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Project 717

October 28, 2005

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

Subject: **NEDO-33181, Revision 1, "NP-2010 COL Demonstration Project  
Quality Assurance Plan," October 2005 (TAC # MC8168)**

The subject Quality Assurance Plan is contained in Enclosure 1. This document provides the description of the quality assurance plan scope which GE Energy, Nuclear, as supplier for ESBWR engineering services, will implement in fulfilling the contractual requirements within the scope of contracts with Dominion Nuclear North Anna, LLC and NuStart Energy Development, LLC. This document is provided to assist the NRC in preparation for the upcoming NRC inspection of the ESBWR Quality Assurance Program.

If you have any questions about the information provided here, please let me know.

Sincerely,

David H. Hinds  
Manager, ESBWR

DD68

Enclosure:

1. NEDO-33181, Revision 1, "*NP-2010 COL Demonstration Project Quality Assurance Plan*," October 2005

cc: WD Beckner USNRC (w/o enclosures)  
AE Cubbage USNRC (with enclosures)  
LA Dudes USNRC (w/o enclosures)  
GB Stramback GE/San Jose (with enclosures)

MFN 05-114  
Enclosure 1

**ENCLOSURE 1**

**MFN 05-114**

**NEDO-33181, Revision 1, "NP-2010 COL Demonstration  
Project Quality Assurance Plan," October 2005**

**MFN 05-114**  
**Enclosure 1**

**ENCLOSURE 1**

**MFN 05-114**

**NEDO-33181, Revision 1, "NP-2010 COL Demonstration  
Project Quality Assurance Plan," October 2005**



**GE Energy  
Nuclear**

3901 Castle Hayne Rd  
Wilmington, NC 28401

NEDO-33181  
Revision 1  
Class I  
eDRF# 0000-0037-8794

OCTOBER 2005

**NP-2010 COL DEMONSTRATION PROJECT  
QUALITY ASSURANCE PLAN**

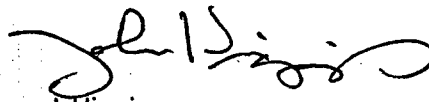
Prepared for:

Dominion Nuclear North Anna, LLC  
Contract: DE-FC07-05ID14635

NuStart Energy Development, LLC  
Contract: DE-FC07-05ID14636

Approved by:

  
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Project Manager - Dominion

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**IMPORTANT NOTICE REGARDING CONTENTS OF THIS REPORT  
Please Read Carefully**

The only undertakings of the General Electric Company (GE) respecting information in this document are contained in the contracts between NuStart Energy Development, LLC and GE, Cooperative Agreement Subaward By and Between NuStart Energy Development, LLC and General Electric Company, effective May 4, 2005, and Dominion Nuclear North Anna, LLC, Cooperative Agreement Subaward between Dominion Nuclear North Anna, LLC and General Electric Company, effective May 31, 2005, as amended to the date of transmittal of this document, and nothing contained in this document shall be construed as changing the contract. The use of this information by anyone other than NuStart Energy Development, LLC and Dominion Nuclear North Anna, LLC, or for any purpose other than that for which it is furnished by GE, is not authorized; and with respect to any unauthorized use, GE makes no representation or warranty, express or implied, and assumes no liability as to the completeness, accuracy, or usefulness of the information contained in this document, or that its use may not infringe privately owned rights.

**Acknowledgement**

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## 1.0 Quality Assurance Scope

This document provides the description of the quality assurance plan scope which GE Energy, Nuclear (GE), as Supplier for ESBWR engineering services, will implement in fulfilling the contractual requirements within the scope of Contracts:

DE-FC07-05ID14635      Dominion Nuclear North Anna, LLC

DE-FC07-05ID14636      NuStart Energy Development, LLC

These contracts encompass Phase 1 and Phase 2 of the DOE NP-2010 COL (US NRC Construction and Operating License) Demonstration Project.

This issue of the Quality Assurance Plan addresses those activities and elements needed to support the DOE NP-2010 COL Demonstration Project. However, if necessary, the plan will be updated in a timely manner as work scope, interfaces and requirements are further defined.

Refer to Figure 1 for scope of quality assurance by GE. The overall quality assurance responsibilities of GE, as Supplier, will encompass all quality related activities performed by GE as well as those performed by its subcontractors during execution of the Program, including:

- Planning, scheduling
- Engineering and design of: NSSS, Turbine Island, I&C, Plant Civil/Structural works, Systems, Equipment and Components
- Structural, design, safety and performance analyses
- Cost estimation

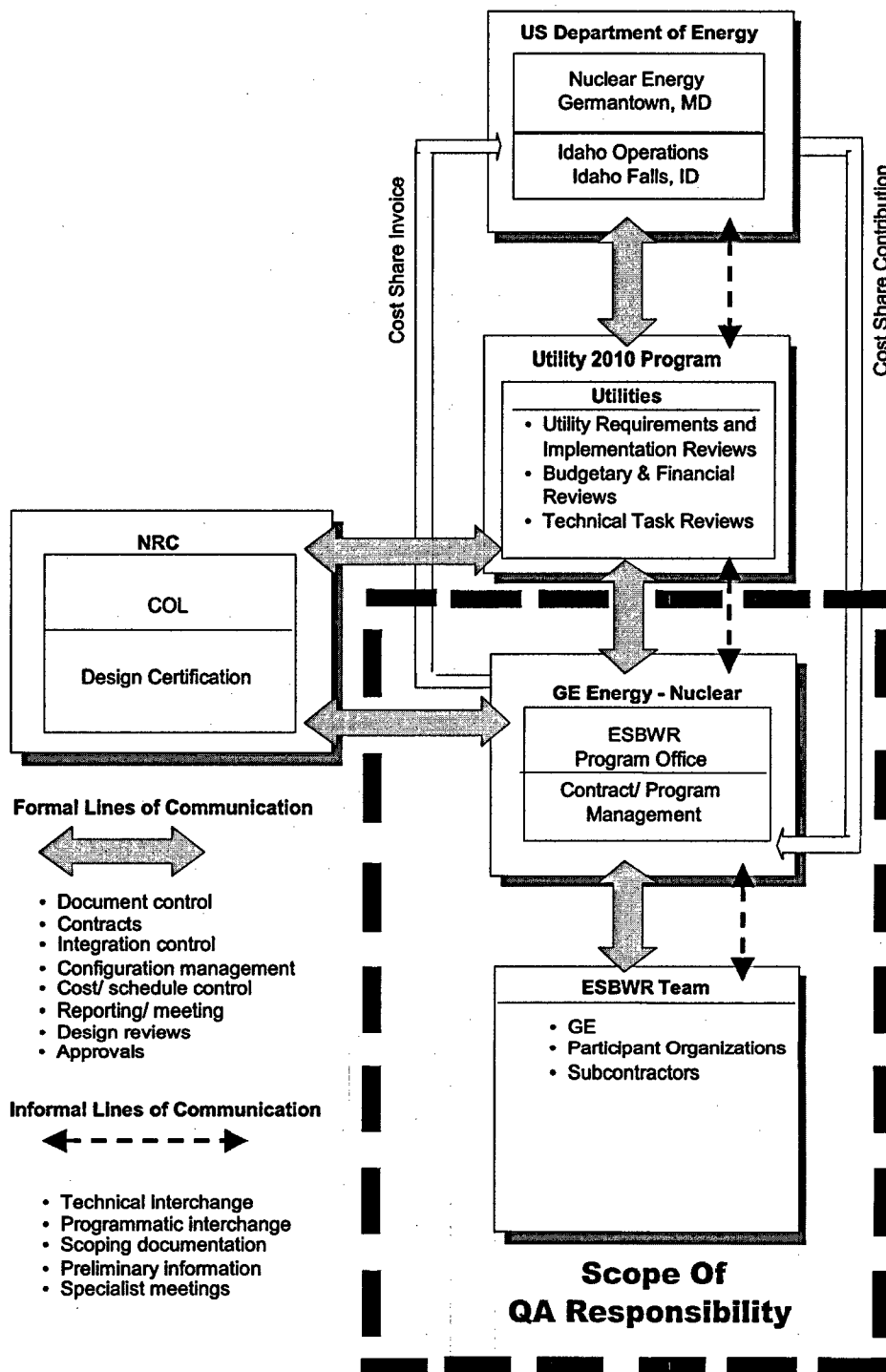


Figure 1 NP-2010 COL Demonstration Project GE QA Scope

## **2.0 GE Quality Assurance System**

GE Quality System Hierarchy is illustrated in Figure 2. The hierarchy is shown with GE Company Policy as governing. Below the GE Company Policy are the GE Nuclear Energy Policies and Procedures. Regulations such as 10CFR50 Appendix B, ANSI/ASME NQA-1, and ISO-9001 provide a basic structure of the documented GE quality system and also guide the organization and content of the implementing quality assurance manuals and procedures. In addition, customer requirements further guide the structure of this Quality System and the implementing plans and procedures.

The implementation of this quality management system will assure the quality of the projects and provide a solid foundation for nuclear safety and reliable power generation.

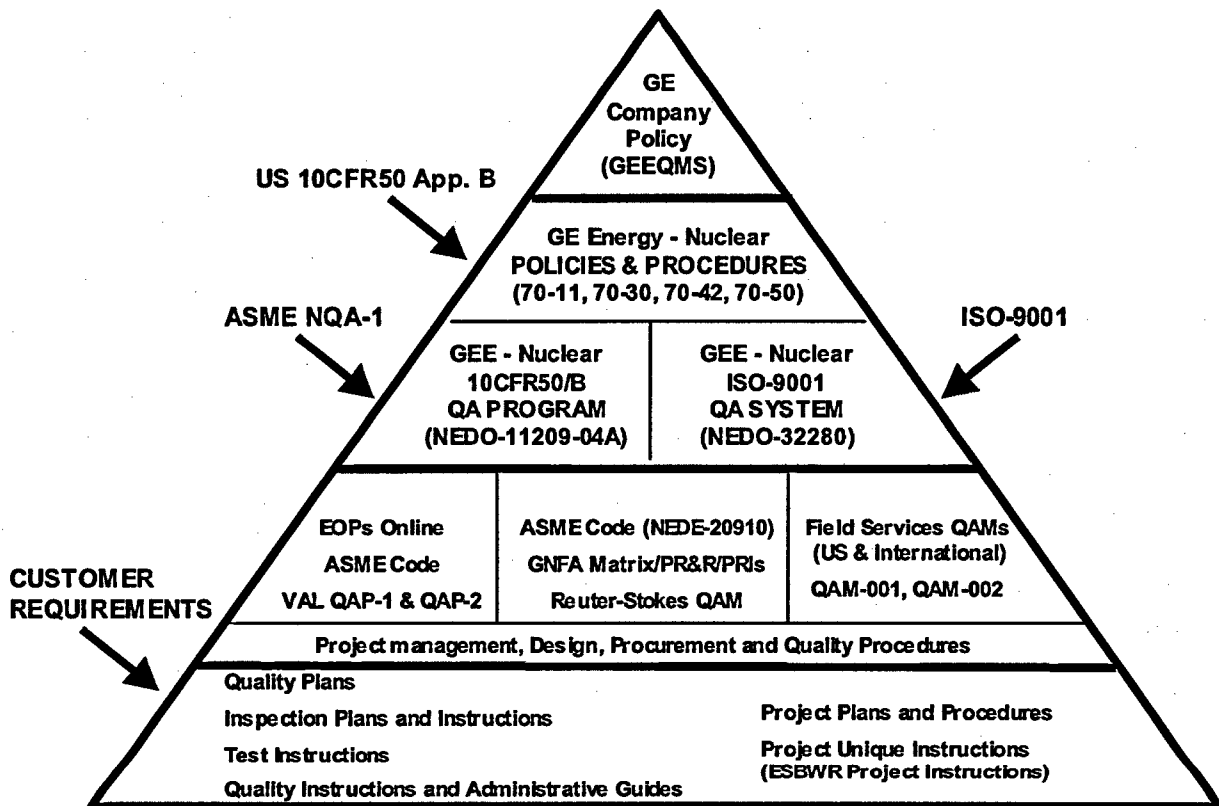


Figure 2 GE Quality System Hierarchy

## 2.1 GE Quality Assurance Program Description

The standard GE Quality Assurance (QA) Program, NEDO-11209-04A, Revision 8, GE Nuclear Energy Quality Assurance Program Description, is structured in accordance with the outline of the 18 criteria of Appendix B of 10 CFR Part 50 (1993), U.S. NRC Code of Federal Regulations, Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing Plants, and US NRC Regulatory Guide 1.70 (1975), Standard Format and Content of Safety Analysis Report for Nuclear Power Plants. The USNRC has accepted the implementation of the GE standard QA Program as meeting ANSI N45.2 series standards and applicable USNRC Regulatory Guides, and ANSI/ASME NQA-1-1983, Quality Assurance Requirements for Nuclear Facility Applications as endorsed by USNRC Regulatory Guide 1.28, Revision 3 (August, 1985), US Nuclear Regulatory Commission, Quality Assurance Program Requirements (Design and Construction) for the certification of the ABWR in the United States. This QA Program is used throughout GE on all BWR nuclear power plant work, including the design certification of material for the U.S. ABWR and ABWRs operating in other countries. A copy of NEDO-11209-04A QA Program is provided as Attachment 1.

The ASME has also accepted the implementation of the standard GE QA Program with implementing procedures as meeting the quality requirements of the ASME when it awarded GE N Certificate No. N-1888 in San Jose (see Exhibit 1), NPT Certificate No. N-1151 in Wilmington, NA Certificate N-2510 in Wilmington, and NPT Certificate N-2703 in Cleveland.

Lloyd's Register Quality Assurance has accepted the standard GE QA Program and the GE Quality System Description for ISO-9001, NEDO-32280, GE-NE Quality System Description for ISO-9001, as meeting the quality requirements of ISO-9001:1994 Certificate No. 100503 (see Exhibit 2). This ISO program has been revised to ISO-9001:2000 version and is in an assessment and re-certification process. A final draft of the updated version of ISO-9001:2000 QA Program is provided as Attachment 2.

See Table 1 for a detailed comparison of various applicable Quality Assurance Standards.

Exhibit 1

06/14/2005 09:42 FAX 2125918589

ASME CONFORMITY ASSESS

003/003



# CERTIFICATE OF AUTHORIZATION

This certificate accredits the named company as authorized to use the indicated symbol of the American Society of Mechanical Engineers (ASME) for the scope of activity shown below in accordance with the applicable rules of the ASME Boiler and Pressure Vessel Code. The use of the Code symbol and the authority granted by this Certificate of Authorization are subject to the provisions of the agreement set forth in the application. Any construction stamped with this symbol shall have been built strictly in accordance with the provisions of the ASME Boiler and Pressure Vessel Code.

**COMPANY:**

GE NUCLEAR ENERGY  
1989 LITTLE ORCHARD STREET  
SAN JOSE, CALIFORNIA 95125

**SCOPE:**

CONSTRUCTION OF SECTION III, DIVISION 1 COMPONENTS FOR WHICH OVERALL RESPONSIBILITY IS RETAINED AND FOR WHICH FABRICATION IS SUBCONTRACTED TO APPROPRIATE CERTIFICATE OF AUTHORIZATION HOLDERS AND AS A MATERIAL ORGANIZATION SUPPLYING FERROUS AND NONFERROUS MATERIAL AT THE ABOVE LOCATION AND WITH ADDITIONAL PROCUREMENT, RECEIVING, INSPECTION, STORAGE AND SHIPPING AT 262 FREDDY LANE, VINELAND, NJ 08360

**AUTHORIZED:**

NOVEMBER 10, 2004

REVISED: MAY 9, 2005

**EXPIRES:**

OCTOBER 14, 2007

**CERTIFICATE NUMBER:**

N-1888

Chairman of The Boiler  
And Pressure Vessel Committee

Director, Accreditation and Certification

The American Society of Mechanical Engineers



Exhibit 1 (Continued)

The American Society of Mechanical Engineers



## CERTIFICATE OF ACCREDITATION

This certificate accredits the named company as having had the adequacy of their quality assurance program verified for the scope of the activity shown below in accordance with the applicable rules of the Boiler and Pressure Vessel Code of the American Society of Mechanical Engineers (ASME). This certificate does not include authorization to use code symbol stamp. The accreditation granted by this certificate is subject to the provisions of the agreement set forth in the application.

**COMPANY:**

**GE NUCLEAR ENERGY  
1989 LITTLE ORCHARD STREET  
SAN JOSE, CALIFORNIA 95125**

**SCOPE:**

**CONSTRUCTION OF CLASS 1, 2, 3 & MC VESSELS, CLASS 1, 2 & 3 PUMPS, VALVES AND PIPING SYSTEMS, CLASS 2 & 3 STORAGE TANKS, CLASS C CORE SUPPORT STRUCTURES AND AS A MATERIAL ORGANIZATION SUPPLYING FERROUS AND NONFERROUS MATERIAL AT VARIOUS LOCATIONS. ACCREDITED BY ASME**

**AUTHORIZED:**

**NOVEMBER 10, 2004**

**REVISED: MAY 8, 2005**

**EXPIRES:**

**OCTOBER 14, 2007**

**CERTIFICATE NUMBER:**

**N-3157**

**Chairman of The Boiler  
And Pressure Vessel Committee**

**Director, Accreditation and Certification**



Exhibit 2



**CERTIFICATE OF APPROVAL**

*This is to certify that the Quality Management System of:*

**GE Nuclear Energy  
San Jose, California, USA**

*has been approved by Lloyd's Register Quality Assurance  
to the following Quality Management System Standards:*

**ISO 9001:2000,  
ANSI/ISO/ASQ Q9001-2000**


*The Quality Management System is applicable to:*

**Design, Procurement, Supply, and Servicing  
of Nuclear Power Plants and Related Systems and  
Components, including the Development of Control  
Instrumentation Software and Maintenance of Plant  
Monitoring Software in accordance with TickIT.**

*This certificate is valid only in association with the certificate schedule bearing the same  
number on which the locations applicable to this approval are listed.*

Approval  
Certificate No: 100503

Original Approval: March 3, 1994  
Current Certificate: May 2, 2003  
Certificate Expiry: March 31, 2006

  
Issued by LRQA, Inc. Houston



This statement is subject to the provision on the reverse.  
This approval is granted on an ongoing basis by LRQA and is subject to periodic audits and monitoring by LRQA.  
The use of the LRQA Accredited Mark and the Accreditation in respect of those activities covered by the Accreditation Certificate Number 007  
Further clarification regarding the scope of this certificate and the applicability of ISO 9001:2000 requirements may be obtained by consulting the organization.



Exhibit 2 (Continued)



**CERTIFICATE SCHEDULE**

**GE Nuclear Energy**

**Locations**

San Jose, California, USA

Vineland, New Jersey, USA

**Activities**

Design, Procurement, Supply, and Servicing of Nuclear Power Plants and Related Systems and Components, including the Development of Control Instrumentation Software and Maintenance of Plant Monitoring Software in accordance with TickIT.

