9 General Worker Responsibilities

Every individual working on the GLE project, to include contractor personnel, is responsible for quality. Each worker has an obligation to identify concerns using the corrective action process with respect to work within their scope of responsibility whenever the health and safety of the workers, the public, or the environment is involved; or when continued work will produce results that are not in compliance with the QA Program. This corrective action process is controlled by approved written policies, plans, and/or procedures that apply to all GLE personnel. The authority and responsibility for stopping work, the criteria and documentation required to process the stop work, and the actions required before work may resume, are detailed in approved written policies, plans, and/or procedures. This process ensures safety-related activities are controlled until the deficiency or unsatisfactory condition has been resolved.

3. QUALITY ASSURANCE PROGRAM

The GLE QA Program applies to all workers at all levels of the organization, to include contractor personnel, who perform quality-affecting activities associated with safety-related aspects of the facility. While this QAPD document is formatted following the 18 elements of American National Standards Institute (ANSI)/American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1, *Quality Assurance Program Requirements for Nuclear Facilities (Ref. 5)*, the QA Program is risk-informed and utilizes only those elements and principles appropriate for assuring the quality-related aspects of the fuel cycle facility.

The QAPD states GLE policies, assigns responsibilities, and specifies requirements governing implementation of the QA Program for the design, construction, operation, and decommissioning of the GLE Commercial Facility. Specific processes and controls, which implement the provisions of the QA Program, are delineated in approved written policies, plans, and/or procedures. When work cannot be accomplished as specified in implementing QA policies, plans, and/or procedures, or accomplishment of such work would result in an unsafe condition, work is stopped until proper corrective action is taken. If a procedure cannot be used as written, then work is stopped until the procedure is changed.

Personnel performing or managing activities affecting quality are indoctrinated or trained on the QA Program and appropriate QA implementing policies, plans, and/or procedures. Each manager is responsible for the applicable indoctrination, training, and qualification of their personnel. Line management, of those organizations implementing the QA Program or portions thereof, regularly assesses the adequacy of the program for which they are responsible through an appropriate combination of reviews, approvals, self-assessments, or audit processes; thereby, assuring its effective implementation. Responsible senior managers regularly assess the adequacy and effective implementation of the QA Program through methods such as review meetings and by reviewing audit and corrective action reports.

The QA Program is applied to the design, fabrication, testing, operation, procurement, inspection, maintenance, and modification of IROFS and activities affecting those IROFS. The QA Program, in addition to other management measures, ensures IROFS are available and reliable to perform safety functions when needed.

3.1 Quality Levels

Three QA Levels have been established and apply throughout the life of the GLE Commercial Facility from design and construction through testing, startup, operation, maintenance, modification, and decommissioning. The three QA levels are as follows:

QL-1 – QL-1 is applied to single (sole) IROFS preventing or mitigating a high consequence event. Management measures are applied to each QL-1 IROFS consistent with the type of IROFS to assure that the IROFS remains reliable at its credited failure frequency when called upon to be available. Also, all applicable QA Program requirements are applied to QL-1 IROFS in a manner necessary to achieve this goal.

QL-2 – QL-2 is applied where two or more IROFS are credited to prevent or mitigate a high consequence event, or where any single (sole) IROFS prevents or mitigates an intermediate consequence event. Management measures are applied to QL-2 IROFS consistent with the type of IROFS to assure that the IROFS remain reliable at its credited failure frequency when called upon to be available. All applicable QA Program requirements are also applied to QL-2 IROFS in a manner necessary to achieve this goal.

The extent to which attributes of management measures and QA Program elements are applied to QL-1 and QL-2 IROFS is determined by evaluating the factors that contribute to the reliability of each IROFS. The management measure and QA element attributes for those aspects of the activity that influence the reliability of the IROFS are determined by evaluating the design, function, and task analyses associated with operating and maintaining the IROFS and by assigning the characteristic to the attribute taking into consideration the following:

- Risk significance,
- Applicable regulations, industry codes, and standards,
- Complexity or uniqueness of an item/activity and the environment in which it has to function,
- Quality history of the item in service or activity,
- Degree to which functional compliance can be demonstrated or assessed by test, inspection, or maintenance methods,
- Anticipated life span,
- Degree of standardization,

- Importance of data generated, and
- Reproducibility of results.

The management measure and QA element attributes assigned to each IROFS are approved through the CM process associated with ISA baseline documents and specifically through approval of the IROFS Boundary Definition Packages as the design matures, procedures and training are developed, and pre-operational readiness reviews are conducted. See Appendix A for additional information regarding Fire Safety IROFS.

QL-3 – QL-3 applies to items that are neither QL-1 nor QL-2. QL-3 items (not IROFS) are controlled in accordance with standard commercial practice and do not require the application of management measures.

3.2 Application of Management Measures

To ensure IROFS are available and reliable to perform safety functions when needed, GLE shall apply the appropriate rigor for each management measure, as discussed below.

3.2.1 Configuration Management

The elements of configuration management, specifically, the CM policy, design requirements, document control, change control, and application of assessments, are applied equally for the QL-1 and QL-2 IROFS (there are no QL-3 level IROFS by definition).

3.2.2 Maintenance

The application of the types of maintenance (corrective, including calibration, preventative, surveillance, and monitoring, and functions testing) and the frequencies of this maintenance is highly dependent on the type of IROFS, the specific components within the IROFS boundary, the historical failure frequency associated with the components or with the human elements of performance, and the reliability required of the IROFS. Therefore, the application of maintenance attributes is chosen using the information obtained by evaluating the nine areas of consideration presented in Section 3.1 (not all of which apply to each type of IROFS).

3.2.3 Training and Qualifications

A certain minimum training is required for workers working with, or in the vicinity of, hazardous operations that are governed by IROFS. This is applicable to areas where QL-1 and QL-2 IROFS are involved to protect aspects of the work area.

