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QUALITY ASSURANCE PROGRAM DESCRIPTION

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ACRONYMS AND ABBREVIATIONS

Acronym	Definition
A2LA	American Association for Laboratory Accreditation
ANS	American Nuclear Society
ASME	American Society of Mechanical Engineers
CAQ	Condition Adverse to Quality
CFR	Code of Federal Regulations
EPRI	Electric Power Research Institute
GEH	GE Hitachi Nuclear Energy
GNF	Global Nuclear Fuel
IAS	International Accreditation Services
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Standards Organization
LAB	Laboratory Accreditation Services
M&TE	Measuring and Test Equipment
MRA	Mutual Recognition Arrangement
NQA	Nuclear Quality Assurance
US NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
QA	Quality Assurance
QAP	Quality Assurance Program
QAPD	Quality Assurance Program Description
P&L	Profit and Loss Center
RIS	Regulatory Issue Summary
SSC	Structures, systems or components

US NRC ACCEPTANCE LETTER

INTRODUCTION

This QAPD has been adopted by the following companies affiliated with General Electric Company (GE) that are engaged in providing products and services to the nuclear power industry and which have agreed to be bound by the provisions of this QAPD, including the assignment of authority and responsibility set forth herein: GE-Hitachi Nuclear Energy LLC, GE-Hitachi Nuclear Energy Americas LLC, GE-Hitachi Nuclear Energy International LLC, Global Nuclear Fuel Americas, LLC, Global Nuclear Fuel Japan, Ltd. and Reuter-Stokes, Inc. Additional companies affiliated with GE may adopt this QAPD in the future by agreeing to be bound by its provisions. For ease of reference this QAPD is identified as a topical report issued by GE Hitachi Nuclear Energy (GEH) notwithstanding that it has been adopted by the companies identified above. References to GEH in this QAPD shall be interpreted to refer to and apply to each of the companies that have adopted this QAPD.

The companies that have adopted this QAPD are comprised of both operating components and business-specific organizations. These organizations are responsible for activities including, but not limited to, marketing, design, procurement, manufacture, installation, inspection, testing, servicing, project management, and operation of certain nuclear power plant products, fuel and fuel services, and radioactive material packaging and transportation. GEH also offers engineering services such as system studies, diagnostics, fuel and service analyses, and product and service testing.

SCOPE

Although the companies that have adopted this QAPD are global in nature, this QAPD describes the quality program applied to meet the requirements of the United States of America contained in 10 CFR Part 50, Appendix B. Therefore, this program applies to work for the nuclear industry in the United States and where contractually invoked internationally. Specifically it applies to work involving structures, systems and components (SSC) for nuclear power plants and fuel reprocessing plants that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The business may extend this program to other areas that do not meet these criteria. In addition, this Appendix B program may be adopted to meet the requirements of 10 CFR Part 71, Subpart H for transportation of radioactive material.

SECTION 1 ORGANIZATION

1.1 General

This Section describes the GEH organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation in accordance with 10 CFR Part 50 Appendix B and NQA-1.

The GEH organizational structure encompasses those positions responsible for establishing, managing, verifying, and interpreting the GEH Quality Assurance (QA) program. This QAPD describes the relationships of organizations within GEH, and between GEH and principal contractors with overall responsibilities and authority for performing activities within the scope of the QAPD.

Adherents to this QAPD include the following organizational elements:

On-Site in Wilmington	Off-Site
GEH Headquarters	GEH-San Jose (engineering office)
GNF-A	GNF-J
Services	GEH-Vallecitos Nuclear Center
Manufacturing	GEH-Philadelphia Service Shop
New Plant Projects	Reuter Stokes
Support Organizations: Engineering Procurement Information Management	Customer Sites (GEH or GNF-A) where services are performed
Quality Oversight: NQA, Support Services QA (calibration, QA record control, personnel certification)	

1.2 Organizational Description

1.2.1 Organizational Structure

For the purposes of managing this Quality Assurance Program (QAP), the organizational structure is shown in Figure 1. There are three main elements which report to the CEO.

1.2.1.1 P&L's

The business is comprised of several areas with financial responsibility for delivery of products and services called Profit and Loss Centers (P&L's) including:

- Services
- New Plant Projects
- Manufacturing
- Global Nuclear Fuel
- Reuter Stokes

1.2.1.2 Support Organizations

Support Organizations facilitate the activities of the P&L's and include:

- Procurement
- Engineering
- Information Management

1.2.1.3 Quality

The Quality organization has four components that provide oversight including:

- Nuclear Quality Assurance (NQA)
- QA Support Services
- P&L specific Quality Leaders
- Support Organization Quality Leaders (excluding Information Management)

1.2.2 Management Positions

1.2.2.1 President and Chief Executive Officer

The companies that have adopted this QAPD have authorized the President and Chief Executive Officer (hereinafter the "President") of GE-Hitachi Nuclear Energy LLC to establish the quality program as described in this document and have committed each of the companies to implement it. The President is hereby authorized and shall be responsible for the implementation of activities that ensure quality, including establishing the GEH QA policy. Several programmatic and technical authorities of the President are delegated to each P&L Business Leader.

Nevertheless, the President retains duties and responsibilities that cannot be delegated. These include but are not limited to:

- Approving this QAPD;
- Establishing the GEH organizational structure, including the organizational roles, responsibilities, authority and accountability;
- Integrating Quality Assurance program activities into overall business activities; and
- Monitoring key performance indicators as part of a management review.

The President directs the Quality Leader in fulfillment of these responsibilities. The President reports to the Governing Board of GE-Hitachi Nuclear Energy LLC.

1.2.2.2 Business Leaders for P&L's and Support Organizations

Activities affecting quality are performed under the direction of Business Leaders who report to the President for purposes of the responsibilities of this QAPD and 10 CFR Part 50 Appendix B. Business Leaders ensure that personnel working under their management are trained in accordance with written procedures, and that only trained personnel are permitted to perform activities affecting quality.

Reporting to the Business Leaders may be Managers or Technical Leaders, who have been trained in accordance with this QAPD and in the implementing written procedures. These individual managers are tasked with assuring that only trained personnel are permitted to perform those activities for which they are qualified.

1.2.2.3 Quality Leader

The GEH Quality Leader has been delegated the responsibility and authority from the President to develop, manage and maintain a QA Program to plan and perform activities to develop, implement and verify the effectiveness of the GEH QAPD. The Quality Leader maintains this QAPD and a QA Organization that is appropriately sized to effectively manage its duties and responsibilities.

The following positions report to the Quality Leader:

1.2.2.3.1 Nuclear Quality Assurance Leader

The Nuclear Quality Assurance (NQA) Leader is responsible for performing independent oversight audits to assess the implementation and effectiveness of the quality program. In performing these duties, the NQA Leader has access to the President to discuss quality-related issues.

1.2.2.3.2 Support Services Quality Leader

The Support Services Quality Leader is responsible for the activities of qualification and certification of personnel affecting quality, calibration and control of measuring and test equipment, and quality records storage and maintenance. This responsibility includes control and maintenance of related systems and processes.

1.2.2.3.3 P&L Specific Quality Leaders

Each P&L is assigned an independent representative from the QA Organization who reports to the Quality Leader for purposes of the responsibilities of this QAPD and 10 CFR Part 50 Appendix B. These P&L Spcific Quality Leaders are responsible for periodically auditing their assigned organizations and managing the QA employees who verify the functions performed by the P&L organization. This structure is designed to provide sufficient independence from cost and schedule when opposed to quality and safety considerations, provides the required independence between the performers and the verifiers, and enables a direct line of communication to the Quality Leader.

1.2.2.3.3 Support Organization Quality Leaders

Each Support Organization (except Information Management) is assigned an independent representative from the QA Organization who reports to the Quality Leader for purposes of the responsibilities of this QAPD and 10 CFR Part 50 Appendix B. These Support Organization Quality Leaders are responsible for periodically auditing their assigned organizations and managing the QA employees who verify the functions performed by the Support Organization. This structure is designed to provide sufficient

independence from cost and schedule when opposed to quality and safety considerations, provides the required independence between the performers and the verifiers, and enables a direct line of communication to the Quality Leader.

1.2.3 Functional Responsibilities

The functional responsibilities of P&L Organizations, Support organizations and the Quality Organization are shown in Figure 2:

1.2.4 Interface responsibilities

Interfaces are defined in one of two methods. Either through policy in the case of defining interfaces between legal entities or by procedures.

1.3 All Employees and contractors

All employees and contractors are responsible for incorporating quality in their routine work activities such as, but not limited to qualifying suppliers, preparing, reviewing, verifying and approving designs, purchasing, generating procurement documents, manufacturing, installation, auditing and controlling records.

1.4 Authority to Stop Work

All employees and contractors have the authority and responsibility to stop work if continuing is detrimental to the final product or is masked by successive manufacturing activities or if the activity is not compliant with the procedural guidance or would create an unsafe situation.

The GEH Quality Leader and, NQA Leader or designee have the authority and the responsibility, to issue a stop work notice and control further processing, delivery, installation or use of nonconforming products. This authority is assigned by the President to ensure that cost and schedule considerations do not override quality or safety considerations.