Procurement, Inspection, and Shipping.

Approval  
Certificate No: 100503

Original Approval: March 3, 1994  
Current Certificate: May 2, 2003  
Certificate Expiry: March 31, 2006

Page 1 of 1



This document is subject to the provisions on the reverse.  
This approval is granted on the condition that the certificate holder will maintain the certification in accordance with the provisions of the UKAS Quality Management System.  
The certificate holder is responsible for ensuring the validity of the certification in accordance with the provisions of the UKAS Quality Management System.  
The certificate holder is responsible for ensuring the validity of the certification in accordance with the provisions of the UKAS Quality Management System.

**Table 1 Comparison of QA Standards**

**Quality Assurance Program Standards/Requirements**  
**Equivalency Review of U.S. and International Standards**

<b>Program Element Description</b>	<b>10CFR50 App. B</b>	<b>ANSI/ASME NQA-1-1994</b>	<b>ISO 9001 2000</b>
<b>Introduction</b>	Introduction	Introduction	
Objective/Purpose	0	1	1
Scope/Application	0	2	1
Terms and Definitions	ANSI N45.2-1971	4	3
<b>Organization</b>		Basic Reqmt. 1	
Structure	1, N45.2-1971	1, 1S-1 (2.1)	5.5
Objectives	1, N45.2	1S-1 (2.1)	5.4
Responsibility/Authority	1, N45.2	1, 1S-1 (2)	5.5.1, 5.5.2
Organizational freedom	1, N45.2	1	5.5.2
Delegation	1, N45.2	1, 1S-1 (2.2)	-
Interface control	1, N45.2	1, 1S-1 (3.2)	-
<b>Quality Assurance Program</b>		Basic Reqmt. 2	
Establishing, Documenting and Implementing	2, N45.2-1971	2	4.1, 4.2.1
Scope of Application	2, N45.2	2	4.2.2 a)
Resource Management	2, N45.2	2	4.1 f), 6
Indoctrination/Training/Qualification	2, N45.2	2, 2S-4	6.2
Training/Qualification for Audit Personnel	2, N45.2.23-1978	2S-3, ANSI N45.2.23-1978	-
Training/Qualification for Insp./Test Personnel	2, N45.2.6-1978	2S-1, ANSI N45.2.6-1978	-
Training/Qualification for NDE Personnel	2, SNT-TC-1A	2S-2, SNT-TC-1A	-
Management assessment and Reviews	2, N45.2	2	5.6

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ANSI Standard		ANSI N45.2-1971	
<b>Design Control</b>	3, N45.2-1971	Basic Reqmt. 3	
Definition and Control	N45.2.11-1974/Sect. 2	3	7.3.1
Input	N45.2.11/Sect. 3	3, 3S-1(2)	7.3.2
Process	N45.2.11/Sect. 4	3S-1(3)	7.3.1-7.3.4
Independent Verification & Review	N45.2.11/Sect. 6	3, 3S-1 (4)	7.3.5*
Validation	-	-	7.3.6
Change Control	N45.2.11/Sect. 8	3, 3S-1 (5)	7.3.7
Organization & Interface Control	N45.2.11/Sect. 5	3, 3S-1 (6)	7.3.1
Documentation and Records	N45.2.11/Sect. 7,10	3, 3S-1 (7)	7.3.4-7.3.7
Software Design Control	-	NQA-2a-1990(Part 2.7)	-
Competence, Training and Qualification	N45.2.11-1974/Sect. 2.2	N45.2.11-1974/Sect. 2.2	6.2
ANSI Standard		ANSI N45.2.11 -1974	
<b>Procurement Document Control</b>		Basic Reqmt. 4	
Scope of Work	4, N45.2-1971	4S-1(2.1)	7.4.2
Include/reference Applicable Requirements in PO	4, N45.2	4, 4S-1(2.2)	7.4.2
QA Program Requirements (for supplier)	4, N45.2	4, 4S-1(2.3)	7.4.2 (c)
Right of Access	N45.2	4S-1(2.4)	7.4.3
Documentation Requirements	N45.2	4S-1(2.5)	-
Nonconformance Reporting	10CFR21	4S-1(2.6)	-
Spare and Replacement Parts	-	4S-1(2.7)	-
Document Review	6, N45.2	4S-1(3)	7.4.2
Document Changes	6, N45.2	4S-1(4)	-
<b>Instructions, Procedures, and Drawings</b>		Basic Reqmt. 5	
Written Instructions, Procedures, and Drawings	5, N45.2-1971	5	4.2.1, 7.1
Perform Activities Following Documentation	5, N45.2	5	7.5.1
Acceptance Criteria for Activities	5, N45.2	5	7.5.1

<b>Document Control</b>		Basic Reqmt. 6	
Preparation, Review, Approval, and Issuance	6, N45.2-1971	6, 6S-1 (2)	4.2.1,4.2.3
Changes	6, N45.2	6, 6S-1 (3)	4.2.3
<b>Control of Purchased Items and Services</b>		Basic Reqmt. 7	
Procurement Planning	N45.2.13-1976/Sect. 2	7, 7S-1 (2)	7.4.1*
Supplier selection	N45.2.13/Sect. 4	7, 7S-1 (3)	7.4.1*
Bid Evaluation	N45.2.13/Sect. 5	7S-1 (4)	-
Supplier Performance Evaluation	N45.2.13/Sect. 6	7S-1 (5)	7.4.1*
Supplier Generated Documents	N45.2.13/Sect. 6.3	7S-1 (6)	-
Changes in Items or Services	N45.2.13/Sect. 6.4	7S-1 (7)	-
Acceptance of Items or Services	N45.2.13/Sect. 10	7, 7S-1 (8)	7.4.3*
Control of Supplier Nonconformances	N45.2.13/Sect. 8	7S-1 (9)	-
Commercial Grade Items	10CFR21	7S-1 (10)	-
ANSI Standard		ANSI N45.2.13-1976	
<b>Identification and Control of Items</b>		Basic Reqmt. 8	
Establish Controls to Identify Items	8, N45.2-1971	8	7.5.3
Identification Methods	8, N45.2	8, 8S-1 (2)	-
Identification and Traceability of Items	8, N45.2	8, 8S-1 (3.1)	7.5.3
Limited Life Items	-	8, 8S-1 (3.2)	-
Maintaining Identification of Stored Items	8, N45.2	8, 8S-1 (3.3)	-
<b>Control of (Special) Processes</b>		Basic Reqmt. 9	
Process control	9, N45.2-1971	9, 9S-1 (2)	7.5.1
Special Processes	9, N45.2	9, 9S-1 (3)	7.5.2
Responsibility	9, N45.2	9S-1 (3.1)	7.5.2
Acceptance Criteria	9, N45.2	9S-1 (3.2)	7.5.2 (a)
Records	17, N45.2	9S-1 (3.3)	7.5.2 (d)
Special Requirements	9, N45.2	9S-1 (3.4)	7.5.2 (c)

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<b>Inspection</b>		Basic Reqmt. 10	
Independence of Inspection Personnel	10, N45.2-1971	10, 10S-1(3.1)	-
Qualification of Inspection Personnel	N45.2.6-1978	10S-1 (3.2)	6.2.2
Inspection Hold Points	10, N45.2	10S-1 (4)	8.2.4
Inspection Planning (characteristics, methods, acceptance criteria)	10, N45.2	10,10S-1 (5)	8.1 a), 8.2.4
In-Process Inspection	10, N45.2	10, 10S-1 (6)	8.2.4
Combined Inspection and Monitoring	10, N45.2	10S-1 (6.2)	8.2.4
Final Inspection	10, N45.2	10, 10S-1 (7)	8.2.4
In-service Inspection	10, N45.2	10, 10S-1 (8)	-
Records	17, N45.2-1971	10, 10S-1 (9)	8.2.4
<b>Test Control</b>		Basic Reqmt. 11	
Planning	11, N45.2-1971	11	-
Test Requirements	11, N45.2	11, 11S-1(2)	-
Test Procedures (Other than for Computer Programs)	11, N45.2	11, 11S-1(3)	-
Computer Program Testing	-	11S-2	-
Test Results	11, N45.2	11, 11S-1(4)	-
Test Records	11, N45.2	11, 11S-1(5)	-
<b>Control of Measuring and Test Equipment</b>		Basic Reqmt. 12	
Selection	12, N45.2-1971	12, 12S-1 (2)	7.6
Calibration	12, N45.2	12, 12S-1 (3.1)	7.6 a) ,b)
Control	12, N45.2	12, 12S-1 (3.2)	7.6
Commercial Devices	N45.2	12S-1 (3.3)	-
Handling and Storage	*	12S-1 (4)	7.6 e)
Identification and Status Indication	N45.2	(ISO/IEC 17025)	-
Records	N45.2	12S-1 (5)	7.6
(Additional) ISO/IEC 17025:1999 -Environmental control	5.3**	5.3**	-
Suitable methods	5.4**	5.4**	-

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Appropriate Equipment and Software	5.5**	5.5**	-
<b>Handling, Storage, and Shipping</b>	13, N45.2-1971	Basic Reqmt. 13	
Documented Procedures	13, N45.2-1971	13, 13S-1(2)	-
General Requirements	13, N45.2	13S-1 (3.1)	-
Procedures for Special Items	13, N45.2	13S-1 (3.2)	-
Tools and Equipment	13, N45.2	13S-1 (3.3)	-
Operator skills/training	*	13S-1 (3.4)	-
Marking or Labeling	N45.2	13S-1 (4)	7.5.5*
Classification of Items	N45.2.2-1972/Sect2.7	N45.2.2(1972)/Sect2.7	-
Packaging	N45.2.2/Sect 3	N45.2.2/Sect 3	7.5.5*
Shipping	N45.2.2/Sect 4	N45.2.2/Sect 4	7.5.5*
Receiving	N45.2.2/Sect 5	N45.2.2/Sect 5	7.4.3*
Storage	N45.2.2/Sect 6	N45.2.2/Sect 6	7.5.5*
Handling	N45.2.2/Sect 7	N45.2.2/Sect 7	7.5.5*
Additional Requirements		NQA-2 (1986) Part 2.2	
Inspection, Test, and Operating Status		Basic Reqmt. 14	
Identification of Test/Operating Status of Items	14, N45.2-1971	14	7.5.3
Specify Authority to Change Item Status	14, N45.2	14	-
Status Indicators for valves and Switches	14, N45.2	14	-
<b>Control of Nonconforming Items</b>		Basic Reqmt. 15	
Identification	15, N45.2-1971	15, 15S-1 (2)	8.3
Segregation	15, N45.2	15, 15S-1 (3)	-
Disposition Control	15, N45.2	15, 15S-1 (4.1)	8.3
Responsibility and Authority	15, N45.2	15, 15S-1 (4.2)	8.3
Competency of Personnel (Dispositioner)	*	15, 15S-1 (4.3)	-
Disposition	15, N45.2	15, 15S-1 (4.4)	8.3
Repaired or Reworked Items	15, N45.2	15, 15S-1 (4.5)	8.3

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Notification to Affected Organizations	15, N45.2	15	8.3
Reportability of Nonconformances (safety related)	10CFR Part 21	10CFR Part 21	8.3
<b>Corrective Action</b>		Basic Reqmt. 16	
Identification of Conditions Adverse to Quality	16, N45.2-1971	16	8.5.2 a)
Identification of Root Cause	16, N45.2	16	8.5.2 b)
Corrective Action (to preclude recurrences)	16, N45.2	16	8.5.2 c), d)
Documentation	16, N45.2	16	8.5.2 e)
Reporting	16, N45.2	16	8.5.2*
Verification of Corrective Action (Follow-up)	N45.2.12-1977/sect 4.5	16	8.5.2 f)
Preventive Action	16*	16	8.5.3**
ANSI Standard	ANSI N45.2.12-1977	ANSI N45.2.12-1977	
<b>Quality Assurance Records</b>	17, N45.2-1971	Basic Reqmt. 17	
Record System (documented procedure)	N45.2.9-1974/Sect 2.1	17, 17S-1(2.1)	4.2.4
Generation of Records (Legible, Complete)	N45.2.9/Sect 3.2	17, 17S-1(2.2)	4.2.4
Record Authentication/Validation	N45.2.9/Sect 3.2	17, 17S-1(2.3)	-
Index, Retention, Storage	N45.2.9/Sect 3.2	17S-1(2.4, 2.8, 4.1)	-
Distribution	N45.2.9/Sect 3.2	17, 17S-1(2.5)	-
Identification (with related activity)	N45.2.9/Sect 3.2	17, 17S-1(2.6)	4.2.4
Classification (Lifetime or Nonpermanent)	N45.2.9/Sect 2.2	17S-1(2.7)	-
Retention of Records	N45.2.9/Sect 3.2	17, 17S-1(2.8)	4.2.4
Corrected Information in Records	N45.2.9/Sect 3.2	17S-1(2.9)	-
Receipt control and Status	N45.2.9/Sect 4	17S-1(3.2, 3.3)	-
Storage	N45.2.9/Sect 5.3	17, 17S-1(4.1)	4.2.4
Preservation	N45.2.9/Sect 5.4	17, 17S-1(4.2)	4.2.4*
Safekeeping (preclude unauthorized access)	N45.2.9/Sect 5.5	17, 17S-1(4.3)	-
Facility	N45.2.9/Sect 5.6	17, 17S-1(4.4)	-
Retrieval	N45.2.9/Sect 6	17, 17S-1(5)	4.2.4

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Disposition	N45.2.9/Sect 7	17, 17S-1(6)	4.2.4
Personnel Records	17	2S-1 to 2S-4	6.2.2 e)
Retention Times of Materials and Specimens	-	-	-
ANSI Standard		ANSI N45.2.9-1974	
<b>Audits/Assessments</b>	18, N45.2.12-1977	Basic Reqmt. 18	
Audit Schedule	N45.2.12/Sect 3.5	18, 18S-1 (2)	8.2.2
Audit Plan	N45.2.12/Sect 3.4	18, 18S-1 (3.1)	8.2.2
Personnel (authority, freedom)	18, N45.2	18, 18S-1 (3.2)	8.2.2
Selection of Audit Team	N45.2.12/Sect 4.2.2	18S-1 (3.3)	8.2.2
Performance (using checklists etc)	N45.2.12/Sect 4.3	18, 18S-1 (4)	8.2.2
Reporting	N45.2.12/Sect 4.4	18, 18S-1 (5)	8.2.2
Response (from Management)	N45.2.12/Sect 4.5.1	18, 18S-1 (6)	8.2.2
Follow-up Action	N45.2.12/Sect 4.5	18, 18S-1 (7)	8.2.2
Records	N45.2.12/Sect 5	18, 18S-1 (8)	8.2.2
Audits (reviews) to promote improvement	-	-	8.1 c)**
Management Self-assessment	-	-	-
ANSI Standard		ANSI N45.2.12-1977	

Legend:

Qxx – Safety Guide

S – Supplementary to Basic Requirements (BR)

- Not addressed

\* Not adequately described

\*\* Described in detail

GE-Stds Comparison –

Feb 03, 2003



## **2.2 GE Quality Assurance Program Implementation**

GE has a well established system of quality assurance manuals, operating procedures, and instructions to implement technical, quality assurance and quality control requirements in the performance of all activities affecting quality. An index of GE's Engineering Operating Procedures, which satisfy a majority of the quality assurance programmatic elements, is presented in Table 2.

This QA Plan complements the existing GE standard program and procedures, as required, to meet project unique requirements. GE Engineering-unique QA procedures and requirements are documents and controlled through the use of Engineering Service Instructions (ESIs). ESBWR Project-unique QA procedures and requirements are documented and controlled through the use of ESBWR Project Instructions (EPis).

Table 2 Index of GE's Engineering Operating Procedures

TAB/TITLE		REV. DATE	REV. NO.
<b>FORWARD</b>			
<b>SPA</b>	Statement of Policy & Authority	2/19/03	3
<b>TABLE OF CONTENTS</b>			
<b>TOC</b>	Table of Contents	9/29/05	191
<b>10 EOP MANUAL ADMINISTRATIVE CONTROL</b>			
<b>10-2.00</b>	Control and Administration of Engineering Operating Procedures	9/29/05	16
<b>15 ENGINEERING OPERATING SYSTEM</b>			
<b>15-1.00</b>	EOP Counsels	9/29/05	76
<b>15-2.00</b>	Engineering Operating Procedures Application	6/30/05	19
<b>20 ORGANIZATION AND FUNCTION</b>			
<b>20-2.00</b>	Organization Directory	4/26/01	12
<b>20-4.10</b>	Design Engineering and SCO Manufacturing Interface Agreement	2/13/02	17
<b>20-4.20</b>	GE-NE and Reuter-Stokes Inc. Interface Agreement	6/26/96	3
<b>20-4.30</b>	GE-NE and VO Interface Agreement	4/17/02	1
<b>25 RESOURCE PLANNING, MEASUREMENT, AND COST CONTROL</b>			
<b>25-2.00</b>	Customer Requests, Proposals and Sales Contracts, and Order Processing	10/29/02	4
<b>25-4.00</b>	Work Authorization	6/26/96	10
<b>25-5.00</b>	Work Planning and Scheduling	6/11/03	10
<b>25-5.10</b>	Design Inputs and Customer Technical Requirements	8/13/03	2
<b>30 PRODUCT DEFINITION AND CONTROL</b>			
<b>30-3.00</b>	Product Definition	9/29/05	6
<b>30-3.40</b>	Product Data Management System	8/23/04	6
<b>30-5.00</b>	Engineering Records Documentation Supplied by External Sources	12/10/02	6
<b>30-7.00</b>	Technical Design Procedures	9/9/02	12
<b>35 PRODUCT DEVELOPMENT</b>			
<b>35-1.00</b>	New Product Introduction	1/14/05	7
<b>35-2.00</b>	Conceptual Design Studies	8/13/03	2
<b>35-3.00</b>	Engineering Tests	3/12/98	13
<b>35-3.10</b>	Special Engineering Tests/Inspections at Operating Plants	11/3/99	8
<b>35-3.20</b>	Calibration Control	9/13/04	10
<b>35-3.30</b>	Laboratory/Service Tests	6/26/96	3

Table 2 (Continued)