The specific application of training and qualifications, consistent with the general descriptions provided in GLE License Application (LA) Section 11.3, are driven by a task analysis that addresses human factors elements, complexity of the safety function carried out, and basic knowledge of the individuals involved. Based on the task analysis, appropriate training is developed utilizing classroom, performance-based on-the-job, testing, etc. commensurate with the nine areas of consideration presented in Section 3.1 (not all of which apply to each type of IROFS). This is a standard element of a systematic approach to training.

3.2.4 Procedures

Activities associated with the operation of IROFS are governed by policies, plans, and/or procedures associated with all aspects of the task. Procedures involving implementation of IROFS are controlled according to the CM Program to assure proper, accurate, valid procedures are used regardless of the quality level.

However, some complex activities (depending on the type and nature of IROFS) require procedures that have higher levels of human factors elements incorporated in their use (such as in-hand use, step-by-step check offs, two-person verification of action confirmation, etc.) The amount of rigor applied to each task is based on the task analysis to determine the application level of detail needed in the procedure and the appropriate usage of policies. These decisions use information identified by the nine areas of consideration, as applicable, presented in Section 3.1.

3.2.5 Audits and Assessments

A basic level of audits and assessments is applied to IROFS. However, as identified in GLE LA Section 11.8.18, the frequencies are commensurate with the status and importance of the activity, and again, the nine areas of consideration presented in Section 3.1 are used in developing these frequencies.

3.2.6 Incident Investigations

Incidents associated with IROFS failure and/or degradation are investigated and resolved with the same approach regardless of quality level.

3.2.7 Records Management

Records for activities associated with IROFS implementation are managed with the same approach regardless of quality level.

3.2.8 Other Quality Assurance Elements

The various quality assurance elements dovetail with one or more of the management measures presented above. Under Design Control, Procurement Control, Document Control, Control of Purchased Items and Services, Identification and Control of Materials, Parts and Components, Control of Measuring and Test Equipment, Handling Storage and Shipping Controls, Control of Nonconforming Items, Corrective Action, and Quality Assurance Records, there is no distinctions within the program with respect to QL-1 and QL-2 level IROFS.

4. DESIGN CONTROL

Design management utilizes approved written policies, plans, and/or procedures to control the design process including inputs, analysis, outputs, reviews/checks/approvals, change control, technical interfaces, and administrative activities. Design policies, plans, and/or procedures assure applicable requirements are correctly translated into design documents.

Design is based upon sound engineering judgment, scientific principles, and applicable codes and standards. Design management ensures that design documents are prepared, reviewed, checked, and approved by qualified individuals. Design documents include requirement documents, drawings, reports, criteria, specifications, analysis, computer programs, system descriptions, technical reports, and the ISA. Work scope and responsibilities between design groups and disciplines are defined. Design management includes the following:

- Organizations in which the Design Control System is to be implemented;
- Design interface responsibilities between internal and external organizations;
- Exchange of technical information between internal and external organizations;
- Use of implementing design policies, plans, and/or procedures;
- Establishment of technical requirements and design standards;
- Selections and performance of design practices, to include review methods;
- Preparation of design documents;
- Extent of design reviews, to include technical reviews, peer reviews, modeling, and alternate calculations, as appropriate;
- Design output document control, to include review, approval, release status identification, distribution, and revision of documents;
- Determination and specification of acceptance criteria, required tests and inspections, and program requirements for records;
- Maintenance and retention of design documents; and
- Controls for design change.

Determination of the required rigor of design control is based upon the design phase and the ISA performed in compliance with 10 CFR 70, *Domestic Licensing of Special Nuclear Material (Ref. 6)*. The ISA establishes the identification and functions of IROFS and the significance to safety of functions performed by those IROFS.

The design of SSCs, involving a higher than normal level of risk, including those SSCs designated as IROFS, are subject to a greater degree of design control and verification. Design output documents for IROFS such as specifications, system descriptions, and drawings contain requirements for appropriate inspections, testing, and maintenance. Useful life expectancy is a design consideration to facilitate development of facility decommissioning, disassembly, and disposal plans.

Software used to produce or manipulate data directly used in the design, analysis, and operation of SSCs relied on for safety are developed, validated, and controlled per approved written policies, plans, and/or procedures. Commercially available software is not validated but the results are independently reviewed and verified.

Records of the design process are maintained as discussed in Section 7, Document Control, and Section 18, Quality Assurance Records. The details and implementation of requirements pertaining to design control are performed in accordance with applicable approved written engineering and design policies, plans, and/or procedures.

5. PROCUREMENT CONTROL

Provisions for control of the procurement process (sourcing), procurement documents, and procured materials, components, and services are described in approved written procurement policies, plans, and/or procedures. Design bases and other requirements necessary to provide reasonable assurance of quality are included or referenced in documents for procurement of items or services relied on for safety. Procurement documents for QL-1 items or services include, as appropriate for the item or service being procured, the following:

- Scope of work;
- Basic technical requirements including drawings, specifications, codes, and industrial standards with applicable revision data, test and inspection requirements, special processes, and special requirements for tasks such as designing, fabricating, cleaning, identification marking, erecting, packaging, handling, shipping, and storage;
- QA requirements, to include requirements for the supplier to have an acceptable QA Program or a system of management measures consistent with the applicable portions of the GLE QA Program. The extent of the required program is dependent upon the type and use of the item or services being procured;
- Requirements for the control of nonconformances and changes, including provisions to control and report nonconformance and changes to products being delivered;
- Requirements on sub-tier suppliers including the specification of procurement requirements on sub-tier suppliers, if applicable;
- Documentation requirements, to include requirements identifying documents to be submitted for information, review, or approval, instructions on record retention, turnover and disposition, and the requirements for delineating the technical and quality data required for ordering recommended spare and replacement parts and assemblies.

Requirements are established in approved written policies, plans, and/or procedures for content, review, approval, and change of procurement documents. Changes to the procurement documents shall be subject to the same degree of control as was utilized in the preparation of the original procurement document.

