Global Laser Enrichment

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QUALITY ASSURANCE PROGRAM DESCRIPTION

FOR THE

GE-HITACHI GLOBAL LASER ENRICHMENT LLC COMMERCIAL FACILITY

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FOR THE
GE-HITACHI GLOBAL LASER ENRICHMENT LLC
COMMERCIAL FACILITY

Revision 6

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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.
3	12/14/2010	ALL	Incorporate NRC RAI responses submitted to the NRC via letter on November 19, 2010 in response to the NRC RAI letter dated October 20, 2010, and the projected responses to the NRC RAI letter dated November 12, 2010, requesting information on Appendix A.
4	02/08/2011	All	Clarified 10 CFR 21 and Appendix A of 10 CFR 70 applicability for each quality level under Section 1.0. Added Appendix B to incorporate Quality Assurance process associated with the credited portions of building and equipment support structures. Applied minor editorial corrections and review cycle comment resolutions.
5	04/08/2011	All	Incorporated updates of various sections based on responses to NRC RAIs and applied review cycle comment resolutions.
6	TBD	ALL	Incorporated updates of various sections based on responses to NRC questions during phone discussions (documented in NRC meeting summary dated July 1, 2011). Primary changes include removal of QL-B and Appendix B process and minor changes to Definitions. Removed redundant acronym declarations throughout.

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GLOSSARY AND ACRONYMS

AISC – American Institute of Steel Construction

ANS – American Nuclear Society

ANSI – American National Standards Institute

ASME – American Society of Mechanical Engineers

As-constructed – Identification that documentation has been confirmed to be functionally equivalent to the final field configuration.

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).

ASTM – American Society for Testing and Materials

Audit – Used to monitor compliance with regulatory requirements and license commitments. 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.

Available and Reliable to Perform Their Function When Needed – Based on the analyzed, credible conditions in the integrated safety analysis (ISA), 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.

Basic Component – A SSC, or part thereof, designated as an IROFS identified as QL-1 or QL-2, 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 10 CFR 70, order, or license issued by the U.S. Nuclear Regulatory Commission (NRC) could create a substantial safety hazard (i.e., exceed the performance requirements of 10 CFR 70.61). Basic components include QL-1 and QL-2 identified 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.

When applied to IROFS identified as QL-NFPA, a basic component is a SSC, or part thereof, that affects the safety function of the IROFS that is directly procured by the licensee or a facility or activity subject to the requirements of the National Fire Protection Administration (NFPA) Code of Record, and in which a defect or failure to comply with requirements of the NFPA Code of Record could create a substantial safety hazard. Basic component includes QL-NFPA identified 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, to the extent required by the NFPA Code of Record.

CAQ – Condition Adverse to Quality (see definition)

CEO – Chief Executive Officer

CFR – Code of Federal Regulations

Commercial Grade Item – A SSC, or part thereof that affects its QL-1 and/or QL-2 identified 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).

When applied to items identified as QL-NFPA (being items in facilities and activities licensed pursuant to 10 CFR 70), commercial grade item means an item that is (1) not subject to design or specification requirements that are unique to facilities or activities; (2) used in applications other than those facilities and activities; and (3) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacture's published product description.

Condition Adverse to Quality (CAQ) – An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, or non-conformances.

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 IROFS to perform their functions when needed.

Contractor Personnel – Persons who are not GLE/GEH/GNF employees or active pensioners. Contract personnel have been contracted to provide a service or activity.

Corrective Action – A measure taken to rectify significant conditions adverse to quality and to preclude repetition.

CM – Configuration Management (see definition)

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 QL-1 and/or QL-2 identified IROFS function.

When applied to items identified as QL-NFPA, critical characteristics are those important to design, material, and performance characteristics of a commercial grade item that will provide reasonable assurance that the item will perform its intended QL-NFPA identified IROFS function.

Decommission – To remove a facility or site safely 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.

Dedication Process – An acceptance process undertaken to provide reasonable assurance that a commercial-grade item to be used as a basic component will perform its intended QL-1 and/or QL-2 identified IROFS function and, in this respect, is deemed equivalent to an item designed and manufactured under QL-1 or QL-2 requirements in accordance with the GLE QAPD. 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 the GLE QAPD. The process is considered complete when the item is designated for use as a basic component applicable to QL-1 and/or QL-2 IROFS.

When applied to items identified as QL-NFPA (being items in facilities and activities licensed pursuant to 10 CFR 70), the dedication process is applied to commercial-grade items to be used as basic components to provide reasonable assurance that they will perform their intended QL-NFPA identified IROFS function and are deemed equivalent to an item designed and manufactured under QL-NFPA requirements in accordance with the GLE QAPD. This assurance is achieved by confirming that the commercial-grade item is manufactured to established, acceptable national codes or standards that include one or more independent product endorsement based on qualification testing or periodic testing of selected characteristics of the item except in cases where such listing/approval is not required by codes and standards. In all cases, the applicable provisions of the GLE QAPD will be used to conduct the dedication process. The process is considered complete when the commercial-grade item is designated as a basic component.

Dedicating Entity – The organization that performs the dedication process for QL-1 and QL-2 identified IROFS. 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.

