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MFN 14-018

March 31, 2014

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

Subject: GEH Quality Assurance Topical Report NEDO-11209, "GE Hitachi Nuclear Energy Quality Assurance Program Description," Revision 11, March 2013

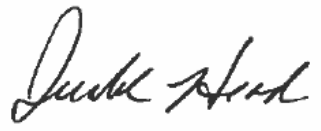
This letter transmits Revision 11 of the GE Hitachi Nuclear Energy (GEH) Quality Assurance Program Description (QAPD) NEDO-11209 for NRC review and approval per 10 CFR 50.4(b)(7)(ii). Enclosure 1 contains NEDO-11209 Revision 11. A roadmap detailing the changes from NEDO-11209-A Revision 9 to NEDO-11209 Revision 11 is contained in Enclosure 2.

NEDO-11209 Revision 11 has been reformatted for easier referencing. Additionally, international standards have been incorporated into both the main body of the GEH Quality Assurance Program Description and into a new Part III: Supplemental Details. The QAPD was also updated to reflect changes to the GEH organization. This information was discussed during the pre-submittal meeting held with the US NRC on February 20, 2014 (ML14057A415).

NEDO-11209 Revision 11 is a standard topical report that will be applied for the Boiling Water Reactor (BWR) fleet through its adoption at business units affiliated with the 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. As such, GEH requests that the NRC staff review and approve this submittal by September 26, 2014.

If you have any questions about the information provided here, please contact me at (910) 819-5692 or Rich Augi at 910-819-6366.

Sincerely,



Jerald G. Head
Senior Vice President, Regulatory Affairs
GE-Hitachi Nuclear Energy Americas LLC

Project No. 710

Enclosures:

1. NEDO-11209, Revision 11, "GE Hitachi Nuclear Energy Quality Assurance Program Description," March 2014 – Non-Proprietary Information – Class I (Public)
2. Roadmap for NEDO-11209, Revision 11 – Non-Proprietary Information – Class I (Public)

cc: JA Golla, NRR/DPR/PLPB
SS Philpott, NRR/DPR/MSD/MSPB
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PLM Specification 000N7524 R0

ENCLOSURE 1

MFN 14-018

NEDO-11209, Revision 11,
"GE Hitachi Nuclear Energy Quality Assurance Program Description,"
March 2014

Non-Proprietary Information – Class I (Public)

HITACHI **GE Hitachi Nuclear Energy**

GE-Hitachi Nuclear Energy Americas LLC
3901 Castle Hayne Road
Wilmington, North Carolina 28401

NEDO-11209
REVISION 11
March 31, 2014

Class I (Public)

Quality Assurance Topical Report

GE Hitachi Nuclear Energy

Quality Assurance Program Description

PREPARED BY: Carmen Alonso
CARMEN ALONSO, QUALITY OVERSIGHT LEADER

REVIEWED BY:
TAMMY ORR, NUCLEAR OVERSIGHT SENIOR VICE PRESIDENT

IMPORTANT NOTICE REGARDING CONTENTS OF THIS REPORT

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REVISION HISTORY

Revision	Description			Date	Author
	Page	Section	Change		
9	Complete re-write			06/28/10	E.L. Jordan
Incorporation of NRC RAI responses and editorial changes	i	Title Page	Reformatted	12/09/10	E.L. Jordan
	1 - 8	1	re-written (RAI 1 to 4)		
	9	2.1	Spelling		
	14	3.4	reworded (RAI 7)		
	18	3.6	Detail added (RAI 8)		
	29	7.8	Spelling		
	43	13.3	Detail added (RAI 9)		
	53	18.3.1	Detail added (RAI 11)		
	54	18.4	Reworded (RAI 11)		
	56	Appx. A	Detail added (RAI 6)		
Created Approved Final Version	All	All	Added “-A”; “August 2011”	08/08/11	E.L. Jordan
	Mult.	All	NQA-1-2008 added to commitment statements of each sec.		
	iv - vii	TOC	Updated		
	NA		Inserted NRC Letter		
	NA		Added SE and RAIs		
10	All	All	General format changes to acronym references and text per writers guide and bulleted lists	12/20/12	M. Gerdes
	iv, v, vi, vii	TOC	Updated		
	viii	All	Updated acronyms and abbreviations		
	1	1.1	Clarified QAPD adherents and removed org. elements table		
	1	1.2.1, 1.2.1.1, 1.2.1.2, 1.2.1.3	Updated to reflect current organizational structure		
	3 & 4	1.2.2.3	Removed NQA & Support Services titles, which are now included in Quality Programs, combined P&L and Support Quality Leaders to “Org. Specific Quality Leaders”, added Continuous Improvement		
	4	1.4	Removed NQA title and added QA organization		
	6	Fig. 1	Replaced figure with new reflecting		

Revision	Description			Date	Author
	Page	Section	Change		
			current organizational structure		
	7	Fig. 2	Replaced table with new reflecting current organizational structure		
	22	6.4	Clarified to current process for all temporary changes.		
	24	7.5	Clarified to remove conditionality of nonconformance reporting		
	28	7.10	Eliminated 1st bullet exception to Requirement 7		
	33	10.2	Clarified to include how activities are defined		
	42 & 43	15.3	Eliminated 2nd sentence in Rework and Repair definition to align with current procedure requirements		
	50	18.4	Updated to reflect current organization responsible for Internal Audits		
10	All	All	Admin change to include "-A" on all page headers	1/21/2013	M. Gerdes
	7	Fig. 2	Admin change to correct spelling of New Plant Projects		
11	All	All	Reformatted text and sections	3/13/2014	R. Augi
	Multiple	All	Updated for organization changes		
	Multiple	Multiple	Incorporated portions of NEDO-32280, "GEH ISO-9001 Quality Management System" into NEDO-11209		
	Multiple	Multiple	Clarified NQA-1 commitments		
	All	All	Formatted overall structure of the QAPD to align with NEI-06-14		
	6	Policy Statement	Added Policy Statement		
	9	Scope /Applicability	Moved Introduction to this section, Scope rewritten		
	16	1.7.1	Added "Delegation Inside the GEH Organization"		
	18	Figure 2	Deleted		
	21	2.8	Added "Quality Assurance Program Description Management" section		
	39	7.10	Added Perry Johnson to list of accredited calibration bodies		
	51	12.5.3	Added "Out of Calibration" section		

Revision	Description			Date	Author
	Page	Section	Change		
	57	16.1, 16.3, 16.4	Added Corrective Action Program details		
	65	18.3.3	Added “Audit Performance” section		
	67	Part III	Added “Supplemental Details”		
	74	Part IV	Moved “Regulatory Commitments” from Appendix A		

POLICY STATEMENT

GE Hitachi Nuclear Energy (GEH) is committed to achieving the highest quality products and services through the disciplined application of the GEH Quality Management System (QMS). GEH shall provide the required designs, components, materials, parts, and services in response to customer contract requirements and in full accord with applicable standards and regulations in a manner that will ensure the health and safety of the public and workers. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations (CFR), the applicable Nuclear Regulatory Commission (NRC) Facility Operating Licenses, regulatory guidance documents, applicable laws and regulations of the state and local governments, and ISO 9001 (most recent edition).

GEH has developed and implemented a QMS in order to document the company's best business practices, better satisfy the requirements and expectations of its customers, and improve the overall management of the company. The GEH QMS is comprised of this Quality Assurance Program Description (QAPD) and the implementing procedures. Together they provide for control of GEH activities that affect the quality of safety-related nuclear plant structures, system, and components (SSCs) and include all planned and systematic activities necessary to provide adequate confidence that such SSCs will perform satisfactorily in service. This QAPD may also be applied to certain equipment and activities that are not safety-related, but support safe plant operations, or where other NRC guidance establishes program requirements. GEH strives to continually improve the overall effectiveness of the Quality Management System.

The QAPD is the top-level policy document that establishes the manner in which quality is to be achieved and presents GEH's overall philosophy regarding achievement and assurance of quality. Implementing procedures assign more detailed responsibilities and requirements, and define the organizational interfaces involved in conducting activities within the scope of the QMS. Compliance with the QAPD and implementing procedures is mandatory for personnel directly or indirectly associated with implementation of the GEH QMS.

Caroline Reda, President and CEO

GE Hitachi Nuclear Energy

3/13/2014

Date

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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
EHS	Environmental Health and Safety
EPRI	Electric Power Research Institute
GEH	GE Hitachi Nuclear Energy
GNF	Global Nuclear Fuel
GSC	Global Supply Chain
IAS	International Accreditation Services
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Standards Organization
LAS	Laboratory Accreditation Services
M&TE	Measuring and Test Equipment
MRA	Mutual Recognition Arrangement
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
QMS	Quality Management System
PJLA	Perry Johnson Laboratory Accreditation, Inc.
P&L	Profit and Loss Center
RIS	Regulatory Issue Summary
SCAQ	Significant Condition Adverse to Quality
SSC	Structures, systems and components

PART I INTRODUCTION

1.0 SCOPE/APPLICABILITY

This Quality Assurance Program Description (QAPD) implements the GE Hitachi Nuclear Energy (GEH) Quality Management System and has been adopted by the following companies affiliated with the General Electric Company (GE) and the GE Power and Water business unit 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.
- GE Reuter-Stokes Inc.

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 the quality program.

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 with compliance verified by periodic audits and self assessment activities.

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 new plant designs and engineering services such as system studies, diagnostics, fuel and service analyses, and product and service testing.

This QAPD is divided into the following parts:

- Part I: Introduction
- Part II: QAPD Details (per 10 CFR 50 Appendix B)
- Part III: Supplemental Details
- Part IV: Regulatory Commitments

Part II of this QAPD describes the portion of the QMS required to meet the requirements of the United States of America contained in 10 CFR Part 50 Appendix B, 10 CFR Part 21, and ASME NQA-1-2008 Edition with the NQA-1a-2009 Addenda. 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. GEH may extend this program to other areas that do not meet these criteria.

Part III addresses the supplemental portions of the QMS that are not specifically addressed by 10 CFR 50 Appendix B or NQA-1 to create an integrated quality program for projects that may refer to ISO 9001, GS-R-3, KTA-1401 and others as applicable. Part III is not reviewed or approved by the NRC.

In some cases, Part II and Part III of this QAPD are supplemented by quality plans at specific locations or functional areas of GEH to assist in the implementation of the specific requirements for those activities. In all cases, this QAPD will be a referenced document. Regardless, this QAPD document is the overall description of the GEH Nuclear Energy Quality Assurance Program that implements the GEH Quality Management System. When there are conflicts between the requirements of any of these documents, the QAPD shall be followed, and the conflict shall be reported in accordance with Part II, Section 16 of this document.

This QAPD is applicable at the following GEH facilities and other locations performing contracted services:

- Wilmington, NC
- San Jose, CA
- Pleasanton, CA (Vallecitos Site)
- Twinsburg, OH (Reuter Stokes)
- Philadelphia, PA (Service Shop)
- Kurihama, Japan (NOTE: GNF-J utilizes Part I and II of this QAPD for 10 CFR 50, Appendix B activities. GNF-J maintains a separate ISO quality program that is not covered under the scope of this QAPD)

PART II QAPD DETAILS

1.0 ORGANIZATION

1.1 General

This Section describes the GE Hitachi Nuclear Energy (GEH) organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying the Quality Assurance Program Description (QAPD).