QL-1 and QL-2 items may be procured as commercially available items provided that the item is subjected to a dedication process. Items and services not relied on for safety may be designated as QL-2 or QL-3 and may be procured as commercially available items.

5.1 Dedication Process

Whenever possible, basic components (i.e., IROFS or parts thereof) are procured from suppliers that possess and implement a QA Program meeting the requirements of 10 CFR 50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants (Ref. 7),* and that have been evaluated and placed on an Approved Supplier List. If an IROFS or part thereof cannot be procured as a basic component due to the applicable supplier not possessing an approved QA Program, then GLE will formally dedicate a commercial-grade item for use as or in an IROFS (basic component).

In cases where commercial-grade items are to be procured and then dedicated for use as IROFS or parts thereof, the procurement process procedures include requirements that GLE define to the supplier those elements of the supplier's process controls that are mandatory and any other requirements necessary to assure critical characteristics are met.

6. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting the availability or reliability of IROFS are prescribed by, and accomplished in accordance with, documented specifications, requirements, policies, plans, procedures, instructions, and drawings of a type appropriate to the circumstance. These documents include or reference appropriate acceptance criteria for determining prescribed activities have been satisfactorily accomplished. Standard guidelines for the format, content, review, and approval processes for GLE documents are established in approved written policies, plans, and/or procedures.

GLE uses a hierarchy of policies, plans, and procedures to implement the requirements established for the GLE Project. Policies establish senior management expectations with regard to quality and safety. Implementing policies, plans, and procedures provide specific instructions to workers performing quality-affecting activities associated with safety-related aspects of the GLE Commercial Facility. Policy, plan, and/or procedure preparation, review, and approval are the responsibility of the manager of each functional area. The QA function reviews QA implementing policies, plans, and procedures for compliance and consistency with the QA Program and to ensure the provisions of the QA Program are effectively incorporated into the implementing policies, plans, and procedures. Compliance with policies, plans, and procedures is mandatory. In the case of conflict or error involving a policy, plan, and/or procedure, the activity in question shall be placed in a safe condition and the policy, plan, and/or procedure shall be corrected or changed before proceeding to implementation. Activities that require skills normally possessed by qualified personnel do not require detailed step-by-step delineation in a policy, plan, or procedure. These activities are performed in accordance with documents of a type appropriate to the circumstance such as planning sheets, job descriptions, external manuals, or other applicable form.

7. DOCUMENT CONTROL

GLE documents, and changes to documents, prescribing or specifying quality requirements or activities affecting the availability and/or reliability of IROFS, are controlled in a manner to ensure the use of the correct document. Such documents, including changes thereto, are reviewed for adequacy and approved for release in accordance with a defined, management-approved process. Policies, plans, procedures, and instructions ensure documents are: (1) prepared and reviewed for adequacy, correctness, and completeness by a qualified individual; (2) approved for release; and (3) used appropriately in performing the activity. Obsolete or superseded documents are removed or appropriately identified. Policies, plans, and procedures identify documents to be controlled, responsibility for preparing, reviewing, approving, and issuing documents to be used, and require the establishment of current and updated distribution lists. Policies, plans, and procedures are maintained under revision control.

8. CONTROL OF PURCHASED ITEMS AND SERVICES

The procurement of items and services is controlled to ensure conformance with requirements. The controls provide the following, as appropriate: supplier (source) evaluation and selection; evaluation of objective evidence of quality furnished by the supplier; source inspection; audit; and examination of items or services upon delivery or completion.

Sourcing activities are planned and documented to ensure a systematic approach to the procurement process. The GLE sourcing function is responsible for procurement planning and bid evaluation. The QA function provides procurement QA support, such as verification or surveillance of the suppliers QA Program; receipt inspections; installation inspections; and review of procurement documents during receipt inspections. The design function assists the QA and sourcing functions by performing evaluations of supplier's technical capabilities. The design function is also responsible for determining specific methods of acceptance to be applied to purchased items and reviewing the specific method of acceptance to be applied to services. The design function is also responsible for approval of dispositions and technical evaluation of supplier nonconformances for items and services dispositioned as "repair" or "use-as-is."

Supplier selection is based, in part, on an evaluation of the supplier’s capability to provide items or services in accordance with the requirements of sourcing documents. Supplier evaluations may include audits or assessments of the supplier program or system for ensuring quality or an evaluation of the supplier's history of providing an identical or similar product that performs satisfactorily in actual use. Measures are established to interface with the supplier and to verify supplier's performance, as necessary.

A supplier working to the GLE QA Program shall be indoctrinated or trained on the QA Program and the applicable implementing policies, plans, and/or procedures governing the work being performed. Supplier work performed under the GLE QA Program is subject to the same controls implemented for GLE personnel. Supplier-generated documents are reviewed for acceptability. Acceptability verification activities are based on quality level, complexity, and quantity of items or services provided. Technical documents used as input to design processes, such as analyses, calculations, or drawings, require an independent technical review. Supplier furnished material, equipment, or services related to safety are reviewed for acceptability by performing, as appropriate, one or more of the following, to the items or services being procured:

- Monitoring, witnessing, or observing activities performed by the supplier,
- Receiving inspection, and/or
- Post-installation testing.

Supplier nonconformances may be identified either by GLE or by the supplier. Nonconforming items are not released for use until the nonconforming condition is reviewed and accepted by GLE and the implementation of the disposition is verified, except under conditional release provisions. Records of supplier nonconformance are maintained.

9. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

Controls are established for QL-1 and QL-2 items and services to ensure only correct and accepted items and services are used or installed. Identification is maintained on the items, in documents traceable to the items, or in a manner that assures identification is established and maintained.