TAB/TITLE		REV. DATE	REV. NO.
<b>40 ENGINEERING TECHNOLOGY AND DESIGN</b>			
40-2.00	Quality Information Systems	6/26/96	2
40-3.00	Engineering Computer Programs	12/10/02	20
40-3.10	Engineering Data Banks	2/25/00	4
40-3.20	Data Acquisition Systems Control	6/26/96	2
40-7.00	Design Reviews	8/10/00	10
40-9.00	ASME Code Design Certification	3/13/02	12
40-9.20	ASME Code Effective Date	12/2/04	11
40-12.00	Materials and Processes Engineering Control	12/11/01	3
40-17.00	Reliability Studies	4/17/02	4
40-18.00	Packaging of GE-NE – Procured or Manufactured Items	7/2/98	6
<b>42 TECHNOLOGY AND DESIGN CONTROL</b>			
42-1.00	Design Process	8/23/04	13
42-4.00	Engineering Instructions	3/19/03	0
42-5.00	Material Requests	3/31/05	12
42-6.00	Independent Design Verification	8/23/04	15
42-6.10	Deferred Design Verification	8/23/04	6
42-8.00	Document Initiation or Change by ERM/ECN	8/23/04	10
42-10.00	Design Record File	5/21/04	14
42-12.20	Material and Equipment Traceability Requirements	6/26/96	4
<b>45 PROCUREMENT</b>			
45-1.00	Procurement Initiation and Control	3/31/05	13
45-4.00	Supplier Services/Equipment Document Review	3/19/03	14
45-6.00	Deviation Disposition Requests from Suppliers	5/22/02	11
45-6.10	Supplier Change Request	3/27/00	6
<b>50 MANUFACTURING</b>			
50-3.00	Material Review Board	1/25/99	11
50-4.00	ASME Code Effectivity Date Reconciliation	12/11/01	4
<b>55 CHANGE CONTROL</b>			
55-2.00	Engineering Change Control	12/11/01	10
55-3.00	Field Deviation Disposition Request	8/23/04	12
55-3.20	Field Disposition Instruction	6/26/96	4
55-4.00	Change Control Board	5/22/02	6
55-10.00	Interchangeability Requirements	10/29/02	3
<b>60 DOCUMENT CONTROL</b>			
60-3.00	Document Requirements	9/29/05	0
60-3.10	Design Document Distribution	9/29/05	9
60-3.20	Quality-Related Computer Data	6/26/96	2
60-6.00	Drafting Manual Control	9/9/02	7
60-7.00	Protection of Safeguards Information	5/21/04	2

Table 2 (Continued)

TAB/TITLE		REV. DATE	REV. NO.
<b>65 SAFETY AND LICENSING</b>			
65-2.00	Product Safety Requirements	5/22/02	10
65-2.10	Safety-Related Classification	4/10/98	12
65-2.20	Dedication of Commercial Grade Items	9/30/04	14
<b>70 OPERATING PLANT SUPPORT</b>			
70-3.00	Spare and Renewal Parts	5/21/04	20
70-4.00	Repair/Refurbishment Services	4/26/01	7
70-5.00	Operation and Maintenance Instruction Manuals	3/13/02	4
70-6.00	Warranty Services	10/29/02	3
70-7.00	Nuclear Emergency Support Program	2/17/05	6
70-8.00	Tool Design and Procurement Process	12/12/00	1
70-9.00	Welding Control	10/29/02	1
<b>75 PRODUCT QUALITY</b>			
75-2.00	Qualification and Certification of Personnel	1/14/05	13
75-3.00	Self-Assessment, Corrective Action and Audits	5/12/05	10
75-4.00	Material Inspection and Release	9/13/04	5
75-4.10	Control of Nonconforming Material	3/27/00	6
75-4.20	Material Handling, Storage and Shipping	6/11/03	7
75-4.30	Customer Supplied Material	3/27/00	3
75-5.00	Quality and Technical Training	9/30/04	13
75-6.00	Quality Assurance Records	9/29/05	7
75-7.00	Statistical Techniques	6/26/96	1
<b>80 GENERAL ADMINISTRATION</b>			
80-5.00	ASME Quality Assurance Program	6/26/96	8
<b>85 FORMS INDEX</b>			
85-1.00	Forms	1/14/05	17
85-3.00	Reproducible Forms	6/30/05	46

## 2.3 ESBWR COL Demonstration Project Quality Program

All applicable elements of regulations and standards shall be addressed in the project quality plan either by documentation of an appropriate procedure in this program or by reference to the applicable procedure established as a separate document. The project quality procedures will address quality assurance and quality control requirements applicable to the project phase including, but not limited to, the following program elements and processes:

- Project organization
  - structure including interfaces and relationships with the Customer and Suppliers
  - functional responsibilities and authorities
- Quality assurance program
  - regulatory requirements including US codes and standards applicable to the scope of supply or service
  - every Supplier and Subcontractor of safety related and ASME code product or service will be required to have a documented and approved quality program, or will perform subject to the GE QA Program
  - The project unique requirements in this quality plan will be under configuration revision control. If changes to the GE Quality Assurance Program cause substantive conflicts with the project quality assurance plan, the Customer will be notified and GE will evaluate and propose resolution.
- Design process (EOP 42.-1.00)
  - design control including customer inputs, design, analysis and records
  - design verification and validation activities performed by competent individuals other than those who performed the original design
  - design change control - changes to design inputs and final designs are justified and subject to design control measures
  - configuration management
- Document control (EOPs 60-3.10, 60-3.20, 60-5.00, 60-5.10, 60-7.00)

- development, review, approval and configuration of drawings, specifications, procedures, instructions and other documents is controlled
- Procurement process
  - procurement documents including quality assurance and control requirements, review and approvals (EOP 42-5.00 and 45-1.00),
  - selection, evaluation and assessments of subcontractor capabilities and quality system (EOP 45-1.00),
  - review and approval of subcontractor design, process procedures and work product (EOP 30-5.00 and 45-4.00).
- Access and Rights of Reviews and Audits
  - The representatives of the Customer will have access to GE's and GE Subcontractor's facilities to review all quality assurance programs, procedures, engineering and quality control records related to the project, as specified by the appropriate contracts
- Control of nonconformances
  - Any design/engineering deviation will be treated as design change in accordance with EOP 55-2.00 and 55-4.00
- Reporting Defects and Noncompliance Under 10CFR21
  - GE shall have the responsibility of immediately reporting any existing or potential nonconformance or deficiency that could create a substantial safety hazard or lead to a Technical Specification Safety Limit violation, whether or not such nonconformance or deficiency is related to work performed by GE or by others
  - GE shall require suppliers to report any existing or potential nonconformance or deficiency that could create a substantial safety hazard or lead to a Technical Specification Safety Limit violation, whether or not such nonconformance or deficiency is related to work performed by them or others.
  - P&P 70-42 identifies the procedures and individuals responsible for the reporting process.
- Training and qualification of personnel

- Indoctrination/training and certification of personnel shall be commensurate with scope, complexity, importance of activities, and the education, experience, and proficiency of the person in accordance with P&P 70-30 and EOPs 40-9.00 and 75-2.00
- Audits
  - internal audits of project activities will be performed by lead auditors on a periodic basis as specified by the appropriate contract to evaluate performance and compliance with the project Quality Plan and the implementing procedures, during the life of the project. Results of these audits will be regularly reported to the Customer and GE management.
- Corrective actions (for significant conditions adverse to quality)
  - corrective and preventative actions initiation, commitment tracking, statusing, and closure.
  - follow-up to ensure completion and control.
- Quality assurance records

All requirements of EOP 42-10.00, EOP 60-3.10 and EOP 75-6.00 shall be complied with)

### 3.0 GE Organization

This section defines the organization and functional responsibilities and authorities of the organizations within GE to assure that the management is directed toward satisfying the quality objectives of providing safe and reliable nuclear power plants. The organization of GE's ESBWR Project is shown in Figure 4. GE business segments and functional organizations are charged with the responsibility to plan and execute project activities.

**The NPP and Engineering & Technology General Managers** are responsible to provide leadership for the business planning, missions, technology, engineering resources, operation and management of activities. The General Manager is responsible for establishing quality policy and direction. The General Manager is also responsible to select a qualified project manager based upon education, skills and experience required for the specific project.

**The ESBWR Project Managers** provide overall project management and are responsible for the administration and control of engineering, production and delivery, and quality related activities for the assigned project.

**The ESBWR Engineering Manager and Functional Managers** are responsible to provide leadership for the overall administration, operation and quality of the assigned business segment/function. The manager is responsible to coordinate quality assurance program objectives and implementation of technical, quality and regulatory requirements throughout their assigned missions and processes to assure delivery of quality products to the satisfaction of the customer.

**The Quality Manager** is responsible to provide leadership for developing and overall coordination of the quality assurance program objectives, measurement of objectives, adequate resources, and quality initiatives for improvement of processes used by GE for product and service offerings including but not limited to, reporting to top management on the performance of the quality assurance system and ensuring the promotion of awareness of customer requirements throughout the organization.

The responsibility assignments within the organization are intended to achieve the required quality by those responsible for performing the activities and to provide verification of the quality by other trained personnel not having this direct responsibility. Verification by inspection and test is performed by quality assurance (QA) and/or quality control (QC) personnel who have organizational freedom.



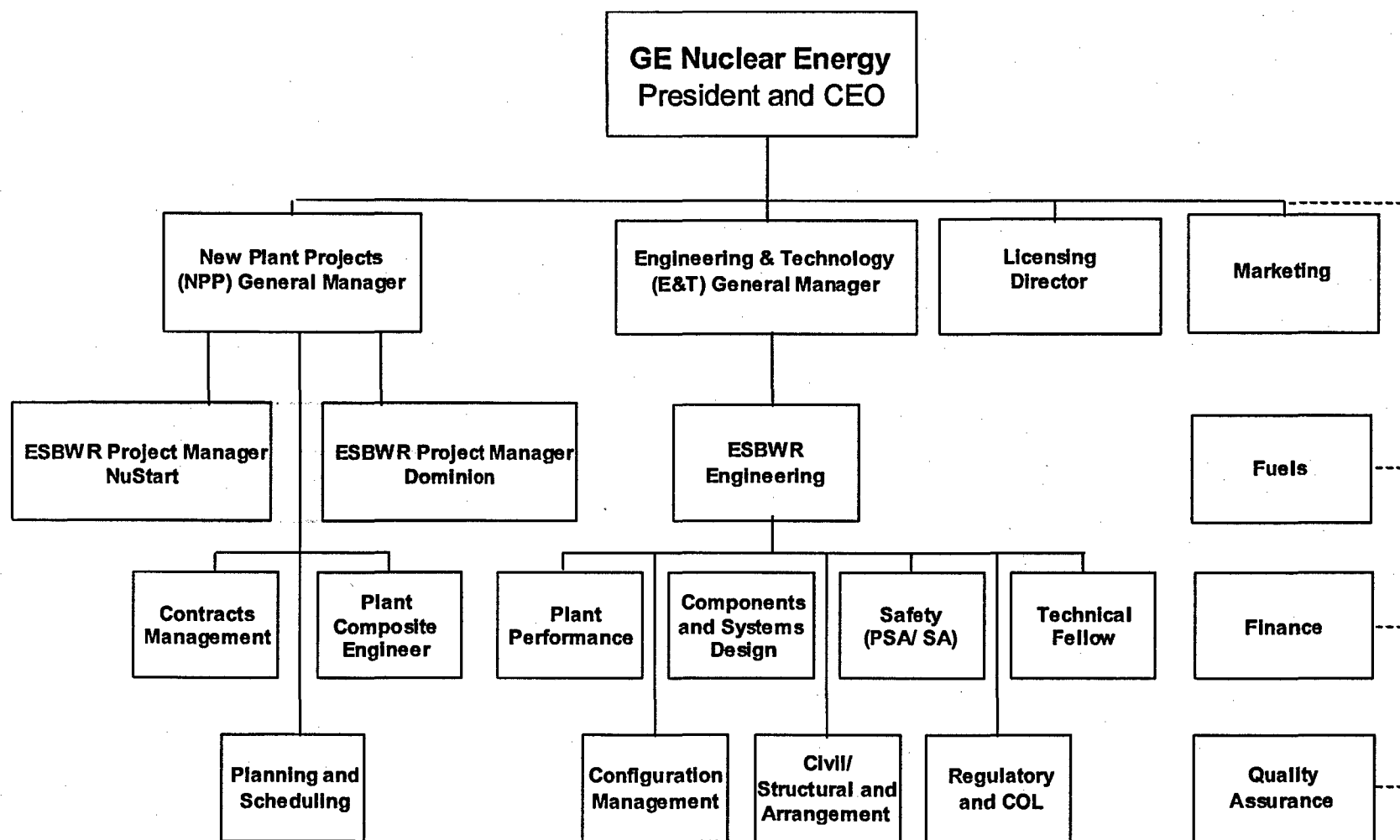


Figure 4 ESBWR COL Demonstration Project Organization

### **3.1 ESBWR Project Organization**

GE, as the prime supplier for the ESBWR design activity, will assemble a project team which will represent a select group of companies with a spectrum of worldwide expertise and capabilities, and which encompasses those attributes required to produce a high quality nuclear power plant design.

The project organization structure is intended to clearly establish functional responsibilities and authorities of GE and its major subcontractors performing design, design certification and COL demonstration activities.

The Manager, Quality of Engineering and Technology, irrespective of other responsibilities, will ensure that the requirements of the quality program, project procedures, and the referenced codes and standards are implemented and maintained.

#### 4.0 References

1. (ATTACHMENT 1) GE Nuclear Energy Quality Assurance Program Description, NEDO-11209-04A, Revision 8, March 31, 1989.
2. (ATTACHMENT 2) GE Nuclear Energy ISO-9001 Quality System Description, NEDO-32280 (Draft), December 20, 2002.
3. GEEQMS, GE-Energy Quality Policy Manual, 2005.
4. NEDE-20910, Compliance manual for ASME Boiler and Pressure Vessel Code, Section III Division 1 and Section VIII Division 1, Revision 7, 1977.

NEDO-33181 Revision 1

**ATTACHMENT 1**  
**GE Nuclear Energy**  
**Quality Assurance Program Description**  
**NEDO-11209-04A**

NEDO-11209-04A  
REVISION 8  
CLASS 1  
MARCH 31, 1989

## GE NUCLEAR ENERGY QUALITY ASSURANCE PROGRAM DESCRIPTION

ISSUED BY QUALITY ASSURANCE SYSTEMS OF THE  
NUCLEAR QUALITY ASSURANCE

APPROVED:



J. M. CASE, MANAGER

NUCLEAR QUALITY ASSURANCE

---

GE NUCLEAR ENERGY • GENERAL ELECTRIC COMPANY  
SAN JOSE, CALIFORNIA 95125

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• Gary G. Zech to P.W. Sick, "GE Nuclear Energy Organizational Changes," March 16, 1994	
• P.W. Sick to Document Control Desk, "GE Nuclear Organizational Changes," July 25, 1994	
• Suzanne C. Black to P.W. Sick, "GE Nuclear Organizational Changes," September 30, 1994	
• P.W. Sick to Document Control Desk, "GE Nuclear Organizational Changes," January 24, 1994	

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# ABBREVIATIONS

AEWRP-	Advanced Boiling Water Reactor Program	8
AE-	Architect Engineer	
ANSI-	American National Standards Institute	
ANT-	Advance Nuclear Technology	
ASME-	American Society of Mechanical Engineers	
B&PV-	Boiler and Pressure Vessel	
BS-	Bachelor of Science	
BWR-	Boiling Water Reactor	
Calib.-	Calibration	
CFR-	Code of Federal Regulations	
CRD-	Control Rod Drive	
EI-	Engineering Instruction	
ECN-	Engineering Change Notice	
EOP-	Engineering Operating Procedures	
ES-	Engineering Services	8
DDR-	Deviation Disposition Request	
FDDR-	Field Deviation Disposition Request	
FDI-	Field Disposition Instruction	
FE-	Fuel Engineering	8
GE-	General Electric	
GENE-	GE Nuclear Energy	8
GESSAR-	General Electric Standard Safety Analysis Report	
Insp.-	Inspection	
Instr.-	Instrument	
IR-	Inspection Report	
lb-	Pound	
LWR-	Light Water Reactor	
MFL-	Master Parts List	
MR-	Material Request	
MRB-	Material Review Board	
NDE-	Nondestructive Examination	
NECSD-	Nuclear Energy Customer Service Department	
NEFO-	Nuclear Energy Finance Operation	
NF&CM-	Nuclear Fuel and Components Manufacturing	
NF&CM-QA-	Quality Assurance, Nuclear Fuel and Components Manufacturing	
NFPA-	National Fire Protection Association	
NO-	Nuclear Operations	
NQA-	Nuclear Quality Assurance	8
NPSD-	Nuclear Plant Services Department	
NRC-	Nuclear Regulatory Commission	
NSP-	Nuclear Services Procedures	
NSSS-	Nuclear Steam Supply System	

ABBREVIATIONS (Continued)

8	NTL-	Nuclear Technology Licensing
	P&ID-	Process and Instrumentation Diagram
	P&P-	Policies and Procedures or Practices and Procedures
8	PQA-	Product Quality Assurance
	PQC-	Product Quality Certification
	PSAR-	Preliminary Safety Analysis Report
	Rev.-	Revision
	RPV-	Reactor Pressure Vessel
	QA-	Quality Assurance
	QC-	Quality Control
8	QRS-	Quality Requirements Specification
	RIS-	Requisition Instruction Sheet
8	R-S, Inc.-	Reuter-Stokes, Inc.
	WA-	Work Authorization



UNITED STATES  
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WASHINGTON, D. C. 20555

NEDO-11209  
3-31-89

MAR 31 1989

Mr. Joe M. Case  
Acting Quality Assurance Systems Manager  
GE Nuclear Energy  
General Electric Company  
175 Curtner Avenue  
San Jose, CA 95125

Dear Mr. Case:

SUBJECT: ACCEPTANCE OF AMENDMENT 8 TO GENERAL ELECTRIC COMPANY (GE)  
QA TOPICAL REPORT

We have reviewed the following information relative to your QA program:

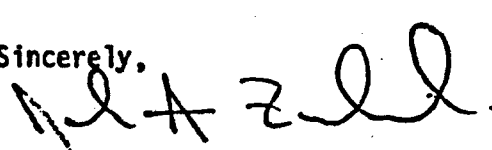
QA Program Description: Topical Report NEDO-11209, proposed Amendment 8  
submitted by your letter of March 3, 1989.

Response to Questions: Your letter to NRC dated March 16, 1989.

We find that the QA program description continues to meet the requirements  
of 10 CFR 50, Appendix B; therefore, the changes are acceptable.

Please include a copy of this letter in your plan and provide the plan to  
the NRC in accordance with 10 CFR 50.4(b)(7)(ii). That is, submit one signed  
original of the revised plan to the Nuclear Regulatory Commission, Document  
Control Desk, Washington, D.C. 20555. Contact the staff reviewer, Jack  
Spraul, on (301) 592-1023, or his supervisor, Frank Hawkins, on (301) 492-  
1009, if there are any questions.