1. The GEH organizational structure encompasses those positions responsible for establishing, managing, implementing, verifying, interpreting, and continually improving the GEH Quality Management System (QMS).
2. This QAPD describes the relationships of organizations within GEH, and between GEH and principal contractors, in regard to responsibilities and authority for performing activities within the scope of the QAPD.
3. Adherence to this QAPD includes the organizational elements located at the GEH headquarters facility in Wilmington, NC and all satellite facilities of GEH.
4. Additionally, adherence to this QAPD may be applied to work performed at customer or supplier locations where required by either regulations or contract requirements.

1.2 Management Commitment

1. The GEH businesses shall implement this quality program and demonstrate, by performance outside and inside the Company, total dedication to the attainment of quality leadership.
2. GEH management is committed to implement and maintain a Quality Management System and continually improve its effectiveness by:
   - Communicating to the organization the importance of meeting customer, statutory and regulatory requirements
   - Establishing the quality policy
   - Ensuring that quality objectives are established
   - Conducting management reviews
   - Ensuring the availability of resources
3. Top management ensures that the quality programs are communicated to all employees. To achieve this, any or all of the following may be used:
   - Company communications
   - All employee meetings
   - Staff meetings
   - Internal correspondences and memos
   - Training

1.3 Organizational Structure

1. For the purposes of managing the GEH Quality Management System, the organizational structure is shown in Figure 1.

2. Organizational Charts that depict typical organizational structure and functional descriptions are controlled and included in applicable plans, procedures and instructions and in project plans/procedures for specific work/project to be performed.

1.3.1 Profit and Loss Organizations

The GEH business is comprised of distinct areas with financial responsibility for delivery of products and services called Profit and Loss Organizations (P&Ls) including Nuclear Fuels & Services and Nuclear Plant Projects.

1.3.1.1 Nuclear Fuels & Services

1. The Nuclear Fuels & Services business is comprised of the two organizations - Fuels and Services.
2. The Services organization includes multiple business segments responsible for the marketing and/or delivery of all non-fuel parts and services to GEH nuclear power plant customers worldwide including: design and engineering, replacements, inspections, and modified/repaired products provided to comply with regulatory requirements, support continued plant operation, or to improve plant performance.
3. The Fuels organization includes multiple business segments responsible for marketing and/or delivery of all fuel related parts and services to nuclear power plant customers worldwide including: design and engineering, replacement, inspections, and modified/repaired products provided to comply with regulatory requirements, support continued plant operation, or to improve plant performance.
4. Additionally, fuel may be provided and field services performed at the client's site or at a GEH authorized service facility. Activities performed at the customer site locations or GEH's authorized service facilities are controlled by quality plans, procedures and instructions, as applicable.

1.3.1.2 Nuclear Plant Projects

Nuclear Plant Projects (NPP) has the primary responsibility to manage development, design, analysis, procurement, and construction of nuclear power plants.

1.3.2 Support Organizations

Support Organizations facilitate the activities of the P&Ls and include:

- Engineering
- Global Supply Chain
- Sourcing
- Information Management
- Nuclear Oversight
  - Quality
  - Regulatory Affairs
  - Environmental Health and Safety
- Finance
- Sales and Marketing
- Communications

- Legal
- Human Resources

1.3.3 Nuclear Oversight

The Nuclear Oversight organization supports the business by providing:

- Quality Oversight
- Performance Improvement, including the Corrective Action Program

1.4 Management Positions

Key organizational management positions are described below. The specific organizational titles for the quality assurance functions are identified in procedures. The authority to accomplish the quality assurance functions described is delegated to the incumbent's staff as necessary to fulfill the identified responsibility. Any internal disagreements that cannot be resolved through the system described in this QAPD are to be submitted to the President's office for resolution

1.4.1 President and Chief Executive Officer

1. The President reports to the President of GE Power and Water and the Governing Board of GE-Hitachi Nuclear Energy LLC.
2. The President has executive responsibility and sets appropriate policy, goals and objectives to ensure the total quality of all GEH products and services.
3. The President retains specific duties and responsibilities that cannot be delegated. These include but are not limited to:
    - Approving this QAPD through the Statement of Policy
    - Establishing the GEH organizational structure, including the organizational roles, responsibilities, authority and accountability
    - Integrating quality assurance program activities into overall business activities
    - Monitoring key performance indicators as part of a management review
4. The GEH President has established forums for communication and periodic reviews of quality objectives and business commitments with the business segments and quality management, including but not limited to:
    - Periodic reviews of business and quality objectives (customer scorecards, delivered product defects, corrective actions, trends, and process improvements)
    - Management reviews of the status and adequacy of the GEH Quality Management System

1.4.2 Nuclear Oversight (NOS) Senior Vice President

1. The GEH NOS Senior Vice President (SVP) reports to the President and Chief Executive Officer.
2. The GEH NOS SVP is responsible for governance and implementation of the QAPD in accordance with regulatory requirements and GEH company requirements/commitments.
3. The NOS SVP reports to top management on the performance of the quality program and any need for improvement.

4. The NOS SVP is responsible for maintaining this QAPD and an organization that is appropriately staffed to effectively manage its duties and responsibilities.
5. The NOS SVP assigns the responsibility to appropriate quality leaders in the business the authority and organizational freedom to carry out the following:

   (a) identification of quality assurance issues;
   (b) initiation of corrective action;
   (c) verification that required action has been properly implemented;
   (d) limitation to or control of further processing, delivery or installation of a nonconforming item, or unsatisfactory condition until proper disposition has occurred;
   (e) performance of audits for the adherence to and effectiveness of the overall quality assurance program; and
   (f) freedom to oversee and verify compliance with the regulatory requirements and industry and international standards.

1.4.2.1 Quality Oversight Leader

1. The Quality Oversight Leader reports to the NOS SVP.
2. The Quality Oversight Leader is assigned the responsibility for the activities of quality program audits to assess the effectiveness of implementation of the requirements set forth in this QAPD.
3. Additional responsibilities include the implementation of cross-functional and cross-organizational activities as assigned by the GEH NOS SVP.
4. 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 NOS SVP.

1.4.2.2 Performance Improvement Leader

1. A representative from the NOS Organization who reports to the GEH NOS SVP and is assigned the responsibility for ensuring business results are achieved through effectively monitoring performance, identifying specific actions to improve less-than-expected performance, and implementing change to improve performance.
2. The Performance Improvement Leader has the responsibility to implement the GEH Corrective Action Program.

1.4.3 Business Leaders for Profit and Loss Organizations (P&L) and Global Supply Chain Organizations

1. Activities affecting quality are performed under the direction of Business Leaders who report to the President for purposes of the responsibilities of this QAPD.
2. 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.
3. Reporting to the P&L Business Leaders are the P&L Quality Leaders.

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

1.4.3.1 Profit & Loss Quality Leaders

1. Representatives from the P&L Organization who report directly to the P&L Business Leader and dotted line to the GEH NOS SVP and are assigned the responsibility to support the implementation of the quality requirements set forth in this QAPD for the organization they are assigned.
2. These Quality Leaders are responsible for verification that administrative controls are implemented or assuring that an activity has been correctly performed within their assigned organizations.
3. This verification includes leadership of quality engineers, inspection personnel, and performance of independent assessment or verification activities.
4. 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 Business Leader and the NOS SVP.

1.4.4 Sourcing General Manager

1. The Sourcing General Manager is responsible for the quality management of the GEH supplier base.
2. The Sourcing General Manager is responsible for providing a process for receiving inspection activities.

1.4.5 Functional Responsibilities

The functional responsibilities of P&L Organizations, Support Organizations, and the NOS Organization are detailed in implementing procedures.

1.4.6 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.

1.5 Responsibilities of all Employees and Contractors

All employees and contractors are responsible for the following:

- Ensuring strict compliance with laws and regulations pertaining to the quality, safety, and performance requirements in every country where GEH products and services are offered.
- Incorporating quality in their routine work activities such as, but not limited to: qualifying suppliers; preparing, reviewing, verifying, and approving designs; purchasing; preparing procurement documents; manufacturing; installation; assessing; and controlling records.

- Reporting conditions that are not consistent with the requirements of the QAPD through the Corrective Action Program.

1.6 Authority to Stop Work

1. All employees and contractors have the authority and responsibility to stop work if continuing the work is or could be detrimental to the final product or would be masked by successive manufacturing activities or if the activity is not compliant with the procedural guidance or would create an unsafe condition.
2. The GEH NOS SVP, Nuclear Oversight organization and the P&L Quality Leaders have the authority and the responsibility to issue a stop work notice and control further processing, delivery, installation, or use of nonconforming products or services.
3. This authority is to ensure that cost and schedule considerations do not override quality or safety considerations.

1.7 Delegation

1.7.1 Delegation Inside the GEH Organization

1. Each Manager, Supervisor or Leader may assign the performance of their duties to their direct reports who are qualified to perform such duties. However, the responsibility for those duties cannot be assigned or delegated.
2. Managers, Supervisors or Leaders, if qualified, may perform the work for their subordinates.
3. Sufficient authority to accomplish the assigned tasks is also delegated, although the President, NOS SVP and other positions identified herein retain overall responsibility for the program.

1.7.2 Delegation Outside the GEH Organization

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

- The organizational elements responsible for the 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 Quality Assurance Program and the extent of management oversight is established.
- The performance of delegated work is formally evaluated.

1.8 Commitment

In establishing its organizational structure, GEH commits to compliance with 10 CFR Part 50 Appendix B, Criteria I, and NQA-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 1.