Items are identified and controlled, as necessary, from initial receipt and fabrication of the items, up to and including installation and use, to assure only correct and accepted items are used or installed. Physical identification is used to the maximum extent possible. When physical identification is either impractical or insufficient to control the item, physical separation, procedural controls, or other means are employed. When markings are used, measures are established to ensure the markings are clear, legible, or machine readable, and do not have a detrimental effect on the function or service life of the item. Markings are transferred to each part of an identified item when subdividing and are not to be obliterated by surface treatments or coatings unless other means of identification are provided. Traceability of items to specific records is provided when specified by codes, standards, or specifications. Where specified, items having a limited operating or shelf life are identified and controlled to preclude use of items whose operating or shelf life has expired.

10. CONTROL OF SPECIAL PROCESSES

Special processes affecting quality of items and services are controlled. Policies, plans, procedures, instructions, drawings, checklists, travelers, work orders, or other appropriate means are used to control special processes. These special processes assure special process parameters are controlled and specified environmental conditions are maintained.

Special processes that control or verify quality (that is, those used in welding, heat treating, and nondestructive examination) are performed by qualified personnel using approved written policies, plans, and/or procedures in accordance with specified requirements, codes, or standards. When the outcome of the process is highly dependent on personal skills, such individuals are certified in accordance with specified requirements. When the outcome is highly dependent on control of process parameters, the process and equipment are pre-qualified in accordance with specified requirements. Special process policies, plans, and/or procedures prescribe the necessary equipment, process parameters, calibration, and acceptance criteria. Records are maintained of currently qualified personnel, processes, and equipment for special processes.

11. INSPECTION

Planned inspections are performed, as required, to verify conformance of items or activities to specified requirements. Inspection requirements are specified in approved written policies, plans, and/or procedures, with provisions for documenting and evaluating the inspection results. Personnel performing inspections are qualified based on experience, education, or certification, as appropriate. Personnel other than those who performed or directly supervised the work being inspected perform inspection for acceptance.

Inspection planning may utilize hold points, where applicable, to ensure work does not bypass required inspections. The hold points are established in documents that control the work. Work does not proceed beyond an inspection hold point without specific documented consent of the designated inspection representative.

The planning of inspection activities, methods, and attributes is based on: 1) the importance of the item or activity to be inspected; 2) mandatory inspections required by codes, standards, regulatory requirements, and commitments; 3) the complexity of the item or activity; and 4) the quality history of the process. Inspection planning includes characteristics to be inspected, responsibility, method, measuring and test equipment, acceptance criteria, referenced instructions, and design documents.

When a sample is used to verify acceptability of a group of items, the sampling policy, plan, or procedure is documented and clearly identifies the sampling basis. If inspection of completed work is impossible or disadvantageous, indirect verification by process monitoring is provided. Both inspection and process monitoring are provided, when necessary, to ensure quality. Final inspections include a record review of the results and resolution of any nonconformance(s) identified by prior inspections. Acceptance by final inspection verifies conformance of the item to specified requirements. Modifications, repairs, or replacements of items performed subsequent to final inspection require re-inspection or re-test, appropriate to the circumstances, to verify acceptability. Inspection records contain, as a minimum, the item inspected, date of inspection, inspector, type of observation and inspection plan, results or acceptability, and action taken in connection with any identified nonconformances.

12. TEST CONTROL

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

Tests include design verification tests, acceptance tests, preoperational and operational tests, and post-maintenance tests. Planning for tests may include mandatory hold points, as required. Test policies, plans, and/or procedures contain the following information, as appropriate:

- Test purpose or objectives, responsibilities, characteristics to be tested, hold points, and test methods to be employed;
- References and related documents;
- Provisions for ensuring prerequisites for a given test have been met, to include, as applicable, calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, and provisions for data acquisition;
- Adequate instrumentation is available and suitable environmental conditions are maintained;
- Provisions for documenting and evaluating the test results for conformance with acceptance criteria; and
- Qualifications for test personnel.

In lieu of test policies, plans, and procedures, appropriate sections of related documents (such as, American Society for Testing and Materials' [ASTM] methods, external manuals, maintenance instructions, approved drawings, or travelers with acceptance criteria) may be used. Such documents must include adequate instructions to ensure the required quality of work. Test records contain the following information: item tested; test date; tester or data recorder; type of observation; test policy, plan, procedure, or reference; results and acceptability; actions taken in connection with any deviations noted; and person evaluating the results.

13. CONTROL OF MEASURING AND TEST EQUIPMENT

Measuring and Test Equipment (M&TE) used in activities affecting the availability or reliability of IROFS are controlled, calibrated, and adjusted at specified intervals to maintain equipment performance within required limits. Policies, plans, and procedures ensure that devices and standards used for measurement, tests, and calibration activities are of the proper type, range, and accuracy. Calibration control is not necessary for rulers, tape measures, levels, and other such devices. A list of devices is established to identify those items within the calibration control system. This identification listing includes, as a minimum, the due date of the next calibration and any use limitations (when calibrated for limited use).

M&TE is calibrated at specified intervals or prior to use against equipment having a known valid relationship to nationally recognized standards. If no nationally recognized standard exists, the basis for calibration is documented. M&TE is properly handled and stored to maintain accuracy. When M&TE is found to be out of calibration, as-found data are recorded, and an evaluation is made and documented as to the validity of previous inspection, test results, and of the acceptability of items previously inspected or tested. Out-of-calibration devices are tagged or segregated and are not used until re-calibrated. When M&TE is consistently found to be out of calibration, it is repaired or replaced. Calibrations are also performed when personnel performing measurements and tests deem the accuracy of the equipment suspect. Records are maintained and equipment is suitably marked or otherwise identified to indicate its calibration status.

14. HANDLING, STORAGE, AND SHIPPING

Material and equipment are handled, stored, and shipped in accordance with design and procurement requirements to protect against damage, deterioration, or loss. Special coverings, equipment, and protective environments are specified and provided where necessary for the protection of particular items from damage or deterioration. When such special protective features are required, their existence is verified and monitored as necessary to ensure they continue to serve the intended function.