Sincerely,

  
John A. Zwolinski, Deputy Director  
Division of Licensee Performance  
and Quality Evaluation  
Office of Nuclear Reactor Regulation

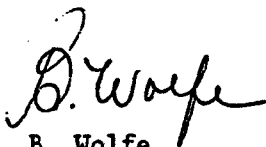
**GENERAL ELECTRIC COMPANY  
175 CURTNER AVENUE  
SAN JOSE, CALIFORNIA 95125**

**STATEMENT OF POLICY AND AUTHORITY**

It is the policy of the GE Nuclear Energy to attain quality leadership, and to achieve and maintain high quality in products and services through timely and effective compliance with all quality requirements.

This document describes the 10CFR Part 50 Quality Assurance Program which is to be used by the GE Nuclear Energy to fulfill the regulatory aspects of this policy. All managers within the GE Nuclear Energy with quality-related responsibilities have full authority to implement the applicable elements of the program within their respective areas of responsibility. Implementation of the Quality Assurance Program is a basic responsibility of each of the organizations within the GE Nuclear Energy.

The implementation of this GENE Quality Assurance Program has the unqualified endorsement and support of General Electric management.



B. Wolfe  
Vice President and General Manager  
GE Nuclear Energy

## INTRODUCTION

A Quality Assurance (QA) Program is provided by the GE Nuclear Energy (GENE) to assure the required effort, equipment, procedures, and management are directed toward satisfying the quality objectives of providing safe and reliable systems, services and components, and complying with the provisions of the following documents: Appendix B of 10CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants"; NRC Regulatory Guide 1.28, "Quality Assurance Program Requirements"; ANSI N45.2-1971, "Quality Assurance Program Requirements for Nuclear Power Plants" and applicable sections of the ASME Boiler and Pressure Vessel Code. The extent of the QA program implementation is consistent with contract requirements.

The program herein described is structured in accordance with the outline of the 18 criteria of Appendix B of 10CFR Part 50, and NRC Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants" - Light Water Reactor (LWR) Edition dated September 1975.

This document describes the QA Program which is applied generally throughout the GENE, but which is specifically applicable to the safety-related functional aspects of systems, services and components, within the domestic scope of supply. This scope of supply includes nuclear steam supply systems (NSSS), services, and nuclear fuel. Systems, services, and components, included in the scope of supply are considered "safety-related" if they prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The quality of any systems, services, or components not classified "safety-related" is controlled in accordance with the importance of the overall functions to be performed by these items.

The Nuclear Regulatory Commission (NRC) will be given notification of programmatic changes in the QA Program as described herein, prior to implementation, except changes which do not decrease the effectiveness of the program, or those that reflect organizational changes. Organizational changes affecting the QA Program will be reported to the NRC within 30 days after implementation. This QA Program description will be reviewed at least annually and revised, if necessary, to reflect programmatic and organizational changes.

The QA Program is designed to provide assurance that the quality-related work elements for systems, components (including spare and replacement parts), and services included in the scope of supply, are identified and controlled. Specific responsibilities of personnel and organizations are assigned and documented for quality-related activities throughout the major steps of design, construction, and field services of the nuclear power plant projects, encompassing the broad phases of:

- o Contract definition
- o Preliminary design
- o Systems and components design and specification
- o Supplier evaluation and selection
- o Material and component procurement
- o Fabrication and assembly of components and systems
- o Inspection and testing
- o Cleaning, packaging, and shipping
- o Installation and erection of systems, components,
- o Preoperational and startup testing
- o Field Services

In addition to the Nuclear Quality Assurance (NQA), the various line organizations have specifically designated QA responsibilities. Documented procedures require each such organization to administer its own activities and conduct self-audits as required, in addition to audits of suppliers to assure compliance with the QA Program for their assigned scope of responsibilities. These audits in turn are augmented by audits of these organizations by NQA.

Where specific GENE job titles, document titles, or specific procedures or forms are identified in NEDO-11209, the use of equivalent titles, forms, or procedures is acceptable. However, when job responsibilities or procedural controls as described in this topical report are changed, the changes will be reported to the NRC.



## 1 ORGANIZATION

### 1.1 GENERAL

Organizational structuring and functional responsibility assignments in the GENE are based on recognition of QA as an interdisciplinary function with quality-related activities being performed by many organizational components and individuals from top-level management down to individual contributors.

The authorities and responsibilities of persons and organizations performing quality-related activities are established, assigned, and documented in formal document systems. Persons and organizations assigned QA functions are given appropriate and sufficient authority and organizational freedom to: identify quality problems; initiate, recommend, or provide solutions to quality problems; verify implementations of solutions, and prevent further processing, delivery, installation, or utilization of a nonconforming item until proper dispositioning has occurred.

The organizational structure and functional responsibility assignments are such that: (1) attainment of quality objectives is accomplished by individuals assigned responsibility for specifying quality requirements or performing work to specifications; (2) verification of conformance to established quality requirements is accomplished by those who do not have direct responsibility for specifying, producing, or expediting products; and (3) personnel in key QA functions have direct access to top-level GENE management.

### 1.2 ORGANIZATIONAL FUNCTIONS

An abbreviated organization chart showing the GENE, and specifically those organizational components concerned with supplying systems, services, and components and with performing QA activities during design, purchase, manufacture, site construction, field service, and test, is shown as Figure 1-1.

The Nuclear Quality Assurance (NQA), Fuel Engineering (FE), Nuclear Plant Services Department (NPSD), Engineering Services (ES), EWR Technology, Nuclear Fuel & Components Manufacturing (NFCM), Reuter-Stokes, Inc. (R-S, Inc.), Advance Nuclear Technology (ANT), Nuclear Energy Finance Operation (NEFO), report to the General Manager of Nuclear Operations (NO). The General Managers of Nuclear Operations, Advanced EWR Program (AEWRP), Nuclear Energy Customer Services Department (NECSD), and Nuclear Technology Licensing (NTL) report to the Vice President and General Manager of GE Nuclear Energy (GENE). The Manager, NQA, has unrestricted access, at his determination, to the Vice President and General Manager of GENE regarding quality-related matters.

The General Manager, Nuclear Operations has been designated by the Vice President and General Manager, GENE, as the quality conscience of the GENE. As the quality conscience of the GENE, the General Manager, NO has the following responsibilities: (1) to assure that the intent of the GENE quality policies are reflected in the products and services that are intended to be used in nuclear facilities; (2) to assure that a system is in place for independently measuring the performance of all GENE organizations that have an effect on the quality of those products and services of GENE that are intended to be used in nuclear facilities; and (3) to assure that a system is in place to promptly resolve identified issues that could have an impact on the ability of all GENE organizations to satisfy the GENE quality policies and other quality-related commitments.

8 The NQA is a staff organization assigned responsibility for establishing the GENE level quality-related policies and procedures (P&Ps). The GENE level quality-related policies and procedures thus established are issued by the Vice President and General manager, GENE. The NQA is also assigned responsibility for integrating, measuring, and auditing the various functional organizations involved in the business. Audit reports prepared by the NQA are issued independently by the NQA to the appropriate top-level GENE management. Procedures and practices are evaluated to assure conformance with applicable GE Corporate and GENE quality-related P&Ps, and to assure integration of individual quality planning into an overall QA Program. The NQA is responsible for auditing compliance of the overall QA Program with applicable codes, standards, and regulations. The NQA is also assigned the responsibility for monitoring the technical excellence of GENE products and services by participating in management review boards independent of the comprehensive design verification and review programs carried out by the line organizations. The Manager, NQA, is further assigned responsibility for QA communication to the QA line organizations within the GENE by providing technical guidance, advice and counsel based on current QA technology as it relates to the business. This technical guidance, advice, and counsel is directed toward specifying how the line organizations are to comply with the GENE Quality Policy and related procedures.

8 The GENE Vice President and General Manager has established a Quality Council to aid NQA in fulfilling its assigned integration and QA communications responsibilities and to provide a communications medium within the GENE and to the GENE Vice President and General Manager on quality-related matters. One of the primary objectives of the Council is to assure total quality system coverage, uniformity, consistency, and continuity, while eliminating system deficiencies and redundancies. The Council is 8 chaired by the Manager, NQA and consists of the managers responsible for QA in each of the major organizations within the GENE. The Council normally meets quarterly to review the status of quality-related programs and projects and to plan future efforts. The Council provides QA managers in the line organizations with direct access to top-level management and provides a forum for the review of quality problems and corrective actions.

8 NPSD, FE, ES, ANT, ABWRP, EWR Technology, NECSD, NF&M, NEFO, and Reuter-Stokes, Inc. are line organizations with responsibility for planning and implementing the QA functions performed within their areas of responsibility. Procedures require that the detailed QA program planning and implementation performed by these line organizations comply with the overall quality system requirements which are established by NQA in the GENE Quality Policy and quality-related Procedures. The QA activities related 8 to design, purchase, manufacture, and projects/services management, as they are performed by the line organizations, are described in the succeeding paragraphs.

Administrative control (salary review, hire/fire, position assignment) and QA direction of each department-level organization are the responsibility of the individual department-level managers. The individual QA managers have the authority, independence, and organizational freedom to identify quality-related problems; initiate, recommend, or provide solutions to conditions adverse to quality; and to verify implementation of such solutions. Each QA manager is provided a direct line of communication to his department-level manager on all quality-related matters.

The overall EWR system design and the detail design of items of equipment manufactured by the GENE organizations are provided by the GENE engineering organizations. Detail design of items of equipment

fabricated by subcontractors for direct shipment to the reactor site is provided by GENE engineering or by a subcontractor subject to GENE approval. Detail design of the GENE supplied systems and components, whether fabricated by the GENE or its subcontractors, is required to meet GENE specified system design requirements by application of appropriate specifications and design controls. A continuity of engineering control is maintained from the conceptual design phase through purchasing of materials, manufacturing, field installations, and preoperational and startup testing. To assure compatibility with Owner/AE design scope, GENE has identified specific interface requirements needed for input to GENE designs in a series of fill-in questionnaire documents which are furnished to the Owner/AE for completion and return to GENE engineering organizations during the design phase. The GENE engineering organizations have design change control responsibility for all GENE designed systems, components. Development engineering organizations contribute to the overall quality system by providing basic technical information and advanced inspection techniques resulting from planned development programs and through performance of necessary development and qualification tests.

The QA activities related to GENE manufactured, and GENE-field service products are under the various managers of QA. The Manager, Quality Assurance, Nuclear Fuel and Components Manufacturing (NF&QM), is responsible for providing QA planning and QA program implementation for equipment such as control rods, control rod drives (CRDs), steam separators, CRD hydraulic control modules, fuel bundles, channels, and fuel assembly components, which are manufactured in Wilmington, North Carolina. He is also responsible for providing QA planning and QA program implementation for purchased material and equipment used in the manufacture of F&QM products. The Vice President, Engineering & QA, Reuter-Stokes, Inc., is responsible for all QA planning and QA program implementation for procurement, manufacturing, engineering, and services provided by Reuter-Stokes, Inc. The Manager, Project Services, ANT is responsible for all QA planning and QA program implementation for procurement, manufacturing, engineering, and services provided by ANT. The Manager, Project Services, ABWRP is responsible for all QA planning and QA program implementation for procurement, manufacturing, engineering, and services provided by the ABWRP. The Manager, Product Quality Assurance, (PQA) is responsible for providing or assuring QA planning and QA program implementation for all other equipment, engineering, and services, including procured equipment and procured services, of the GENE. The Manager, PQA, is also responsible for providing or assuring QA planning and QA program implementation for field service activities provided by the GENE. These QA managers report directly to their respective department-level managers and are at the same organizational level as other managers who have product scheduling, expediting, and fabricating responsibilities; however, the QA manager's responsibilities are separate and independent from these other managers. Products are not released without the approval of the QA manager or his designee.

The QA activities for purchased equipment and purchased material and services are under the direction of assigned Quality Assurance Managers in NF&SD, NF&QM, ANT, ABWRP, or R-S, Inc. The QA Managers are at the same organizational level as managers with procurement, product scheduling, and expediting responsibilities. The QA Manager is responsible for defining QA requirements to suppliers of equipment and services and for assuring supplier compliance with GENE requirements through surveillance, audits, and review and approval of quality-related documentation. The GENE quality reviews of Owner/AE/Constructor field installation activities are performed by the QC Site Representative, under the direction of the Manager, PQA, as applicable by contract. The purpose of such reviews is to verify that GENE systems and components are properly received, handled, stored, and installed in compliance with GENE requirements. These reviews are intended to satisfy GENE interests relative to warranty fulfillment. When GENE is responsible for implementation of changes, modification, completion of manufacturing actions, or other field construction activity with respect to equipment and field services supplied by GENE, the QC Site Representative provides surveillance, monitoring, auditing, and other QA/QC activities.

- 8 | Liaison between the Owner and GENE on all quality-related matters is through the appropriate Fuel Projects or Services Manager. The Fuel Projects or Services Managers are responsible for assuring that unique contract requirements involving quality-related matters are transmitted to the affected line organizations within the GENE for planning and implementation. The Licensing & Consulting Services component has the primary responsibility for defining the product safety standards and for assuring that applicable new regulatory requirements related to quality and safety are made known to the responsible functional organizations within the GENE. When the Owner is responsible for installation and testing of GENE supplied systems and components, technical direction\* during field installation, and preoperational and startup testing is provided to the Owner by the GENE Resident Site Manager, and staff. Quality assurance planning and services are provided to the GENE Resident Site Manager by the assigned GENE QC Site Representative as needed. Installation, preoperational and startup testing engineers and specialists assigned to NPSD have the responsibility for planning and providing technical direction for the installation or preoperational and startup testing activities. Changes to plant design, resulting in changes to delivered equipment or systems, are handled in one of two ways. First, if the Owner is responsible to implement the change, where GENE has provided the design and/or hardware required by the change, GENE supplies the technical direction and quality reviews of the implementation of the change. Second, if the change results in a responsibility by GENE for incorporation of the change, GENE provides or procures implementation services and also provides inspection or surveillance at the point of implementation to verify acceptable implementation of the change requirements. Manufacturing and testing work which is normally done in the manufacturing facilities of GENE, or its suppliers, but which has been deferred for field implementation, is provided or obtained by GENE. Inspection or surveillance is provided by GENE to verify acceptable implementation of work requirements.

- 8 | QA communication relationships are established within the GENE, including a channel of communications directly between each of the QA line organizations to their department-level managers. A separate channel of communications is also available for the line QA managers to the Manager, NQA, through the Quality Council. This communication channel is established for developing common solutions to quality-related problems, and for providing a second line of communication to GENE management on such quality-related matters as stop-work actions.

The tabulation in Table 1-1, "Typical Quality Assurance Organizational Responsibilities" identifies the GENE organizations having line responsibilities for specifying, attaining, and verifying quality requirements for GENE supplied systems, components, and services. Additional responsibilities are further identified in other sections of this program description.

- 8 | A summary of prime and contributing functional responsibilities of each of the GENE organizations is shown in Table 1-2. A further breakdown of functional responsibilities for GENE QA organizations and other major organizations performing quality-related functions is detailed in Subsection 1.3.

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\* Technical direction is defined as technical guidance, advice, and counsel based on current engineering, field services and installation practices, which is provided to the Owner's staff.

### 1.3 QA FUNCTIONAL RESPONSIBILITIES

#### 1.3.1 Nuclear Quality Assurance

For the GENE, the Nuclear Quality Assurance (NQA) has the responsibility for coordinating and integrating the QA Program as it relates to fuel projects, services management, engineering, manufacturing, procurement, field services, and construction by appropriate means, including:

- o Developing the GENE P&Ps related to projects, services management, engineering, manufacturing, procurement, field service, and construction QA.
- o Representing the GENE to the NRC, and other government authorities on matters regarding the projects, services management, engineering, manufacturing, procurement, field services, and construction aspects of the overall QA Program.
- o Providing assistance to the GENE marketing, services, and legal organizations on engineering, manufacturing, procurement, field service, and construction-related quality system matters, as requested.
- o Providing technical support and consultation to the GENE licensing activities, as requested.
- o Providing quality system and auditing consultation services to the GENE organizations, as requested.
- o Providing guidance to line organizations on matters related to engineering, and project management QA activities.
- o Initiating stop-work recommendations to the affected GENE manager, as necessary, to prevent further processing, delivery, installation, or utilization of nonconforming or suspect items until proper dispositioning has occurred.
- o Auditing the GENE engineering, project management, manufacturing, procurement, field service, and construction organizations for compliance with their approved quality-related systems, procedures, and instructions.
- o Participating in select design reviews.
- o Providing quality planning for engineering which defines engineering QA program requirements.

#### 1.3.2 Line Organizations - QA

For their assigned product scope, each line organization has the responsibility for assuring conformance with applicable design and QA requirements by appropriate means, including:

- o Developing and documenting a quality system in compliance with the GENE policies, procedures, and applicable codes, standards, and regulatory requirements.
- o Conducting preproduction reviews with engineering to assure mutual understanding of design requirements and manufacturing capability.

- o Preparing product and process quality planning to assure conformance with applicable drawings, specifications, and special instructions issued by design engineering organizations.
- o Providing product and process control to assure that quality planning is properly interpreted and implemented.
- o Providing required receiving, in-process, and final inspection and testing in accordance with QA documented inspection and test procedures.
- o Providing for the calibration and control of measuring and test equipment.
- o Providing for the effective control of nonconforming materials, parts, and components, including stop-work authority.
- o Assuring provision of programs for the required training, qualification, and certification of personnel.
- o Assuring provision for control of handling, storage, and shipping.
- o Assuring provision of a formal corrective action system.
- o Assuring provision for generation, collection, review, approval, transmittal or storage, maintenance and retrieval of all necessary quality records, including supplier records.
- o Assuring provision for audit and other measurements of the effectiveness of the quality system, including supplier quality systems.
- o Providing product release control and certification of product quality.
- o Providing product quality-related problem analyses and initiating or recommending appropriate action.
- o Providing quality assurance planning and requirements for inspection and testing for field implementation of product changes or completion of manufacturing actions, which will provide assurance of specified product quality.
- o Providing for qualification of suppliers of services necessary for field implementation of the design changes or completion of actions deferred for field implementation.
- o Providing, or obtaining provision for, quality assurance and control actions necessary to assure acceptable compliance with quality assurance planning, inspection, and testing requirements established in change documentation and services purchase orders.
- o Reviewing supplier QA Programs for adequacy.
- o Conducting pre-award evaluations to establish supplier qualification.
- o Conducting pre-procurement review with engineering and purchasing, as necessary, to assure clear understanding of quality requirements.