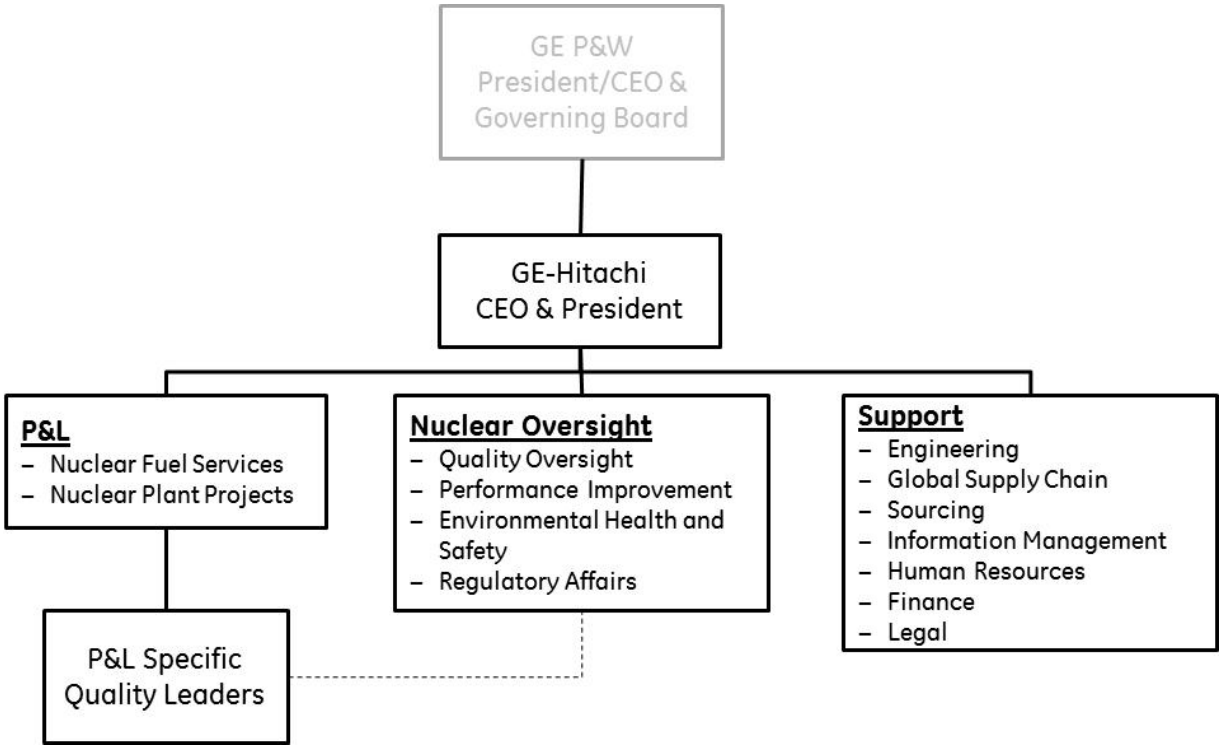

FIGURE 1: ORGANIZATIONAL STRUCTURE

2.0 QUALITY ASSURANCE PROGRAM

2.1 General

This section describes the GE Hitachi Nuclear Energy (GEH) quality assurance program, as documented through this Quality Assurance Program Description (QAPD) and its implementing policies, procedures and instructions, and identifies the associated requirements for planning, implementing, monitoring, and maintaining the program. This program was documented, approved, and implemented prior to the commencement of the activities within its scope.

1. The quality assurance program is maintained and continually improved through the use of quality policies, quality objectives, periodic audit and assessment results, analysis of data, corrective and preventive action, and periodic management review.
2. The quality 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.
3. Controls are provided over activities affecting quality to an extent consistent with the importance of those activities.
4. The President, Nuclear Oversight Senior Vice President and other positions identified herein retain and exercise the responsibility for the scope and implementation of an overall QAPD.
5. 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; instructions, procedures and drawings; document control; control and identification of purchased material parts and components; special processes; test and inspection; control of Measuring and Test Equipment (M&TE); handling, storage and shipping; maintenance of test, inspection and operating status of items; control of nonconforming material; corrective action; records, and audits.
6. Project, product, or service specific Quality Plans may be developed to supplement the requirements of this QAPD and provide for specific contractual requirements and alternate quality assurance standards when necessary.

2.2 Controlled Conditions

1. Planning and performance of activities affecting quality are accomplished under suitably controlled conditions as delineated in appropriate implementing procedures and instructions.
2. Controlled conditions include:
   - The use of appropriate equipment (hardware and software)
   - Suitable workspace and utilities
   - Suitable environmental conditions for accomplishing the activity, such as adequate cleanliness
   - Supporting services to achieve conformity to product and service requirements
   - Assurance that all prerequisites for the given activity have been satisfied.
3. Special controls, processes, test equipment, tools, and skills to attain the required quality of activities or items and verification are provided.

4. Work environment in the manufacturing, assembly, inspection, test, and material storage areas is maintained as required to achieve conformity to product specifications, applicable standards, and regulations.
5. GEH policies, procedures and instructions related to Quality and Environmental Health and Safety, define the implementation of requirements for adequate and safe facilities and plant activities.

2.3 Indoctrination and Training

1. GEH personnel indoctrination and training is commensurate with the scope, complexity, and importance of the activities; and with the education, experience, and proficiency of the personnel performing the activity.
2. Training shall be provided to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities.
3. On-the-job training shall be used if direct hands-on applications or experience is needed to achieve and maintain proficiency.
4. Personnel performing or managing activities affecting quality receive indoctrination and training in their job responsibilities and authority, that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality requirements.
5. Records of indoctrination and training include the employee's name, topic covered and date of completion.

2.4 Qualification Requirements

1. Quality-related activities that require qualification of personnel are listed in this section.
2. Qualification is controlled by written procedures and only those personnel who have met the requirements are permitted to perform these activities.
3. The qualification of inspection, test, auditor, lead auditor and special process personnel shall be certified in writing and records thereof maintained.
4. The need for initial and periodic special physical characteristics and physical examination of personnel shall be identified, and copies of appropriate objective evidence shall be retained.

2.4.1 Nondestructive Examination

The companies that have adopted this QAPD shall 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 examination in accordance with applicable industry codes and standards.

2.4.2 Inspection and Test

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

2.4.3 Lead Auditor

1. Requirements for a lead auditor's qualification are defined in written procedures.
2. The evaluation criteria include education, experience, communication skills, training, audit participation, examination as well as maintenance of proficiency and requalification.
3. Audit team members, including technical specialists, shall have, or be given, appropriate training (including orientation) to develop their competence for performing audits.

2.5 Detection and Correction of Quality Problems

1. 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.
2. The corrective action program is described in Section 16 of this QAPD.

2.6 Assessment of Effectiveness

1. Quality personnel monitor activities affecting quality against acceptance criteria to ensure satisfactory performance. These criteria are outlined in implementing procedures.
2. GEH management reviews the GEH Quality Management System to ensure its continuing suitability and effectiveness. The review is performed to integrate and communicate quality-related matters, problems, corrective actions, status and effectiveness of assigned projects for continuous improvement, and annual reports on the status and adequacy of the quality management system to the top level management. These reviews identify opportunities for improvement and needed changes. Records are maintained of the management review meetings.

   (a) During management reviews, typical input includes the following:
   - Results of audits and assessments
   - Customer feedback
   - Customer and regulatory requirements
   - Process performance and product conformity
   - Status of corrective and preventive actions
   - Follow-up actions from previous management reviews
   - Planned changes that could affect the Quality Management System
   - Recommendations for improvement

   (b) Output from the management review shall include decisions and actions related to the following:
   - Improvement of the effectiveness of the Quality Management System and its processes
   - Improvement of product related to customer requirements
   - Resource needs to ensure proper implementation of the Quality Management System, and assignment of responsibilities for completing actions
3. Managers review those portions of the program under their area of responsibility.
4. To ensure effective implementation, these reviews take place at least once each fiscal year.

2.7 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.

2.8 Quality Assurance Program Description Management

1. Changes that are made to the QAPD that are a reduction in commitment are submitted to the US NRC for review and approval per 10 CFR 50.4(b)(7)(ii).
2. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered to be reductions in commitment:
   (a) The use of a QA standard approved by the NRC which is more recent than the QA standard in the QAPD at the time of the change;
   (b) The use of a quality assurance alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to GEH;
   (c) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;
   (d) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text;
   (e) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which GEH is committed;
   (f) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations; and
   (g) Any change to Part III, “Supplemental Details” or Part IV, “References” that do not entail NRC related standards (i.e. ISO 9001, KTA-1401, GS-R-3).
3. A new revision of the QAPD is created and numbered as NEDO-11209 prior to submittal to the NRC for review and approval. After the NRC approval is received, the QAPD is revised to incorporate the “-A” to the document number (NEDO-11209-A) to denote the NRC approval. For changes per Section 2.7(2) that do not reduce commitments, the NRC acceptance of the previous revision will carry forward by retaining the “-A” on the new revision, and GEH shall submit the revision of the QAPD to the NRC, for information.

2.9 Commitment

In establishing its Quality Assurance Program, GEH commits to compliance with 10 CFR Part 50 Appendix B, Criteria II and NQA-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 2.

3.0 DESIGN CONTROL

3.1 GENERAL

1. The engineering organizations of the companies that have adopted this Quality Assurance Program Description (QAPD) have overall responsibility for the control of the design process from its inception to the final result.
2. 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.
3. The GE Hitachi Nuclear Energy (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.
4. This section describes control of the design inputs, design processes, design analyses, design verification, change control, interface control, Quality Assurance (QA) responsibilities, and documentation and records.
5. 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

1. Engineering is responsible for identifying and documenting design inputs for each design project.
2. Sources of design input may include: customer specifications, design bases, previous similar designs, regulatory requirements, functional requirements, and industry standards as well as other technical, commercial, and performance requirements.
3. 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.
4. 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.
5. Applicable information derived from plant operating and construction experience is made available to the responsible organization as appropriate.
6. When structures, systems, and components (SSC) necessary for safety are selected for a design, the selection and review criteria are conducted according to implementing procedures.
7. 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

1. 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. The procedures related to design and development processes describe the details of the design and development stages with responsibilities and authorities; and appropriate review, verification, and validation activities.
2. For each specific design project, the GEH design organization documents and organizes the design information in sufficient detail to permit the design process to be performed in a correct manner.
3. Appropriate quality standards are also identified and their selection reviewed and approved.

3.3.2 Design Methods

1. The design methods, materials, parts, equipment, and processes that are essential to the function of the structures, systems, and components (SSC) or to the completion of a design report are selected and independently reviewed for suitability for their intended application.
2. 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.
3. The design organization may also maintain applicable lessons learned information derived from experience for use by responsible design personnel.

3.3.3 Design Result

1. The engineering organizations are responsible for delivering design output that meets design process 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
    - For commercial grade items refer to Section 7.8 of this QAPD.
2. 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.

3. 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.
4. Characteristics critical to the safe and proper functioning of the product are classified and designated on the appropriate drawings and specifications according to implementing procedures or appropriate international practices specified by the customer.
5. The design and development outputs provide information for purchasing, production, and product acceptance criteria.
6. Requirements for special processes such as welding, heat-treating, and nondestructive examination are specified on design documentation by the GEH engineer responsible for the design.

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

1. Computer programs used for design analyses include commercially purchased software and software developed for specific applications.
2. 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.
3. Pre-verified computer programs are controlled to ensure that changes are documented and approved by authorized personnel.
4. When pre-verified computer programs are used, the encoded mathematical model does not need to be verified.

3.4.2 Documentation of Design Analyses

1. Documentation of design analyses is legible, reproducible, and includes 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
- Identification of the persons originating and performing the review, verification and approval

2. 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.

3.4.3 Design and Development Review

1. The design and development activities are reviewed according to the requirements of the related design review procedures. The review process evaluates design outputs against input requirements; and provides an opportunity to take actions on any problems identified.
2. The review team consists of representatives of functions concerned with the activity.
3. Records of the results of the reviews and any necessary actions are maintained.

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

1. The responsible design organization identifies and documents the design verification scope and method(s) used.
2. The results of design verification are documented with the identification of the verifier clearly indicated.
3. 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.
4. 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

1. 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.
2. 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

1. The extent of the design verification is a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art and the similarity with previously proven designs.
2. The extent is defined by the originator in the verification scope, agreed to by the verifier, and approved by the supervisor.
3. 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.
4. Known problems affecting previously verified designs and their effects on other features are considered.
5. 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

1. Design reviews for verification may be performed by an individual or by a team.
2. 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 verifications 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

1. Alternate calculations by alternative methods are required for verification of calculations unless pre-verified computer programs are used within their applicable defined limits.

2. The appropriateness of assumptions, input data, and calculation method used are considered.
3. 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

1. 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.
2. Where the test is intended to verify only specific design features, the other features of the design are verified by other approved verification methods.
3. 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.
4. 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.