1.5 Delegation Outside the GEH Organization

Major delegation of work to participants outside of the GEH QA Program, such as subcontractors or suppliers, will be identified and described as follows:

- The organizational elements responsible for delegated work are identified and documented.
- Management controls and lines of communication between the GEH designated person and the delegated organization are identified and documented.

- Responsibility for the QA program and the extent of management oversight is established.
- The performance of delegated work is formally evaluated

Sufficient authority to accomplish the assigned tasks is also delegated, although the President, Quality Leader and other positions identified herein retain overall responsibility for the program.

1.6 Commitment

In establishing its organizational structure, GEH commits to compliance with 10 CFR Part 50 Appendix B, Criteria I, and with NQA-1a-2009, Requirement 1.

FIGURE 1 – ORGANIZATIONAL STRUCTURE

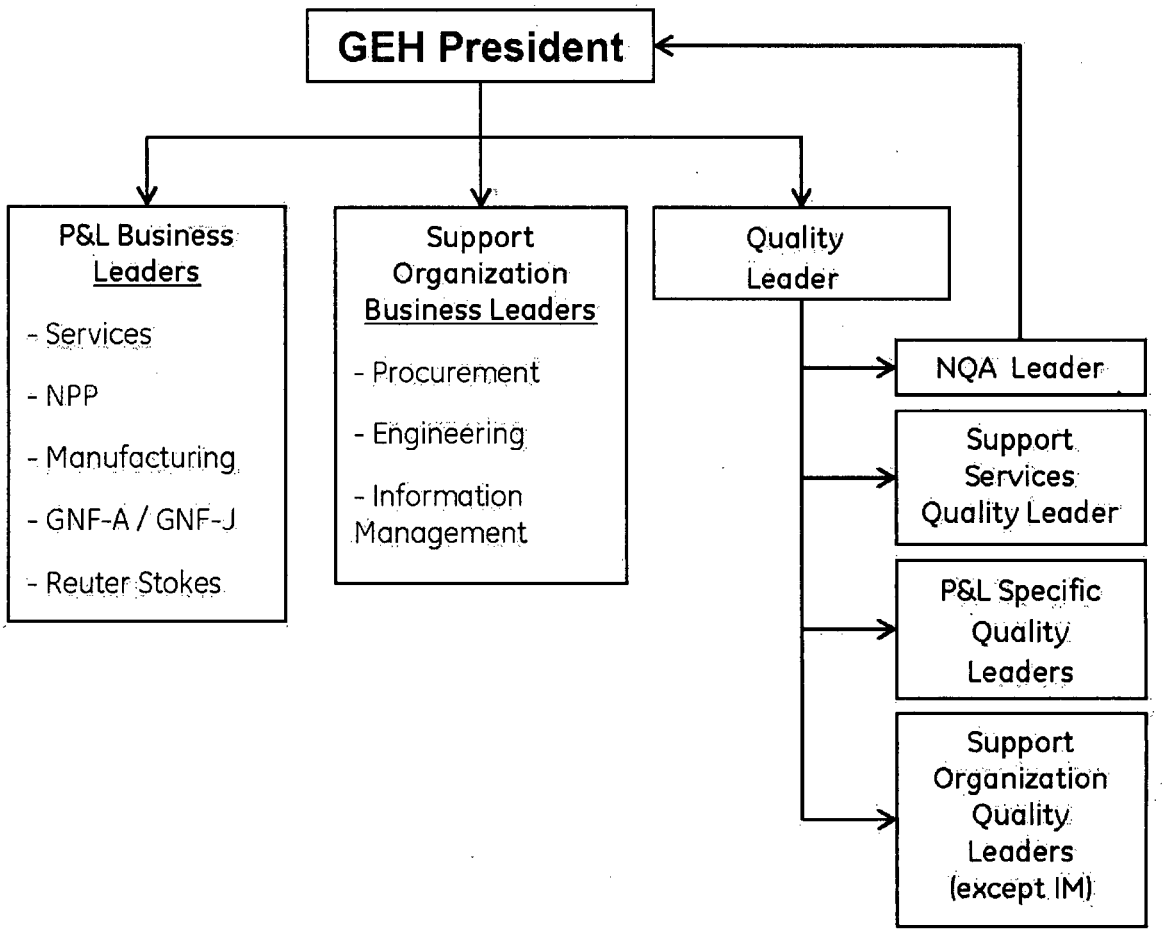

Figure 2 – Functional Responsibilities

	Profit & Loss Centers						Support Organizations			Quality			
	Services	NPP	Manufacturing	GNF-A	GNF-J	Reuter Stokes	Procurement	Engineering	Information Management	NQA Leader	QA Support Services	QA Personnel assigned to Specific P&L's	QA Personnel assigned to specific Support Organizations
Preparing, reviewing, approving, and verifying designs	1	1	1	1	1	X		X	X				
Qualifying suppliers	2	2	2	2	X	X	2						X
Preparing, reviewing, approving, and issuing instructions, procedures, schedules, and procurement documents	X	X	X	X	X	X	X	X	X	X	X	X	X
Purchasing	3	3	3	3	X	X	X						
Verifying supplier activities	2	2	2	2	X	X	2						X
Identifying and controlling acceptable and nonconforming hardware and software	X		X	X	X	X	X	X	X			X	X
Manufacturing			X	X	X	X							
Calibrating and controlling measuring and test equipment	4		4	4	X	X					X		
Qualifying and controlling special processes	X		5	X	X	X						X	
Inspecting	X		5	X	X	X	X					X	X
Testing		X	X		X	X		X	X				
Performing the audit function	6	6	6	6	X	X	6	6		X	X	X	X
Controlling records	X	4	4	4	X	X	X	4	X		X		

X = the indicated organization has the responsibility for that activity.

Numbers indicate activity performed by the following

1. Engineering Support Organization
2. Quality personnel assigned to Procurement support org.
3. Procurement Support Organization
4. QA Support Services
5. Quality personnel assigned to Manufacturing P&L
6. Quality personnel assigned to P&L or Support Organization

SECTION 2 QUALITY ASSURANCE PROGRAM

2.1 General

This section describes the GEH QA program, as documented through this QAPD and its implementing procedures, and identifies the associated requirements for planning, implementation, monitoring and maintenance of the program. This program was documented, approved and implemented prior to the commencement of the activities within its scope.

2.2 Scope

This GEH QA program applies to work performed on safety-related systems, structures and components (SSC) that are within the scope of 10 CFR Part 50, Appendix B. Safety-related SSC prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The program is binding on all companies that have adopted this QAPD; including participating organizations from the President to all employees and contractors whose activities may influence quality. Controls are provided over activities affecting quality to an extent consistent with the importance of those activities. The President, Quality Leader and other positions identified herein retain and exercise the responsibility for the scope and implementation of an overall QA program.

Activities performed at GEH that are included in the scope of this QAPD include but are not limited to: training, indoctrination and certification of personnel; design activities; procurement; document control; control and identification of purchased material parts and components; special processes; test and inspection; control of measuring and test equipment; handling, storage and shipping; maintenance of test, inspection and operating status of items; control of nonconforming material; corrective action; records, and audits.

2.3 Controlled Conditions

Planning and performance of activities affecting quality is accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. Special controls, processes, test equipment, tools and skills to attain the required quality of activity or items and verification are provided.

2.4 Indoctrination

The GEH indoctrination is commensurate with the scope, complexity, and importance of the activities; and with the education, experience, and proficiency of the person involved. Personnel performing or managing activities affecting quality receive indoctrination in their job responsibilities and authority, which includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements. Records of indoctrination and training include the employee's name, topic covered and date of completion.

2.5 Qualification Requirements

Quality-related activities that require qualification of personnel are listed below. Qualification is controlled by written procedures and only those personnel who have met the requirements are permitted to perform these activities.

2.5.1 Nondestructive Examination

The companies that have adopted this QAPD have a written practice for qualification of nondestructive examination personnel who perform processes such as ultrasonic, radiographic, magnetic particle, liquid penetrant, electromagnetic, leak or visual testing.

2.5.2 Inspection and Test

Procedures specify minimum initial capabilities, education, experience, training as well as examination performance, re-evaluation periods and permissible gaps in activity for inspection and test personnel.

2.5.3 Lead Auditor

Requirements for a lead auditor's evaluation are defined in written procedures. The evaluation criteria are communication skills, training, audit participation, examination as well as maintenance of proficiency and requalification.

2.6 Detection and Correction of Quality Problems

A corrective action program has been established to document quality problems, assign actions to correct the problem, take preventative steps to prevent reoccurrence and to verify effective remediation. The corrective action program is described in Section 16.

2.7 Assessment of Effectiveness

QA personnel monitor activities affecting quality against acceptance criteria to ensure satisfactory performance. These criteria are outlined in implementing procedures. The President reviews the overall status and adequacy of the Quality Assurance Program. Managers review those portions of the program under their area of responsibility. To ensure effective implementation, these reviews take place at least once each fiscal year or at least once during the activity, whichever is shorter.