- o Providing quality planning which defines supplier QA program requirements and check lists which define audit requirements.
- o Providing audit/surveillance of supplier quality-system and activities during manufacturing.
- o Reviewing and approving identified supplier fabrication, test, and inspection procedures.
- o Providing for the review and approval or disapproval of supplier deviations from specified quality requirements.
- o Initiating stop work orders through purchasing to prevent further processing, utilization, or shipment of nonconforming or suspect items until proper dispositioning has occurred.
- o Providing surveillance, monitoring, inspection, auditing, and other activities as necessary to assure acceptable implementation of GENE provided or purchased services for changes, modifications, or manufacturing completion of systems or components in the field.
- o For NSSS equipment, FQA assures that Owner conforms with applicable GENE installation requirements by appropriate means, including:
  - o Reviewing and approving selected Owner/AE/Constructor installation procedures.
  - o Providing site surveillance planning for implementation by the GENE Quality Control Site Representative.
  - o Performing surveillance of Owner/AE/Constructor conformance with GENE supplied installation and test documents.
  - o Providing feedback and analysis of installation quality problems and implementation of preventative or corrective action to assure Owner/AE/Constructor compliance with GENE requirements.
- o Providing functional guidance and direction to managers and engineers in implementing applicable portions of the QA Program, and in responding to both internal and external QA audits.
- o Planning and directing preparation of the QA input to customer bid specifications and purchase orders for assigned scope.
- o Planning, directing, and executing periodic audits of quality-related activities and reporting findings to management, including recommended corrective action.
- o Administering a lending library of the various GENE organizations' key QA manuals and quality-related procedures manuals for loan to customers and potential customers.

The GENE engineering organizations are responsible for product design and design control by appropriate means, including:

- o Assuring incorporation of applicable regulatory requirements, codes, standards, criteria, and design bases in the design.
- o Assuring incorporation of project design requirements into the design.
- o Translating the design information onto the appropriate design documents.
- o Verifying the design adequacy either through independent design review, the use of alternate or simplified calculational methods, or by the performance of a suitable testing program.
- o Coordinating design activities among interfacing design engineers and design organizations.
- o Reviewing, approving, issuing, and distributing design documents under a controlled document system.
- o Controlling design changes and changes to design documents in accordance with documented procedures.
- o Providing for the retention, storage, control and retrievability of design record documents.
- o Taking corrective action as necessary to correct design errors and to improve the design control function.
- o Reviewing and approving proposed dispositions to GENE supplied equipment as documented on Field Deviation Disposition Requests (FDDRs) or providing an alternate acceptable disposition for field identified equipment problems.
- o Assuring that approved solutions to field identified equipment problems contain quantitative or qualitative engineering quality requirements that can be measured and verified in the field.
- o Issuing Field Disposition Instructions (FDIs) which clearly identify required work to be performed on equipment or systems that have been delivered to the sites.
- o Assuring that issued FDIs contain quantitative or qualitative engineering quality requirements than can be measured and verified in the field.
- o Assuring that FDDRs and FDIs are reviewed by quality assurance organizations for identification of quantitative or qualitative quality requirements before release to the field for implementation.

The NSSS, Fuel, or Services Project, or Program Manager maintains interface relationships with the Owner, as well as cognizant GE personnel to assure provision of licensing, engineering, QA, and equipment supply activities by appropriate means, including:

- o Directing the GENE performing organizations and others, as applicable, as to the contract scope of supply and the basis definition, and changes thereto.



- o Providing control of design interfaces with engineering, the AE/Constructor, and the Owner.
- o Monitoring to assure contract commitments are satisfied.
- o Providing for coordination, integration, and project management of requisition and operating plant activities performed by contributing GENE organizations. | 8
- o Maintaining recognition of quality requirements for fuel, services, systems, and components, and taking appropriate action to maintain consistent requirements.
- o Identifying the organization (GENE or Owner) responsible to implement the requirements of the FDIRs or FDIIs.
- o Providing technical direction to the Owner for field installation and preoperational and startup testing of GENE supplied systems and components.
- o Providing site management and coordination of quality assurance planning and services received from RQA or RQA site QC representative for installation and testing of GENE supplied equipment and systems. | 8
- o Providing confirmation of acceptable completion of changes, modifications, or completions of manufacturing of systems or components as identified on FDIRs or FDIIs.
- o Providing the Owner with appropriate information as to the status of the project and applicable revisions of project documentation as required by contract.

#### 1.4 QA PERSONNEL RESPONSIBILITIES AND QUALIFICATIONS

The responsibilities, education, and experience requirements of individuals assigned to QA-related managerial and individual contributor positions are formally documented in the GENE position guides which are approved and periodically reviewed by designated levels of management. The responsibilities and qualification requirements of individuals performing inspection and testing operations are formally documented in job descriptions, which are also approved and periodically reviewed by designated levels of management. Qualification requirements for managers responsible for QA activities are shown below:

##### Staff Organization

Titles	Qualification Requirements
8   Manager, NQA Quality Assurance Audits Manager, NQA Quality Assurance Systems Manager, NQA	BS or equivalent qualifications; at least 15 years in responsible managerial or project-type assignments, 10 years of which have been in quality-related work or equivalent experience in the design, construction or operation of a nuclear facility; thorough knowledge of all aspects of the QA Program.
8   Senior Program Managers, Principal Engineers, NQA	BS or equivalent qualifications; at least 12 years in responsible managerial or project-type assignments, 7 years of which have been in quality-related work or equivalent experience in the design, construction or operation of a nuclear facility; thorough knowledge of the QA Program.

##### Line Organizations

Titles	Qualification Requirements
8   Manager, FQA, NPSD Manager, QA, NF&CM Manager, Project Services, ANT 8   Manager, Project Services, ABWRP Manager, Engineering & QA, Reuter-Stokes, Inc.	BS or equivalent qualifications; at least 10 years in responsible managerial or project-type assignments, 5 years of which have been quality-related work, or equivalent experience in the design, construction or operation of a nuclear facility; thorough knowledge of the QA Program for their area of responsibility.

Table 1-1

TYPICAL QUALITY ASSURANCE ORGANIZATIONAL RESPONSIBILITIES

Type of Equipment	Engineering Quality Requirements	Manufacturing Process Procedures	Manufacturing Compliance Verification
Purchased Equipment and Design Services	Engineering Services NPSD	Supplier* Supplier*	FQA FQA
Nuclear Fuel	Fuel Engineering	NFSQM	NFSQM-QA
Manufactured Reactor Equipment	Fuel Engineering Engineering Services Engineering, R-S, Inc.	NFSQM NFSQM Manufacturing, R-S, Inc.	NFSQM-QA NFSQM-QA QA, R-S, Inc.
Controls and Instrumentation	Engineering Services Engineering, R-S, Inc.	Supplier* Manufacturing, R-S, Inc.	FQA QA, R-S, Inc.

\* Designated supplier manufacturing procedures and design documents are reviewed and approved by GENE engineering or QA organizations in accordance with documented procedures.

Table 1-2  
TYPICAL RESPONSIBILITIES/RELATIONSHIPS MATRIX

	NOA	F&CM	FE/ES	NPSD	NECSD	AEWRP	R-S, Inc.
1. Initial contract negotiation	C	C	P	P	P	P	P
2. Design specifications		C	P			P	P
3. Design verification			P			P	P
4. Project schedules (design)			P	P	P	P	P
5. Project schedules (delivery)		C	P	P	P	P	P
6. Licensing technical description			P	C	C	P	
7. NSSS design and development		C	P				
8. Fuel design and development		C	P			P	
9. GENE quality policy	P	C	C	C	C	C	C
10. Product quality <sup>1</sup>	C	P	P	P	P	P	P
11. Quality systems <sup>1</sup>	P	P	P	P	P	P	P
12. Product audits <sup>1</sup>		P	P <sup>2</sup>	P <sup>2</sup>		P <sup>2</sup>	P
13. Quality system audits <sup>1</sup>	P	P	P <sup>2</sup>	P <sup>2</sup>	P <sup>2</sup>	P <sup>2</sup>	P
14. Manufacturing (F&CM)		P	C	C			
15. R-S, Inc. Manufacturing			C	C			P
16. Purchased equipment and services		P	P	P		P	P
17. Installation Engineering and services			P	P			P
18. Preoperational & startup services		C	C	P			
19. Operating Plant Services		C	C	P			
20. Quality assurance records	P	P	P	P	P	P	P
21. Implement FDIRs/FDIs (GENE responsibility)		C	P	P	C		

P - Prime responsibility

C - Contributing responsibility/relationship

<sup>1</sup> Each functional organization in the GENE is responsible for the quality of its own output.

8 | <sup>2</sup> FQA conducts audits.

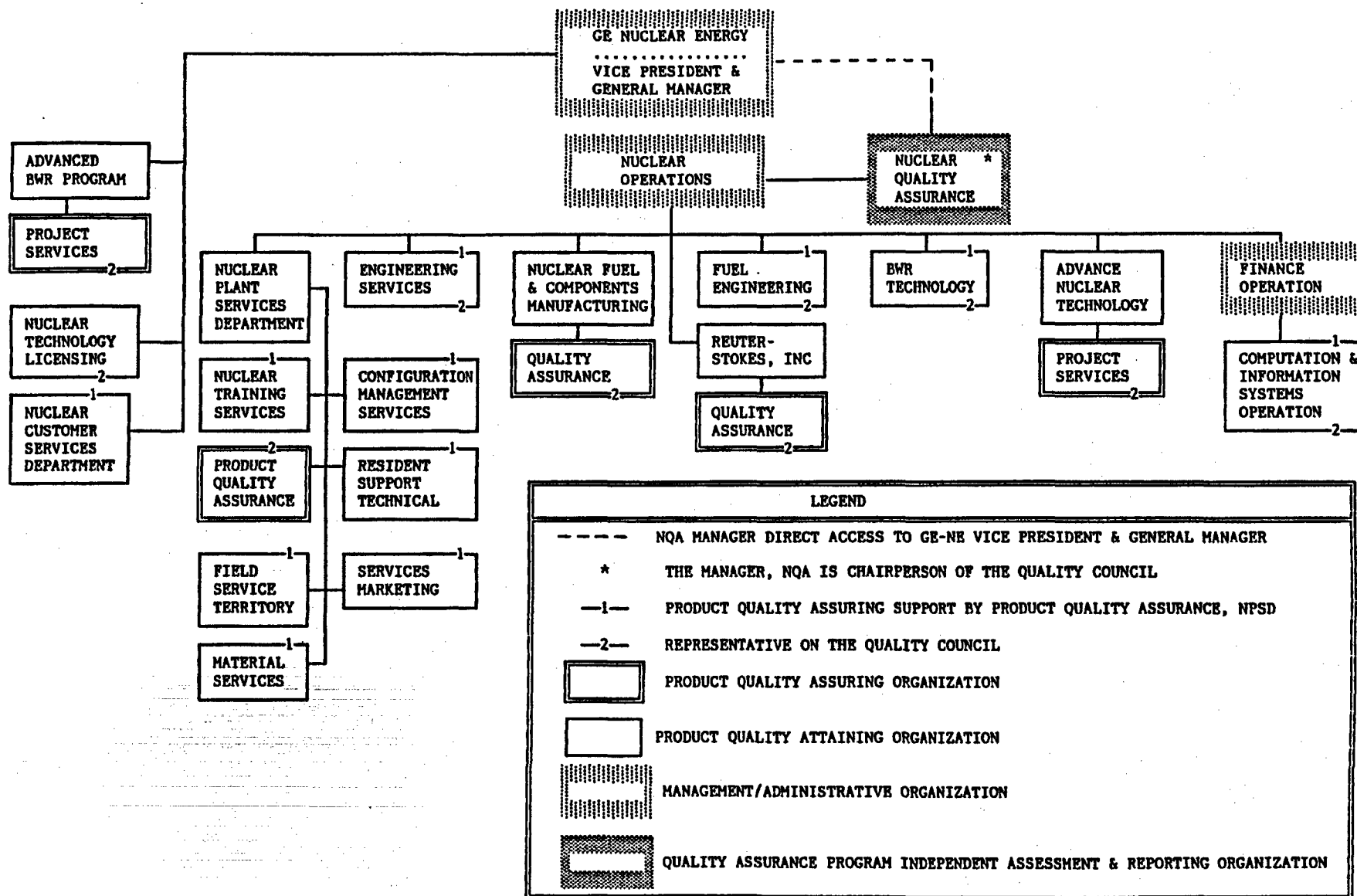


Figure 1-1 GE Nuclear Energy

## 2 QUALITY ASSURANCE PROGRAM

### 2.1 GENERAL

An overall QA program is established, documented, and implemented which encompasses the collective activities and events with their associated responsibilities, efforts, equipment, procedures, interfaces, and management which are necessary to provide the means to meet product quality objectives.

Since many projects are being processed by design, purchasing, services, and manufacturing organizations simultaneously, QA activities which are described in the QA Program are continuously being applied in support of the total GENE scope of responsibility and are applicable to each of the projects throughout those phases of activity for which the GENE is responsible. | 8

The QA Program described herein applies those quality system elements necessary to provide assurance that GENE supplied systems, services, and components meet the quality requirements of the Owner and applicable codes, standards, and regulatory agency requirements. This QA Program is documented in formally controlled document systems and is implemented throughout all phases of nuclear power plant design, field services, construction. All systems, services, components, classified "safety-related" are supplied in accordance with this QA Program.

Training and experience qualifications are defined for each position in GENE. In addition, the program provides for indoctrination and training of personnel performing activities affecting quality in order to provide assurance that appropriate proficiency is achieved and maintained. This indoctrination and training is carried out through various documented procedures, on the job training, personnel contacts, and meetings. These training programs encompass inspectors, testers, shop personnel, and engineers, as appropriate. Quality assurance, manufacturing, engineering, and project/service organizations each develop their own requirements for training and establish their own training programs. The purpose of the training is to assure that personnel responsible for quality-related activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures. | 8

The QA Program provides for conducting activities affecting quality under suitably controlled conditions, including the use of appropriate equipment, suitable environmental conditions, and assurance that prerequisites for the given activity have been satisfied. These prerequisites include consideration of special process controls and skills and the need for special inspection and test equipment where required for verification of quality. | 8

The quality system documentation derives its authority and is structured from the GE Corporate Company-wide Quality Policy down through each organizational level of the GENE. Responsibility for the final review and issuance of the overall QA Program rests with the GENE Vice President and General Manager. Responsible organizations and individuals within the GENE are informed of the mandatory nature of the various quality policies, manuals, and procedures through the GENE Quality Policies and Procedures (P&Ps) issued by the GENE management. Quality-related instructions, manuals, and implementing procedures assign responsibilities making them mandatory for quality-related administrative functions. Shop travelers, work orders, or other planning documents relative to specific projects, processes or work areas are mandatory directives for personnel involved in hardware-related activities, such as production, inspection, and test.

The QA Program provides for the regular management review, through audits or other appropriate means, of organizations participating in the business, and of the status, adequacy, of that part of the QA Program for which they have designated responsibility.

The QA Program is structured to comply with the GENE commitments to the applicable quality-related regulatory guides and ANSI Standards as documented in Table 2-1. This QA Program provides for periodic modification and/or updating of GENE commitments to comply with quality-related regulatory guides and ANSI Standards relating to the GENE scope of supply. New or revised quality-related regulatory guides and reference standards are evaluated and determinations made as to when, how, and to what extent they will be implemented. The GENE commitments to comply with regulatory positions, or NRC-approved alternate positions to quality-related regulatory guides, are then incorporated into the QA Program documentation.

The GENE commitments to comply with applicable regulatory guides not listed in Table 2-1 are documented in the project licensing documents for each nuclear power plant. The NRC-approved licensing documents for a specific nuclear power plant project establish the GENE regulatory guide or alternate position commitments for that project. The commitments to comply with regulatory guides issued or revised subsequent to NRC approval of the project licensing documents are documented in amendments to the NRC-approved project licensing documents.

Classification of safety-related structures, systems, and major components is documented in the project licensing documents and the Project Master Parts List (MPL), and/or is provided through controlled documents to the affected GENE organizations for implementation. Replacement parts not identified in the project licensing documents are classified relative to safety importance using either original or current classification criteria.

## 2.2 QUALITY SYSTEM DOCUMENTATION

8 | The GENE quality-related activities are documented in a series of planned and coordinated policies, procedures, manuals, and instructions defined as QA program documentation. Activities and events comprising the QA Program appropriate to each GENE organization are identified and documented in formally controlled document systems. Quality Assurance system documents, including QA manuals, are distributed to a predominate list of key personnel as controlled copies. Revisions are distributed to the same list with appropriate instructions for replacement and disposition of obsolete documents.

Though the basic scope of the quality system utilized by the various organizations within the GENE is essentially the same, each GENE business organization has its own system of guides, procedures, instructions, manuals, and other implementing documentation that prescribes the methods for carrying out its portion of the overall QA Program. Each of these systems is unique, relates to the activities of the particular organizations involved, and is undergoing continuous review, upgrading, and improvement.

A brief description of the purpose and scope of each of the key document types governing QA activities which demonstrate the implementation of the QA Program is presented below:

General Electric Corporate Company-Wide Quality Policy (No. 20.1). The General Electric Corporate Company-Wide Quality Policy, issued by the Corporate Executive Office, states quality considerations and requirements applicable to all General Electric products and services.

GE Nuclear Energy Quality Policy (No. 70-1). The GENE Quality Policy, issued by the GENE Vice President and General Manager, interprets the Corporate Company-Wide Quality Policy and provides implementing direction to the GENE organizations. This document, which is part of the GENE Policies and Procedures documentation system, establishes the quality policy for GENE products and services, assigns quality-related responsibilities, and identifies interrelationships for policy implementation. The GENE Quality Policy is applicable to all GENE organizations and specifically requires that each GENE organization be in full compliance with the applicable requirements of Company Policy 20.1, Company-Wide Quality, and applicable GENE P&Ps referenced therein. | 8

GENE Quality-Related Procedures. The GENE Procedures are issued by authority of the GENE Vice President and General Manager and/or GENE Staff-Level managers to establish procedures and practices for those quality system elements requiring uniform consideration and application by several or all organizations within the GENE. These policies and procedures are part of the GENE P&P and are supplemental to the GENE Quality Policy. They provide implementing direction in those areas where a standardized, uniform approach is deemed necessary by the GENE management. Listed below are the key quality-related GENE Procedures: | 8

- o Quality System Requirements (No. 70-11):

This procedure supplements GENE Policy No. 70-1 and establishes the minimum quality system requirements to be implemented by GENE organizations in fulfilling licensing commitments, contracts, and internal requisitions for the sale, lease, or transfer of GENE products and services to a customer. | 8

- o Personnel Proficiency in Quality-Related Activities (No. 70-30):

This procedure supplements GENE Policy No. 70-1 and Procedure NO. 70-11 and establishes the minimum personnel proficiency requirements to be implemented within the GENE in support of the QA Program.

- o Reporting of Defects and Noncompliance under 10CFR21 (No. 70-42):

This procedure provides direction for GENE compliance with the requirements of NRC Regulation 10CFR21, Reporting Defects and Noncompliance. Standard practices are established for all GENE organizations for identifying, documenting, evaluating, and reporting potential defects in any licensed nuclear facility or activity, or noncompliance with the provisions of an NRC regulatory requirement relating to a substantial safety hazard.