3.5.6 Design and Development Validation

1. Design validation is performed to ensure that a design meets a customer's requirements. Validation is normally performed for the final product under controlled conditions by testing, lead use assemblies, following the performance of a lead unit(s), environmental testing, system and plant pre-operational and startup testing, mock-up testing, etc., preferably prior to delivery to customer.
2. Requirements for Engineering tests/inspections and tests/inspections at Operating Plants are specified in implementing procedures.

3.6 Change Control

1. Changes to design inputs, final designs, field changes, 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.
2. These measures include evaluation of effects of those changes on the overall design and on any analysis upon which the design is based.
3. 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.
4. The same affected groups or organizations that reviewed and approved the original design documents shall approve design changes.
5. 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.
6. 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.

7. Design change requests from the field are processed in accordance with procedures relating to field deviation disposition requests and field disposition instructions for the communication of instructions to the field to implement approved changes.
8. Records of the changes, reviews, and any necessary actions are maintained in accordance with applicable procedures for processing design records.

3.7 Interface Control

1. The companies that have adopted this QAPD are responsible to control interfaces among themselves and between their organizations and their subcontractors and suppliers.
2. 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.
3. 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.
4. 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

The GEH software design process ensures the following is documented:

1. Software Design Requirements such as operating system, function, interfaces, performance requirements, installation considerations, design inputs and design constraints.
2. Software Design details such as numerical methods, mathematical models, physical models, control flow, control logic, and data flow (may be combined with the software design requirements documentation).
3. Implementation of Software Design – translation of the software design into computer program(s).
4. 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.
5. 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).

1. Configuration Identification - The GEH software responsible organization establishes a baseline as each activity of the software design program is completed.

2. Configuration Change Control - Changes to software are formally documented and are subject to the software design verification process.
3. 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

1. Design documentation and records, that 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.
2. 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-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 3.

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 General

This section describes the GE Hitachi Nuclear Energy (GEH) program that ensures 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, and procedures or instructions including revisions that describe the items or services to be furnished
- Appropriate customer unique requirements, including customer specified surveillance or inspection at the supplier's facility
- The procurement documents also identify appropriate test, inspection and acceptance criteria for evaluating the supplier's performance
- Requirements for qualification of personnel
- Quality Assurance Program Requirements – A reference to the supplier's documented Quality Assurance 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 Quality Assurance 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 per Section 7.8 of this QAPD.

4.3 Review of Procurement Documents

1. Technical or quality changes made as a result of bid evaluations or negotiations are incorporated in the procurement documents prior to issuance.
2. 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-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 4.

5.0 INSTRUCTIONS, PROCEDURES, 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

1. 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 or work instructions. These procedures shall be readily available at their point of use.
2. Activities affecting quality are suspended if they cannot be accomplished as described in controlled implementing procedures.
3. Engineering drawings and specifications are also controlled to ensure that products are identified during all stages of production, delivery, and installation; and that the products are traceable.

5.3 Content of Procedures

1. 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.
2. 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-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 5.

6.0 DOCUMENT CONTROL

6.1 General

GE Hitachi Nuclear Energy (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.

1. The operation and use of the document control system (including electronic systems used to make documents available at points of use) is documented and provides for the following:

   - Identification of internal and external documents to be controlled
   - Identification of the correct document (including revision) to be used and control of superseded documents
   - Distribution for use at the appropriate location
   - Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents
   - Review of documents for adequacy, completeness, legibility 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

2. 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 Quality Assurance Program Description (QAPD)
   (i) Technical requirements
   (j) Nonconformance reports

6.2 Review and Approval of Documents

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

6.3 Changes to Documents

1. 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.
2. The reviewing organization is given access to pertinent background data or information upon which to base their approval.
3. 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.
4. 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

1. Temporary procedures include designation of the period of time during which it is valid to use them.
2. Temporary procedure changes 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-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 6.

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

7.1 General

1. This section describes the GE Hitachi Nuclear Energy (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
   - Identification of Quality Assurance Records

2. GEH retains the responsibility for any outsourced processes that affect product or service conformity with requirements.

7.2 Supplier Evaluation and Selection

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

4. Suppliers that meet the requirements are placed on the GEH Approved Supplier List (ASL) and are subject to periodic re-evaluation and assessments based on the established guidelines and requirements.

7.3 Proposal/Bid Evaluation

1. The proposal/bid evaluation process is required to include a determination of the supplier's capability to conform to technical and quality assurance requirements.
2. 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

1. Supplier generated documents are controlled, processed, and accepted in accordance with established methods.
2. These measures must provide for the acquisition (per procurement document requirements; reference Section 4 of this QAPD), processing, and recorded evaluation of technical, inspection, and test data compared against the acceptance criteria.
3. If GEH approval of supplier procedures is required, this approval is accomplished prior to the supplier's use.
4. Instructions are provided for the retention and disposition of quality assurance records that are to be retained by the supplier.

7.5 Control of Supplier Nonconformances

1. GEH and its suppliers establish and document methods for disposition of nonconforming items and services in their purchase agreements.
2. Suppliers are instructed to send GEH all nonconformance reports from procurement documentation requirements generated during the manufacturing process.
3. As a minimum, nonconformance 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
   - A technical justification for each corrective action identified
4. 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 consists of one or more of the following:
   - A violation of technical or material requirements
   - A violation of a GEH-approved requirement in supplier documents
   - A nonconformance that cannot be corrected by continuation of the original manufacturing process or by rework (i.e., use-as-is)
   - 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 Services

1. Suppliers are required to verify that furnished items or services comply with GEH procurement document requirements before offering the items or services for acceptance.
2. 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 quality function and whose responsibilities and position are described in the supplier's quality assurance 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

1. GEH may accept an item or service by source verification such as monitoring, witnessing, or observing activities performed by the supplier.
2. Source verification is implemented at intervals consistent with the importance and complexity of the item or service.
3. Source verification is planned and performed so that observations of specific activities at predetermined points can be accomplished and may include customer required involvement.
4. 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

1. When receiving inspection is used, items are verified by objective evidence, which includes such features as:

   (a) Item configuration
   (b) Item identification

(c) Item dimensional, physical or other characteristics
(d) Whether or not the item is free from shipping damage
(e) Item cleanliness

2. 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, 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
(c) A review of any objective evidence for conformance to the procurement document requirements

7.7 Supplier Performance Evaluation

1. GEH, as a purchaser of items and services, establishes measures to interface with its suppliers to verify their performance.
2. 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 any 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

3. 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

1. 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.
2. Such controls include, but are not limited to the following:
   (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
   (d) Selection, performance (inspection/test/survey/surveillance), acceptance, and documentation of the dedication methods for determining compliance with the critical characteristic acceptance criteria
3. The commercial grade item or service dedication process will be controlled via documented procedures and retention of objective evidence.

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
(c) Supplier nonconformances to procurement document requirements, including a description of their evaluation and disposition

7.10 Commitment

1. 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-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 7 with the following exceptions:

   - 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), International Accreditation Services (IAS) or Perry

Johnson Laboratory Accreditation, Inc. (PJLA) 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.

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

   - 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 the following US NRC Generic Letters:
     - 89-02, Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products (3/89)
     - 91-05, “Licensee Commercial-Grade Procurement and Dedication Programs” (4/91)

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

8.1 General

GE Hitachi Nuclear Energy (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).

1. Integral to the program are measures for preventing the use, shipment, or installation of incorrect or unacceptable items.
2. The program provides for the identification of each item that is established and maintained throughout fabrication, erection, installation, and use so the item can be traced to its documentation.
3. The identification and control measures provide for relating an item or product (batch, lot, part, or assembly) at any stage, from material receipt through fabrication and shipment to an applicable design drawing, specification, or other pertinent control document.
4. 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

1. Procedures related to material and equipment traceability requirements are used to assure product identification and traceability.
2. Item identification is maintained through the life of the product, component, part, or item so marked.
3. 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.
4. Items in the production stream, whether they are batch, lot, component, or part items, are identified from initial receipt from the supplier through fabrication, delivery, installation, and use.
5. 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

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

8.4 Maintenance of Marking

1. 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.

2. 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.
3. 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-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 8.

9.0 CONTROL OF SPECIAL PROCESSES

9.1 General

The GE Hitachi Nuclear Energy (GEH) program ensures that special processes such as welding, heat treating, and nondestructive examination are properly controlled.

1. Special processes are accomplished by personnel qualified under associated codes, standards, regulations, specifications, design criteria and other special requirements.
2. Special processes are conducted in accordance with the applicable codes, standards, regulations, specifications, design criteria and other special requirements, procedures, and equipment.
3. Control is accomplished through the use of instructions, procedures, drawings, checklists, or other appropriate means within established parameters and is maintained under specified environmental conditions.
4. Each special process work instruction will include, or reference, procedures, personnel, and equipment qualification and calibration 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, and their revalidation, 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-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 9.

10.0 INSPECTION

10.1 General

This section describes the GE Hitachi Nuclear Energy (GEH) program for inspection of items and activities to verify conformance to requirements and adherence to documented instructions, procedures, and drawings.

1. Inspection types include, but are not limited to:
   - source,
   - in process,
   - final,
   - receipt,
   - maintenance,
   - modification,
   - in-service, and
   - operations
2. 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.
3. Appropriately controlled measuring and test equipment (reference Section 12.0 of this QAPD) shall be used in the performance of the inspections.

10.2 Inspection Personnel

1. Inspections are performed by independent personnel who have not performed the work and do not report to the supervisors responsible for the work being inspected.
2. Those activities that require qualified inspection personnel are defined per implementing procedures or instructions.

10.3 Planning

1. Provisions are incorporated into inspection work instructions to ensure inspection planning is properly accomplished to assure quality of product or service.
2. Planning activities identify the characteristics and activities inspected, sample size, inspection methods, acceptance criteria, and organization responsible for performing the inspection.
3. 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.
4. Examinations, measurements, or tests of material or products processed are performed for each work operation where necessary to ensure quality.
5. Inspections and tests are utilized to ensure control of special processes as designated in applicable test and inspection procedures.

10.3.1 Sampling

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

10.3.2 Hold Points

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

10.3.3 Process Monitoring

1. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring process methods, equipment, and personnel are provided.
2. Both inspection and process monitoring are provided when control is inadequate without both.
3. When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This is completed prior to initial use and reconfirmed as necessary.

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

1. Only authorized personnel are permitted to accept the work being inspected.
2. Release of product to ship is authorized by issuing a Product Quality Certificate.

10.5 Records

Appropriate records are established, maintained, and include the following as a minimum:

(a) Item inspected

(b) The date of the inspection
(c) The name of the inspector
(d) The type of observation
(e) The acceptability of the result
(f) 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-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 10.

11.0 TEST CONTROL

11.1 General

1. This section establishes the GE Hitachi Nuclear Energy (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.
2. Characteristics to be tested and test methods to be employed are specified.
3. The test program includes proof tests before installation, preoperational tests, post maintenance tests, post modification tests, and operational tests as appropriate.
4. Test results are documented and their conformance with the test requirements and the acceptance criteria are evaluated.