2.8 Grace Period

A grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis unless otherwise noted. The grace period does not allow the clock for a particular activity to be reset forward. The clock is reset backwards by performing the activity early.

2.9 Commitment

In establishing its Quality Assurance Program, GEH commits to compliance with 10 CFR Part 50, Appendix B, Criteria II and NQA-1a-2009, Requirement 2.

SECTION 3 DESIGN CONTROL

3.1 General

The engineering organizations of the companies that have adopted this QAPD have overall responsibility for the control of the design process from its inception to the final result. In controlling the design process the goal is to ensure that a design and its associated design documentation meet all applicable technical requirements, regulatory requirements, codes and standards and contractual requirements. The GEH design program extends to the control of the design, the control of design changes, and to temporary modifications to structures, systems, components and software (including design reports) subject to the provisions of this QAPD. This section describes control of the design inputs, design processes, design analyses, design verification, change control, interface control, QA responsibilities, and documentation and records. Design control ensures that design inputs are correctly translated into design outputs (such as specifications, drawings, procedures, reports and instructions) so that the final design output can be related to the design input in sufficient detail to permit verification.

3.2 Design Inputs

Engineering is responsible for identifying and documenting design inputs for each design project. Sources of design input may include: customer specifications, design bases, regulatory requirements, functional requirements, industry standards as well as other technical, commercial and performance requirements. The design inputs are specified to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for completing design activities, making design decisions, accomplishing design verification, and evaluating design changes.

Each design requires that the design inputs be verified. The purpose of this verification is to determine whether the design inputs were correctly selected and whether the assumptions made to perform the design activity were adequately identified and reasonable.

Applicable information derived from plant operating and construction experience is made available to the responsible organization as appropriate.

When structures, systems or components (SSC) necessary for safety are selected for a design, the selection and review criteria are conducted according to implementing procedures.

When GEH performs design activities for nuclear licensees, GEH records may not contain all necessary design information. In such cases, GEH will need to obtain verified design inputs from the licensee for use in the design and document them in the GEH records storage system.

3.3 Design Process

3.3.1 Design Responsibility

The Engineering organization develops and maintains procedures that comply with the requirements of this QAPD and that specify the activities that are to be performed in each design project.

For each specific design project, the GEH design organization documents and organizes the design information to sufficient detail to permit the design process to be performed in a correct manner. Appropriate quality standards are also identified and their selection reviewed and approved.

3.3.2 Design Methods

The design methods, materials, parts, equipment, and processes that are essential to the function of the structures, systems, and components or to the completion of a design report are selected and independently reviewed for suitability for their intended application. Design methods are documented, controlled, reviewed, and approved as applicable. Where design activities are repeated, documented design methods are reviewed on a periodic basis to confirm continued applicability and updated as necessary. The design organization may also maintain applicable lessons learned information derived from experience, for use by responsible design personnel.

3.3.3 Design Result

The engineering organizations are responsible for delivering design output that meets design processes requirements to ensure that the design result:

- Is based upon and accurately incorporates verified design inputs
- Is documented in sufficient detail to permit the design to be recreated independently in the absence of the original designer
- Is relatable to the design input by documentation in sufficient detail to support design verification
- Defines criteria for inspections and tests when they are required

- Includes reference to appropriate acceptance criteria
- Identifies assemblies and/or components that are part of the item being designed

To ensure that design inputs are properly related to the design results by design documentation, design results are subjected to a design verification process that requires an independent reviewer to verify that the design complies with the customer requirements, technical requirements, regulatory requirements, and codes and standards. The verifier ensures that appropriate design methods are used, that design inputs are correctly incorporated into the design and that the design output is reasonable when compared with the design input.

3.4 Design Analyses

Design analyses are sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.

3.4.1 Use of Computer Programs

Computer programs used for design analyses include commercially purchased software and software developed for specific applications. The results of computer programs used for design analysis are verified with each use or pre-verified to show the following:

- The computer program produces correct solutions for the encoded mathematical model within defined limits for each parameter employed.
- The encoded mathematical model produces a valid solution to the physical problem associated with the particular application.

Pre-verified computer programs are controlled to ensure that changes are documented and approved by authorized personnel. When pre-verified computer programs are used, the encoded mathematical model does not need to be verified.

3.4.2 Documentation of Design Analyses

Documentation of design analyses is legible, reproducible, and will include the following:

- Identification of the person responsible for the design,
- The scope and/or objective of the analyses,
- Design inputs and their sources,

- Results of literature searches or other background data if applicable,
- Assumptions and indication of those assumptions that must be verified as the design proceeds,
- Methods and equations that are implemented in computer programs, or if a pre-verified computer program is used, the program name and revision, and confirmation that the computer program is used within its approved application,
- Design results, conclusions, and output,
- Review and/or verification and approval,
- A record of comments made or issues raised during review and/or verification, and the resolution of those comments and issues, and
- Identification of the persons originating and performing the review, verification and approval.

Design calculations are identified by subject including the system or component to which the calculation applies, the preparer, the verifier, and date generated, or other pertinent information so that calculations are retrievable.

3.5 Design Verification

The companies that have adopted this QAPD have a design verification program that ensures that design inputs, calculations, changes, and results are independently reviewed and approved by personnel other than the preparer of the design or design document.

3.5.1 Verification Responsibilities

The responsible design organization identifies and documents the design verification scope and method(s) used. The results of design verification are documented with the identification of the verifier clearly indicated. Design verification is performed by one or more competent individuals or groups other than those who performed the design but who may be from the same organization. This verification may be performed by the originator's manager, provided: (a) the manager did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; and (b) the manager is the only individual in the organization competent to perform the verification.

3.5.2 Verification Timing

Design verification is performed prior to releasing the design for procurement, manufacture, construction, licensing submittal or use by another design organization, except where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design is identified and controlled as unverified or conditional. In all cases the design verification is completed prior to relying upon the component, system, structure, or computer program to perform its intended function.

3.5.3 Verification of Modifications

If the design is modified to resolve verification findings, the modified design is verified prior to release or use.

3.5.4 Extent of Design Verification

The extent of the design verification is a function of the importance to safety, the complexity of the design, the degree of standardization and the similarity with previously proven designs. The extent is defined by the originator in the verification scope, agreed to by the verifier, and approved by the supervisor.

Where the design has been previously verified, the verification extent or scope may be reduced; verification need not be duplicated for identical designs. However, the applicability of previously verified designs, with respect to meeting pertinent design inputs, is verified for each application. Known problems affecting previously verified designs and their effects on other features are considered. The original design and associated verification documentation are referenced in records of subsequent application of the verified design.

3.5.5 Verification Methods

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

3.5.5.1 Design Reviews

Design reviews for verification may be performed by an individual or by a team. A design review provides assurance that the final design is correct and satisfactory by addressing the following, where applicable:

- The design inputs were correctly selected.

- Assumptions necessary to perform the design activity are adequately described and reasonable. Where necessary, assumptions are identified for subsequent reverifications when the detailed design activities are completed.
- Appropriate design methods and computer programs were used and design calculations were performed correctly.
- Design inputs were correctly incorporated into the design.
- Design output is reasonable compared to design inputs.
- Design inputs necessary for interfacing organizations are specified in the design documents or in supporting procedures or instructions.
- Suitable materials, parts, processes, and inspection and testing criteria are specified.

3.5.5.2 Alternate Calculations

Alternate calculations by alternative methods are required for verification of calculations unless pre-verified computer programs are used within their applicable defined limits. The appropriateness of assumptions, input data and calculation method used are considered. When calculations are performed by computers, the review also considers the computer program; its associated computer hardware and system software.

3.5.5.3 Qualification Tests

Testing demonstrates adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions are considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design are verified by other approved verification methods. When tests are being performed on models or mockups, scaling laws are established and verified. The results of model test work are documented, subjected to error analysis, where applicable, and evaluated prior to use in the final design. If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification is documented and the item modified and retested or otherwise verified to ensure satisfactory performance.

3.6 Change Control

Changes to design inputs, final designs, field changes, and temporary and permanent modifications and previously verified designs to GEH products are justified and subject to design control measures commensurate with those applied to the original design. These measures include evaluation of effects of those changes on the overall design

and on any analysis upon which the design is based. The evaluations include facility configurations that affect operation or performance of a GEH product such as conditions that occur during operation, maintenance, test, surveillance, and inspection activities. The same affected groups or organizations that reviewed and approved the original design documents approve design changes. When organizational responsibilities change the owner or designee is responsible to designate a new responsible organization that has demonstrated competence in the specific design area and has an adequate understanding of the requirements and intent of the original design.

Where a significant design change is necessary due to a design error, the design and verification procedures are reviewed for adequacy and modified as necessary.

3.7 Interface Control

The companies that have adopted this QAPD are responsible to control interfaces among themselves and between their organizations and their subcontractors and suppliers. Interface control is specified in implementing procedures that assign responsibility to the participating design organizations for review, approval, release, distribution, and revision of documents across design interfaces.