When applied to items identified as QL-NFPA (being items in facilities and activities licensed pursuant to 10 CFR 70), the dedicating entity is the licensee. The licensee, pursuant to 10 CFR 21.21(c), is responsible for reporting defects and failure to comply for the dedicated item, maintaining auditable records of the dedication process, and assumes full responsibility as the dedicating entity.

Defect – Defect means: (1) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in 10 CFR 21 if, on the basis of an evaluation, the deviation could create a substantial safety hazard; (2) the installation, use, or operation of a basic component containing a defect as defined herein; and (3) an error, omission or other circumstance in a design certification, or standard design approval that, on the basis of an evaluation, could create a substantial safety hazard.

Deviation – means a departure from the technical requirements included in a procurement document, or specified in early site permit information, a standard design certification or standard design approval.

Evaluation – means the process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

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.

IBC – International Building Code, Version 2006, as amended by the state of North Carolina

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 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 10 CFR 70, 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.

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.

IROFS – Items Relied on for Safety (see definition)

IROFS Boundary Definition Package – Documents that contain the physical descriptions and parameters of 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.

ISA – Integrated Safety Analysis (see definition)

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.

ISO – International Organization for Standardization

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.

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 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.

NFPA – National Fire Protection Administration

NFPA Code of Record –NFPA Code of Record is a general identifier of the governing codes and standards (such as those NFPA requirements as amended by the state of North Carolina) for the activities associated with QL-NFPA identified IROFS. The NFPA Code of Record is specifically the NFPA Codes and Standards effective at the time of design. The NFPA Code of Record is acknowledged to have standard industry accepted quality control and quality assurance elements specified in sufficient detail to assure that the activities meet the desired criteria specified in the industrial setting. The application of the QA program associated with the NFPA Code of Record is deemed adequate to satisfy the reliability demands of the QL-NFPA identified IROFS since the failure frequencies for them are based on reliability data developed by NFPA. Adequate reliability is established by applying the elements of the GLE QAPD and obtaining the Certificate of Occupancy from the authority having jurisdiction with the accepted compliance, variance, deviation, exemption, exclusion, etc. for the period that the certificate is in place.

NIST – National Institute of Standards and Technology

NQA – Nuclear Quality Assurance

NRC – U.S. Nuclear Regulatory Commission

ORR – Operational Readiness Review

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 usually 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.

Procurement Document – Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.

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.

SCAQ – Significant Condition Adverse to Quality (see definition)

Significant Condition Adverse to Quality (SCAQ) – A Condition Adverse to Quality, which, if uncorrected, could have a serious effect on safety or operability.

Substantial safety hazard – A substantial safety hazard is a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of 10 CFR.

Supplier's QA Program –The supplier of items and/or services may be required to do so under a QA Program other than the GLE QA program. Depending on the services procured, the procurement documentation will specify GLE requirements for the supplier's QA Program consistent with governing guidance, such as, the NFPA Code of Record, and/or the design documents.

Surveillance – The act of monitoring or observing to verify whether an item or activity conforms to specific requirements.

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, public, and the environment.

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).

GLE will apply 10 CFR 21, *Reporting of Defects and Noncompliance* (Ref. 4), in its entirety and 10 CFR 21, Section 21.21, *Notification of failure to comply or existence of a defect and its evaluation,* by quality level as follows:

PROJECT PHASE	QL-1 and QL-2	QL-NFPA
DURING CONSTRUCTION	10 CFR Part 21 in its entirety applies per Section 5	Practices in the National Fire Protection Administration (NFPA) Code of Record apply per Appendix A, Section 5
POST-CONSTRUCTION & OPERATIONS	GLE assumes full responsibility for and is to implement 10 CFR Part 21.21	GLE assumes full responsibility for and is to implement 10 CFR Part 21.21

In addition to the above, the notification requirements of 10 CFR 21.21 apply when the potential for a substantial safety hazard exists, whether or not IROFS are involved. Also, GLE will apply the requirements of 10 CFR 70.50, *Reporting Requirements* (Ref. 5), 10 CFR 70.74, *Additional Reporting Requirements* (Ref. 6), and Appendix A to 10 CFR 70, *Reportable Safety Events* (Ref. 7). These requirements are applicable to each IROFS regardless of the identified quality level.

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 relevant requirements applied to those SSCs and activities designated as Quality Level (QL)-1, QL-2, or QL-NFPA. 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. The organization chart shown in Figure 1 will be kept current as organization changes are made. The organization relationships to be applied during facility construction, operation, and decommissioning are described in Chapter 2 of the License Application. Figure 2-1 depicts the GLE organization during design and construction, and Figure 2-2 depicts the GLE organization during Operations. Further description of the roles and responsibilities of key personnel during the "transition phase" (construction and operations performed concurrently) are described in Chapter 2, Section 2.1.4, of the License Application (*Ref. 11*). The Operations organization will be modified prior to starting decommissioning and that information will be submitted to the Nuclear Regulatory Commission (NRC) for review and approval prior to beginning decommissioning activities, as part of the Decommissioning Plan.

Listed below is a description of project personnel and key positions within the GLE organization as related to QA. Each of the positions listed below have sufficient authority, access to work areas, and organizational independence to carry out their responsibilities.

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 policies, plans, procedures, and work instructions.