Special handling tools and equipment are provided where necessary to ensure items can be handled safely and without damage. Special handling tools and equipment are controlled and maintained in a manner such that they are ready and fit to serve the intended function when needed. Such control includes periodic inspection and testing to verify that special handling tools and equipment have been properly maintained.

Operators of special equipment are experienced or trained as required. Attention is given to marking and labeling items during packaging, shipment, and storage. Additional marking or labeling is provided as necessary to ensure that items can be properly maintained and preserved. This includes indication of the presence of special environments or the need for special control. Special handling, preservation, storage, cleaning, packaging, or shipping instructions are established and used when essential to maintain acceptable quality.

15. INSPECTION, CONTROL, TESTING, AND OPERATING STATUS

Policies, plans, and procedures are established to ensure that the status of inspection and test activities are either marked or labeled on the item or in documents traceable to the item. This activity is required when it is necessary to ensure that required inspections and tests are performed, and to ensure items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.

Status indicators (for example, physical location and tags, markings, work controlling documents, stamps, inspection records, or other suitable means) are utilized when required. This includes indicating the operating status of systems and components (for example, tagging valves and switches) to prevent inadvertent operation. Authority for the application and removal of tags, markings, labels, and stamps is specified.

16. CONTROL OF NONCONFORMING ITEMS

Items and related activities that do not conform to specified requirements are controlled to prevent inadvertent installation or use. Nonconforming items are identified in a manner that does not adversely affect the end use of the item by markings, tagging, and other appropriate methods. Nonconforming items are segregated, when practical, by placing them in a clearly identified and designated area until properly dispositioned. When segregation is impractical or impossible due to physical conditions (for example, size, weight, or access limitations), other measures are employed to preclude inadvertent use of the item.

Nonconforming items are reviewed and dispositioned as "reject," "rework," "repair," or "use-as-is." Further processing, delivery, installation, or use of the nonconforming item is controlled pending an evaluation and approved disposition by personnel as authorized in approved written policies, plans, and/or procedures, and documented notification to affected organizations is provided.

The responsibility and authority for the evaluation and disposition of nonconforming items is defined. The personnel performing evaluations to determine the dispositions have demonstrated competence in the specific area being evaluated, have an adequate understanding of the requirements, and have access to pertinent background information. The disposition of nonconforming items is identified and documented as required to carryout the disposition. Technical justification for the acceptability of nonconforming items dispositioned "repair" or "use-as-is," is documented and subject to design control measures described in Section 3.2, Design Control. The disposition process includes consideration of the need for design documents to be "as-built" to facilitate operations, maintenance, or modification. The as-built records, if the disposition determines such records to be required, reflect the accepted deviation. Repaired or reworked items are re-examined in accordance with the original acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

Nonconformance documentation identifies the nonconforming item, describes the nonconformance, contains the disposition and any re-inspection requirements, and contains the appropriate signatures approving the disposition.

17. CORRECTIVE ACTIONS

Conditions adverse to quality are identified and corrected as soon as practical. In the case of a significant condition adverse to quality, the cause of the condition is determined, and corrective action is taken to preclude recurrence. Significant conditions, their causes, and corrective actions are documented, reported to appropriate levels of management, and follow-up action is taken to verify implementation of corrective actions.

Approved written policies, plans, and/or procedures specify requirements for identification and classification of conditions adverse to quality, trending of significant conditions adverse to quality, criteria for determining trends, and follow-up action to be taken to verify implementation of corrective action.

18. QUALITY ASSURANCE RECORDS

GLE produced QA records that furnish documentary evidence of quality shall be specified, prepared, and maintained in accordance with applicable regulatory requirements and approved written policies, plans, and procedures. QA records shall be legible, identifiable, and retrievable, and shall be protected against damage, deterioration, and loss for the specified record retention duration. Retention periods for the various types of records generated under the QA Program shall be specified in approved policies, plans, and/or procedures.

Custodianship responsibility is assigned for lifetime records storage. Custodianship includes receipt and status control; storage; preservation; and safekeeping using hard copy, microfilm, or an electronic document management system. 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 Records Center.

18.1 Records Management Program

A Records Management Program and Records Center shall be established as early as practicable, consistent with the work activities, and in compliance with QA Program requirements. Specific requirements and responsibilities for generation, classification, retention, receiving, storage, and preserving of QA records are established in approved written policies, plans, and/or procedures.

18.2 Generation, Classification, and Retention of QA Records

GLE design specifications, procurement documents, test procedures, operating procedures, or other documents and procedures shall specify the records to be generated, supplied, or maintained. Documents are considered valid records only if authenticated (e.g., stamped, initialed, or signed and dated by authorized personnel).

Records are indexed to ensure retrievability. Records and/or indexing systems provide sufficient information to permit identification between the record and the item or activity to which it applies. Lifetime records are entered into record storage after receipt or validation. Temporary storage in approved containers is provided until records are entered into lifetime storage. Records are classified for retention purposes as lifetime records or nonpermanent records in accordance with the criteria provided below. Records classified as lifetime records are access controlled in the GLE Records Center. Records classified as nonpermanent records are controlled by the responsible organization for the designated retention period.

18.2.1 Lifetime Records

Lifetime records are defined in accordance with ASME NQA-1-1994, Supplement 17S-1, Section 2.7.1, Supplementary Requirements for Quality Assurance Records. The applicable document that specifies the record indicates those to be forwarded for lifetime storage. In the case of specified records produced by supplier, an agreement for records turnover is established.

Lifetime records are retained for the life of the item to which they apply or as required by a regulatory agency. Storage is in a central location unless the applicable procedure specifies otherwise. Records may be originals, copies, or electronic format.

18.2.2 Nonpermanent Records

Nonpermanent records are those required to show evidence that an activity was performed in accordance with applicable requirements. Nonpermanent records are not retained for the life of a particular item. Nonpermanent records are retained by the responsible organization until they are no longer useful. The retention periods for nonpermanent records are established in approved policies, plans, and/or procedures.