Quality Assurance Program Manuals and Document Systems. Documents describing the QA Program and prescribing the detailed quality-related activities of individual organizations are prepared, issued, and maintained by the responsible organizations, such as: engineering, manufacturing, and quality assurance. Such documentation consists of, e.g., engineering operating procedures, QA plans and procedures, and inspection and test planning. Key manuals and document systems are:

- o ASME Quality Assurance Program Manual (GENE) (NEDE-20387):

This manual describes the GENE QA Program which meets all of the applicable requirements of Section III of the ASME Boiler and Pressure Vessel Code. It has been accepted by the ASME as a basis for issuance of a Certificate of Authorization.



- o Engineering Operating Procedures (NEDE-21109):

This manual contains documentation of the design control system. The criteria of 10CFR50, Appendix B, are addressed in the procedures to the extent that engineering activities are involved.

- o Nuclear Services Procedure:

8 | This manual contains documentation establishing uniform courses of action for quality-related services organizations activities, and establishes interface requirements and responsibilities for nuclear services, engineering, and other GENE organizations activities.

- o NQA Practices and Procedures:

This manual contains documentation describing specific requirements and controls for performing activities for which the NQA is responsible.

- o Nuclear Plant Services QA Manuals:

Each of these manuals contain documentation describing specific requirements and controls for performing field service activities for which the NPSD is responsible.

- o Advance Nuclear Technology Policies and Instructions:

8 | This manual contains documentation describing specific requirements and controls for performing activities for which ANT is responsible.

- o Reuter-Stokes, Inc. QA Manual:

8 | This manual contains documentation describing specific requirements and controls for performing activities for which R-S, Inc. is responsible.

- o NF&QM - ASME B&PV Code Quality Assurance Manual (NEDE-20910):

This manual contains a detailed description of the NF&QM QA Program established in compliance with the applicable requirements of ASME Boiler and Pressure Vessel Code, Section III and Section VIII. It has been accepted by ASME as a basis for issuance of Certificate of Authorization.

- o NF&QM - Practices and Procedures:

These practices and procedures document the basic business policies, assigned responsibilities and administrative instructions established by NF&QM management.

- o NF&QM - QA Section Administrative Routines:

8 | These administrative routines or procedures document the activities assigned specifically to the NF&QM QA in order to control product quality.

Implementing Document Types. The document types listed below are representative of those used by the various GENE organizations to implement the QA Program.

- Acceptance standards
- Audit plans and procedures
- Calibration procedures
- Corrective action procedures
- Design control procedures
- Engineering drawings and specifications
- Handling, storage, packing and shipping procedures
- Inspection instructions
- Inspector and tester stamp control procedures
- Material identification and control procedures
- Measuring and test equipment control procedures
- Nonconforming material control procedures
- Preproduction quality evaluation procedures
- Process and personnel qualification procedures
- Process control procedures
- Product/process quality plans
- Purchased material quality control plans
- Purchased service quality plans
- Quality assurance document control procedures
- Quality assurance records specifications and instructions
- Quality control standard instructions
- Receiving inspection plans
- Shipment release control procedures
- Supplier evaluation and selection procedures
- Test instructions

A network of policies, document systems, manuals, and implementation documents is designed to provide the QA Program procedures, specifications, and documentation necessary to support the GENE objectives of providing safe and reliable systems and components, and complying with the requirements of applicable codes, standards, laws and regulatory agency requirements.

Table 2-1  
NRC REGULATORY GUIDE POSITIONS

NRC Regulatory Guide	ANSI Standard	GENE Position
1.28 - June 7, 1972, "Quality Assurance Program Requirements (Design & Construction)"	N45.2-1971	<p>Comply with the provisions of Regulatory Guide 1.28 (June 7, 1972) and the requirements and guidelines in ANSI N45.2-1971, except as follows:</p> <ol style="list-style-type: none"> <li>1. Section 4.3, first paragraph, third sentence: This sentence is not considered applicable since the first paragraph of Section 4.3 identifies three alternate methods for verifying or checking the adequacy of design. All other sentences of Section 4.3 will be complied with.</li> <li>2. Section 14, second paragraph, second sentence; This sentence is interpreted to mean that necessary handling tools and equipment will be used and controlled on work under GE jurisdiction. It does not mean that GE will necessarily provide handling tools and equipment. The provision of such tools and equipment is a contractual consideration.</li> <li>3. Section 18, fourth paragraph, first sentence: To the extent required by contract, GE will maintain records which correctly identify the "as built" condition of items as furnished by GE for the life of the particular item, rather than for the life of the plant.</li> <li>4. Section 18, fourth paragraph, second sentence: This sentence is not considered applicable. Refer to the committed GE position on Regulatory Guide 1.88.</li> <li>5. Section 19, second paragraph, first sentence: This sentence is revised to read, "Audits shall be performed, as necessary: (1) to provide ..."</li> <li>6. Section 19, second paragraph, second sentence: This sentence revised to read, "Followup action shall be taken as needed. This action may include reaudit of deficient areas."</li> </ol>
1.30 - August 11, 1972 "Quality Assurance Requirements for the Installation, Inspection & Testing of Instrumentation & Electrical Equipment"	N45.2.4-1972	Implement regulatory position.

Table 2-1

NRC REGULATORY GUIDE POSITIONS (Continued)

NRC Regulatory Guide	ANSI Standard	GENE Position
1.37 - March 16, 1973, "Quality Assurance Requirements for Cleaning of Fluid Systems & Associated Components of Water-Cooled Nuclear Power Plants."	N45.2.1-1973	Comply with the provisions of Regulatory Guide 1.37, March 16, 1973, including the requirements and recommendations in ANSI N45.2.1-1973, except as follows: Section 5, sixth paragraph, recommends that local rusting on corrosion resistant alloys be removed by mechanical methods. This recommendation shall be interpreted to mean that local rusting may be removed mechanically, but that it does not preclude the use of other removal means.
1.38 - Rev. 2, May 1977, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage & Handling of Items for Water-Cooled Nuclear Power Plants."	N45.2.2-1972	<p>Comply with the provisions of Regulatory Guide 1.38, Rev. 2, May 1977, including the regulatory position relative to ANSI N45.2.2-1972, except as follows:</p> <ol style="list-style-type: none"> <li>1. Section 3.7.1(1): GE will use cleated, sheathed boxes up to 1000 lb rather than 500 lb. This type of box is safe for, and has been tested for, loads up to 1000 lb. Other national standards allow this; see Federal Specification PPP-B-601. Special qualification testing may be required for loads above 1000 lb.</li> <li>2. Section 3.7.2: Skids or runners shall be used on containers with a gross weight of 100 lb or more. Skids or runners shall be fabricated from 3x4-inch nominal lumber size minimum and laid flat except where this is impractical because of the small dimensions of the container.</li> <li>3. Section 4.3.4: Since title to equipment generally changes hands at the time it is moved off the supplier's dock into the carrier, GE will make these inspections "immediately prior to loading" rather than "after loading," as presently indicated. To have this inspection, and possible repair performed after loading presents legal complications, as once the equipment enter the transport vehicle, the carrier has some responsibility and our customer has ownership.</li> <li>4. Appendix Section A3.4.1(4) and (5). During printing of the standard, a transposition occurred between the last sentence of (4) and (5). The correct requirements are as follows: <p>(4) "However, preservatives for inaccessible inside surfaces of pumps, valves, and pipe for systems containing reactor coolant water shall be the water flushable type."</p> </li> </ol>

Table 2-1

NRC REGULATORY GUIDE POSITIONS (Continued)

NRC Regulatory Guide	ANSI Standard	GENE Position
1.38 (continued)		(5) "The name of the preservative used shall be indicated to facilitate touch-up."
		5. Appendix Section A3.4.3(3): Inert gas blankets are currently used on the reactor pressure vessel (RPV) and on some of the heat exchangers supplied by GE. Provisions are made for measuring and maintaining the RPV blanket pressure within the required range during shipment and storage. Heat exchangers or tanks containing carbon steel which require an inert gas blanket will be inerted prior to shipment. During storage, provision shall be made for measuring and maintaining the inert gas blanket pressure within the required range within each pressurized purged item or container.
		6. Appendix Section A3.7.1(3) and (4). GE will work to the following requirement in lieu of items (3) and (4): Fiberboard boxes shall be securely closed either with a water resistant adhesive applied to the entire area of contact between the flaps, or all seams and joint shall be sealed with not less than 2-inch wide, water-resistant tape.
1.39 - Rev. 2 September 1977, "Housekeeping Requirements for Water-Cooled Nuclear Power Plants."	N45.2.3-1973	Implement regulatory position.
1.58 - Rev. 1, September 1980, "Qualification of Nuclear Power Plant Inspection, Examination, and testing Personnel."	N45.2.6-1978	Comply with the provisions of Regulatory Guide 1.58, Rev. 1, September, 1980, including the regulatory position relative to ANSI/ASME N45.2.6-1978, except as follows:
		1. In lieu of paragraph 2.4 of ANSI N45.2.6, GENE personnel who are responsible for reviewing and approving inspection and test procedures or performing inspection and test activities are considered certified by the fact that they have been evaluated on the basis of training, past experience and performance on related jobs and found fully competent and qualified in the documented functions of their assignment. Non-destructive examination procedures will be prepared or reviewed and approved, and performed by personnel who have been qualified to SNT-TC-1A.

Table 2-1

NRC REGULATORY GUIDE POSITIONS (Continued)

NRC Regulatory Guide	ANSI Standard	GENE Position
1.58 (continued)		2. In lieu of the formal educational documentation outlined in paragraph C.6 of Regulatory Guide 1.58, Rev. 1, September, 1980, inspectors and testers who do not hold a high school diploma or the General Education Development (GED) equivalent of a high school diploma are evaluated on the basis of past experience and performance on similar jobs to assure that they are fully qualified to perform their assigned duties.
1.64 - Rev. 2, June 1976, "Quality Assurance Requirements for the Design of Nuclear Power Plants."	N45.2.11-1974	Comply with the provisions of Regulatory Guide 1.64, Rev. 2, June 1976, including the regulatory position relative to ANSI N45.2.11-1974, except for the following modifying provisions to the second paragraph of Section 6.1 of ANSI N45.2.11-1974:

Table 2-1

NRC REGULATORY GUIDE POSITIONS (Continued)

NRC Regulatory Guide	ANSI Standard	GENE Position
1.64 (continued)		<ol style="list-style-type: none"> <li>1. If, in an exceptional circumstance, the designer's immediate supervisor is the only technically qualified individual available in the organization to perform a design verification by design review, this review may be conducted by the supervisor, providing that: <ol style="list-style-type: none"> <li>(a) the justification is individually documented and approved in advance by the supervisor's management; and</li> <li>(b) QA audits cover frequency and effectiveness of use of supervisors as design verifiers, to guard against abuse.</li> </ol> </li> <li>2. An individual who contributed to a given design may participate in a group verification of that design provided that the individual who contributed to the design (a) does not verify his contribution to the design, and (b) does not serve as the chairman or leader of the group verification activity.</li> </ol>
1.74 - February 1974, "Quality Assurance Terms & Definitions."	N45.2.10-1973	Implement regulatory position.
1.88 - Rev. 2, October 1976, "Collection, Storage & Maintenance of Nuclear Power Plant Quality Assurance Records."	N45.2.9-1974	<p>Comply with the provisions of Regulatory Guide 1.88, Rev. 2, October 1976, including the regulatory position relative to ANSI N45.2.9-1974, except as follows:</p> <ol style="list-style-type: none"> <li>1. Classification - As specified in Section 3.2.5, QA records will be classified by GENE as "lifetime" or "non-permanent" in accordance with the definitions provided in Section 2.2 of ANSI N45.2.9-1974. The supplement to this alternate position identifies the classification so assigned by GENE for each QA record type and is based on the guidance furnished in Appendix A of ANSI N45.2.9-1974.</li> <li>2. Procurement - In accordance with the second sentence of Section 1.2, ANSI N45.2.9-1974, the GENE will identify in procurement documents the QA records which are to be supplied to or maintained for the GENE or the Owner by suppliers or sub-suppliers, including those GE organizations other than the GENE.</li> </ol>

\* See Supplement to Regulatory Guide 1.88 Alternate Position on page 2-13.

Table 2-1

NRC REGULATORY GUIDE POSITIONS (Continued)

NRC Regulatory Guide	ANSI Standard	GENE Position
1.88 (continued)		<p>3. Storage and Maintenance - Records classified as "lifetime" will be furnished to the Owner or stored and maintained in accordance with the provisions of Section 5 of ANSI N45.2.9-1974. In lieu of the requirements of Sections 5.2-5.6 for "non-permanent" records, such records will be stored in metal file cabinets as permitted in NFPA-1975 for Class 3 records to prevent loss, damage, or deterioration and maintained in a manner designed to permit accurate retrieval. "Nonpermanent" records listed in the supplement, which are generated by GENE or provided to GENE suppliers in accordance with contract requirements, will be retained for period of time as specified in the supplement to this alternate position. After elapsed retention times, "nonpermanent" records may be disposed of at the option of the GENE or the supplier. Concurrence with this disposition of nonpermanent records by the Owner is through endorsement of the GE Topical Report NEDO-11209 by its reference in the Owner's Safety Analysis Report.</p> <p>4. Indexing - The GENE will comply with a substitute to paragraph 3.2.2 of ANSI N45.2.9-1974, which reads: "Both lifetime and nonpermanent records shall be listed in an index or system of indexes. The index or system of indexes shall include as a minimum, record retention times and the location of the records within the record system. Index systems used by organizations for the retention of records shall provide information which can be used to identify equipment or material."</p> <p>5. Special Processed Records - The GENE will comply with a substitute to paragraph 5.4.3 of ANSI N45.2.9-1974, which reads: "Special Processed Records - Provisions shall be made for special processed records (such as radiographs, photographs, negative, and microfilm) to prevent damage from excessive light, stacking, electromagnetic fields and temperature. These provisions will be delineated in GENE internal instructions which will incorporate, or take into consideration, available manufacturer's recommendations."</p>
1.94 - Rev. 1, April 1976, "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants."	N45.2.5-1974	Not applicable to standard BWR scope of supply.



Table 2-1

NRC REGULATORY GUIDE POSITIONS (Continued)

NRC Regulatory Guide	ANSI Standard	GENE Position
1.116, Rev. O-R, June 1976, "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems"	N45.2.8-1975	Comply with the provisions of Regulatory Guide 1.116, Rev. O-R, June 1976, including the regulatory position relative to ANSI N45.2.8-1975, except as follows: Regulatory Position 3 - comply with the implementation of Regulatory Guide 1.68 as described in GESSAR, Chapter 14, "Initial Test."
1.123, Rev. 1, July 1977, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants"	N45.2.13-1976	<p>Comply with the provisions of Regulatory Guide 1.123, Rev. 1, July 1977, including the regulatory position relative to N45.2.13-1976, except as follows: For items within the GENE scope of supply, the third sentence of ANSI N45.2.13-1976, Section 8, Control of Nonconformances, paragraph 8.2, item b., is revised to read: "Nonconformances to the contractual procurement requirements or Purchaser approved documents and which consist of one or more of the following shall be submitted to the Purchaser for approval of the recommended disposition prior to shipment when the nonconformance could adversely affect the end use of a module or shippable component<sup>*</sup> relative to safety, interchangeability, operability, reliability, integrity, or maintainability.</p> <ol style="list-style-type: none"> <li>1. Technical or material requirement is violated.</li> <li>2. Requirement in Supplier documents, which have been approved by the Purchaser, is violated.</li> <li>3. Nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.</li> <li>4. The item 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."</li> </ol>
None issued	N45.2.12-1977 "Requirements for Auditing of Quality Assurance Programs for Nuclear Power Plants"	Comply with the requirements of ANSI/ASME N45.2.12-1977.

\* A module is an assembled device, instrument, or piece of equipment identified by serial number or other identification code, having been evaluated by inspection and/or test for conformance to procurement requirements regarding end use. A shippable component is a part or subassembly of a device, instrument, or piece of equipment which is shipped as an individual item and which has been evaluated by inspection and/or test for conformance to procurement requirements regarding end use.