Design information transmitted across interfaces identifies the status of the design information, as verified or unverified, for the document provided, and identifies incomplete items that require further evaluation, review, or approval. Where it is necessary to initially transmit design information by other informal means, the transmittal is confirmed promptly by a controlled document.

3.8 Software Design Control

The design process for development of software that falls under the requirements of 10 CFR Part 50, Appendix B is documented, approved by the responsible organization and controlled.

3.8.1 Software Design Process

Activities in the software design process consists of the following:

- Identification of Software Design Requirements such as operating system, function, interfaces, performance requirements, installation considerations, design inputs and design constraints

- Software Design details such as numerical methods, mathematical models, physical models, control flow, control logic, data flow (may be combined with the software design requirements documentation)
- Implementation of Software Design – translation of the software design into computer program(s)
- Software Design Verification performed by an individual other than the developer, who is competent in both the verification process and the implementing procedures, programming standards and conventions.
- Computer Program Testing performed in accordance with the requirements of the computer test control procedures discussed in Section 11, Test Control.

3.8.2 Software Configuration Management

The GEH software configuration management program includes, but is not limited to the following activities until such computer software is retired (i.e. removed from use).

- Configuration Identification - The GEH software responsible organization establishes a baseline as each activity of the software design program is completed.
- Configuration Change Control - Changes to software are formally documented and are subject to the software design verification process.
- Configuration Status Control – Controls include a process for maintaining the status of changes that are proposed and approved, but not implemented and provide for notification to affected organizations.

3.9 Documentation and Records

Design documentation and records, which provide evidence that the design and design verification processes were properly performed are collected, stored, and maintained in accordance with Section 17, Quality Assurance Records. Design documentation and records include not only final design documents, such as drawings and specifications, and revisions to those documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design.

3.10 Commitment

In establishing provisions for design control, GEH commits to compliance with 10 CFR Part 50, Appendix B, Criteria III and NQA-1a-2009, Requirement 3

SECTION 4 PROCUREMENT DOCUMENT CONTROL

4.1 General

This section describes the GEH program to ensure that sufficient technical, quality and regulatory requirements to ensure the requisite level of quality are included or referenced in the documents for procurement of items and services. The program is applied to all phases of procurement and may require verification of activities of suppliers below the first tier.

4.2 Procurement Document Contents

The following requirements and information are included in procurement documents, as applicable:

- Scope of Work Statement – A statement of the scope of work to be performed by the Supplier.
- Technical Requirements - Drawings, specifications, codes, standards, regulations, procedures or instructions, including revisions that describe the items or services to be furnished.
- The procurement documents also identify appropriate test, inspection and acceptance criteria for evaluating the supplier's performance.
- Quality Assurance Program Requirements – A reference to the supplier's documented QA Program that has been reviewed and determined to meet the applicable requirements of 10 CFR Part 50, Appendix B consistent with the circumstances of the procurement. Alternately, Suppliers may work to the GEH QA Program and implementing procedures.
- Right of Access – Provisions for access to the Supplier's and subtier Supplier's facilities and records for surveillance or audit by GEH, their designated representative and others authorized by GEH.
- Documentation Requirements - Identification of supplier documentation to be submitted to GEH for information, review or approval. The time of submittal will also be specified. GEH will specify retention times and disposition requirements for records to be kept by the Supplier.
- Nonconformances – The procurement documents specify the GEH requirements for the Supplier's reporting of nonconformances including invoking the requirements of 10 CFR Part 21 if applicable.

- Spare and Replacement Parts – The procurement documents specify the applicable requirements to identify spare and replacement parts or assemblies and the related data required for ordering these parts or assemblies.
- Commercial Grade Items - Procurement documents for Commercial Grade Items that will be procured by GEH for use as safety-related items contain technical and quality requirements such that the procured item can be appropriately dedicated.

4.3 Review of Procurement Documents

Technical or quality assurance changes made as a result of bid evaluations or negotiations are incorporated in the procurement documents prior to issuance. Personnel performing reviews have access to pertinent information and an adequate understanding of the requirements and intent of the procurement documents.

4.4 Procurement Document Changes

Changes to procurement documents are subject to the same level of control as was exercised in the preparation of the original procurement documents.

4.5 Commitment

In establishing controls for procurement documents, GEH commits to compliance with 10 CFR Part 50, Appendix B, Criteria IV and NQA-1a-2009, Requirement 4.

SECTION 5 PROCEDURES, INSTRUCTIONS, AND DRAWINGS

5.1 General

This section establishes the requirements to ensure that activities affecting quality are prescribed by, and performed in accordance with implementing procedures or work instructions *(i.e.,* approved procedures, instructions, and drawings).

5.2 Requirements

Activities affecting quality are prescribed by controlled implementing procedures of a type appropriate to the circumstance and will be accomplished in accordance with these implementing procedures and/or work instructions. Activities affecting quality are suspended if they cannot be accomplished as described in controlled implementing procedures.

5.3 Content of Procedures

The activity is described to a level of detail that is based on one or more of the following: the complexity of the task, the need to ensure consistent and acceptable results, the significance of the item, the work environment, or worker proficiency and ability.

Quantitative and/or qualitative acceptance criteria are included for determining that prescribed activities have been satisfactorily accomplished and that prescribed results have been satisfactorily attained.

5.4 Commitment

In establishing procedural controls, GEH commits to compliance with 10 CFR Part 50 Appendix B, Criteria V and NQA-1a-2009, Requirement 5.

SECTION 6 DOCUMENT CONTROL

6.1 General

GEH has established the necessary measures and governing procedures to control the preparation of, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled to ensure that correct documents are being employed. The operation and use of the control system (including electronic systems used to make documents available) is documented and provides for the following:

- Identification of documents to be controlled;
- Identification of the correct document (including revision) to be used and control of superseded documents;
- Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents;
- Review of documents for adequacy, completeness, and correctness prior to approval and issuance.
- A method for providing feedback from users to continually improve procedures and work instructions.
- Coordinating and controlling interface documents and procedures.

The types of documents to be controlled include, but are not limited to; (a) drawings such as design, construction, installation, and as-built drawings; (b) engineering calculations; (c) design specifications; (d) purchase orders and related documents; (e) vendor-supplied documents; (f) audit, surveillance, and quality verification/inspection procedures; (g) inspection and test reports; (h) instructions and procedures for activities covered by this QAPD; (i) technical requirements, and (j) nonconformance reports.

6.2 Review and Approval of Documents

Individuals other than the preparer review documents for adequacy, accuracy, and completeness. Prior to issuance or use, the reviewed documents are approved. This review process is applied to all subsequent revisions. A listing of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

6.3 Changes to Documents

Changes to documents, other than those defined in implementing procedures as minor changes, are reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization is given access to pertinent background data or information upon which to base their approval.

Minor changes to documents, such as inconsequential editorial corrections, do not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a classification will be clearly delineated in implementing procedures.

6.4 Temporary Documents

Temporary procedures include designation of the period of time during which it is valid to use them. Temporary procedure changes that clearly do not change the intent of the procedure are approved by two members of the staff knowledgeable in the areas affected by the procedures.

6.5 Commitment

In establishing procedural controls, GEH commits to compliance with 10 CFR Part 50 Appendix B, Criteria VI, and NQA-1a-2009, Requirement 6.

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

7.1 General

This section describes the GEH program for ensuring that purchased items and services meet specified requirements. The program's systematic activities are performed to written procedures and include the following:

- Procurement document preparation, review, and change control according to the requirements of Section 4.0 of this QAPD;
- Selection of procurement sources;
- Proposal/bid evaluation and award;
- Evaluation of GEH contractor/supplier performance;
- Oversight including any hold and witness point notifications;
- Control of nonconformances;
- Corrective action;
- Acceptance of an item or service; and
- Identification of QA records.

7.2 Supplier Evaluation and Selection

A supplier is selected based on a pre-qualification process performed by GEH before a contract or purchase order is awarded. During the pre-qualification review the supplier's capability to provide items or services in accordance with GEH Sourcing requirements is determined.

Measures for evaluating and selecting procurement sources are documented and include one or more of the following elements:

- An evaluation of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use. This evaluation is required to reflect the supplier's current capability.
- An evaluation of the supplier's current QA records. This evaluation must be supported by documented qualitative and quantitative information that can be objectively evaluated.

- An evaluation of the supplier's technical and quality capabilities, based upon a direct review and inspection of supplier's facilities and personnel, and the supplier's implementation of its QA program.

7.3 Proposal/Bid Evaluation

The proposal/bid evaluation process is required to include a determination of the supplier's capability to conform to technical and quality assurance requirements. Before the contract is awarded, GEH must resolve, or obtain commitments to resolve, unacceptable quality conditions identified during the proposal/bid evaluation.

7.4 Control of Supplier Generated Documents

Supplier generated documents are controlled, processed, and accepted in accordance with established methods. These measures must provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data compared against the acceptance criteria. If GEH approval of supplier procedures is required, this approval is accomplished prior to supplier's use.

Instructions are provided for the retention and disposition of QA records that are to be retained by the supplier.