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 Manager

The QA Manager reports to the GLE President and CEO and is responsible for establishing and maintaining the QA Program to include the Corrective Action Program. The QA Manager has the authority, access to work areas, and organizational independence to ensure the requirements of this QAPD are properly implemented. The QA 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 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 Manager shall have at least two years of 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 managing the design function in developing the conceptual design for the GLE Commercial Facility, to include, but not limited to, development of design requirements, design basis, 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. 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 Sourcing Manager

The Sourcing Manager reports operationally to the GLE President and CEO and reports functionally to the GE Hitachi Global Supply Chain General Manager. The Sourcing Manager is responsible for procurement and providing procurement material control services, to include, but not limited to, supplier/vendor/contractor (hereafter referred to as supplier when used interchangeably) qualification coordination, purchasing, and contracting. The Sourcing Manager is also responsible for supply strategy and development of qualified long-lead-time and complex-system suppliers.

The Sourcing 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 Sourcing 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. 8), 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

Four 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 four 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 or intermediate 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 their 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.

QL-NFPA – QL-NFPA is applied to fire suppression systems identified as IROFS only. The QA program elements that apply to fire suppression systems identified as IROFS and activities are described in Appendix A. These QA program elements are based on the same 18 elements as the main body of the QAPD and include the applicable requirements of NFPA Codes and Standards for credited fire suppression systems. Management measures are applied to QL-NFPA IROFS consistent with the type of IROFS to assure that the IROFS remain reliable at their credited failure frequency when called upon to be available. All applicable QA Program requirements described in Appendix A are also applied to QL-NFPA IROFS in a manner necessary to achieve this goal.

QL-3 – QL-3 applies to items other than those designated as QL-1, QL-2, or QL-NFPA. QL-3 items (not IROFS) are controlled in accordance with standard industrial practice (for example International Organization for Standardization [ISO] based programs) and do not require the application of management measures.

NOTE: All IROFS are maintained at the QL-1 or QL-2 level except the fire suppression system IROFS, FS-02, that is maintained at QL-NFPA. No IROFS are maintained as QL-3 level items.

The extent to which attributes of management measures and QA Program elements are applied to QL-1, QL-2, and QL-NFPA 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,
- Applicable Human Factors Engineering elements,
- 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 elements 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 preoperational readiness reviews are conducted.

3.2 Application of Management Measures

To ensure IROFS are available and reliable to perform safety functions when needed, GLE shall apply the appropriate management measures, as discussed below. The provisions in the License Application Chapter 11, Management Measures," are applicable to IROFS designated as QL-1, QL-2, and QL-NFPA.

3.2.1 Configuration Management

The elements of configuration management as presented in the License Application, Chapter 11, specifically the CM policy, design requirements, document control, change control, and application of assessments, are applied as management measures to QL-1, QL-2, and QL-NFPA IROFS. Additional information on how the configuration management elements are applied are included in Sections 4 through 20 of the main body of this document (for QL-1 and QL-2 IROFS), and Appendix A (for QL-NFPA IROFS).

3.2.2 Maintenance

The application of the types of maintenance (including corrective, calibration, preventative, surveillance, monitoring, and functions testing as presented in the License Application, Chapter 11) 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 areas of consideration presented in Section 3.1, *Quality Levels* (not all of which apply to each type of IROFS). Additional information on maintenance elements are included in Sections 4 through 20 of the main body of this document (for QL-1 and QL-2 IROFS), and Appendix A (for QL-NFPA 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, QL-2, and QL-NFPA 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) (Ref. 11) Section 11.3, *Training and Qualifications*, are driven by a task analysis that addresses human factors elements, the complexity of the safety function being carried out, the existing knowledge of individuals who will be involved with the task, as well as the skills needed to perform the task. Based on the task analysis, appropriate training is then developed utilizing classroom, performance-based on-the-job, testing, etc. commensurate with the areas of consideration presented in Section 3.1, *Quality Levels* (not all of which apply to each type of IROFS). This is a standard element of a systematic approach to training. Additional information on the training and qualification elements are included in

Sections 4 through 20 of the main body of this document (for QL-1 and QL-2 IROFS), and Appendix A (for QL-NFPA IROFS).

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) 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 areas of consideration, as applicable, presented in Section 3.1, *Quality Levels*.

3.2.5 Audits and Assessments

A basic level of audits and assessments is applied to IROFS. However, as identified in Section 19, *Audits and Assessments* (for QL-1 and QL-2), and Appendix A (Section 19 for QL-NFPA), the frequencies are commensurate with the status and importance of the activity, and again, the areas of consideration presented in Section 3.1, *Quality Levels,* 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 QA 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. QL-1 and QL-2 level IROFS use the requirements specified in Sections 4 through 20. QL-NFPA level IROFS use the requirements specified in Appendix A.

4. DESIGN CONTROL

Engineering 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. Engineering 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. Typical engineering management responsibilities related to design control include:

- Controlling exchange of technical information between internal and external organizations;
- Defining design interface responsibilities between internal and external organizations;
- Implementing design policies, plans, and/or procedures;
- Establishing technical requirements and design standards;
- Selecting and performing design practices, including review methods;
- Preparing design documents;
- Defining the extent of design reviews, to include technical reviews, peer reviews, modeling, and alternate calculations, as appropriate;
- Managing design output document control, to include review, approval, release status identification, distribution, and revision of documents;
- Determining and specifying acceptance criteria, required tests and inspections, and program requirements for records;
- Maintaining design documents; and
- Controlling design change. This will be accomplished according to implementing design policies, plans, and/or procedures.