18.3 Records Center

The Records Center shall protect against the risk of loss or deterioration of lifetime records. Hard copy or microfilm storage facilities shall meet the requirements of ASME NQA-1-1994, Supplement 17S-1, Section 4.4, Supplementary Requirements for Quality Assurance Records. For electronic storage, backups or duplicate files are generated. Lost or damaged records are replaced unless deemed impractical with the concurrence of the QA organization.

The GLE Records Center shall be access controlled and a list shall be maintained designating personnel with permitted access to the records. The Records Center shall not be left unattended unless it is properly secured. Access to the Records Center shall be formally requested and approved by the manager responsible for records management.

18.4 Retrieving and Dispositioning QA Records

Single copy records are checked out of storage only if they cannot be copied and then only for a limited period. Temporary protection in such cases is provided by prudent business practices (e.g. record of custody, office environment, and work place security).

Records maintained by a supplier at its facility or other locations shall be accessible to GLE directly or through the Sourcing function. The supplier's records are not disposed of until contractual requirements are satisfied.

For computer codes and computerized data used for activities relied on for safety, procedures are provided for maintaining readability and usability of older codes and data as computing technology changes. The procedures include transfer of older forms of information and codes associated with older computing equipment to contemporary computing media and equipment.

18.5 Correcting or Replacing Information in QA Records

The Records Management System is subject to annual assessment as defined in GLE LA, Section 11.5.2, *Scheduling of Audits and Assessments*. Corrections to records are reviewed and approved by the originating organization. The corrections include the date and the identification of the individual authorized to issue the correction. Replacement, restoration, or substitution of lost or damaged records is performed in accordance with implementing policies, plans, and/or procedures. These policies, plans, and/or procedures provide for appropriate review and approval by the originating organization and any additional information associated with the replacement.

19. AUDITS

Audits are performed to verify compliance with the QA Program and to determine its effectiveness. Audits of organizations performing quality-affecting activities associated with safety-related aspects of the facility are performed at a frequency commensurate with the status and importance of the activity. Audits are performed on both internal and external organizations providing products or services to the project.

Audits are performed in accordance with policies, plans, procedures, and/or checklists by personnel who do not have direct responsibility for performing the activities being audited. A plan is prepared for each audit to identify the audit scope, requirements, audit personnel, activities to be audited, applicable documents, organizations to be audited, schedule, and policies, plans, procedures, or checklists. Auditors (including technical specialists) have training or experience commensurate with the scope, complexity, or special nature of the audit.

Organizations being audited provide access and assistance to the audit personnel. Objective evidence is examined to determine if the QA Program elements are being implemented effectively. Audit results are discussed with the audited organization's management, and conditions requiring prompt corrective action are reported immediately to the audited organization's management. The audit report includes the following information, as appropriate:

- Description of the audit scope,
- Identification of the auditors,
- Identification of persons contacted during audit activities,
- Summary of audit results, to include a statement on the effectiveness of the QA Program elements audited, and
- Description of each reported adverse audit finding in sufficient detail to enable corrective action taken by the audited organization.

Audit results are documented, reported to, and reviewed by responsible management. Management of the audited organization or activity investigates adverse audit findings, schedules corrective action, including measures to prevent recurrence (if appropriate), and notifies the QA organization of the action taken. Adequacy of audit responses is evaluated by the QA organization and verification of corrective action is documented. Follow-up action is taken to verify the implementation and effectiveness of the corrective action and to determine if repetitive problems require further corrective action. Audit records include audit plans, audit reports, written responses to the audit findings, and the record of completion of corrective action.

20. PROVISIONS FOR CHANGE

The QA Program is reviewed and revised as necessary to reflect any changes that occur during the design, construction, operation, and decommissioning phases. In addition, the QA Program is revised when corrective actions, regulatory, organizational, or work scope changes warrant changes to the QA Program.

The QA Program is maintained current through design, construction, operation, and decommissioning of the facility. The QA Program is kept current as the design, construction, operation, and decommissioning activities progress, and appropriate changes are made based on any of the following:

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

21. REFERENCES

1. 10 CFR 70.4, *Definitions*, U.S. Nuclear Regulatory Commission, 2008.

2. 10 CFR 70.61, *Performance Requirements,* U.S. Nuclear Regulatory Commission, 2008.

3. 10 CFR 70.64, *Requirements for New Facilities or New Processes at Existing Facilities*, U.S. Nuclear Regulatory Commission, 2008.