7.5 Control of Supplier Nonconformances

GEH and its suppliers establish and document methods for disposition of nonconforming items and services in their purchase agreements. Suppliers are instructed to send GEH all nonconformance reports from procurement documentation requirements generated during the manufacturing process. As a minimum, nonconforming reports are obligated to contain the following:

- A description of the nonconforming item,
- An evaluation of the nonconforming item,
- At least one recommended corrective action, and
- A technical justification for each corrective action identified.

Nonconformances to the contractual procurement requirements or GEH approved documents are required to be submitted to GEH for approval of the recommended disposition prior to shipment when the nonconformance could adversely affect the end use of a module or shippable component relative to safety; the interchangeability of that

component, its operability, its reliability, its integrity or its maintainability. Such nonconformances include, but are not limited to: (a) a violation of technical or material requirements; (b) a violation of a GEH-approved requirement in supplier documents; (c) a nonconformance that cannot be corrected by continuation of the original manufacturing process or by rework (i.e., use-as-is); or (d) an item that does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired (i.e., repair).

7.6 Acceptance of Items or Service

Suppliers are required to verify that furnished items or services comply with GEH procurement document requirements before offering the items or services for acceptance. The extent of verification activities performed by GEH is a function of the relative importance, complexity and quantity of the items or services procured and the supplier's past performance relative to quality.

7.6.1 Methods of Acceptance

GEH methods for accepting supplier-furnished items or services ensure that items or services comply with GEH procurement document requirements and include one or more of the following, as appropriate to the items or services being procured:

7.6.1.1 Certificate of Conformance

When a certificate of conformance is used to accept an item or related service the following are considered minimum requirements.

- The certificate identifies the purchased item or service to the specific procurement document.
- The certificate identifies the specific procurement document requirements met by the purchased item or service, such as codes, standards and other specifications. The procurement document requirements identified include any approved changes, waivers, or deviations applicable to the item or service.
- The certificate identifies any procurement document requirements that have not been met, together with an explanation and the means for resolving the nonconformances
- A person who is responsible for this QA function and whose responsibilities and position are described in the supplier's QA program attests to the certificate.
- The certification process, including the implementing documents to be followed in filling out a certificate and the administrative implementing documents for review

and approval of the certificates, are described in the GEH or supplier's implementing procedure.

- Measures are identified to verify the validity of certificates and the effectiveness of the certification process (i.e., by audit of the supplier or by an independent inspection or test of the item). GEH will conduct verifications at intervals commensurate with the past quality performance of the supplier.

7.6.1.2 Source Acceptance

GEH may accept an item or service by source verification such as monitoring, witnessing, or observing activities performed by the supplier. Source verification is implemented at intervals consistent with the importance and complexity of the item or service. Source verification is planned and performed so that observations of specific activities at predetermined points can be accomplished. Documented evidence of acceptance of source verified items or services are retained by GEH, and furnished to the receiving destination of the item and the supplier.

7.6.1.3 Receiving Inspection

When receiving inspection is used, items are verified by objective evidence, which includes such features as: (a) the item's configuration, (b) its identification, (c) the item's dimensional, physical or other characteristics, (d) whether the item is free from shipping damage, and (e) its cleanliness.

Receiving inspection is coordinated with a review of supplier documentation.

7.6.1.4 Post-installation Testing

When post-installation testing is used, test requirements and acceptance criteria are mutually established by GEH and the customer.

7.6.1.5 Acceptance of Services

In cases involving procurement of services only, such as third-party inspection; engineering and consulting services; auditing; and installation, repair, overhaul, or maintenance work, GEH accepts the service by any or all of the following methods: (a) a technical review of the data produced; (b) a surveillance and/or audit of the activity; or (c) a review of any objective evidence for conformance to the procurement document requirements.

7.7 Supplier Performance Evaluation

GEH, as a purchaser of items and services, establishes measures to interface with its suppliers to verify their performance. These measures include any of the following:

- Establishing an understanding between GEH and the supplier regarding the requirements and specifications identified in the procurement documents;
- Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements
- Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement document requirements
- Identifying and processing necessary change information
- Establishing the method to be used to document information exchanges between GEH and the particular supplier
- Establishing the extent of source surveillance and inspection
- Determining an additional or modified design criteria
- Analyzing exceptions or changes requested or specified by the supplier and determining the effects that such changes may have on the intent of the procurement documents or quality of the item or service furnished
- Ensuring that GEH verification activities do not relieve the supplier of its responsibilities for verification of quality achievement

If there is no ongoing receipt inspection or operating experience with which to analyze the supplier for a period of twelve months, an annual evaluation is performed as follows:

- Review of supplier-furnished documents and records such as certificates of conformance, nonconforming notices, and corrective actions
- Results of previous source verifications, audits, and receiving inspections
- Operating experience of identical or similar products furnished by the same supplier
- Results of audits from other sources (e.g., customer, ASME, or NRC audits)

7.8 Commercial Grade Items and Services - Dedication

Utilization of commercial grade items or services is permitted if controls are in place to provide reasonable assurance that the item or service will perform its intended safety

function. Such controls include, but are not limited to: (a) a determination that the item or service performs a safety function; (b) confirmation that the item or service meets the applicable commercial grade item definitions; (c) identification and documentation of the critical characteristics, including acceptance criteria; and (d) selection, performance, acceptance and documentation of the dedication methods for determining compliance with the critical characteristic acceptance criteria.

7.9 Records

Records are maintained to indicate the performance of the following functions: (a) supplier evaluation and selection; (b) acceptance of the items or services procured; and (c) supplier nonconformances to procurement document requirements, including a description of their evaluation and disposition.

7.10 Commitment

In establishing a program for the control of items and services, GEH commits to compliance with 10 CFR Part 50, Appendix B, Criteria VII and NQA-1a-2009 Requirement 7 with the following exceptions:

- NQA-1a-2009, Part I, Requirement 7, paragraph 600(b) is revised to read as shown in the second paragraph of section 7.5, "Control of Supplier Nonconformances", of this QAPD.
- GEH considers 10 CFR Part 50 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies, which may provide items or services to GEH, as not requiring evaluation or audit.
- When purchasing commercial grade calibration services from a calibration laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met:
  - The purchase documents impose any additional technical and administrative requirements, as necessary, to comply with the GEH QA program and technical provisions. At a minimum, the purchase document will require that the calibration certificate/report include identification of the laboratory equipment/standard used.
  - The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.

- A documented review of the supplier's accreditation will be performed and will include a verification of each of the following:
  - The calibration laboratory holds a domestic accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP), the American Association for Laboratory Accreditation (A2LA), ACLASS Accreditation Services, Laboratory Accreditation Bureau (LAB) or International Accreditation Services (IAS) as recognized through the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).
  - The accreditation is based on ANS/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories".
  - The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, ranges, and uncertainties.

The GEH program for dedication of commercial-grade items commits to be consistent with:

- NQA-1a-2009, Subpart 2.14,
- EPRI NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety. Related Applications", 6/88 as endorsed and modified by US NRC Generic Letters:
  - 89-02, Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products (3/89), and
  - 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs" (4/91).

SECTION 8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

8.1 General

GEH has established a program to provide for the identification and control of materials, parts, and components (partially fabricated assemblies, consumables and limited shelf life items). Integral to the program are measures for preventing the use, shipment or installation of incorrect or unacceptable items. The program provides for the identification of each item that is maintained throughout fabrication, erection, installation and use so the item can be traced to its documentation. The identification and control measures provide for relating an item of product (batch, lot, part or assembly) at any stage, from material receipt through fabrication and shipment to an applicable drawing, specification or other control document. When required by codes, standards, contract or specifications, traceability will be maintained to specific material certifications, test reports, heat numbers, heat treatment lot numbers or other attributes.

8.2 Identification Methods

Item identification is maintained through the life of the product, component, part, or item so marked. This identification is accomplished using heat numbers, part numbers, serial numbers or other appropriate means; and is located either on the item or on records traceable to the item. Items in the production stream, whether they are batch, lot, component or part items, are identified from initial receipt from the supplier, through custom fabrication, to delivery, installation and use. The identification corresponds to a listing or other specifying process that relates the product, component, or part to the product delivered.

8.3 Preference for Physical Marking

Where practical, physical identification is given preference to other forms of identification. When physical identification is neither practical nor sufficient, physical separation, procedural control, or other appropriate means will be used.

8.4 Maintenance of Marking

Markings will be transferred to each part of an item when subdivided and will not be obliterated or hidden by surface treatment or coatings unless other means of maintaining identification are utilized. Where identification marking of an item is employed, the marking will be clear, unambiguous and indelible, and will be applied in such a manner as not to affect the function or quality of the item. Measures to maintain

or replace identification markings will be based on the expected length of time in storage and environmental conditions so that they are not obliterated due to handling, aging or deterioration.

8.5 Limited Life Items

Measures are established to track the age of limited shelf life items so that they cannot be used after the established lifetime has expired. Provisions are made for updating inventory records.