Table 2-1

NRC REGULATORY GUIDE POSITIONS (Continued)

NRC Regulatory Guide	ANSI Standard	GENE Position
1.146 - August 1980, "Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants."	N45.2.23-1978	<p>Comply with the provisions of Regulatory Guide 1.146, August, 1980, including the regulatory position relative to ANSI/ASME N45.2.23-1978, except as follows:</p> <ol style="list-style-type: none"> <li>1. In lieu of the system to qualify lead auditors, as covered in paragraphs 2.3 and 4.2, General Electric management will evaluate each candidate for lead auditor on an individual case basis. Certification of qualification will be documented showing (1) education, (2) major training programs, (3) professional licenses/certificates held, (4) general experience, and (5) auditing experience of the candidate leading to his certification as a lead auditor. The Quality Assurance Manager of the applicable component reviews and determines whether the candidate is or is not qualified to be a lead auditor.</li> <li>2. For any new lead auditors initially certified after August, 1981, a record will be made of the evaluation of the candidate. Such records will be classified nonpermanent and maintained with certification of qualification.</li> </ol>

SUPPLEMENT TO THE  
ALTERNATE POSITION ON REGULATORY GUIDE 1.88

SAFETY-RELATED AND/OR ASME CODE RECORD TYPES,  
STORAGE/MAINTENANCE RESPONSIBILITY  
AND RETENTION CLASSIFICATION

	Storage/ Maintenance Responsibility *	GENE Retention Classification *
A-1 Design Records		
Applicable Codes & Standards used in Design	G	L
As-Constructed Drawings	N/A	
Certified Design Specifications - Code Equipment	O**	L
Certified Stress Reports - Code Equipment	O**	L
Design Calculations & Record of Checks (Design Verification)	G	L
Design Change Requests (Engineering Change Notices)	G	L
Design Deviations (Nonconformance Reports)	G	L
Design Procedures and Manuals (EOP Manuals)	G**	A
Design Reports (Nonproprietary)	O	L
Design Reports (Proprietary)	G	L
Design Review Reports	G	L
Drawing Control Procedures (GE Drafting Manual) (EOP Manual)	G	A
GE-Approved Supplier Drawings and Procedures	G	L
NDE Specifications	G**	L
Operation and Maintenance Manuals	O**	L
Preoperation and Startup Test Specifications	O**	L
Purchase & Design Specifications & Amendments (including purchased part drawings for design and build orders)	O	L
Purchased Part Drawings for items used in GENE manufacture	G	L
QA System Audit Reports	G**	B
Quality Requirements Summary (GENE) Make Reactor Equipment)	O	L
Reports of Engineering Surveillance of Field Activity	N/A	
Safety Analysis Report (GE Input)	O**	L
Stress Reports	G**	L
Systems Descriptions (Nonproprietary System Design Specifications)	O	L
Systems Descriptions (Proprietary System Design Specifications)	G	L
Systems Process and Instrumentation Diagrams (P&ID)	O**	L
Technical Analysis, Evaluations, and Reports (Nonproprietary Topical Reports)	O	L
Technical Analysis, Evaluations, and Reports (Proprietary Topical Reports)	G	L

SUPPLEMENT TO THE ALTERNATE POSITION  
ON REGULATORY GUIDE 1.88 (Continued)

	Storage/ Maintenance Responsibility*	GENE Retention Classification*
<b>A.2 Procurement Records (Procured Engineered Equipment)</b>		
Audit Reports	G	B
Procurement Procedures (NSP Manual)	G**	A
Procurement Specification	O**	7
Purchase Order (unpriced) including Amendments	O	7
Purchaser's (GENE) Pre-Award QA Survey	G**	B
Product Quality Certification	O**	7
QA Records Binder (Specified Supplier Manufacturing Records)	O	7
Receiving Records	N/A	
Supplier's QA Program Manual	G	D
Welding Procedures	G	L
<b>A.3 Manufacturing Records (GENE Make)</b>		
Applicable Code Data Reports	O**	L
As-Built Drawings and Records (Parts and Assembly Drawings)	G	L
As-Built Drawings and Records (Outline Drawings)	O**	L
ASME Code - Permanent Records Index	O**	L
Certificate of Inspection & Test Personnel & Qualification	G	A
Certificates of Compliance (Product Quality Certification)	O**	L
Cleaning Procedures	G	10
Eddy-Current Examination Procedures	G	10
Eddy-Current Examination Final Results	G	L
Electrical Control Verification Test Results	G	L
Ferrite Test Procedures	G	10
Ferrite Test Results	G	L***
Forming & Bending Procedure Qualifications	G	7
Heat Treatment Procedures	G	10
Heat Treatment Records	G	L
Hot Bending Procedure	G	10
In-Process (Final) Inspection & Test Results	G	10
Insp. & Test Instr. & Tooling Calib. Procedures & Records	G	C
Liquid Penetrant Examination Procedure	G	10
Liquid Penetrant Examination Final Results	G	L
Location of Weld Filler Material	G	L
Magnetic Particle Examination Procedure	G	10
Magnetic Particle Examination Final Results	G	L
Major Defect Repair Records (except San Jose Manufactured Code Items)	G	L

SUPPLEMENT TO THE ALTERNATE POSITION  
ON REGULATORY GUIDE 1.88 (Continued)

	Storage/ Maintenance Responsibility*	GENE Retention Classification*
Major Defect Repair Records (San Jose Manufactured Code Items)	O**	L
Materials Properties Records (except San Jose Manufactured Code Items)	G	L
Materials Properties Records (San Jose Code Items)	O**	L
Nonconformance Reports	G	L
Packaging, Receiving, and Storage Procedures (except those contained in QA Manuals)	G	10
Performance Test Procedure & Results Records	G	L
Pipe and Fitting Location Report	G	L
Pressure Test Procedure	G	10
Pressure Test Results	G	L
Product Equipment Calibration Procedure	G	C
Product Equipment Calibration Records	G	C
8   Product Quality Checklist (NF&CM only) (when specified by QRS)	O**	L
Purchase Orders for Material used on GENE Make Items	G	10
Purchaser's (GENE) Pre-Award QA Survey	G	B
QA System Audit Report	G	B
QA Manuals, Procedures & Instructions	G	A
Radiographic Procedures	G	10
Radiographic Review Forms (except San Jose Manufactured Code Items)	G	L
Radiographic Review Forms (San Jose Manufactured Code Items)	O**	L
Radiographs (except San Jose Manufactured Items)	G	E
Radiographs (San Jose Items)	O**	E***
Receiving Inspection Records	G	7
Safety-Related Items Log (San Jose Manufactured Items)	G	L
Ultrasonic Examination Procedures	G	10
Ultrasonic Examination Final Results	G	L
Supplier Certificates of Conformance accompanied by Special Specified Data	G	L
Supplier's QA Program Manual	G	D
Welding Materials Control Procedures (except those contained in QA manuals)	G	10
Welding Personnel Qualification	G	7***
Welding Procedure Qualifications and Data Reports	G	7***
Welding Procedures	G	L
Work Processing and Sequencing Documents	G	10

SUPPLEMENT TO THE ALTERNATE POSITION  
ON REGULATORY GUIDE 1.88 (Continued)

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- \* See legend. Records transmitted to Owner are consistent with contract requirements.  
\*\* Where GENE supplies QA records to the Owner, GENE will normally retain copies as needed for for GENE business purposes. The GENE records storage, however, should  
\*\*\* not be considered as Owner's second storage facility without GENE agreement.  
For orders placed after June 1, 1978, this retention period is extended to 10 years from shipment of the product.

LEGEND

- N/A - Not applicable to GENE (Owner or AE scope of Responsibility)  
G - Retained by or For GENE  
O - Transmitted to Owner  
L - Lifetime retention (life of the item)  
7 - 7 years retention (from date of generation)  
10 - 10 years retention (from date of generation)  
A - Retained for 3 years after being superseded or invalidated  
B - Retained until corrective action is completed or 3 years (whichever is later)  
C - Retained until recalibrated  
D - Retained until purchase order is closed out  
E - Retained for lifetime per NRC request or until NRC permits their disposal

### 3 DESIGN CONTROL

#### 3.1 GENERAL

The design of structures, systems, and components, is controlled within the various GENE organizations to assure safe and reliable performance of products and services to be supplied. The design control processes are documented in practices and procedures which establish the responsibilities and interfaces of each organizational unit that has an assigned design responsibility. The practices and procedures include measures to assure that:

- o design requirements are defined and design activities are carried out in a planned, controlled, and orderly manner;
- o appropriate quality requirements and standards are specified in design documents;
- o suitable materials, components, and processes are specified in design documentation;
- o appropriate design verification methods are selected and implemented by individuals or groups not having direct responsibility for the original design; and
- o design changes are controlled to the same level as was applied to the original design, including review and approval by the same organization that performed the original review and approval unless another responsible organization is designated by GENE management.

Each GE BWR offered for sale is of a current product line which has been engineered as a "Standard Plant" design for several ratings. The "Standard Plant" designs, and changes thereto, are reviewed for conformance to GE product safety standards and to applicable NRC regulations independent of sales commitments, and are updated as necessary to assure compliance with changes to these standards and regulations. Modifications to the "Standard Plant" for a particular sale are made only pursuant to the contract with the Owner, provided safety and warranty conditions are not adversely affected. Since each nuclear system sale (called "project" after sale is made) is based on a "Standard Plant", it is not necessary to repeat the review of the "Standard Plant" design documentation for each project, but only to review the modifications, if any, for each project.

The GENE engineering organizations define and document acceptable and approved materials, parts, equipment, and processes. The definition is documented in controlled design manuals and standard specifications. Standard off-the-shelf commercial items are included. The standard specifications are reviewed, approved, and issued in accordance with the engineering review system. In addition, all equipment designers have available to them direct consultation services of materials engineers during the design action and design review phases. Application selection of materials is based upon this review system, and review for suitability occurs during the engineering review for design verification action. Where engineering experience identifies a need for testing confirmation, suitable controlled qualification tests are performed.

Each discrete GENE design is subject to the GENE design control system. The GENE design control measures are applied to: analyses for performance parameters; reactor physics; stress; thermal; hydraulic; radiation; accidents; compatibility of materials; accessibility for in-service inspection, maintenance and repair; and specification of criteria for inspection and test.

8 | The contractual design basis and data unique to a specific project is defined to the engineering organizations by the authorizing management. The information is documented in the appropriate release document, e.g. the Work Authorization (WA) or equivalent, which authorizes and initiates the engineering work for the project.

### 3.2 DESIGN INTERFACE CONTROL

To provide assurance of structure, system, and component interface compatibility, GENE design documents are distributed for information, review, and coordination by affected design organizations. The responsible engineer is required to have design documents reviewed for interface compatibility by individuals having responsibility for the interfacing documentation in order to assure that there is no conflict in the design objectives and that the product resulting from the interfacing designs will function as planned. When required by contract, design documents are also furnished to the Owner and/or his agents to provide for interface compatibility review and coordination by Owner/agent design organizations.

### 3.3 NUCLEAR STEAM SUPPLY SYSTEM

Design specifications and data sheets containing design basis and other data for a specific contract are developed by the design engineer based on the applicable project/program release document and issued to the responsible design organizations in the early months following the receipt of an order. The design controlling documents provide the basis for detailed systems, structure, and component design and typically include the system and structure design specifications, piping and instrumentation diagrams, process diagrams, functional control diagrams, and instrument engineering diagrams.

8 | The design specifications, data sheets, and design controlling documents incorporate the design and safety requirements for each plant. These designs are subject to independent design verification within engineering, as described in Subsection 3.8. These designs are also reviewed by the project engineer for each project before they can be applied to that project (see Item 2 of Table 3-1). The project engineer and project manager assigned to the particular project are responsible for overall project coordination, but are not directly responsible for the preparation of the engineering design or documentation issued for the project. The various engineering organizations of the GENE are responsible for the design and design control activities for the GE BWR. Engineering personnel are authorized to define and prepare performance parameters and to document the design of systems and equipment. They obtain necessary internal engineering interface consultation and services as required. They provide final design approval in accordance with documented engineering practices and procedures. Responsibility for internal design document control is vested in the engineering support organizations of the GENE. Responsibility for interface control with the Owner is assigned to the responsible project/service or program manager.

In addition to the design specifications, data sheets, and design control documents, engineering organizations issue general standard design specifications which for designing components which satisfy the system and structures requirements. These standard design specifications identify applicable codes, standards, regulations, and other requirements to be utilized to assure compliance with safety criteria, quality levels, and other specific requirements which have been imposed to obtain acceptable quality, safety, and reliability. These design specifications are subject to design verification review prior to issue. The original issue and any subsequent changes to the document for the project are subjected to review for project application by the project engineer.



A design freeze review is made of the engineering work after the design documents have been issued and the Owner has had an opportunity to review them for adherence to the contractual requirements and to provide interface design data from the balance of plant design (see Item 4 of Table 3-1). The system design freeze review is made by a review team coordinated by the review team leaders, and covers the data sheets, the design controlling documents, and the general standard design specifications described above. The team includes (1) the project licensing engineer who participates in the review of the documents against requirements of the PSAR and any applicable amendments, (2) the responsible design engineers who participate in the review to provide necessary design information and who initiate and follow through on any required changes, and (3) the project engineer who participates in the review of the documents against the contract requirements.

Following implementation of any changes required as a result of the design freeze review, the design is considered frozen and further changes to the design documentation will be made only for the following reasons: (1) requests by the Owner for changes from the original plant as sold, (2) changes to meet requirements of applicable codes, standards, and regulatory agencies, (3) feedback from recent plant startup testing or operating plant experience, or (4) other information identifying changes required to make a system or equipment function properly and safely. Results of design freeze reviews are documented and filed in a controlled manner for future reference in accordance with applicable codes, standards, and regulations. For identification of those positions or organizations responsible for the various types of reviews held in GENE, refer to Table 3-1.

#### 3.4 DESIGN OF PURCHASED EQUIPMENT

The design documentation of GENE purchased components (including instrumentation and controls and materials used in the fabrication of GENE manufactured components) consists of one or more of the following documents: equipment purchase specification which specify general requirements, including materials, processes, workmanship, and acceptance criteria; purchased part drawings which show the outline and interface requirements; and specific data sheets or project sheets which define the project unique requirements of the equipment. The responsible engineer prepares the specifications, drawings and data sheets and is responsible for assuring that they conform to the input requirements such as the project WA, the nuclear system data sheets, system design control documents, interface control drawings, the general design specifications, and applicable codes, standards and regulations. The designs are subject to design verification review including a review to assure that the design documents meet any unique project requirements. Initial issues of purchase specifications for engineered equipment are reviewed by purchasing and QA prior to supplier bidding. Changes to the documents after the purchase order is placed, are controlled as described in Subsection 3.10, "Design Change Control".

The purchase documentation identifies the documents, such as drawings, procedures, calculations, and test data which must be submitted by the supplier for review and approval by engineering and/or QA (see Item 5 of Table 3-1).

Product design and quality requirements are transmitted from engineering to purchasing through controlled issuance of documents which identify the product and specify applicable drawings, specifications, and QA requirements. Initial issuance and revisions are controlled by written procedures.

#### 3.5 DESIGN OF REACTOR EQUIPMENT COMPONENTS

Design documentation for reactor equipment manufactured by NFGCM consists of specific detailed product drawings augmented by design and process specifications necessary to fabricate, inspect, and test

8 | the finished product. The responsible engineer assures that the design documents conform to the project WA, the nuclear system data sheets, the system design control documents, the general design specifications, and the applicable codes, standards, and regulations before release to manufacturing. The design documents are subjected to a design verification review and a review by cognizant materials engineers. Reviews are also conducted with NF&QM Manufacturing Engineering and NF&QM QA to assure compatibility with manufacturing and quality control technology and capability. Changes initiated after this point are controlled as described in Subsection 3.10, "Design Change Control".

Product requirements are transmitted to NF&QM through issuance of controlled Engineering Instructions (EI), or in the case of spare and renewal parts, by Requisition Instruction Sheets (RISs). These documents specify the applicable drawings and specifications.

### 3.6 DESIGN OF CONTROLS AND INSTRUMENTATION

The system design controlling documentation for controls and instrumentation consists of design specifications, instrument engineering diagrams, functional control drawings, and general controls and instrumentation specifications which incorporate the general functional, environmental, material, and test requirements. The responsible engineer obtains interface review of the documents he has initiated and assures that they meet the requirements of the project WA, applicable nuclear system data sheets, system design control documents, interface control drawings, and general design specifications, as well as the applicable codes, standards, and regulations. Reviewers include the project engineer and other engineers responsible for systems or equipment with which there exists a design interface. In addition design verification review is performed to assure correctness and completeness of design, including specification of the appropriate quality requirements.

The detail design of controls and instrumentation by engineering and subcontractor-designers encompasses the generation of system elementary diagrams and connection diagrams, panel and rack arrangement drawings, purchased part drawings, instrument data sheets, manufacturing drawings, and instruction manuals. The instrument data sheets define the characteristics of the measurable parameters, the instrument environmental ranges, accuracies, set points, and locations of instruments required by the system design. These detail design documents are subjected to design verification review. The detail design makes use of standard products and purchased components which have been procured in accordance with approved functional specifications, and qualified for performance and design adequacy in accordance with documented procedures by a separate testing group. Design requirements, qualification, test reports, calculations, and other design data are reviewed for design adequacy in accordance with documented procedures. Product requirements are transmitted from engineering to the manufacturing organization through issuance of controlled documents which specify applicable drawings, specifications, and project unique requirements. Changes to the control and instrumentation documents after release to manufacturing are controlled as described in Subsection 3.10, "Design Change Control".

### 3.7 DESIGN OF FUEL

Nuclear system performance requirements and bases for nuclear fuel are specified by Fuel Engineering (FE). Detailed fuel drawings and specifications are prepared and subjected to a design verification review. These documents are reviewed with NF&QM manufacturing and QA personnel to assure compatibility with manufacturing and quality control technology and capability prior to release for manufacture. Changes to drawings or specifications are made through the use of Engineering Change Notices (ECNs) that are reviewed for consistency within cognizant organizations, and are approved by the engineering

organization that approved the original design. Design changes affecting system design or the design of non-fuel components are reviewed for system interface compatibility with other affected organizations in the GENE.

Product requirements are transmitted from engineering to manufacturing through issuance of controlled documents bases which specify applicable drawings and specifications. Fuel Engineering also specifies other project unique requirements to NF&OM through the issuance of controlled WAs and EIs.

Design review, design release, and design change control systems are formally documented and implemented for all designs of fuel components, and assemblies.

### 3.8 DESIGN VERIFICATION

Design verification is a process for an independent review of designs against design requirements to confirm that the designer's methods and conclusions are consistent with requirements, and that the resulting design is adequate for its specified purpose. Product designs and each application thereof are verified, consistent with contract requirements. Design verification is performed and documented by persons other than those responsible for the design using the method specified by the design organization. The methods of design verification include one or more of the following: design review, qualification testing, alternate or simplified calculations, or checking. When qualification testing is used as the sole means of verifying design adequacy, a prototype or initial production unit is tested under the most adverse operational conditions expected to be experienced by the product (see Item 1 of Table 3-1).

For a given application, no additional verification is required for spare and renewal parts which are the same as those originally supplied. If spare or renewal parts for an application are of a modified or different design from the original design, the differences between the new part and the original part are verified for the application. If spare or renewal parts are used in a new application (a different system, different power plant, etc.) the designs are verified for the differences between the new and old application.

### 3.9 TEAM DESIGN REVIEW

A team design review is a formal independent evaluation of designs by persons other than those directly responsible and accountable for the design. These activities are ongoing reviews of designs, selected by engineering management to evaluate the adequacy of product designs including concepts, the design process, methods, analytical models, criteria, materials, applications, or development programs. When appropriate, design reviews are used to verify that product designs meet functional, contractual, safety, regulatory, industrial codes and standards, and GENE requirements. The design review team selection depends on the product design and the type of review. The team's technical competence will fall into three broad categories: (1) those with broad experience on similar products, (2) those with specialized technical expertise such as in heat transfer, materials, structural analysis, etc., and (3) those with a functional expertise such as manufacturing engineering, product service, legal, etc. (see Item 3 of Table 3-1).

### 3.10 DESIGN CHANGE CONTROL

Following issuance of engineering documents, a design change control procedure is implemented with controls commensurate with those applied to the original design. Measures for documenting and dispositioning errors and deficiencies in the design and for determining and implementing corrective

actions are described in this section as well as Subsection 3.11, "Field Change Control". The end result, after all changes have been incorporated, is reflected in accurate drawings, specifications and other documents which fully describe the final design for equipment supplied. The control procedure requires that every change must be documented, design verified, approved by the responsible engineer, and reviewed by the appropriate interfacing components. The responsible engineer is charged with the responsibility for defining all other design documents affected by the change, and for resolving and coordinating changes with other engineers whose documents are affected. The Engineering Change Notice (ECN) is used for documenting the change and its approval.

The ECNs are identified, issued, and controlled in accordance with documented procedures. Copies of the ECNs are distributed to design interface personnel, including the responsible engineer who approved the change, the project manager, and to engineering, manufacturing, purchasing, and QA personnel in other organizations, as appropriate. Design changes affecting interface conditions between Owner-supplied and GENE supplied equipment are identified and reviewed by the project manager with the Owner or his designated representative. Such documented changes are transmitted by the project manager to the Owner or his designated representative for implementation of design and field changes, as appropriate, in his interfacing scope of supply.