11.2 Test Requirements

1. Test requirements and acceptance criteria are provided in an applicable design, or other pertinent technical document, and are approved by the responsible design organization.
2. Criteria are defined that specify when testing is required and activities that require qualified test personnel.
3. Required tests are controlled under appropriate environmental conditions using the tools and equipment, including appropriately controlled measuring and test equipment (reference Section 12.0 of this QAPD), necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria.
4. The tests performed obtain the necessary data with sufficient accuracy for evaluation and acceptance.
5. 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

1. Test procedures include or reference the test configuration and test objectives.
2. 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.
3. Prerequisites include the following, as applicable:

   (a) The test 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
   (f) The provisions for data acquisition must be working and in good order

4. 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.

1. Computer program test procedures provide for demonstrating the adherence of the computer program to documented requirements.
2. For those computer programs used in design activities, computer program test procedures provide for assuring that the computer program produces correct results.
3. 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.
4. 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.
5. In-use test procedures are developed and documented to permit confirmation of acceptable performance of the computer program in the operating system.
6. 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.
7. 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.
8. 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
   (i) The reports, records, standard formatting, and conventions in which the results must be reported

11.4 Test Results

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

11.5 Test Records

1. 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.
2. 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
   (g) The name of the person evaluating test results
3. 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
   (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-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 11.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 General

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

12.2 Selection of Equipment for Use

1. Selection of M&TE is based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements.
2. The utilization of M&TE is traceable to their application and use.

12.3 Calibration Process

1. M&TE are calibrated at prescribed intervals, or whenever the accuracy of the M&TE is suspect, or prior to use.
2. 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 or verification is documented.
3. M&TE is safeguarded from adjustments that would invalidate the measurement result.
4. M&TE is protected from damage and deterioration during handling, maintenance and storage.
5. Calibration tolerance relative to the accuracy of reference standards used and the M&TE calibrated shall be addressed in calibration documentation. When tolerance ratios become close, the basis for the selection of the specific reference standard shall be technically justified.

12.4 Control of Calibration Status

1. M&TE are suitably marked, tagged, labeled, or otherwise identified to indicate calibration status and establish traceability to calibration records.
2. M&TE that is overdue for calibration or found to be out-of-calibration is tagged and/or segregated, removed from service, and not used until it has been recalibrated.

3. M&TE consistently found to be out-of- calibration will be repaired or replaced.

12.5 Records

12.5.1 General

Records are established and maintained to indicate calibration status and the capability of M&TE 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.

12.5.3 Out of Calibration

1. When M&TE is lost, damaged or found out-of-calibration, the validity of previous measurements, inspections, or test results, and the acceptability of items previously inspected or tested from the last acceptable calibration shall be evaluated.
2. The responsible quality organization assesses and records the validity of the previous measuring results.
3. Appropriate action is taken on the equipment and any product affected.

12.6 Commitment

In establishing a M&TE calibration program, GEH commits to compliance with 10 CFR Part 50 Appendix B, Criteria XII and NQA-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 12.

13.0 HANDLING, STORAGE, AND SHIPPING

13.1 General

1. GE Hitachi Nuclear Energy (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.
2. Customer supplied material is controlled to ensure that the material is received, inspected, stored, and maintained in a controlled environment; and that any customer supplied material that is lost, damaged, or is otherwise unsuitable for use be reported to the customer.
3. The design of packaging and shipping containers is procedurally controlled by packaging related procedures for GEH Procured or Manufactured Items.

13.2 Instructions

Cleaning, handling, storing, packaging, shipping, and preservation of items are controlled by written instructions, drawings, specifications or other pertinent documents. Sufficient labeling is provided to identify the items and to indicate any special conditions needed to prevent degradation.

13.3 Special Controls

1. Special controls (such as containers, shock absorbers, and accelerometers) and environments (such as inert gas atmospheres, specific moisture content levels, and temperature levels) are provided and verified when required to maintain acceptable quality.
2. The presence of these special environments is indicated by marking the exterior of the container to prevent premature penetration of the sealing boundary.
3. The need for special controls or specific procedures is established on a case by case basis according to the item’s complexity, use, and sensitivity to damage. Consideration for critical, sensitive, perishable or high-value items should be incorporated in controls and procedures.

13.4 Special Tools and Equipment

1. Special handling tools and equipment will be used and controlled as necessary to ensure safe and adequate handling.
2. Special handling tools and equipment will be inspected and tested at specified time intervals, or prior to use, 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-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 13.

14.0 INSPECTION, TEST, AND OPERATING STATUS

14.1 General

GE Hitachi Nuclear Energy (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

1. 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, or released for subsequent operations or shipment.
2. The inspection and test status is maintained through the use of physical location, status indicators (such as tags, markings, shop travelers, stamps, or 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-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 14.

15.0 NONCONFORMING MATERIAL OR COMPONENTS

15.1 General

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

15.2 Identification and Control

1. 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.
2. Nonconforming items that are segregated are placed in a clearly identified and designated hold area until they can be properly dispositioned.
3. 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.
4. 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

1. The responsibility and authority for the evaluation and disposition of nonconforming items is defined in implementing procedures.
2. Responsibility for the control of further processing, delivery, installation, or use of nonconforming items is designated in writing.
3. 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
   (c) Access to pertinent background information
4. Dispositions can include:

   - Rework – the process by which an item is made to conform to original requirements by completion or correction.
   - 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.
   - 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.

5. Technical justification for the acceptability of a nonconforming item dispositioned in either the repair or use-as-is categories must be documented.
6. Nonconformances to design requirements dispositioned use-as-is or repair are subject to design control measures commensurate with those applied to the original design.
7. Required as-built records reflect the use-as-is or repair condition.
8. When required by contract, the proposed disposition is submitted to the Customer for approval prior to acceptance for delivery.
9. Each nonconformance is reviewed to determine if such nonconformity may exist in the delivered products. If there is a concern that a nonconformance could lead to creation of a substantial safety hazard, a request to initiate an evaluation is made in accordance with the Corrective Action Program for Reporting of Defects and Noncompliance Under 10 CFR Part 21.

15.4 Re-examination

1. Reworked, repaired, or replacement items are re-examined in accordance with applicable procedures and with the original acceptance criteria, unless otherwise stipulated.
2. 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-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 15.

16.0 CORRECTIVE ACTION PROGRAM

16.1 General

1. The GEH Corrective Action Program utilizes a system of implementing procedures to establish the necessary measures to promptly identify, control, document, classify, and correct Conditions Adverse to Quality (CAQs).
2. The GEH implementing procedures ensure that appropriate actions are initiated following the determination of CAQs in accordance with regulatory requirements and applicable quality standards.
3. These measures ensure that corrective actions are adequately documented and not inadvertently nullified by subsequent actions. Completion of corrective actions shall be confirmed.
4. GEH implementing procedures require personnel to identify known CAQs.
5. When complex issues arise, such that an immediate determination of whether a CAQ exists cannot be made, the GEH Corrective Action Program identifies a process for the documentation and timely evaluation of the issue.
6. If there is a concern that a CAQ that could result in a substantial safety hazard, a safety evaluation is requested in accordance with the Corrective Action Program for Reporting of Defects and Noncompliance Under 10 CFR Part 21.
7. 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 and reported to responsible management. Their cause is determined and actions to preclude their recurrence are taken.
8. Implementing procedures for the Corrective Action Program are used to ensure that:
   - All corrective actions from audits and self-assessments, all nonconformances, and customer complaints are analyzed to detect conditions or potential CAQs.
   - Changes in processes or procedures resulting from corrective and preventive actions are implemented and recorded.
9. The Corrective Action Program and related tools are utilized to document, track status, and maintain records of corrective and preventive action activities and results.
10. Warranty service and customer complaint related procedures are used to ensure that customer complaints are documented, dispositioned and resolved.

16.2 Identification of Trends

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

16.3 Corrective Action

1. Appropriate corrective actions are taken to resolve CAQs observed during internal or external audits.

2. Implementing procedures define the requirements for:

   - Reviewing CAQs and determining their severity level
   - Determining the root causes and their effects and extents
   - Evaluating the need for action to avoid recurrence
   - Determining and implementing corrective action needed
   - Reviewing corrective actions taken

16.4 Preventive Action

1. GEH identifies actions to eliminate the causes of SCAQs in order to prevent their reoccurrence. Preventive actions are taken as appropriate to address the causes of the problems.

16.5 Commitment

In establishing corrective action requirements, GEH commits to compliance with 10 CFR Part 50 Appendix B, Criteria XVI and NQA-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 16.

17.0 QUALITY ASSURANCE RECORDS

17.1 General

1. GE Hitachi Nuclear Energy (GEH) has established measures to provide provisions for the identification, administration, receipt, storage, preservation, safekeeping, retrieval, and disposition of all records such that damage or loss does not occur.
2. Quality records are established to provide objective evidence of conformance to requirements and effective implementation of the GEH quality management system.
3. The records system is defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation.
4. The applicable design specifications, procurement documents, test procedures, operational procedures, or other documents specify the records generated, supplied, and maintained. Records shall be traceable to associated items and activities, and accurately reflect the work accomplished or information required.
5. Records may be hard copy, electronic, or both.
6. Records shall be examined for adequacy, legibility, and completeness.
7. Safekeeping of records includes access control and protection from equipment malfunction.
8. Records shall remain legible, readily identifiable and retrievable, even after hardware, software or technology changes.

17.2 Administration

17.2.1 Personnel

1. Requirements and responsibilities for record transmittal, receipt, location, distribution, retention, maintenance, and disposition are described in implementing procedures.
2. 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 of data, the 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. Record controls shall provide for retrievability within planned retrieval times based on the record classification, type or content.

17.2.3 Corrections

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

17.3 Classification

Records are classified as Lifetime or Nonpermanent.

17.3.1 Lifetime Records

1. 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
   (d) Provision of required baseline data for in-service inspections and in-service tests.

2. 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

1. 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.
2. The retention period for nonpermanent records is established in implementing procedures.

17.4 Receipt Control

1. The person or organization responsible for receiving the records is designated.
2. 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 their possession.
3. 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.

4. 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

1. Documents are considered valid records only if stamped, initialed, authenticated, or signed and dated by authorized personnel.
2. This authentication may take the form of a statement by the responsible individual or organization.
3. 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

1. 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
    - Dust or airborne particles
2. Activities that may be detrimental to the records are prohibited in the designated storage area.
3. Access to the processing, storage, and retrieval of records is limited to authorized personnel.
4. 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 and dual.

1. Single storage consists of a storage facility, vault, room, or containers with a minimum two-hour fire rating.
2. 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.
3. 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. The requirements of Section 17.6.1 shall apply to both facilities.

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 are met.

17.6.4 Retention

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

17.6.5 Duplication/Transfer

Provisions are established to ensure that when records are duplicated or transferred to the same media or different media for the purpose of maintenance or storage, that the duplication or transfer is appropriately authorized, and that record content, legibility and retrievability are maintained.

17.7 Electronic Records

1. For Quality Assurance Records in electronic media, the GEH program includes controlling procedures with provisions for the generation, distribution, use, maintenance, storage, and disposition of electronic records.
2. The procedures identify the acceptable media on which electronic records may be created and stored. Also, the procedures include provisions to verify that the media is appropriate, suitable for the capture or storage of records, and error/defect free.
3. Electronic documents shall be authenticated with appropriate information on the media or with the information contained within or linked to the document itself.