8.6 Commitment

In establishing provisions for identification and control of items, GEH commits to compliance with 10 CFR Part 50, Appendix B Criteria VIII and NQA-1a-2009, Requirement 8.

SECTION 9 CONTROL OF SPECIAL PROCESSES

9.1 General

The GEH program ensures that special processes such as welding, heat treating, and nondestructive examination are properly controlled.

Special processes are accomplished by personnel qualified under associated codes, standards, regulations, specifications, design criteria and other special requirements.

Special processes are conducted in accordance with the applicable codes, standards, regulations, specifications, design criteria and other special requirements, procedures, and equipment. Control is accomplished through the use of instructions, procedures, drawings, checklists, or other appropriate means within established parameters and are maintained under specified environmental conditions.

Each special process work instruction will include, or reference, procedures, personnel and equipment requirements appropriate to that particular process.

9.2 Criteria

A process is designated "special" if the success of the process is highly dependent on the control of the process or the skill of the operators, or both and if the specified quality cannot be readily determined by inspection or test of the product.

9.3 Non-Standard Processes

For special processes not covered by existing codes or standards, or where product requirements exceed those of established codes or standards, the necessary requirements for the qualification of personnel, procedures, or equipment are defined or referenced in procedures or work instructions.

9.4 Responsibility

The organization performing the special process is responsible for adherence to the approved procedures and processes.

9.5 Records

Records are maintained as appropriate for the qualified personnel, processes and equipment for each special process.

9.6 Commitment

In establishing measures for the control of special processes, GEH commits to compliance with 10 CFR Part 50 Appendix B, Criteria IX and NQA-1a-2009, Requirement 9.

SECTION 10 INSPECTION

10.1 General

This section describes the GEH program for inspection of items and activities to verify conformance with the documented instructions, procedures, and drawings. Inspection types include, but are not limited to: source, in process, final, receipt, maintenance, modification, in-service and operations. Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings.

10.2 Inspection Personnel

Inspections are performed by personnel who have not performed the work and do not report to the supervisors responsible for the work being inspected. Those activities that require qualified inspection personnel are defined.

10.3 Planning

Provisions are incorporated into inspection work instructions to ensure inspection planning is properly accomplished. Planning activities identify the characteristics and activities inspected, sample size, inspection methods, acceptance criteria, and organization responsible for performing the inspection. Inspection requirements and acceptance criteria include requirements specified in the applicable design documents or in other pertinent technical documents approved by the responsible design organization. Examinations, measurements, or tests of material or products processed are performed for each work operation where necessary to ensure quality.

10.3.1 Sampling

If sampling procedures are used, they are based on standard statistical methods or industry practices with either engineering or QA approval.

10.3.2 Hold Points

Mandatory inspection hold points that require documented consent of the designated representative prior to the work proceeding are specified in appropriate documents. Consent to waive specified hold points is recorded prior to continuation of work beyond the designated hold point.

10.3.3 Process Monitoring

If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel are provided. Both inspection and process monitoring are provided when control is inadequate without both.

10.3.4 Re-inspection

Modifications, repairs, or replacements of items performed after final inspection require re-inspection or retest, as appropriate, to verify acceptability.

10.4 Final Inspection

10.4.1 Resolution of Nonconformances

A records review of the results and resolution of nonconformances identified by prior inspections will be included as part of the final inspection.

10.4.2 Inspection Requirements

The GEH final inspection requirements include verification of the following: completeness of the product or service, markings, calibration, adjustments, protection from damage or other characteristics as required to verify the quality and conformance of the item to the specified requirements.

10.4.3 Acceptance

Only authorized personnel are permitted to accept the work being inspected.

10.5 Records

Appropriate records are established, maintained and include the following as a minimum: item inspected, (a) the date of the inspection, (b) the name of the inspector, (c) the type of observation, (d) the acceptability of the result, and (d) one or more references to information on any action taken in connection with nonconformances.

10.6 Commitment

In establishing inspection requirements, GEH commits to compliance with 10 CFR Part 50, Appendix B, Criteria X and NQA-1a-2009, Requirement 10.

SECTION 11 TEST CONTROL

11.1 General

This section establishes the GEH program to control testing to collect data such as for design input or to verify conformance of an item to specified requirements, or to demonstrate satisfactory performance for service. Characteristics to be tested and test methods to be employed are specified. The test program includes proof tests before installation, preoperational tests, post maintenance tests, post modification tests and operational tests as appropriate. Test results are documented and their conformance with the test requirements and the acceptance criteria are evaluated.

11.2 Test Requirements

Test requirements and acceptance criteria are provided in an applicable design or other pertinent technical document, and are approved by the responsible design organization. Criteria are defined that specify when testing is required and activities that require qualified test personnel. Required tests are controlled under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria. The tests performed obtain the necessary data with sufficient accuracy for evaluation and acceptance.

If temporary changes to the approved configuration of a facility are required for testing purposes, approval by the responsible design organization is required prior to performing the test.

11.3 Test Procedures

11.3.1 Test Procedures for Other than Computer Programs

Test procedures include or reference the test configuration and test objectives. Test procedures also include provisions for assuring that prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed. Prerequisites include the following, as applicable: (a) the instrumentation must be properly calibrated; (b) the appropriate equipment must be used; (c) the test must be conducted by personnel who are trained in the procedures; (d) the condition of the test equipment and the item to be tested must meet test specifications; (e) suitable environmental conditions must exist in the test location; and (6) the provisions for data acquisition must be working and in good order.

Alternately, appropriate sections of related documents, such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, may be used. Such documents include or are supplemented with appropriate criteria listed above to ensure adequate procedures for the test.

11.3.2 Test Procedures for Computer Programs

This section applies to the testing of computer programs and, as appropriate, to the computer hardware and operating system. Computer program test procedures provide for demonstrating the adherence of the computer program to documented requirements. For those computer programs used in design activities, computer program test procedures provide for assuring that the computer program produces correct results. The procedures also provide for evaluating technical adequacy through comparison of test results from alternative methods such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature.

For those computer programs used for operational control, computer program test procedures provide for demonstrating required performance over the range of operation of the controlled function or process.

In-use test procedures are developed and documented to permit confirmation of acceptable performance of the computer program in the operating system. In-use test procedures are performed after the computer program is installed on a different computer, or when there are significant changes in the operating system. Periodic in-use manual or automatic self-check in-use tests are performed for those computer programs in which program errors, data errors, computer hardware failures, or instrument drift can affect the required performance of the program.

Test procedures or plans are required to specify the following, as applicable to the test parameters: (a) the required tests and test sequence; (b) the required ranges of input parameters; (c) the stages at which testing is required; (d) the criteria for establishing test cases; (e) the requirements for testing logic branches; (f) the criteria for hardware integration; (g) anticipated output values; (h) the acceptance criteria to be used to evaluate whether a test is successful; and (i) the reports, records, standard formatting, and conventions in which the results must be reported.

11.4 Test Results

Test results are documented and evaluated by a responsible authority to ensure that test requirements have been satisfied. Test results for design qualification tests are evaluated by the responsible design organization.

11.5 Test Records

Test records are established and maintained to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet its documented requirements. Test records vary depending on the test type, purpose, and application, but contain the following information, as a minimum: (a) the item tested, (b) the date of the test; (c) the name of the tester or data recorder; (d) the type of observation required; (e) the results and acceptability of those results, (f) any action taken in connection with deviations from the original testing specification or procedure; and (g) the name of the person evaluating test results.

In addition to the above, test records for computer programs also contain the following information: (a) the name of the computer program tested including the system software used; (b) the computer hardware used; (c) the type of test equipment and if applicable, calibrations used, (d) any simulation models used, where applicable and (e) any test problems encountered.

11.6 Commitment

In establishing test control requirements, GEH commits to compliance with 10 CFR Part 50, Appendix B, Criteria XI and NQA-1a-2009, Requirement 11.

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 General

GEH has established a program including governing procedures to control the calibration, maintenance, storage and use of measuring and test equipment (M&TE). The procedures cover equipment such as indicating and actuating instruments and gages, tools, reference and transfer standards, and nondestructive examination equipment. The suppliers of commercial-grade calibration services are required to comply with control measures as described in Section 7 of this QAPD. Calibration and control measures are not required for commercial equipment such as rulers, tape measures, levels, etc., if such equipment provides the required accuracy. Measuring and test equipment is properly handled and stored to maintain accuracy.

12.2 Selection of Equipment for Use

Selection of measuring and test equipment is based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements. Measuring and test equipment are traceable to their application and use.

12.3 Calibration Process

Measuring and test equipment are calibrated at prescribed intervals, whenever the accuracy of the measuring and test equipment is suspect or prior to use. Calibration is conducted against certified equipment or reference standards having known valid relationships to nationally recognized standards, or to international standards, which are known to be equivalent to and verified against corresponding nationally recognized standards. The program requires that traceability to the reference standards be maintained. Where no such standards exist, the basis for calibration is defined.