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. 9). 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. Information from design output documents for IROFS (such as, IROFS Boundary Definition Packages, specifications, system descriptions, and drawings) provides inputs for the development of appropriate inspection, test, and maintenance instructions and/or procedures with necessary details and acceptance criteria. 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 and QL-2 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;
- Applicability of 10 CFR Part 21;
- QA requirements, to include right of access to the supplier's facilities and records for inspection or audit by the buyer/sourcing, designated representatives, and/or any other authorized parities;
- A description of the interrelationships and areas of responsibility and authority for the organization if workers are performing activities relied on for safety (such as architect/engineer, constructor, construction manager, and operator);
- 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; and
- 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 review, approval, and control as was utilized in the preparation of the original 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 (that is, QL-1 and/or QL-2 identified 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. 10), 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) identified as QL-1 and/or QL-2.

In cases where commercial-grade items are to be procured and then dedicated for use as QL-1 and/or QL-2 identified 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.

Policies, plans, procedures, instructions, and drawings, and changes thereto, are controlled in accordance with Sections 4 and 7 of this QAPD.

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, procedures, instructions, and drawings are maintained under revision control.

Changes to documents other than minor changes are reviewed for adequacy, correctness, and completeness, prior to approval and issuance. Major changes are reviewed and approved by the same organization that performed the original review and approval unless other organizations are specifically designated.

Minor changes to documents, such as inconsequential editorial corrections, may be made to documents without being subject to the review and approval requirements specified above. Approved procedures define the responsibilities and acceptance criteria for making minor changes.

Temporary changes to documents are processed, documented, and approved in accordance with approved polices, plans, instructions, and procedures.

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 supplier's QA Program; receipt inspections; installation inspections; and review of procurement documents during receipt inspections. The design function is responsible for determining specific methods of acceptance to be applied to purchased items. The design and QA functions are responsible for determining specific methods for acceptance of services such as technical verification of data produced, surveillance, and/or audit of the activity, or review of objective evidence. The specific method of acceptance for services is dependent on the nature of the service being provided.

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 implementation of the disposition is verified, except where otherwise controlled and documented according to approved procedures. 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.

Controls to ensure that only correct and accepted items are installed include, but are not limited to:

- Receipt inspection according to approved procedures as discussed in Section 11, *Inspection*;
- Nonconformance control according to approved procedures as discussed in Section 16, *Control of Nonconforming Items*;
- Onsite handling and storage according to approved procedures as discussed in Section 14, *Handling, Storage, and Shipping*; and
- Drawings and specifications for construction, erection, and field fabrication, etc. as developed under Section 4, *Design Control.*

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 prequalified 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 retest, 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 IROFS or other item or computer program to specific requirements and to demonstrate satisfactory performance for service are planned and executed in accordance with written and approved policies, plans, procedures, instructions, or NFPA Codes and Standards, as applicable. 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, acceptance criteria, test methods, and hold points to be employed;
- References and related documents;
- Provisions for ensuring adequate instrumentation is available and suitable environmental conditions are maintained;
- 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;
- 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 the 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 commercial devices such as rulers, tape measures, levels, and stop watches. 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 recalibrated. 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 carry out 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 4, *Design Control*. The disposition process includes consideration of the need for design documents to be "as-constructed" to facilitate operations, maintenance, or modification. The as-constructed records, if the disposition determines such records to be required, reflect the accepted deviation. Repaired or reworked items are reexamined 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 documenting conditions adverse to quality including identification, classification, appropriate notifications, and corrective actions taken. In addition, follow-up actions to verify implementation of corrective actions and trending are required for significant conditions adverse to quality.

18. QUALITY ASSURANCE RECORDS

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. In the case of records produced by suppliers that furnish documentary evidence of quality, an agreement for records turnover and maintenance is established. 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 an approved records retention schedule.

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

Applicable 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, or otherwise authenticated) and validated (verified to be legible, retrievable). This authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organizations. These records may be originals or reproduced copies. Supplier furnished lifetime records that furnish objective evidence of quality will be authenticated and validated prior to being designated as a record. Authentication may take the form of a statement by the responsible individual or organization.

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. The indexing system shall include, as a minimum, record retention and the location of the record within the record system. Records shall be distributed, handled, and controlled in accordance with written procedures.

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 unless otherwise specified. 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 as those which meet one or more of the following criteria in accordance with ASME NQA-1-1994, Supplement 17S-1:

- Those which would be of significant value in demonstrating capability for safe operation;
- Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item;
- Those which would of significant value in determining the cause of an accident or malfunction of an item; and/or
- Those which provide required baseline data for in-service inspections.

The applicable document that specifies the record indicates those to be forwarded for lifetime storage. Lifetime records are entered into record storage after authentication and validation. Turnover agreements for temporary storage of records will be established for any person or organization approved to store temporary records. Turnover agreements will provide storage requirements, maximum allowable time limit for temporary storage, and responsibilities.