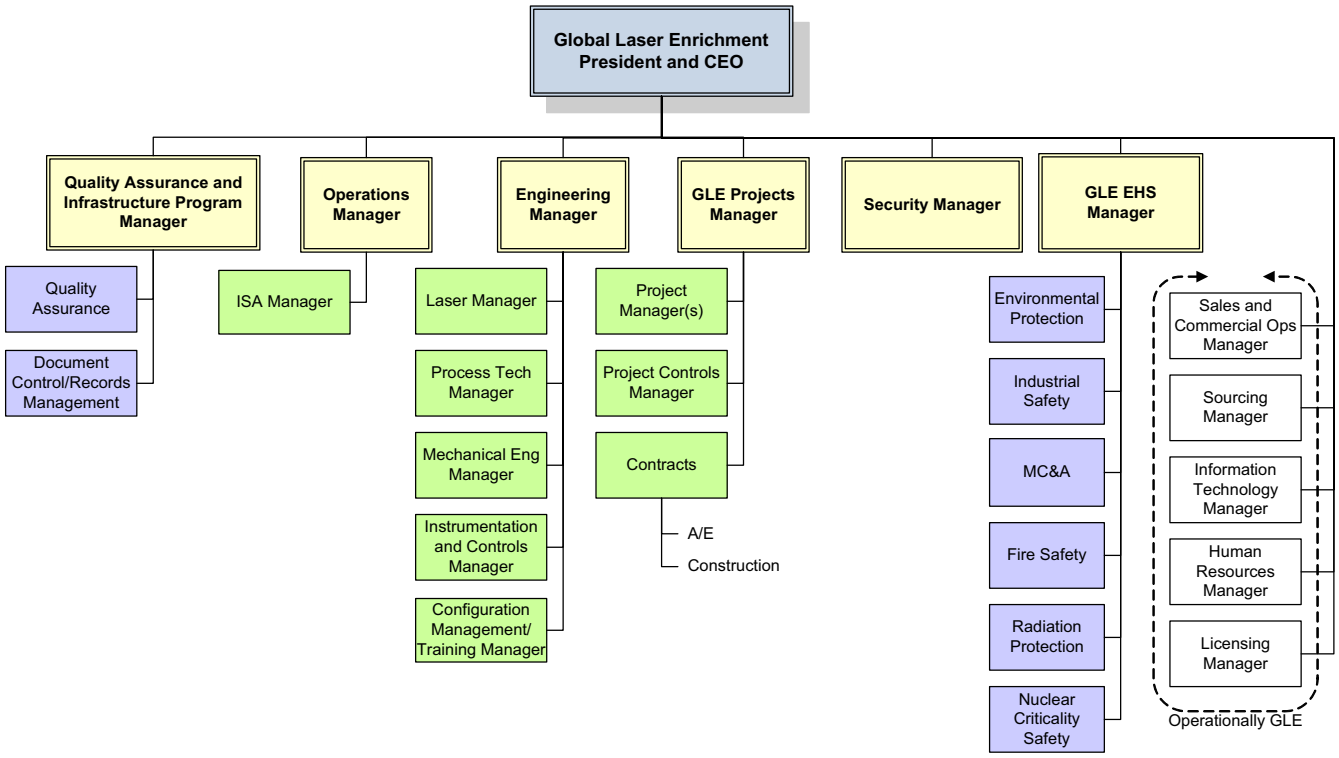
4. 10 CFR 21, *Reporting of Defects and Noncompliance*, U.S. Nuclear Regulatory Commission, 2008.

5. ANSI/ASME NQA-1, *Quality Assurance Program Requirements for Nuclear Facilities*, American National Standards Institute/American Society of Mechanical Engineers Standard, New York, NY, 1994.

6. 10 CFR 70, *Domestic Licensing of Special Nuclear Material,* U.S. Nuclear Regulatory Commission, 2008.

7. 10 CFR 50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*, U.S. Nuclear Regulatory Commission, 2008.

Figure 1. Global Laser Enrichment Project Design and Construction Phase Organization Chart.



Appendix A
Fire Safety IROFS Exemption

This Appendix describes the extent to which Sections 2 through 19 of this QAPD apply to the fire safety systems IROFS items and activities or defines exceptions and describes alternatives. The fire safety systems to which this Appendix applies are detailed in the IROFS FS-02 Boundary Document (AEC – Fire Protection Program, Automatic Fire Suppressions Systems, IROFS FS-02), which also includes a list of applicable National Fire Protection Association (NFPA) codes and standards.

The following elements apply as specified below for fire safety systems IROFS items and activities.

Section 2 – Organization – Section 2 of this QAPD applies in its entirety.

Section 3 – Quality Assurance Program – Section 3 of this QAPD applies with the following exceptions and/or alternatives:

- The fire safety systems IROFS are not classified as either QL-1 or QL-2 as described in Paragraph 3.1, Quality Levels.

- Paragraph 3.2, Application of Management Measures, applies with the following exceptions and/or alternatives:

  a. Where applicable, management measures Paragraphs 3.2.1, Configuration Management, 3.2.3, Training and Qualifications, 3.2.4, Procedures, 3.2.5, Audits and Assessments, 3.2.6, Incident Investigations, 3.2.7, Records Management, and 3.2.8, Other Quality Assurance Elements, are described in fire safety system design documents and applicable NFPA codes and standards.

  b. Paragraph 3.2.2, Maintenance applies except that application of maintenance attributes shall be as required by the applicable NFPA Codes and Standards.

Section 4 – Design Control – Section 4, Design Control, of this QAPD is replaced in its entirety by the following alternatives:

- The fire safety systems IROFS are designed according to the requirements of the applicable NFPA Codes and Standards, and:

  a. The fire safety systems defined in IROFS FS-02 are described by design documents (including drawings, specifications and calculations). The fire safety systems are procured by bid and award process. The successful fire protection subcontractor prepares fabrication drawings, data sheets, and calculations for submittal and review. Design documents are prepared, reviewed, checked, and approved by qualified individuals. The fire safety systems IROFS are designed, fabricated, installed, inspected, and maintained according to the requirements of the design documents, NFPA Codes and Standards, Manufacturer's requirements, and UL listing requirements.

Appendix A
Fire Safety IROFS Exemption

b. The NFPA Codes and Standards referred to in this document are considered the Code of record and are limited to the NFPA Codes and Standards effective at the time of design.

Section 5 – Procurement Control – Section 5, Procurement Control, of this QAPD is replaced in its entirety by the following alternatives:

- Suppliers and/or sub-tier suppliers are not required to maintain a QA Program other than as specified and necessary to maintain their certifications, and listings to provide services and/or hardware associated with the design, erection, inspection, test, and certification of fire safety systems.

- Paragraph 5.1, Dedication Process, does not apply. Fire safety system acceptance testing requirements are described in the design documents and applicable NFPA codes and standards. Functional testing by the licensed contractor(s) selected to provide and install the fire safety systems provides the assurance of quality that the fire safety systems IROFS will perform as required when called upon.

Section 6 – Instructions, Procedures, and Drawings – Section 6, Instructions, Procedures, and Drawings, of this QAPD is replaced in its entirety by the following alternative.

- Fire safety systems instructions, procedures, and drawings include or reference NFPA acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.

Section 7 – Document Control – Section 7, Document Control, of this QAPD is replaced in its entirety by the following alternative.

- Fire safety systems document control shall meet the requirements of applicable NFPA codes and standards.