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

1. Electronic records are subject to the same retention requirements as paper records.
2. 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

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

3. 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.
4. Transfer of authentication authority is documented and controlled in accordance with written procedures.

17.7.6 Storage

1. Electronic media should be stored in a dust-free environment and away from electronic devices and demagnetizing equipment such that no unacceptable degradation of the media occurs during the established retention period.
2. 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.
3. 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

1. 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.
2. 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-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 17, Generic Letter 88-18, and RIS 2000-18.

18.0 AUDITS

18.1 General

1. The GE Hitachi Nuclear Energy (GEH) audit program is 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.
2. 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.
3. Audit results are documented and reviewed by responsible management.
4. Follow-up action is taken where indicated.
5. If work under this QAPD is delegated to others, then the work is to be audited by GEH in accordance with this QAPD.

18.2 Personnel

1. 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.
2. 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.
3. 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

1. 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.
2. Internal audits of organizations and activities are conducted prior to placing a facility in operation and at least once a year subsequently.
3. Once activities have been established, internal audits are conducted to ensure all GEH Quality Assurance Program elements are evaluated for each functional area within a period of two years.
4. Activities with durations of less than one year are audited at least once during the life of the activity.
5. The audit schedule is reviewed periodically and revised, as necessary, to ensure that coverage is current.
6. When necessary to ensure adequate coverage, the scheduled audits may be supplemented by focused, in-depth audits or self-assessments covering specific subjects.

18.3.2 Audit Plan

1. The auditing organization develops and documents an audit plan specific to each audit.
2. 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, schedules, and written procedures or checklists to be used.

18.3.3 Audit Performance

1. Elements selected for audit shall be evaluated against specified requirements.
2. Objective evidence shall be examined to the depth necessary to determine if the elements are effectively implemented.
3. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

18.3.4 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 quality assurance program elements that were audited
(e) A description of each adverse audit finding in sufficient detail to enable an effective corrective action to be taken by the audited organization

18.3.5 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

The Quality Oversight organization is responsible for internal audits of the implementation of the requirements stated in this QAPD to accomplish the following:

- to ensure compliance with the overall Quality Assurance Program,
- to ensure compliance with the applicable codes, standards, and regulations,
- to ensure the QAPD is effectively implemented,
- to ensure the QAPD is adequate and maintained.

18.5 Supplier Audits

1. Supplier quality assurance 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.
2. In addition to triennial audits, annual evaluations of suppliers are conducted as described in Section 7 of this QAPD.

3. 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.
4. 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.
5. 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

1. Management of the audited organization or activity performs the following activities:
   - Investigates adverse audit findings
   - Schedules corrective action, including measures to prevent recurrence of significant conditions adverse to quality
   - Notifies the auditing organization in writing of action taken or planned
2. Responses to audit findings are evaluated by the auditing organization.
3. 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-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 18 and RIS 2000-18.

PART III SUPPLEMENTAL DETAILS

1.0 MANAGEMENT RESPONSIBILITY

1.1 General Requirements

1. The Quality Management System as delineated in this Quality Assurance Program Description (QAPD) is implemented, maintained and continually improved through the use of implementing procedures, quality objectives, audit results, analysis of data, corrective and preventive action, and management review.
2. To establish and implement this Quality Management System (QMS), GEH has:
   - Identified and documented the processes needed, and their application throughout the organization.
   - Determined the sequence and interaction of these processes.
   - Determined criteria and methods needed to ensure that the operation and control of the processes are effective, and are documented in quality plans and implementing procedures.
   - Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes.
   - Established systems to monitor, measure, and analyze these processes.
   - Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes.

1.2 Planning

1.2.1 Quality Objectives

1. Quality objectives are established throughout the organization to implement the quality policy, to meet process and product requirements, and to facilitate continual improvement.
2. During management review meetings, quality objectives are reviewed against set goals and past performance.

1.2.2 Quality Management System Planning

1. Quality system processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective.
2. Various quality objectives and documents comprising the QMS are periodically reviewed and appropriate changes are made. These changes may be in response to changing circumstances, such as process or organizational change or to improve the effectiveness of the quality system.
3. Before implementing, each quality assurance programmatic change is reviewed to ensure that it does not conflict with the integrity of the QMS.

1.3 Internal Communication

1. To achieve the effectiveness of the QMS, the following internal communication channels are established within GEH:
   - Broadcast communications

- Indoctrination sessions or staff meetings
- Quality Council (to review, integrate and communicate quality-related matters, problems, corrective actions, status and effectiveness of assigned projects for continuous improvement, and annual reports on the status and adequacy of the quality management system to the top level management)

2. The subject matter discussed may include performance and/or improvements upon quality objectives, customer feedback, customer/regulatory requirements, and adequacy of quality system, processes, and procedures. The distribution of results from management reviews, internal audit results, etc. are also used as communication tools regarding the effectiveness of the QMS.

1.4 Management Review

1.4.1 General

Top management of GEH reviews the GEH QMS to ensure its continuing suitability and effectiveness. These reviews identify opportunities for improvement and needed changes.

1.4.2 Review Input

During management reviews, typical input includes the following:

- Quality objectives
- Results of audits
- Customer feedback
- Process performance and product conformity
- Status of corrective and preventive actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the Quality Management System
- Recommendations for improvement

1.4.3 Review Output

Review output from the management review shall include decisions and actions related to the following:

- Improvement of the effectiveness of the QMS and its processes
- Improvement of product related to customer requirements
- Resource needs to ensure proper implementation of the QMS, and assignment of responsibilities for completing actions

2.0 RESOURCE MANAGEMENT

2.1 Provision of Resources

1. The GEH business segments have the responsibility of planning and implementing the quality assurance functions performed within their area of responsibility. The quality assurance activities related to design, procurement, production, installation, inspection, and test of the product and services are performed by the business segments and supporting organizations.
2. The business segments are responsible for identifying quality requirements, quality related activities to be performed, and for providing adequate resources to:

- Plan, develop processes, implement requirements, and deliver products and services to customer satisfaction
- Maintain and continually improve the QMS
- Enhance delivered quality and customer satisfaction
- Perform audit and oversight activities

3.0 PRODUCT REALIZATION

3.1 Planning of Product Realization

1. The processes needed for product realization have been developed and are consistent with the requirements of the other processes of the QMS.
2. All products and services shall meet the applicable quality requirements addressed in Part II of this QAPD and the following:
   - Customer procurement requirements specified in contracts, purchase orders, procurement documents, work authorizations, specifications, or equivalent controlled documents
   - Industrial, regulatory, environmental, and safety standards and controls as specified by controlled work authorization, specification, customer procurement requirements, or equivalent controlled documents, as applicable to the business
3. Implementing procedures related to work planning and scheduling require the responsible manager to develop and document the work plan for the overall job, including appropriate consideration of purchase order requirements, quality requirements, organizational interfaces, verification, and job closure.
4. Implementing procedures related to new product introduction describe the detailed process for the development and introduction of new products.
5. Other considerations during product realization planning include product specific:
   - Quality objectives and requirements (customer wants, regulatory, technical and quality)
   - Processes (design engineering, procurement, supplier evaluation)
   - Documentation (drawings, specifications, procedures, plans, instructions)
   - Resources (personnel with appropriate skills and qualifications, facilities, equipment)
   - Verification, validation, monitoring, inspection and test requirements (evidence of results, certifications and Quality Assurance Records)
   - Acceptance criteria
6. Product realization planning and requirements for customer site work are addressed in applicable project and quality plans.

3.2 Customer-related Processes

3.2.1 Determination of Requirements Related to the Product

Proposals and contracts are reviewed to determine customer requirements in accordance with implementing procedures for commercial risk and approval, work planning and scheduling, design inputs and customer technical requirements, and spare and renewal parts. This includes customer's stated requirements or intended expectations, regulatory requirements, product specification, and any other GEH identified requirements.

3.2.2 Review of Requirements Related to the Product

1. Prior to contract acceptance, various product and service related requirements are reviewed in accordance with the commercial risk and approval process to ensure that:
    - Product and service requirements are defined
    - Contract requirements differing from those previously stated are resolved
    - GEH has the ability to meet the defined requirements
    - Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance
2. Implementing procedures define processes and requirements for review and acceptance of customer technical requirements and design inputs for design and engineering services, and requirements for review and acceptance of requirements for spare and renewal parts.

3.2.3 Customer Communication

1. Customer Account Leaders/Project Managers are responsible for fulfilling customer requirements for product information, inquiries, and orders including amendments. Responsible Customer Account Leaders/Project Managers monitor customer satisfaction with products through customer feedback methods and direct communication with the goal of improving customer satisfaction.
2. Direct customer communications is accomplished utilizing media, such as:
    - Product Services Information Letters (SIL)
    - Internet website for engineering services
    - Request for quote inquiries
    - Customer feedback and/or complaints

4.0 PRODUCTION AND SERVICE PROVISION

4.1 Control of Production and Service Provision

1. GEH will plan and implement production and service activities (including field services) under controlled conditions, which include:
    - The availability of information that describes the characteristics of the product/service
    - The availability of work instructions
    - The use of suitable equipment and trained/qualified personnel
    - The availability and use of monitoring and measurement equipment
    - The implementation of monitoring and measurement activities
    - The implementation of product/service release, delivery and post-delivery activities
2. Manufacturing suppliers are evaluated to ensure their capability to produce under controlled conditions including suitable equipment, processes, personnel skills, procedures, and work instructions, and utilization of calibrated measuring and test equipment for product acceptance.
3. Servicing of material/equipment is performed by the applicable business in accordance with the customer's contract.
4. Field services are provided under individual project or quality plans, as applicable to the contract.

4.2 Identification and Traceability

1. Unique identification and traceability of materials, parts and components, is addressed in Part II, Section 8.0 of this QAPD.
2. The status of materials, parts and components is addressed in Part II, Section 14.0 of this QAPD.
3. All GEH engineering drawings and specifications are controlled according to implementing procedures to ensure that products are identified during all stages of production, delivery, and installation; and that they are traceable.
4. Product definition documentation is controlled as Quality Assurance Records per implementing procedures.
5. Procedures related to material and equipment traceability requirements are used to assure product identification and traceability.
6. Procedures related to material inspection and release ensure that inspected and tested products are identified appropriately to indicate monitoring and measurement status.
7. Inspection and test status at customer sites is controlled in accordance with applicable project and quality plans.

4.3 Customer Property

1. Procedures pertaining to customer supplied material ensure that customer supplied material is received, inspected, stored, maintained in a controlled environment, and that any customer supplied material that is lost, damaged, or is otherwise unsuitable for use be reported to the customer.
2. Implementing procedures that define control of proprietary information ensure that customer supplied documents are protected and handled in a controlled manner.

5.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

5.1 General

1. GEH plans and implements periodic self-assessments and audits, performs measurement and analysis, and determines improvements as needed to:
   - Demonstrate conformity of the product and services
   - Ensure conformity of the QMS
   - Continually improve the effectiveness of the QMS
2. These requirements and methods are identified in the procedures for audits, self-assessments and the Corrective Action Program.
3. Procedures are established for assessing statistical trends and include determination of applicable methods, including statistical techniques, and the extent of their use.

5.2 Monitoring and Measurement

5.2.1 Customer Satisfaction

1. GEH's commitment to customer satisfaction includes serving customer needs with reliable, consistent, and superior products and service, while maintaining the highest standards of integrity.