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, electronic, 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 generated will also meet the requirements of ASME NQA-1-1994, Supplement 17S-1, Section 4.4, *Supplementary Requirements for Quality Assurance Records.* 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 by the QA Organization or management of the audited organization 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, and as applicable written responses to the audit findings, the documentation of corrective action completion, and documentation of corrective action verification.

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; and
- Changes due to regulations, commitments, reorganizations, 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. 10 CFR 70.50, *Reporting Requirements*, U.S. Nuclear Regulatory Commission, 2008.

6. 10 CFR 70.74, *Additional Reporting Requirements*, U.S. Nuclear Regulatory Commission, 2008.

7. Appendix A to 10 CFR 70, *Reportable Safety Events*, U.S. Nuclear Regulatory Commission, 2010.

8. 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.

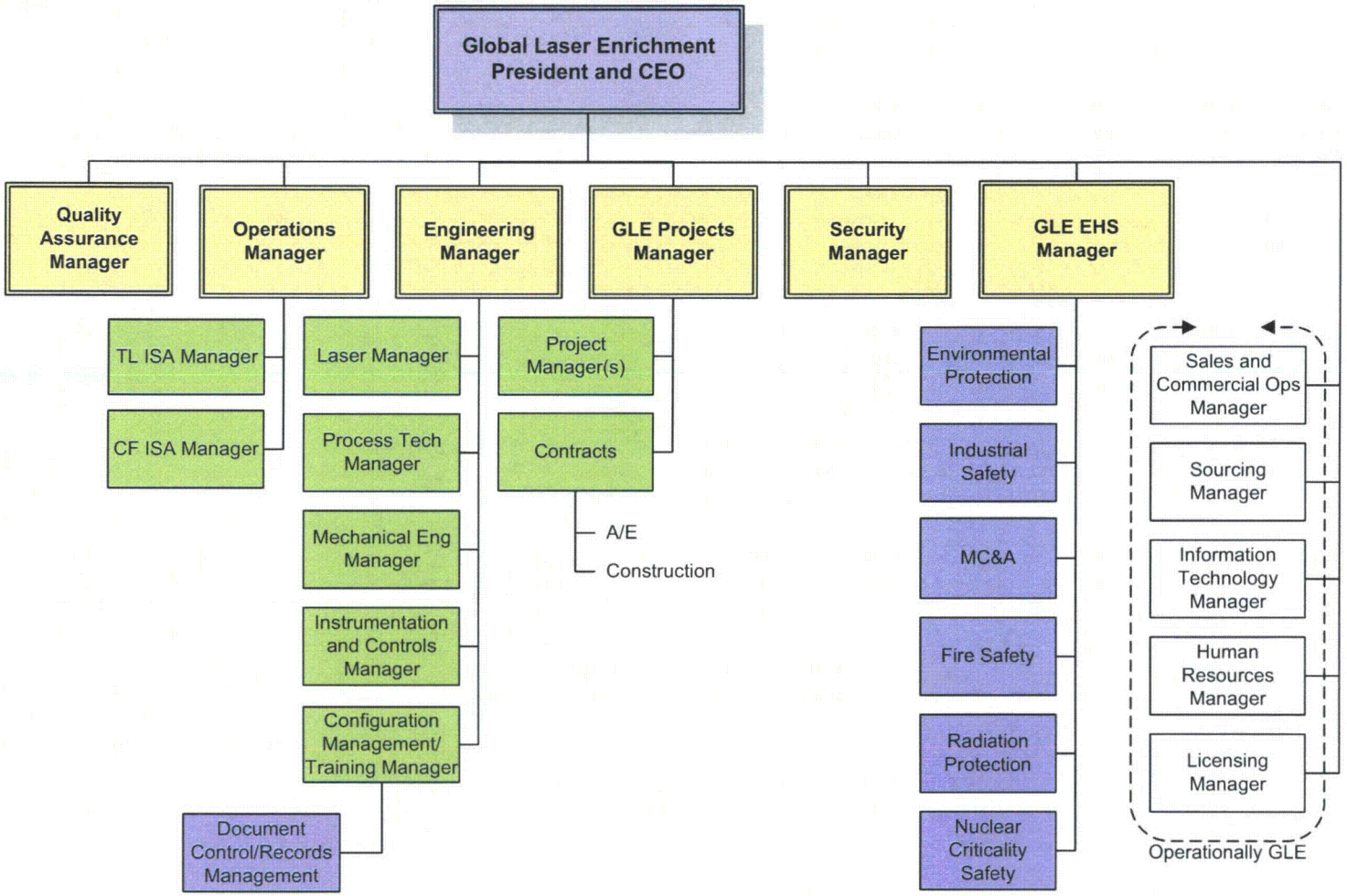
9. 10 CFR 70, *Domestic Licensing of Special Nuclear Material,* U.S. Nuclear Regulatory Commission, 2008.

10. 10 CFR 50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*, U.S. Nuclear Regulatory Commission, 2010.

11. *License Application for GE-Hitachi Global Laser Enrichment LLC Commercial Facility*, Revision 3, TBD.