12.4 Control of Calibration Status

Measuring and test equipment are suitably marked, tagged, labeled, or otherwise identified to indicate calibration status and establish traceability to calibration records. Equipment that is overdue for calibration or found to be out-of-calibration, is tagged and/or segregated, or removed from service, and not used until it has been recalibrated. Measuring or test equipment consistently found to be out-of- calibration will be repaired or replaced and an evaluation is made and documented of the validity of previous measurements since the last calibration and of the acceptability of previously inspected items.

12.5 Records

12.5.1 General

Records are established and maintained to indicate calibration status and the capability of measuring and test equipment to satisfactorily perform its intended function.

12.5.2 Reports and Certificates

Calibration reports and certificates reporting the results of calibrations include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements.

12.6 Commitment

In establishing a measuring and test equipment calibration program, GEH commits to compliance with 10 CFR Part 50, Appendix B, Criteria XII and NQA-1a-2009, Requirement 12.

SECTION 13 HANDLING, STORAGE, AND SHIPPING

13.1 General

GEH has established a program to control the handling, storage, packaging, cleaning, shipping, and preservation of items to prevent inadvertent damage or loss, and to minimize deterioration.

13.2 Instructions

Cleaning, handling, storing, packaging, shipping, and preservation of items are controlled by written instructions and sufficient labeling is provided to identify the items and to indicate any special conditions needed to prevent degradation.

13.3 Special Controls

Special controls (such as containers, shock absorbers, accelerometers) and environments (such as inert gas atmospheres, specific moisture content levels and temperature levels) are provided when required to maintain acceptable quality. The presence of these special environments is indicated by marking the exterior of the container to prevent premature penetration of the sealing boundary. The need for special controls or specific procedures are established on a case by case basis according to the item's complexity, use and sensitivity to damage.

13.4 Special Tools and Equipment

Special handling tools and equipment will be used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment will be inspected and tested at specified time intervals and in accordance with procedures to verify that the tools and equipment are adequately maintained.

13.5 Operators

Operators of special handling and lifting equipment will be experienced or trained in the use of the equipment.

13.6 Commitment

In establishing provisions for handling, storage, and shipping, GEH commits to compliance with 10 CFR Part 50, Appendix B, Criteria XIII and NQA-1a-2009, Requirement 13.

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

14.1 General

GEH has established a program to identify the inspection and test status of individual items and for indicating the operating status of equipment, such as valves and switches. Implementing procedures specify the authority for the application and removal of these status indicators.

14.2 Inspection and Test Status

Inspection and test status indicators provide assurance that items that have not successfully passed required inspections and/or tests are not inadvertently installed, used, operated, released for subsequent operations or shipment. The inspection and test status is maintained through the use of physical location, status indicators (such as tags, markings, shop travelers, stamps, inspection records) or other suitable means.

14.3 Commitment

In establishing measures for control of inspection, test, and operating status, GEH commits to compliance with 10 CFR Part 50, Appendix B, Criteria XIV and NQA-1a-2009, Requirement 14.

SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

15.1 General

GEH has established a program to control nonconforming items and to prevent inadvertent test, installation or use. Nonconforming items have a deficiency in characteristic, documentation, or procedure that makes the quality of the item or activity unacceptable or indeterminate. Controls provide for identification, documentation, evaluation, segregation (when practical), and disposition of nonconforming items, and for notification to affected organizations.

15.2 Identification and Control

Nonconforming items are identified by legible marking, tagging, or other methods not detrimental to the item, on the item, the container, or the package containing the item. Nonconforming items that are segregated are placed in a clearly identified and designated hold area until they can be properly dispositioned. When segregation is impractical or impossible due to physical conditions, such as size, weight, or access limitations, other administrative measures are employed to preclude inadvertent use of a nonconforming item. Further processing, delivery, installation, or use of a nonconforming item is administratively controlled until an evaluation of the item is completed by authorized personnel, and the appropriate disposition for that item is determined.

15.3 Disposition

The responsibility and authority for the evaluation and disposition of nonconforming items is defined in implementing procedures. Responsibility for the control of further processing, delivery, installation, or use of nonconforming items is designated in writing. Personnel performing evaluations to determine a disposition must have the following qualifications: (a) demonstrated competence in the specific area they are evaluating; (b) possess an adequate understanding of the requirements; and (c) access to pertinent background information.

Dispositions can include:

Rework – the process by which an item is made to conform to original requirements by completion or correction. This can be accomplished by repeating or completing one or more steps in the previously planned manufacturing process.

Repair – the process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement. This is accomplished by the addition of manufacturing steps that were not included in the original manufacturing plan.

Use-as-is – a disposition permitted for a nonconforming item when it has been established that the item is satisfactory for its intended use.

Reject – the item is unsuitable for use and is to be designated as scrap or returned to the vendor.

Technical justification for the acceptability of a nonconforming item dispositioned in either the repair or use-as-is categories must be documented. Nonconformances to design requirements dispositioned use-as-is or repair are subject to design control measures commensurate with those applied to the original design. Required as-built records reflect the use-as-is or repair condition.

15.4 Re-examination

Reworked, repaired or replacement items are re-examined in accordance with applicable procedures and with the original acceptance criteria, unless otherwise stipulated. Repaired items may use alternate acceptance criteria if the need is established during the repair plan design review.

15.5 Commitment

GEH commits to compliance with 10 CFR Part 50, Appendix B, Criteria XV and NQA-1a-2009, Requirement 15.

SECTION 16 CORRECTIVE ACTION

16.1 General

The GEH Corrective Action program utilizes a system of governing procedures to implement the necessary measures to promptly identify, control, document, classify and correct Conditions Adverse to Quality (CAQs). The GEH implementing procedures ensure that appropriate actions are initiated following the determination of CAQs in accordance with regulatory requirements and applicable quality standards. These measures ensure that corrective actions are adequately documented and not inadvertently nullified by subsequent actions. GEH procedures require personnel to identify known CAQs. When complex issues arise such that an immediate determination whether a condition adverse to quality exists, the GEH program identifies a process for the documentation and timely evaluation of the issue.

A significant condition adverse to quality (SCAQ) is a failure, malfunction, deficiency, defective item, or nonconformance that, if uncorrected, could have a serious effect on safety or operability. SCAQs are documented, reported to responsible management, their cause is determined and actions to preclude its recurrence are taken.

16.2 Identification of Trends

Reports of conditions that are adverse to quality are analyzed to identify trends in quality performance. Significant conditions and trends adverse to quality are reported to the appropriate level of management.

16.3 Commitment

In establishing corrective action requirements, GEH commits to compliance with 10 CFR Part 50, Appendix B, Criteria XVI and NQA-1a-2009, Requirement 16.

SECTION 17 QUALITY ASSURANCE RECORDS

17.1 General

GEH has established measures to provide provisions for the administration, receipt, storage, preservation, safekeeping, retrieval and disposition of all records. The records system is defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation. The applicable design specifications, procurement documents, test procedures, operational procedures or other documents specify the records generated, supplied and maintained. Records may be hard copy, electronic, or both. The program requires that records be examined for adequacy, legibility and completeness. Safekeeping of records includes protection from equipment malfunction and access control.

17.2 Administration

17.2.1 Personnel

Requirements and responsibilities for record transmittal, receipt, location, distribution, retention, maintenance, and disposition are described in implementing procedures. Training is provided for individuals or organizations in charge of the generation of electronic records, data and media storage, the implementation of security measures, the migration or regeneration of data, and the recovery of data.

17.2.2 Indexing System

An indexing system provides sufficient information to permit identification between the record and the item or activity to which it applies.

17.2.3 Corrections

Records are corrected in accordance with procedures that provide for appropriate review or approval by the originating organization. The correction includes the date and the identification of the person authorized to issue such correction.

17.3 Classification

Records are classified as Lifetime or Nonpermanent.

17.3.1 Lifetime Records

Lifetime records are those that meet one or more of the following criteria: (a) significant value in demonstrating capability for safe operation; (b) significant value in maintaining, reworking, repairing, replacing, or modifying an item; (c) significant value in determining the cause of an accident or malfunction of an item; or (d) provision of required baseline data for in-service inspections and in-service tests.

Lifetime records are maintained for the life of the particular item, while it is installed in the plant, or stored for future use.

17.3.2 Nonpermanent Records

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

17.4 Receipt Control

The person or organization responsible for receiving the records is designated. This designee is responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage and for providing protection from damage or loss during the time that the records are in his/her possession.

At a minimum, a receipt control system includes the following: (a) a method for designating the required records; (b) a method for identifying records received; (c) procedures for receipt and inspection of incoming records; and (d) a method for submittal of completed records to the storage facility without unnecessary delay.

Each receipt control system is structured to permit a current and accurate assessment of the status of records during the receiving process.

17.5 Authentication

Documents are considered valid records only if stamped, initialed, authenticated, or signed and dated by authorized personnel. 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 organization. These records may be originals or reproduced copies.

17.6 Storage

17.6.1 General

Records will be stored at a predetermined location in facilities, containers, or a combination thereof, constructed and maintained in a manner that minimizes the risk of loss, damage, or destruction from:

- Natural disasters such as winds, floods, or fires;
- Environmental conditions such as high and low temperatures and humidity;
- Infestation of insects, mold, or rodents; or
- Dust or airborne particles.