2. Customer Feedback and related information is used to gauge company performance against customer requirements.
3. Direct communications are established with customers by the GEH Customer Service representatives, Account Leaders and Project Managers to inquire, monitor, and ensure that customer requirements are fulfilled.
4. General Expectations for customer satisfaction are to:
    - Drive customer satisfaction and loyalty.
    - Deliver results with a sustained compliance culture.
    - Continually improve everything we do, leveraging Lean and Six Sigma methodologies.
    - Achieve operational excellence that our employees and customers feel.
    - Provide and understand customer needs and make every reasonable effort satisfy them before, during, and after every transaction.
    - Make every effort to honor commitments to customers that reflect our expertise and capabilities while providing clear and timely communications.

5.2.2 Monitoring and Measurement of Process

1. Self-assessments, in addition to audits and measurement methods, where applicable, are applied to demonstrate the ability of the processes of the QMS to achieve planned results. This QAPD and implementing procedures for the Corrective Action Program define activities such as:
    - Setting quality objectives
    - Performing self-assessments
    - Initiating actions to correct identified deficiencies
    - Conducting management reviews
2. Control of nonconforming material related procedures detail the process of documenting and controlling nonconforming products and services.

5.3 Analysis of Data

1. Data is collected and analyzed to demonstrate effectiveness of the QMS and to evaluate the following:
    - Customer satisfaction (complaints, feedback, scorecards)
    - Conformity to product and services requirements (nonconformances, analyses, and trends)
    - Corrective Action Program
    - Suppliers (performance trend)
2. Data collected at various sources is analyzed to assess and improve customer satisfaction, product quality, process trends, and supplier performance.
3. In addition to standard data analysis tools, Six-Sigma continuous process improvement techniques may be incorporated.
4. Procedures related to statistical techniques list various techniques for use by GEH personnel.

6.0 SAFETY CULTURE & SAFETY CONSCIOUS WORK ENVIRONMENT

GEH management performs the following actions to establish the appropriate safety conscious work environment within GEH operations:

1. Ensures common understanding of the key aspects of safety culture within the organization.
2. Provides the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization.
3. Reinforces a learning and questioning attitude at all levels of the organization.
4. Provides the means by which the organization continually seeks to develop and improve its safety culture.

PART IV REGULATORY COMMITMENTS

Within Part I and Part II of this QAPD, GEH commits to compliance with the following standards:

- 10CFR Part 50 Appendix B
- ASME NQA-1-2008 Edition with the NQA-1a-2009, Part I in its entirety and Part II for those activities within GEH's scope as an NSSS supplier as described in contract specific quality plans.
- 10 CFR Part 21
- 10 CFR Part 70, Subpart D (70.22(f)) for licensing of special nuclear material
- 10 CFR Part 71
- 10 CFR Part 72, Subpart G for storage of radioactive material and waste

GEH also commits to the following guidance documents:

- 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"
- US NRC 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"

Within Part I and Part III of this QAPD, GEH commits to compliance with the following standards:

- ISO 9001, Quality Management Systems
- IAEA GS-R-3, Management System for Facilities and Activities
- KTA 1401, General Quality Requirements
- JEAC 4111, Quality Assurance Code for Safety in Nuclear Power Plants
- ISO 14001:2004, Environmental Management Systems
- OHSAS 18001:2007, Health and Safety Management Systems

Additional standards may be committed to in project specific or work specific quality plans and implementing procedures as required.

ENCLOSURE 2

MFN 14-018

Roadmap for NEDO-11209, Revision 11

Non-Proprietary Information – Class I (Public)

Rev 9 Section	Rev 9 Section Description	Rev 11 Section		Summary of Change
	Cover Page		Cover Page	Removed President and CEO signature, moved to new "Policy Statement" sub-section
	Disclaimer		Disclaimer	No change
	Revision History		Revision History	Updated
			Policy Statement	Added sub-section
	Table Of Contents		Table Of Contents	Updated
	Acronyms & Abbreviations		Acronyms & Abbreviations	Added "Perry Johnson Laboratory Accreditation Inc."
	Introduction	Part I	Introduction	Incorporated old "Scope" section, added new structure of QAPD and details for Part III
	Scope			
SECTION 1	Organization	Part II	1.0	No change
1.1	General	Part II	1.1	Removed organizational elements table (Rev 10) Minor changes to accommodate integration of ISO9001 and GS-R-3
		Part II	1.2	Added "Management Commitment" sub-section
1.2	Organizational Description	Part II	1.3	Combined 1.2 and 1.2.1. Added paragraph on control and location of typical organizational structure and functional descriptions
1.2.1	Organizational Structure	Part II	1.3	
1.2.1.1	P&Ls	Part II	1.3.1	Removed listing of P&Ls, moved to 1.3.1.1 & 1.3.1.2
		Part II	1.3.1.1	Added "Nuclear Fuels & Services" sub-section
		Part II	1.3.1.2	Added "Nuclear Plant Projects" sub-section
1.2.1.2	Support Organizations	Part II	1.3.2	Modified for Nuclear Oversight Organization, added other support organizations
1.2.1.3	Quality	Part II	1.3.3	Renamed "Nuclear Oversight" and updated description of the Nuclear Oversight organizational structure
1.2.2	Management Positions	Part II	1.4	Added introduction paragraph
1.2.2.1	President and Chief Executive Officer	Part II	1.4.1	Rewritten, removed duplicate items that are now covered in the Statement of Policy and added #2 & #4
1.2.2.2	Business Leaders for P&L's and Support Organizations	Part II	1.4.3	Added #3
1.2.2.3	Quality Leader	Part II	1.4.2	Renamed "Nuclear Oversight Leader", added #2, #3 & #5

Rev 9 Section	Rev 9 Section Description	Rev 11 Section		Summary of Change
1.2.2.3.1	Nuclear Quality Assurance Leader	Part II	1.4.2.1	Changed to "Quality Oversight Leader" and defined reporting relationship of this position to the NOS SVP and clarified the responsibilities of the position
1.2.2.3.2	Support Services Quality Leader	Part II	1.4.2.1	NOTE: this was changed from "Nuclear Quality Assurance Leader" and "Support Services Quality Leader" to "Quality Programs Leader" in Revision 10. The responsibilities of the "Quality Programs Leader" were tranisitioned to the "Quality Oversight Leader" (new Section 1.4.2.1) in Revision 11
		Part II	1.4.2.2	Added "Performance Improvement Leader" (added in Revision 10)
		Part II	1.4.4	Added sub-section "Sourcing General Manager"
1.2.2.3.3	P&L Specific Quality Leaders	Part II	1.4.3.1	Modified #1 for reporting structure change Removed responsibility for auditing (moved to "Quality Oversight Leader", Section 1.4.2.1
1.2.2.3.3	Support Organization Quality Leaders			Combined with "P&L Specific Quality Leaders" in Revision 10
1.2.3	Functional Responsibilities	Part II	1.4.5	Removed "shown in Figure 2" and replaced with "detailed in implementing procedures"
1.2.4	Interface responsibilities	Part II	1.4.6	No change
1.3	All Employees and contractors	Part II	1.5	Added "Responsibilities" to the title of the sub-section and added first and last bullets
1.4	Authority to Stop Work	Part II	1.6	Updated for organization changes and clarified conditions for issuing a stop work."
		Part II	1.7	Added "Delegation" section
		Part II	1.7.1	Added "Delegation Inside the GEH Organization" sub-section #3 came from Revision 9 Section 1.5
1.5	Delegation Outside the GEH Organization	Part II	1.7.2	See above for relocation of #3 to 1.7.1
1.6	Commitment	Part II	1.8	No change
Figure 1	Organizational Structure	Part II	Figure 1	Updated for organization changes
Figure 2	Functional Responsibilities			Deleted
SECTION 2	QUALITY ASSURANCE PROGRAM	Part II	2.0	No change

Rev 9 Section	Rev 9 Section Description	Rev 11 Section		Summary of Change
2.1	General	Part II	2.1	Combined General & Scope Added #1 & #6, updated for organization changes Statement on applicability of the QAPD to SSC is now in Part I Section 1.0 "Scope/Applicability
2.2	Scope			
2.3	Controlled Conditions	Part II	2.2	#1: added "…as delineated in appropriate implementing procedures and instructions." #2: added second and fourth bullets Added #4 & #5
2.4	Indoctrination	Part II	2.3	Added #2 & #3
2.5	Qualification Requirements	Part II	2.4	Added #3 & #4
2.5.1	Nondestructive Examination	Part II	2.4.1	Changed "testing" to "examination in accordance with applicable industry codes and standards."
2.5.2	Inspection and Test	Part II	2.4.2	Grammatical changes
2.5.3	Lead Auditor	Part II	2.4.3	#1: changed "evaluation" to "qualification" #2: changed "The evaluation criteria are communication…" to "The evaluation criteria include education, experience, communication…" Added #3
2.6	Detection and Correction of Quality Problems	Part II	2.5	Grammatical change
2.7	Assessment of Effectiveness	Part II	2.6	Added #2 Moved President review of overall status and adequacy to Section 1.4.1
2.8	Grace Period	Part II	2.7	No change
		Part II	2.8	Added "Quality Assurance Program Description Management" section
2.9	Commitment	Part II	2.9	No change
SECTION 3	DESIGN CONTROL	Part II	3.0	No change
3.1	General	Part II	3.1	No change
3.2	Design Inputs	Part II	3.2	#2: added "previous similar designs"
3.3	Design Process	Part II	3.3	No change
3.3.1	Design Responsibility	Part II	3.3.1	1: added last sentence
3.3.2	Design Methods	Part II	3.3.2	No change
3.3.3	Design Result	Part II	3.3.3	#1: added last bullet Added #4, #5 & #6

Rev 9 Section	Rev 9 Section Description	Rev 11 Section		Summary of Change
3.4	Design Analyses	Part II	3.4	No change
3.4.1	Use of Computer Programs	Part II	3.4.1	No change
3.4.2	Documentation of Design Analyses	Part II	3.4.2	No change
		Part II	3.4.3	Added “Design and Development Review”
3.5	Design Verification	Part II	3.5	No change
3.5.1	Verification Responsibilities	Part II	3.5.1	Grammatical change
3.5.2	Verification Timing	Part II	3.5.2	No change
3.5.3	Verification of Modifications	Part II	3.5.3	No change
3.5.4	Extent of Design Verification	Part II	3.5.4	#1: added “the state of the art”
3.5.5	Verification Methods	Part II	3.5.5	No change
3.5.5.1	Design Reviews	Part II	3.5.5.1	No change
3.5.5.2	Alternate Calculations	Part II	3.5.5.2	No change
3.5.5.3	Qualification Tests	Part II	3.5.5.3	No change
		Part II	3.5.6	Added “Design and Development Validation” section
3.6	Change Control	Part II	3.6	Added #7 & #8
3.7	Interface Control	Part II	3.7	No change
3.8	Software Design Control	Part II	3.8	No change
3.8.1	Software Design Process	Part II	3.8.1	Grammatical changes
3.8.2	Software Configuration Management	Part II	3.8.2	No change
3.9	Documentation and Records	Part II	3.9	No change
3.10	Commitment	Part II	3.10	No change
SECTION 4	PROCUREMENT DOCUMENT CONTROL	Part II	4.0	No change
4.1	General	Part II	4.1	No change
4.2	Procurement Document Contents	Part II	4.2	Added third and fifth bullets Last bullet, added “per Section 7.8 of this QAPD”
4.3	Review of Procurement Documents	Part II	4.3	Grammatical change
4.4	Procurement Document Changes	Part II	4.4	No change
4.5	Commitment	Part II	4.5	No change
SECTION 5	PROCEDURES, INSTRUCTIONS, AND	Part II	5.0	Rearranged items in title to match NQA-1