    - Section 2.1.4, *Transition From Design and Construction to Operations*
    - Section 11.3, *Training and Qualifications*
    - Section 11.5.2, *Scheduling of Audits and Assessments*

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



Appendix A
Fire Suppression IROFS Exemption

This Appendix describes the extent to which Sections 1 through 20 of this QAPD apply to QL-NFPA IROFS (such as the fire suppression systems identified as IROFS) items and activities or defines exceptions and describes alternatives. The fire suppression 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 suppression systems identified as IROFS items and activities.

Section 1 – Introduction – Section 1 of this QAPD applies in its entirety.

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

Section 3 – Quality Assurance Program – Section 3 of this QAPD applies consistent with the processes as applied to QL-1 and QL-2 identified IROFS or as indicated when the processes differ.

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

> Engineering 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. Engineering 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. Typical engineering management responsibilities related to design control include:
>
> - Controlling exchange of technical information between internal and external organizations;
> - Defining design interface responsibilities between internal and external organizations;
> - Implementing design policies, plans, and/or procedures;

Appendix A
Fire Suppression IROFS Exemption (Continued)

- Establishing technical requirements and design standards;
- Selecting and performing design practices, including review methods;
- Preparing design documents;
- Defining the extent of design reviews, to include technical reviews, peer reviews, modeling, and alternate calculations, as appropriate;
- Managing design output document control, to include review, approval, release status identification, distribution, and revision of documents;
- Determining and specifying acceptance criteria, required tests and inspections, and program requirements for records;
- Maintaining design documents; and
- Controlling design change. This will be accomplished according to implementing design policies, plans, and/or procedures.

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. 9). The ISA establishes the identification and functions of IROFS and the significance to safety of functions performed by those IROFS.

The fire suppression systems identified as IROFS are described by design documents (including drawings, specifications, and calculations). The fire suppression systems are procured by a bid and award process using qualified licensed suppliers. The fire protection installation supplier prepares fabrication drawings, data sheets, and calculations for submittal and review. Design documents are prepared, reviewed, checked, and approved by qualified independent individuals. The fire suppression systems identified as IROFS are designed, fabricated, installed, inspected, and maintained according to the requirements of the design documents, NFPA Codes and Standards, Manufacturer's requirements, and nationally recognized testing lab listing requirements.

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

Software products used to produce or manipulate data directly used in the design, analysis, and operation of the Fire Suppression systems identified as IROFS are either commercially available software or proprietary software that is part of a listed system. Software is not validated, but the results are independently reviewed and verified.

Appendix A
Fire Suppression IROFS Exemption (Continued)

Records of the design process are maintained as discussed in Section 7, Document Control, and Section 18, Quality Assurance Records, as modified by Appendix A. 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.

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

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 basis 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-NFPA items or services include, as appropriate for the item or service being procured, the following:

- Scope of work;
- Basic technical requirements including drawings, specifications, applicable NFPA Codes and 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;
- Suppliers and/or sub-tier suppliers are not required to maintain a QA Program other than as specified and necessary to maintain their licenses, certifications, and listings to provide services and/or equipment associated with the design, erection, inspection, test, and certification of fire suppression systems;
- A description of the interrelationships and areas of responsibility and authority for the organization if workers are performing activities relied on for safety (such as architect/engineer, constructor, construction manager, and operator);
- 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; and

Appendix A
Fire Suppression IROFS Exemption (Continued)

- 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.

- Following construction and acceptance (by the authority having jurisdiction for NFPA Codes and Standards), GLE will provide notification to NRC of post-construction deficiencies (if a defect or noncompliance could lead to a substantial safety hazard, etc.) on the fire protection IROFS per the intent of 10 CFR Part 21.21.

- The application of the QA Program consistent with those identified in the NFPA Codes and Standards to GLE and supplier activities is sufficient to control the quality of procured items that are relied on for safety. Procured commercial grade items, once received and accepted by applicable elements of this Appendix and by the issuance of a Certificate of Occupancy, are designated as basic components.

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 and review and approval for changes will be at the same level as the original document.

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

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. NFPA Codes and Standards establish the minimum standards and requirements for the design, testing, installation, inspection, and maintenance of fire suppression systems credited as IROFS.

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

Appendix A
Fire Suppression IROFS Exemption (Continued)

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. Safe condition is defined as a condition that may require implementation of compensatory measures. 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.

Policies, plans, procedures, instructions, and drawings, and changes thereto, are controlled in accordance with Appendix A, Sections 4 and 7, of this QAPD.

Section 7 – Document Control – Section 7 of this QAPD is replaced in its entirety by the following text:

GLE documents, and changes to documents, prescribing or specifying quality requirements or activities affecting the availability and/or reliability of fire suppression systems identified as 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. Control of changes to GLE documents is a component of configuration management.

Policies, plans, procedures, instructions, and drawings are maintained under revision control. Changes to documents other than minor changes are reviewed for adequacy, correctness, and completeness, prior to approval and issuance. Major changes are reviewed and approved by the same organization that performed the original review and approval unless other organizations are specifically designated.

Minor changes to documents, such as inconsequential editorial corrections, may be made to documents without being subject to the review and approval requirements specified above. The applicable procedures define the organization's authorized positions authorized and acceptance criteria for making minor changes.

Appendix A
Fire Suppression IROFS Exemption (Continued)

Temporary changes to procedures are approved by two members of the management staff, at least one of whom is the Facility Manager. The applicable procedure controls the process, documentation, and approval of the temporary changes.