Activities that may be detrimental to the records are prohibited in a designated storage area. Access to the processing, storage, and retrieval of records is limited to authorized personnel. Provisions have been made to prevent damage from harmful conditions (such as excessive light, stacking, electromagnetic fields, temperature, and humidity), as applicable to the specific media utilized for record storage.

17.6.2 Facility Types

GEH uses two methods of providing storage - single or dual. Single storage consists of a storage facility, vault, room, or containers with a minimum two-hour fire rating. The design and construction of a single storage facility, vault room, or container will be reviewed for adequacy by a person competent in fire protection or contain a certification or rating from an accredited organization.

Dual facilities, containers, or a combination thereof are located at facilities that are sufficiently remote from each other to eliminate the chance exposure to a simultaneous hazard.

17.6.3 Temporary Storage

When temporary storage of reviewed and approved records (such as for processing, review, or use) is required, the storage facility or container will provide a one-hour fire rating, unless dual storage requirements of are met.

17.6.4 Retention

Integral to the GEH records storage program is an implementing procedure that records retention periods. This procedure notifies personnel of record retention requirements and helps to ensure that records are maintained for their retention periods.

17.7 Electronic Records

For QA records in electronic media, the GEH program includes provisions for the generation, distribution, use, maintenance, storage, and disposition of electronic records. The plan identifies the acceptable media on which electronic records may be created and stored. Also, the program includes provisions to verify that the media is appropriate, suitable for the capture or storage of records, and error/defect free.

17.7.1 Indexing system

The software name, version, and equipment (hardware) used to produce and maintain the electronic media are identified on the record.

17.7.2 Corrections

A new record is to be generated when substantial corrections or changes to previous electronic records are required.

17.7.3 Retention

Electronic records are subject to the same retention requirements as paper records. Retention requirements for electronic records also identify and maintain the information system (software/hardware), the documentation that describes the information system operation and use, and the record standard it produces.

17.7.4 Receipt

The person or organization responsible for receiving the records is also responsible for organizing and implementing an inventory of system applications, record formats, and programs required to process and retrieve electronic records.

17.7.5 Authentication

For electronic records, authentication is accomplished by manually affixing a seal, signature, an electronic representation (user ID/password combination, digital signature) or other acceptable process control that ensures genuineness, validity, or reliability. Authorized personnel with access to electronic records and information systems should

have a unique user ID/password for access. The system should provide controls for users who enter or alter information in electronic records to ensure its data integrity and prevent unauthorized alteration or erasure. Transfer of authentication authority is documented and controlled in accordance with written procedures.

17.7.6 Storage

Electronic media should be stored in a dust-free environment, away from electronic devices and demagnetizing equipment. Media should be maintained at the constant temperature of 40 to 80 degrees Fahrenheit (4.4 to 26.7 degrees Celsius), with a constant relative humidity of 30 to 50 percent. Magnetic and optical media should be tested periodically to identify any loss of data, to ensure that they are free of permanent errors, and that the record system hardware/software still supports the retrieval of the records.

17.7.7 Obsolescence

An electronic record migration/regeneration program is implemented for electronic records stored in media with a standard life expectancy that fails to meet the specific retention period. This program is implemented in accordance with documented procedures that provide for appropriate record authentication, quality verification of the completion, and accuracy of the data transferred.

17.8 Commitment

In establishing a quality assurance records program, GEH commits to compliance with 10 CFR Part 50, Appendix B, Criteria XVII, NQA-1a-2009, Requirement 17, Generic Letter 88-18, and RIS 2000-18.

SECTION 18 AUDITS

18.1 General

The GEH audit program was designed to verify compliance to quality assurance program requirements, to verify that performance criteria are met, to determine the effectiveness of the program, and to provide a comprehensive independent evaluation of activities and procedures. Audits are performed in accordance with written procedures or checklists by qualified personnel who do not have direct responsibility for performing the activities being audited. Audit results are documented and reviewed by responsible management. Follow-up action is taken where indicated. When any work carried out under the requirements of the QA program is delegated to others, the work is audited by the QA audit program.

18.2 Personnel

An audit team is identified prior to the beginning of each audit. This team contains one or more auditors; and is led by a lead auditor. The lead auditor organizes and directs the audit and verifies that the audit team has the necessary experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Audit personnel are given sufficient authority and organizational freedom to make the audit process meaningful and effective.

18.3 Audit Documentation

18.3.1 Annual Audit Schedule

An audit schedule is documented at the beginning of each year to document the planned, periodic coverage of internal functions performing quality related activities and the performance of suppliers. Internal audits of organizations and activities are conducted prior to placing a facility in operation and at least once a year subsequently. Once activities have been established, internal audits are conducted to ensure all QA program elements are evaluated for each functional area within a period of two years. Activities with durations of less than one year are audited at least once during the life of the activity.

The audit schedule is reviewed periodically and revised, as necessary, to ensure that coverage is current. When necessary to ensure adequate coverage, the scheduled audits may be supplemented by focused, in-depth audits covering specific subjects.

18.3.2 Audit Plan

The auditing organization develops and documents an audit plan specific to each audit. This plan identifies the audit scope, requirements, personnel assigned to the audit; the activities to be audited, any organizations to be notified; and the applicable documents, schedule, and written procedures or checklists to be used.

18.3.3 Audit Report

Following the audit, a report is generated and signed by the audit team leader. The report includes the following information, as appropriate: (a) a description of the audit scope; (b) identification of the auditors by name and organization; (c) identification of persons contacted during audit activities; (d) a summary of the audit results, including a statement on the effectiveness of the QA program elements that were audited; and (e) a description of each adverse audit finding in sufficient detail to enable an effective corrective action to be taken by the audited organization.

18.3.4 Audit Records

Audit records are required to include audit plans, audit reports, written replies, and the record of the completion of any corrective actions resulting from the audit.

18.4 Internal Audits

P&L organizations are responsible for internal audits of their areas of responsibility. In addition, the Nuclear Quality Assurance organization is assigned responsibility for auditing the various P&L's for compliance with the overall QA Program with applicable codes, standards, and regulations.

Internal audits of the QA Records organization shall include inspections of systems, software applications, and media to ensure electronic records retrievability, integrity, and retention period requirements are being met.

18.5 Supplier Audits

Supplier QA programs are audited on a triennial basis starting with the year that the first audit occurs and if the procurement scope significantly changes from the originally audited scope. Supplier audits are not required for items that are relatively simple and standard in design, manufacturing and testing or are adaptable to standard or automated inspections or tests of the end product to verify quality characteristics. In addition to triennial audits, annual evaluations of suppliers are conducted as described in Section 7.

If the supplier is implementing the same QA program for other customers that is proposed for use on GEH's contract, the pre-award survey may serve as the first triennial audit. Therefore, when such pre-award surveys are employed as the first triennial audits, they must satisfy the same audit elements and criteria as those on other triennial audits.

If more than one purchaser buys from a single supplier, a purchaser may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. The scope of this audit should satisfy the needs of all of the purchasers, and the audit report should be distributed to all the purchasers for whom the audit was conducted. Each of the purchasers relying on the results of an audit performed on behalf of several purchasers remains individually responsible for the adequacy of the audit.

18.6 Audit Response and Follow-up

Management of the audited organization or activity:

- Investigates adverse audit findings,
- Schedules corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and
- Notifies the auditing organization in writing of action taken or planned.

Audit responses are evaluated by the auditing organization. Follow-up action is taken to verify that any corrective action required is accomplished as scheduled.

18.7 Commitment

In establishing an audit program, GEH commits to compliance with 10 CFR Part 50, Appendix B, Criteria XVIII, NQA-1a-2009, Requirement 18 and RIS 2000-18.

APPENDIX A REGULATORY COMMITMENTS

This section identifies the US NRC Regulatory Guides and the other quality assurance standards that have been selected to supplement and support the GEH QAPD. GEH commits to compliance with these standards to the extent described in this QAPD.

Code of Federal Regulations

- 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"
- 10 CFR Part 71, "Packaging And Transportation Of Radioactive Material"

US NRC Documents and Quality Assurance Standards

- Regulatory Guide 1.28, Revision 4, 2010 – "Quality Assurance Program Requirements (Design and Construction)"
- US NRC Generic Letter 88-18, "Plant Record Storage on Optical Disks"
- US NRC Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products"
- US NRC Generic Letter 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs"
- US NRC RIS 2000-18, "Guidance on Managing Quality Assurance Records in Electronic Media"

Standards:

- ASME NQA-1, 2008 Edition, "Quality Assurance Requirements for Nuclear Facility Applications", with the NQA-1a, 2009 addenda, Part I in its entirety and Part II for those activities within GEH's scope as an NSSS supplier.
- Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TG) as endorsed by US NRC RIS 2000-18
- EPRI NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety. Related Applications" (6/88 as endorsed and modified by US NRC Generic Letter 89-02, Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products")

- ANS/ISO/IEC 17025, "General requirements for the competence of testing and calibration laboratories"