Rev 9 Section	Rev 9 Section Description	Rev 11 Section		Summary of Change
	DRAWINGS			
5.1	General	Part II	5.1	No change
5.2	Requirements	Part II	5.2	#1, Added requirement for procedure to be available at point of use Added #3
5.3	Content of Procedures	Part II	5.3	No change
5.4	Commitment	Part II	5.4	No change
SECTION 6	DOCUMENT CONTROL	Part II	6.0	No change
6.1	General	Part II	6.1	#1: added items for clarification
6.2	Review and Approval of Documents	Part II	6.2	No change
6.3	Changes to Documents	Part II	6.3	No change
6.4	Temporary Documents	Part II	6.4	Removed qualifier “that clearly do not change the intent of the procedure”
6.5	Commitment	Part II	6.5	No change
SECTION 7	CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES	Part II	7.0	No change
7.1	General	Part II	7.1	Added #2
7.2	Supplier Evaluation and Selection	Part II	7.2	Added #4
7.3	Proposal/Bid Evaluation	Part II	7.3	No change
7.4	Control of Supplier Generated Documents	Part II	7.4	Clarified #2
7.5	Control of Supplier Nonconformances	Part II	7.5	#3 wording correction (nonconformance) Removed conditionality of nonconformance reporting from #4 (Revision 10 change)
7.6	Acceptance of Items or Service	Part II	7.6	Grammatical change
7.6.1	Methods of Acceptance	Part II	7.6.1	No change
7.6.1.1	Certificate of Conformance	Part II	7.6.1.1	No change
7.6.1.2	Source Acceptance	Part II	7.6.1.2	#3: added “may include customer required involvement”
7.6.1.3	Receiving Inspection	Part II	7.6.1.3	No change
7.6.1.4	Post-installation Testing	Part II	7.6.1.4	No change
7.6.1.5	Acceptance of Services	Part II	7.6.1.5	No change
7.7	Supplier Performance	Part II	7.7	No change

Rev 9 Section	Rev 9 Section Description	Rev 11 Section		Summary of Change
	Evaluation			
7.8	Commercial Grade Items and Services - Dedication	Part II	7.8	#2.d: clarified #3: added
7.9	Records	Part II	7.9	No change
7.10	Commitment	Part II	7.10	Added Perry Johnson Laboratory Accreditation
SECTION 8	IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS	Part II	8.0	No change
8.1	General	Part II	8.1	Clarified #2 and #3
8.2	Identification Methods	Part II	8.2	#1 added
8.3	Preference for Physical Marking	Part II	8.3	No change
8.4	Maintenance of Marking	Part II	8.4	No change
8.5	Limited Life Items	Part II	8.5	No change
8.6	Commitment	Part II	8.6	No change
SECTION 9	CONTROL OF SPECIAL PROCESSES	Part II	9.0	No change
9.1	General	Part II	9.1	#4: added “qualification and calibration”
9.2	Criteria	Part II	9.2	No change
9.3	Non-Standard Processes	Part II	9.3	No change
9.4	Responsibility	Part II	9.4	No change
9.5	Records	Part II	9.5	Added “and their revalidation”
9.6	Commitment	Part II	9.6	No change
SECTION 10	INSPECTION	Part II	10.0	No change
10.1	General	Part II	10.1	Clarified introduction Added #3
10.2	Inspection Personnel	Part II	10.2	#1: added “independent” #2: added “implementing procedures or instructions.”
10.3	Planning	Part II	10.3	#1: added “to assure quality of product or service” Added #5
10.3.1	Sampling	Part II	10.3.1	No change
10.3.2	Hold Points	Part II	10.3.2	No change
10.3.3	Process Monitoring	Part II	10.3.3	Added #3
10.3.4	Re-inspection	Part II	10.3.4	No change
10.4	Final Inspection	Part II	10.4	No change
10.4.1	Resolution of Nonconformances	Part II	10.4.1	No change

Rev 9 Section	Rev 9 Section Description	Rev 11 Section		Summary of Change
10.4.2	Inspection Requirements	Part II	10.4.2	No change
10.4.3	Acceptance	Part II	10.4.3	Added #2
10.5	Records	Part II	10.5	No change
10.6	Commitment	Part II	10.6	No change
SECTION 11	TEST CONTROL	Part II	11.0	No change
11.1	General	Part II	11.1	No change
11.2	Test Requirements	Part II	11.2	#3: added “including appropriately controlled measuring and test equipment (reference Section 12.0 of this QAPD),”
11.3	Test Procedures	Part II	11.3	No change
11.3.1	Test Procedures for Other than Computer Programs	Part II	11.3.1	#3.a: added “test”
11.3.2	Test Procedures for Computer Programs	Part II	11.3.2	No change
11.4	Test Results	Part II	11.4	No change
11.5	Test Records	Part II	11.5	No change
11.6	Commitment	Part II	11.6	No change
SECTION 12	CONTROL OF MEASURING AND TEST EQUIPMENT	Part II	12.0	No change
12.1	General	Part II	12.1	#3: clarified
12.2	Selection of Equipment for Use	Part II	12.2	#2: clarified
12.3	Calibration Process	Part II	12.3	#2: clarified #3-#5: added
12.4	Control of Calibration Status	Part II	12.4	Out of calibration moved to 12.5.3
12.5	Records	Part II	12.5	No change
12.5.1	General	Part II	12.5.1	No change
12.5.2	Reports and Certificates	Part II	12.5.2	No change
		Part II	12.5.3	Added “Out of Calibration” sub-section
12.6	Commitment	Part II	12.6	No change
SECTION 13	HANDLING, STORAGE, AND SHIPPING	Part II	13.0	No change
13.1	General	Part II	13.1	Added #2 &#3
13.2	Instructions	Part II	13.2	Added “drawings, specifications or other pertinent documents”
13.3	Special Controls	Part II	13.3	#1: added “and verified”

Rev 9 Section	Rev 9 Section Description	Rev 11 Section		Summary of Change
				#3: added last sentence
13.4	Special Tools and Equipment	Part II	13.4	#2: added “or prior to use”
13.5	Operators	Part II	13.5	No change
13.6	Commitment	Part II	13.6	No change
SECTION 14	INSPECTION, TEST, AND OPERATING STATUS	Part II	14.0	No change
14.1	General	Part II	14.1	No change
14.2	Inspection and Test Status	Part II	14.2	No change
14.3	Commitment	Part II	14.3	No change
SECTION 15	NONCONFORMING MATERIALS, PARTS, OR COMPONENTS	Part II	15.0	No change
15.1	General	Part II	15.1	#1 changed to align with NQA-1
15.2	Identification and Control	Part II	15.2	No change
15.3	Disposition	Part II	15.3	Added #8 and #9
15.4	Re-examination	Part II	15.4	No change
15.5	Commitment	Part II	15.5	No change
SECTION 16	CORRECTIVE ACTION	Part II	16.0	The word Program was added to title for clarity
16.1	General	Part II	16.1	#3: added last sentence Clarifications made to statements in bullets 1,4 and 5 Added #6, #8-#10
16.2	Identification of Trends	Part II	16.2	No change
		Part II	16.3	Added “Corrective Action” sub-section
		Part II	16.4	Added “Preventive Action” sub-section
16.3	Commitment	Part II	16.5	No change
SECTION 17	QUALITY ASSURANCE RECORDS	Part II	17.0	No change
17.1	General	Part II	17.1	#1: Added the word “identification” and “such that damage does not occur Added #2 #4: added last sentence #6: clarified Added #8
17.2	Administration	Part II	17.2	No change
17.2.1	Personnel	Part II	17.2.1	#2: clarified

Rev 9 Section	Rev 9 Section Description	Rev 11 Section		Summary of Change
17.2.2	Indexing System	Part II	17.2.2	Added last sentence
17.2.3	Corrections	Part II	17.2.3	#1 & #2: added “or changed” in three places
17.3	Classification	Part II	17.3	No change
17.3.1	Lifetime Records	Part II	17.3.1	No change
17.3.2	Nonpermanent Records	Part II	17.3.2	#2: changed “writing” to “implementing procedures”
17.4	Receipt Control	Part II	17.4	No change
17.5	Authentication	Part II	17.5	No change
17.6	Storage	Part II	17.6	No change
17.6.1	General	Part II	17.6.1	#2: Grammatical change
17.6.2	Facility Types	Part II	17.6.2	#3: added last sentence
17.6.3	Temporary Storage	Part II	17.6.3	No change
17.6.4	Retention	Part II	17.6.4	No change
		Part II	17.6.5	Added “Duplication/Transfer” sub-section
17.7	Electronic Records	Part II	17.7	“#1 and #2: Clarification Added #3
17.7.1	Indexing system	Part II	17.7.1	No change
17.7.2	Corrections	Part II	17.7.2	No change
17.7.3	Retention	Part II	17.7.3	No change
17.7.4	Receipt	Part II	17.7.4	No change
17.7.5	Authentication	Part II	17.7.5	No change
17.7.6	Storage	Part II	17.7.6	#1: added “such that no unacceptable degradation of the media occurs during the established retention period”
17.7.7	Obsolescence	Part II	17.7.7	No change
17.8	Commitment	Part II	17.8	No change
SECTION 18	AUDITS	Part II	18.0	No change
18.1	General	Part II	18.1	#5: clarified
18.2	Personnel	Part II	18.2	No change
18.3	Audit Documentation	Part II	18.3	No change
18.3.1	Annual Audit Schedule	Part II	18.3.1	#6: added “or self-assessment”
18.3.2	Audit Plan	Part II	18.3.2	No change
		Part II	18.3.3	Added “Audit Performance” sub-section
18.3.3	Audit Report	Part II	18.3.4	No change
18.3.4	Audit Records	Part II	18.3.5	No change
18.4	Internal Audits	Part II	18.4	Responsibility for internal audits moved from the

Rev 9 Section	Rev 9 Section Description	Rev 11 Section		Summary of Change
				individual Profit & Loss (P&L's) organizations to the Quality Programs organization.(Revision 10) The Nuclear Quality Assurance organization was removed to reflect organizational changes, responsibilities for auditing the various P&L's was transitioned to the Quality Programs organization (Revision 10). Removed "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." (Revision 10) Added last two bullets
18.5	Supplier Audits	Part II	18.5	Removed "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" Removed "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 audit, they must satisfy the same audit elements and criteria as those on other triennial audits."
18.6	Audit Response and Follow-up	Part II	18.6	No change
18.7	Commitment	Part II	18.7	No change
APPENDIX A	REGULATORY COMMITMENTS	Part IV		Added 10CFR Part 21, 10CFR Part 70 (Subpart D), and 10CFR Part 72 (Subpart G) Added international standards