Section 8 – Control of Purchased Items and Services – Section 8, Control of Purchased Items and Services, of this QAPD is replaced in its entirety by the following alternative:

- The licensed fire protection contractor(s) selected to design, construct/erect, test, and certify the fire safety systems IROFS must demonstrate a satisfactory work history of having successfully installed fire safety systems, and are responsible for meeting the requirements of applicable NFPA Codes and Standards, regarding the control of items and their services.

- Design specifications and other documents for procurement of the fire safety systems IROFS specify such requirements as QA, drawing review and approval, NFPA Codes and Standards, including revision and/or date.

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Section 9 – Identification and Control of Materials, Parts, and Components – Section 9, Identification and Control of Materials, Parts, and Components, of this QAPD is replaced in its entirety by the following alternative:

- The licensed fire protection contractor(s) selected to design, construct/erect, test, and certify the fire safety systems IROFS must demonstrate a satisfactory work history of having successfully installed fire safety systems, and are responsible for meeting the requirements of applicable NFPA Codes and Standards, regarding identification and control of parts, materials, and components.

- Individual fire safety system components as well as the entire fire safety system shall be UL listed for the purpose it is installed.

- Design specifications and other documents for procurement of the fire safety systems IROFS specify such requirements as material control, item identification and segregation, and marking.

Section 10 – Control of Special Processes – Section 10, Control of Special Processes, of this QAPD does not apply to the design, procurement, installation, and maintenance of the fire safety systems IROFS.

Section 11 – Inspection – Section 11, Inspection, of this QAPD is replaced in its entirety by the following alternative:

- The licensed fire protection contractor(s) selected to design, construct/erect, test, and certify the fire safety systems IROFS must demonstrate a satisfactory work history of having successfully installed fire safety systems, and is responsible for meeting the requirements of applicable NFPA Codes and Standards regarding inspection.

- Design specifications and other documents for procurement of the fire safety systems IROFS specify the inspection-related NFPA Codes and Standards, including revision and/or date.

- Design specifications and other documents for procurement of the fire safety systems IROFS require that contractor personnel performing inspections are qualified based on experience, education, or certification, as appropriate.

- Once certified by the contractor and accepted by GLE, inspections of the fire safety systems IROFS is conducted according to the requirements of applicable NFPA Codes and Standards.

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Section 12 – Test Control – Section 12, Test Control, of this QAPD is replaced in its entirety by the following alternative:

- The licensed fire protection contractor(s) selected to design, construct/erect, test, and certify the fire safety systems IROFS must demonstrate a satisfactory work history of having successfully installed fire safety systems, and is responsible for meeting the requirements of applicable NFPA Codes and Standards regarding testing.
- Design specifications and other documents for procurement of the fire safety systems IROFS specify the testing-related NFPA Codes and Standards, including revision and/or date.
- Design specifications and other documents for procurement of the fire safety systems IROFS require that contractor personnel performing tests are qualified based on experience, education, or certification, as appropriate.
- Once certified by the contractor and accepted by GLE, testing of the fire safety systems IROFS is conducted according to the requirements of applicable NFPA Codes and Standards for testing.

Section 13 - Control of Measuring and Test Equipment (M&TE) – Section 13, Control of Measuring and Test Equipment, of this QAPD is replaced in its entirety by the following alternative:

- The licensed fire protection contractor(s) selected to design, construct/erect, test, and certify the fire safety systems IROFS is responsible for meeting the requirements of applicable NFPA Codes and Standards, regarding M&TE.
- Design specifications and other documents for procurement of the fire safety systems IROFS specify the M&TE-related NFPA Codes and Standards, including revision and/or date.
- Once the fire safety systems IROFS are certified by the contractor and accepted by GLE, M&TE used for inspection and test will meet the requirements of applicable NFPA Codes and Standards.

Section 14 – Handling, Storage, and Shipping – Section 14, Handling, Storage, and Shipping, of this QAPD is replaced in its entirety by the following alternative:

- The licensed fire protection contractor(s) selected to design, construct/erect, test, and certify the fire safety systems IROFS must demonstrate a satisfactory work history of having successfully installed fire safety systems, and is responsible for meeting the requirements regarding protection of items and materials.
- Design specifications and other documents for procurement of the fire safety systems IROFS describe what the contractor is required do regarding protection of items and materials.

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- Fire safety system materials are inspected during storage and before installation to determine whether the design/procurement document requirements and manufacturer's requirements for storage and handling have been met.

Section 15 – Inspection, Control, Testing, and Operating Status – Section 15, Inspection, Control, Testing, and Operating Status, of this QAPD is replaced in its entirety by the following alternative:

- Fire safety systems IROFS are inspected, tested, and maintained according to the requirements of applicable NFPA Codes and Standards.

- Surveillance requirements, such as inspection frequency and scope, are according to the requirements of applicable NFPA Codes and Standards.

Section 16 – Control of Nonconforming Items – Section 16, Control of Nonconforming Items, of this QAPD is replaced in its entirety by the following alternative:

- Fire safety system IROFS items subject to inspection by applicable NFPA Codes and Standards and determined to be non-conforming are identified, corrected, and documented according to the requirements of NFPA Codes and Standards.

Section 17 – Corrective Actions – Section 17, Corrective Actions, of this QAPD is replaced in its entirety by the following alternative:

- Conditions other than nonconforming items requiring corrective action in fire safety systems IROFS are identified, corrected, and documented according to the requirements of NFPA Codes and Standards.

Section 18 – Quality Assurance Records – Section 18, Quality Assurance Records, of this QAPD is replaced in its entirety by the following alternative:

- Fire safety system IROFS quality assurance records are documented and maintained according to the requirements of applicable NFPA Codes and Standards.

Section 19 – Audits – Section 19, Audits, of this QAPD is replaced in its entirety by the following alternative:

- Fire safety systems IROFS audits are performed according to the requirements of applicable NFPA Codes and Standards.