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

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; 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 that the supplier meets applicable state licensing requirements; receipt inspections; installation inspections; and review of procurement documents during receipt inspections. The design function is responsible for determining specific methods of acceptance to be applied to purchased items. The design and QA functions are responsible for determining specific methods for acceptance of services such as technical verification of data produced, surveillance of the activity, or review of objective evidence. The specific method of acceptance for services is dependent on the nature of the service being provided. Suppliers and/or sub-tier suppliers are not required to maintain a QA program other than as specified and necessary to maintain their licenses, certifications, and listings to provide services and/or equipment associated with the design, fabrication, installation, inspection, test, and certification of fire suppression systems.

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

Acceptability verification activities for fire suppression systems are established by NFPA Codes and Standards. Technical documents used as input to design processes, such as analyses, calculations, or drawings, require an independent technical review by the design function. Supplier furnished material, equipment, or services related to the fire

Appendix A
Fire Suppression IROFS Exemption (Continued)

suppression systems identified as IROFS 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 implementation of the disposition is verified, except where otherwise controlled and documented according to approved procedures. Records of supplier nonconformance are maintained.

The design function is also responsible for the following:

- Independent technical review of supplier submittals including calculations;
- Monitoring, witnessing, and observation of supplier activities;
- Technical evaluation and disposition of supplier nonconformance;
- Receiving inspection; and/or
- Post-installation testing (post-installation but prior to acceptance).

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

Controls are established for QL-NFPA items and services to ensure only correct and accepted items and services are used or installed. Identification is maintained on the items or in documents traceable to the items per the requirements of NFPA Codes and Standards.

The licensed fire protection supplier(s) selected to design, construct, fabricate, test, and certify the fire suppression systems identified as IROFS must demonstrate a satisfactory work history of having successfully installed fire suppression 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 suppression system components required by NFPA to be listed by a nationally recognized testing lab shall be listed for the purpose that they are installed. Nationally recognized testing lab markings and/or submittal of data sheets indicating

Appendix A
Fire Suppression IROFS Exemption (Continued)

listing with a nationally recognized testing lab and traceable to the item are accepted means of identification.

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

Controls to ensure that only correct and accepted items are installed include, but are not limited to:

- Receipt inspection according to approved procedures as discussed in Section 11 of this Appendix,
- Nonconformance control according to approved procedures as discussed in Section 16 of this Appendix,
- Onsite handling and storage according to approved procedures as discussed in Section 14 of this Appendix, and
- Drawings and specifications for construction, erection, and field fabrication, etc. as developed under Section 4 of this Appendix.

Section 10 – Control of Special Processes – Section 10 of this QAPD is replaced in its entirety by the following text:

Special processes affecting quality of items and services are controlled according to the requirements of applicable NFPA Codes and Standards. Policies, plans, procedures, instructions, drawings, checklists, travelers, work orders, or other appropriate means are used to implement the requirements of applicable NFPA codes and Standards.

Special processes that control or verify quality are performed by qualified personnel using approved written policies, plans, and/or procedures in accordance with specified requirements, and applicable NFPA codes and Standards. Records are maintained according to the requirements of applicable NFPA Codes and Standards.

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

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 licensing, experience, education, or certification, as appropriate. Personnel other than

Appendix A
Fire Suppression IROFS Exemption (Continued)

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.

When the term "inspection" is defined as part of the maintenance measure required to maintain proper function of a fire suppression system identified as an IROFS, the inspection requirements are defined by applicable NFPA Codes and Standards. The licensed fire protection supplier(s) selected to inspect the fire suppression systems identified as IROFS must demonstrate a satisfactory work history of having successfully inspected fire suppression systems, and is responsible for meeting the requirements of applicable NFPA Codes and Standards regarding inspection. Licensed site personnel with qualifying experience and certifications may also perform inspections. Inspections required by NFPA Codes and Standards prior to system acceptance are described in Section 8, *Control of Purchased Items and Services*.

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 retest, 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.

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

Tests required for conformance verification of a fire suppression system identified as an IROFS, item, or computer program are limited to those tests required by NFPA Codes and Standards. Tests are planned, executed, documented, and evaluated according to the requirements of NFPA Codes and Standards. Test results are documented and their conformance with acceptance criteria is evaluated. Tests required to collect data, such as for water supply evaluation or design input, shall be planned, executed, documented, and evaluated according to the requirements of NFPA Codes and Standards.

The licensed fire protection supplier(s) selected to design, construct, fabricate, install, test, maintain, and certify the fire suppression systems identified as IROFS must demonstrate a satisfactory work history of having successfully installed, tested and maintained fire suppression systems, and is responsible for meeting the requirements of applicable NFPA Codes and Standards regarding testing.

Appendix A
Fire Suppression IROFS Exemption (Continued)

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

Design specifications and other documents for procurement of the fire suppression systems identified as IROFS require that supplier(s) performing tests are qualified based on experience, education, or certification, as appropriate.

Tests include design verification tests, acceptance tests, preoperational and operational tests, and post-maintenance tests as defined in applicable NFPA Codes and Standards. 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, acceptance criteria, test methods, and hold points to be employed;
- References and related documents;
- Provisions for ensuring adequate instrumentation is available and suitable environmental conditions are maintained including any compensatory measures to assure that the safety function of the fire suppression system identified as an IROFS is maintained during the testing when it is credited to be available;
- 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 NFPA Codes and Standards 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.

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

The list of devices (items within the calibration control system) is established by the calibration requirements of applicable NFPA Codes and Standards. In many cases the applicable NFPA Code or Standard allows for recalibration of the device or replacement of the device with a new calibrated device.

Appendix A
Fire Suppression IROFS Exemption (Continued)

Measuring and Test Equipment (M&TE) used in activities affecting the availability or reliability of fire suppression systems identified as 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 commercial devices such as rulers, tape measures, levels, and stopwatches. 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).

The licensed fire protection supplier(s) selected to design, construct, fabricate, install, inspect, test, and certify the fire suppression systems identified as 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 suppression systems identified as IROFS specify the M&TE-related NFPA Codes and Standards, including revision and/or date.

Nationally recognized standards include applicable NFPA Codes and Standards, NIST standards, ANSI standards, and ASTM standards.

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 recalibrated. 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.

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

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.

Appendix A
Fire Suppression IROFS Exemption (Continued)

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

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.

The marking, labeling or documenting of inspection and test activity status is limited to the status marking requirements of applicable NFPA Codes and Standards. The impairment, inspection, testing, and maintenance status of fire suppression systems identified as IROFS will be tagged and documented according to the requirements of NFPA Codes and Standards.

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) to indicate impairment. Authority for the application and removal of tags, markings, labels, and stamps is specified.

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

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. Fire suppression systems items identified as IROFS are inspected for conformance to the requirements of applicable NFPA Codes and Standards. Items determined to be non-conforming are identified, and controlled according to the requirements of NFPA Codes and Standards.

The responsibility and authority for the evaluation and disposition of nonconforming items is defined. The GLE personnel or suppliers 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 carry out the disposition. Technical justification for the acceptability of nonconforming items is documented and subject to the control measures described in applicable NFPA Codes and Standards. The disposition process includes

Appendix A
Fire Suppression IROFS Exemption (Continued)

consideration of the need for design documents to be "as-constructed" to facilitate operations, maintenance, or modification. The as-constructed records, if the disposition determines such records to be required, reflect the accepted condition(s). Nonconforming items are reexamined in accordance with the requirements of NFPA Codes and Standards.

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 per the applicable requirements of NFPA Codes and Standards.

Appendix A
Fire Suppression IROFS Exemption (Continued)

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

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.

Conditions requiring corrective action in fire suppression systems identified as IROFS are identified, corrected, and documented according to the requirements of applicable NFPA Codes and Standards.

Approved written policies, plans, and/or procedures specify requirements for documenting conditions adverse to quality including identification, classification, appropriate notifications, and corrective actions taken. In addition, follow-up actions to verify implementation of corrective actions and trending are required for significant conditions adverse to quality.

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

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 for fire suppression systems identified as IROFS include the following documents:

- Documents required by applicable NFPA Codes and Standards
    - Record drawings (as-constructed, including calculations)
    - Acceptance testing

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 an approved records retention schedule. Suppliers and/or sub-tier suppliers of fire suppression systems identified as IROFS are not required to maintain a QA Program other than as specified and necessary to maintain their licenses, certifications, and listings to provide services and/or equipment associated with the design, erection, inspection, test, and certification of fire suppression systems.

Custodianship responsibility is assigned for lifetime records storage. Custodianship includes receipt and status control; storage; preservation; and safekeeping using hard

Appendix A
Fire Suppression IROFS Exemption (Continued)

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

Applicable 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, or otherwise authenticated) and validated (verified to be legible, retrievable). This authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organizations. These records may be originals or reproduced copies. Supplier furnished lifetime records that furnish objective evidence of quality will be authenticated and validated prior to being designated as a record. Authentication may take the form of a statement by the responsible individual or organization.

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. The indexing system shall include, as a minimum, record retention and the location of the record within the record system. Records shall be distributed, handled, and controlled in accordance with written procedures.

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 unless specified otherwise. Records classified as nonpermanent records are controlled by the responsible organization for the designated retention period.

Appendix A
Fire Suppression IROFS Exemption (Continued)

18.2.1 Lifetime Records

Lifetime records are defined as records associated with fire suppression systems which are required by NFPA Codes and Standards to be maintained for the life of the system.

Lifetime records are entered into record storage after authentication and validation. Turnover agreements for temporary records will be established for any person or organization approved to store temporary records. Turnover agreements will provide storage requirements, maximum allowable time limit for temporary storage, and responsibilities.

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).

Appendix A
Fire Suppression IROFS Exemption (Continued)

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.

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

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 internal organizations providing products or services to the project. Suppliers and/or sub-tier suppliers of fire suppression systems identified as IROFS are not subject to audits and are not required to maintain a QA Program other than as specified and necessary to maintain their licenses, certifications, and listings to provide services and/or equipment associated with the design, erection, inspection, test, and certification of fire suppression systems.

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.

Appendix A
Fire Suppression IROFS Exemption (Continued)

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 by the audited organization 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, and as applicable written responses to the audit findings, the documentation of corrective action completion, and documentation of corrective action verification.

Section 20 – Provisions for Change – Section 20 of this QAPD applies in its entirety.