### 3.11 FIELD CHANGE CONTROL

After delivery of equipment and during the installation and startup phases at the plant site, field changes that become necessary fall into two general classes: first, those generated by design changes, and second, those initiated in the field as a result of unique field conditions. In order to accomplish a field change on GENE furnished components, the responsible engineer processes a design change in accordance with Subsection 3.10, "Design Change Control", and issues a Field Disposition Instruction (FDI) which identifies the components affected, the changes to be made, the parts to be replaced, the source of the replacement parts, the disposition of the parts replaced, the procedures to be followed in making the change, and the quality requirements to be met. The responsible engineer is also responsible for providing instructions for the manufacture or procurement of the replacement parts, as applicable, and for assuring that instructions are issued for other projects requiring such changes. The design documentation supporting the FDI is subjected to a design verification review and is reviewed by the project engineer. The field change is then authorized by the project manager prior to distribution of the FDI.

When it becomes necessary to ship products to the site before manufacturing is complete (ship short) either by GENE or its suppliers, an FDI is issued which identifies the work to be completed in the field. Such FDIs identify the necessary engineering and quality requirements.

Changes initiated by field organizations generally are the result of deviations from the planned construction or preoperational conditions. In order to initiate action to accomplish a field change on GENE furnished components, the field organization generates a Field Deviation Disposition Request (FDDR) which identifies the deviation and the proposed changes to correct or compensate for the deviation. The engineering and project management organizations review the FDDR for compliance with the established design criteria and for safety, performance, and functional design requirements. If the proposed method is found to be satisfactory, the FDDR is then reviewed and released for field implementation. If the proposed method for correction does not comply with the established criteria and requirements, the responsible engineer disapproves the FDDR, and an alternate solution is presented by modification of the FDDR or by issuing an approved FDDR. If an FDDR results in a design change, documents are changed by the use of the ECN. When an FDDR indicates an inherent problem which affects more than one project, the responsible engineer issues appropriate ECNs to effect changes to the design documents for all plants

affected. The FDI's, FDDR's, and EON's are formally identified, prepared, and controlled in accordance with documented procedures.

The GENE installation engineers and technical specialists provide technical direction of Owner-implemented field changes during the installation, preoperational and startup testing phases. Also, verification of field change implementation during the installation phase is accomplished by GENE surveillance of GENE supplied systems and components. GENE implemented changes at the site are performed and controlled under the direction of the GENE.

### 3.12 DESIGN CHANGE APPLICATION

The system for assuring controlled changes in the design has been described in preceding subsections. In addition, when conditions adverse to quality or safety are identified in designs, they are documented with proposed corrective action and proposed project application of the corrective action. This is reviewed by appropriate management through a review board to finalize agreement on the necessary design change action and the projects affected. Following management decision to apply the corrective action to specific projects, the responsible engineer makes the necessary design document changes and issues Material Request (MR) changes, Engineering Instruction changes, or FDI's, where appropriate, to implement the design change. As a result, corrective action is applied to all projects where action to correct the cause of the condition is deemed appropriate (see Item 6 of Table 3-1).

Table 3-1  
TYPICAL DESIGN AND APPLICATION REVIEWS

Review Type	Review Scope	Responsible Organization or Individual	Text Reference
1. Design Verification prior to issue of design documentation and changes thereto.	Verification of correct translation of requirements and application.	Designated design engineer for verification.	See Subsection 3.8 "Design Verification."
2. Project application review.	Incorporation of contract requirements.	Project engineer for each project.	See Subsection 3.3, "Nuclear Steam Supply System Design."
3. Team design review to determine adequacy of product design.	Evaluation of design for application of new safety, licensing, or operational requirements.	Review team selected by management.	See Subsection 3.9 "Team Design Review."
4. Design freeze review	Design contract, and licensing compatibility.	Responsible design, licensing, and project engineers.	See Subsection 3.3, "Nuclear Steam Supply Design."
5. Review of vendor design for compliance with purchase specifications.	Vendor compliance with requirements; design adequacy.	Each design engineer responsible for the equipment design.	See subsection 3.4, "Design of Purchased Equipment."
6. Review of significant design change proposals.	Authorization of design change and project application.	Management review board.	See Subsection 3.12, "Design Change Application."

#### 4 PROCUREMENT DOCUMENT CONTROL

Measures are established and documented for the preparation, review, approval, and control of procurement documents to provide assurance that regulatory requirements, design bases, and other requirements which are necessary to assure the requisite level of quality are included or referenced in the documents for procurement of items and services, including spare and replacement parts and subcontractor design services. Design quality requirements, such as documented in drawings and specifications are prepared, reviewed, approved, and issued by the appropriate engineering organizations, prior to order placement. Additional quality compliance requirements, such as supplier QA Program and documentation requirements, and provisions for source surveillance and audit, are prepared, reviewed, approved, and issued by QA organizations for inclusion in the procurement document packages. Reviews of the procurement documents by QA personnel are made to provide assurance that quality requirements are complete and correctly stated and that they can be controlled by the supplier and verified by line-QA personnel. Purchase Specifications are reviewed and signed off by QA on an Engineering Review Memorandum prior to issuance.

The GENE documents for procurement of engineered equipment are approved by the responsible engineer. QA develops QA requirements which are applied to each Material Request for engineered equipment or services and which become a part of the purchase contract. Each purchase order is available to QA for planning purposes.

Quality-related changes in procurement documents are subject to the same level of control as was exercised in the preparation of the original procurement documents. The GENE purchasing organizations close out purchase orders only after ascertaining that all equipment and documentation has been received and that the pertinent records accurately reflect the procurement actions. The pertinent records are then stored and maintained in a systematic and controlled manner in designated record retention areas for the length of time specified by contract or other legal requirements.

The following information and requirements are included in procurement documents, as deemed appropriate by line-QA engineers:

- o GE Supplier Quality Assurance Program - Identification of the requirements of the QA program to be developed and implemented by the supplier, such as design control document preparation and control, purchased material control, control of materials, special process controls, inspection and test control, control of measuring and test equipment, handling, storage, and shipment control, inspection and test status control, nonconforming material control, corrective action, auditing, etc.
- o Basic Technical Requirements - Drawings, specifications, codes, industrial standards, and the applicable requirements of those Regulatory Guides and ANSI Standards identified in Table 2-1, with applicable revision data, test and inspection requirements, including test equipment, special instructions, and requirements such as for designing, fabricating, cleaning, packaging, handling, shipping, and normal or extended storage in the field.
- o Source Surveillance and Audit - Provisions for access to the plant facilities, records, and documentation necessary for source surveillance or audit by the GENE, the Owner, or his agent personnel when the need for such access has been determined.

- o Document Requirements - Identification of supplier documents and records to be prepared, controlled, retained, maintained, submitted, or made available for GENE review and/or approval. Such records include: drawings; specifications; procedures; procurement documents; inspection and test records; personnel and procedure qualifications; material, chemical, and physical property test results; and product quality certifications.
- o Lower Tier Procurement - Extension of applicable requirements of procurement documents to lower tier suppliers.



## 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Documented instructions, procedures, and drawings are utilized to communicate quality requirements throughout all phases of design, purchasing, manufacturing, and construction. Activities affecting quality, including methods of complying with 10CFR50, Appendix B, are delineated, accomplished, and controlled by such documents as policies, procedures, operating instructions, design specifications, shop drawings, planning sheets, test and inspection procedures, and standing instructions. Each organization performing QA-related functions, such as engineering, manufacturing, field services, and QA is responsible for the preparation, review, approval, release, application, and maintenance of its own documentation.

Components, assemblies, and systems furnished by the GENE are inspected or tested in accordance with instructions and/or check lists written for the purpose of communicating quality requirements and inspection and test methods to quality control (QC) inspection and test personnel. These instructions may be included on a shop traveler or be documented on a special inspection or test instruction, depending on the nature or complexity of the quality control operation to be performed. The documents define or reference appropriate quantitative criteria such as dimensions, tolerances, and operating limits or qualitative criteria such as comparative workmanship samples or visual standards for determining that important activities have been satisfactorily accomplished. The associated shop traveler or QA record provides space for recording or stamping identification of the individual performing the inspection or test and is the record of the quality control operation. This document serves as evidence of completion of the operation and certification of the acceptance status of the item(s) being inspected. Other sections of the QA Program description contain more detailed information concerning the specific documents employed in prescribing quality-related activities.

Approval and issuance authority for the various document types is in accordance with issued procedures. The various GENE procedure manuals identify the individuals, organizations, or positions responsible for approval and issuance of such procedures. The GENE Policies and Procedures governing all lower tier procedures and manuals, is approved by the Vice President and General Manager, GENE.

## 6 DOCUMENT CONTROL

Procedures and practices are established, documented, and implemented to control the issuance and use of documents which prescribe activities affecting quality, including: design basis specifications; purchase specifications; test and inspection instructions; manufacturing, construction, and installation drawings; operating procedures; and QA plans and manuals. These measures provide assurance that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are promptly distributed for use at the location where the prescribed activity is performed. Changes to documents are reviewed and approved by representative of the same organization that approved the original document unless another organization is specifically designated by appropriate management. The designated reviewing individual(s) has access to pertinent background information upon which to base the review, and is determined by GENE management to have an adequate understanding of the requirements and intent of the original document.

Through established distribution and communication systems, those participating in an activity are furnished or apprised of current applicable instructions for performing the activity. Participating organizations have documented procedures for control of these documents, and the changes thereto, to assure use of the proper documents and to preclude the possibility of use of outdated or inappropriate documents.

The GENE engineering services organizations are assigned responsibility for the initial distribution, safeguarding of originals and future retrieval of design documents. Controlled distribution lists are maintained to assure that distribution is to responsible individuals and organizations. The GENE organizations utilize a design record retention/retrieval system based on prints made from microfilm/microfiche. When a document is issued or revised, the engineering services organization replaces the prior revision microfilm and relocates it to an obsolete file.

GENE QA-related configuration control documents such as the Project Master Parts List, Work Authorizations, Engineering Instructions, Shop Travelers, Work Orders, QA Plans, QA Procedures and those documents identified in Subsection 2.2 are controlled in accordance with the following provisions:

- o Individuals or organizations responsible for preparing, reviewing, approving, and issuing documents and their revisions are identified by higher level procedures with appropriate authority for such delegation of responsibility.
- o Interface documents are developed, coordinated, controlled, and require mutual agreement between the interfacing organizations.
- o Assurance that proper documents are being used is ascertained by cognizant supervisors and verified by QA through inspection and audits.
- o Distribution lists are established by the issuing organization and include those individuals or organizations with a need to know in order to fulfill their assigned responsibilities.
- o Revised documents are distributed to those on controlled distribution of the original or prior revision of the document. Distribution of changes or additions to issued manuals and other QA documents is made to a controlled distribution list with instructions to the recipient as to the disposition of the obsolete documents.

## 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

Procedures and practices are established and documented to provide assurance that purchased items and services, whether purchased directly or through subcontractors, conform to the procurement document requirements. These measures include provisions, as appropriate, for the following: source evaluation and selection; review of procurement requirements; QA or engineering review of supplier documents; appropriate objective evidence of quality furnished by the supplier; surveillance, inspection, or audit at the source; and examination or review of items or services upon delivery or completion. Documentation of such requirements is originated and maintained by the cognizant QA organizations. Spare and renewal parts that perform safety-related functions are procured to a level of quality standards and controls that are at least as stringent as those employed for the purchase of the original equipment.

Measures for evaluation, certification, or qualification, and selection of procurement sources by engineering and QA personnel include the use of historical quality performance data, source surveys (including a review of the supplier's QA Program), or source qualification programs. Specific provisions for QA review, concurrence and audit of GENE supplier's QA Programs are delineated in purchase orders for safety-related equipment or services. Suppliers of engineered equipment and services are required to document their QA Program in accordance with the applicable elements of ANSI N45.2 and to submit their documented QA Program to the GENE for review. Those comments affecting component quality are resolved prior to commencement of any work which could be affected by the comments.

The GENE suppliers are subject to audit/evaluation by line-QA personnel for evaluation of the sufficiency of the supplier's QA Program and for adequacy of implementation. Each supplier of safety-related equipment or services is audited or evaluated initially to determine acceptability of their QA Program. If acceptable, the supplier is placed on an approved supplier list. Following placement on the approved supplier list, the supplier is either: (1) audited annually to determine the continued acceptability of the supplier's program, or (2) evaluated annually to determine if an audit is required during the upcoming year. When an evaluation is performed, the results are documented and approved by responsible QA personnel. This evaluation considers pertinent factors, such as: the results of previous audits; history of performance of product and/or purchased service; effectiveness of implementation of the supplier's QA Program; and the importance, complexity, and quality requirements of the item or service concerned. Active suppliers of "safety-related" items are audited at least every 3 years.\*

Source inspection or surveillance is performed by line-QA organizations as necessary to assure the required quality of an item or service. The QA organizations may elect not to perform source inspection or surveillance of supplier activities when the quality of the item or service is to be verified by some other method such as: review of test reports, inspection or review upon receipt, or by the performance of acceptance or installation tests. The QA representatives responsible for supplier audit and surveillance are typically assigned responsibilities as follows:

- o Review purchase specifications and drawings to assure a clear understanding of quality requirements.
- o Participate in preproduction reviews with supplier personnel to assure mutual understanding of quality requirements.

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\* May be satisfied by ASME survey.

- o Review suppliers' detailed fabrication process sheets to assure proper sequencing and adequate inprocess inspection, test, and control.
- o Witness and audit various qualifications, tests, inspections, and nondestructive examinations.
- o Audit heat treatment, welding, cleaning, preserving, packing, and packaging activities.
- o Review supplier QA records for compliance with requirements.
- o Audit supplier conformance with established procedures, such as:
  - o Use of approved drawings and procedures
  - o Use of approved product and process quality planning
  - o Use of inspection and test personnel who are organizationally independent from production and scheduling personnel
  - o Document change control
  - o Nonconforming material control
  - o Material identification and traceability control
  - o Control and calibration of measuring equipment
  - o Control of welding
- o Complete product quality certifications prior to release of equipment for direct-to-site shipment.

A Product Quality Certification (PQC) or equivalent certification is transmitted with the equipment whenever safety-related items are shipped to a nuclear power plant. The document certifies that the items identified therein are in conformance with the procurement quality requirements, including applicable codes, standards, and specifications as identified in documents referenced on the certification. Any nonconformances to procurement quality requirements that may exist on modules being shipped are identified or referenced on the certification. (Reference Subsection 15.2, "Reporting of Nonconformances," and Table 2.2, GENE position on Reg Guide 1.123.)

## 8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

Procedures and practices are established and documented which provide for the identification and control of materials, parts, and components, including partially fabricated subassemblies. The identification and control measures are documented in engineering, manufacturing, and QA-originated documents, and are implemented by the appropriate manufacturing, services and QA organizations. Equipment components, including subassemblies or parts, are identified and controlled by serial numbers, part numbers, or heat numbers in accordance with GENE, ASME Code or regulatory requirements.

These measures provide means for assuring that only correct and acceptable items are used during manufacture. Physical identification is specified and utilized to the maximum extent practical. When physical identification is either impractical or insufficient, physical separation, procedural control, or other appropriate means are specified. Identification may be either on the item or on records traceable to the item. 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. Markings are transferred to each part of an item when subdivided so as not to be obliterated or hidden by surface treatment or coatings, unless other means of maintaining identification are utilized. The identification and control measures provide for relating an item of product (batch, lot, part or assembly) at any stage, from material receipt through fabrication and shipment to an applicable drawing, specification, or other control document.

Materials, parts, or components classified as "safety-related" are processed through and released by QA Inspection. Inspections and tests of material received from suppliers are conducted in accordance with the engineering drawing and/or receiving inspection instructions or plans developed by QA to assure verification of material to the requirements of the purchase order. Material is marked or identified in accordance with QA procedures to identify inspection status and maintain identification. As applicable materials traceability is provided in accordance with documented procedures specifically required by the ASME Boiler and Pressure Vessel Code.

Materials organizations are responsible for maintaining raw material, purchased components, and in-process material in a manner which preserves the identification of the items while in the storage areas. Material identification is verified by the Materials organizations prior to release for assembly or installation. Final verification of correct identification is accomplished by QA personnel prior to release for shipping.

Items shipped to the Owner are normally identified by nameplate or other identification marking on the item. In those instances when it is not practical to provide nameplate or identification markings on individual items, identification information is provided in shipping paperwork that is transmitted with each shipment.

## 9 CONTROL OF SPECIAL PROCESSES

Procedures and practices are established and documented to provide assurance that special processes such as welding, heat treating, and nondestructive examination are accomplished under controlled conditions. These special processes are accomplished in accordance with applicable codes, standards, regulations, specifications, design criteria, and other special requirements, using qualified personnel, procedures, and equipment.

Requirements for special processes such as welding, heat treating, and nondestructive examinations are specified by owner's procurement documentation or on design documentation by the GENE engineer responsible for the design. Appropriate inspections and tests to assure control of these special processes are designated in test and inspection procedures.

Manufacturing, Field Service, QA personnel, procedures, and equipment involved or utilized in the execution of control of special processes are qualified to the requirements of applicable codes and standards. Documented evidence of the validity of such qualifications is maintained for all such personnel, procedures, and equipment in accordance with applicable codes and standards. Each cognizant QA organization has the responsibility of periodically monitoring these records to assure the continued validity of all such qualifications. For special processes not covered by existing codes or standards, or where product requirements exceed the requirements of established codes or standards, the necessary qualifications of personnel procedures, or equipment are defined in appropriate documents. | 8

## 10 INSPECTION

Inspection of materials, equipment, processes, and services is defined and executed in accordance with established QA plans, procedures, or instructions to provide assurance that the items conform to applicable drawings, specifications, codes, standards, and regulations.

Examinations or measurements are performed on items in process for each work operation where necessary to provide assurance of quality. Final quality verification inspection activities (for release to inventory or shipping), and in-process inspection of operation which are inaccessible during final inspection, are performed by QC personnel who are organizationally independent from the Manufacturing personnel who performed the work being inspected. These personnel report to the various QA managers and include inspectors, test technicians, and QA representatives who have been trained to meet established performance standards and are periodically evaluated to assure their competence in applicable quality control technologies.

Required accuracy of inspection and measuring devices specified is dependent on the characteristic to be measured and the design tolerances specified. If direct inspection of processed items is impossible or impractical, indirect control by monitoring of processing methods, equipment and personnel is utilized. A combination of direct inspection and process monitoring is provided when control is inadequate without both. Modifications, repairs and replacements are inspected in accordance with original inspection criteria or alternate approved criteria. Sampling is primarily used to verify process parameter control and to verify acceptability of items or lots where a high degree of confidence can be assured through use of statistically significant sampling plans.

Document QA plans, procedures, or instructions are reviewed and approved by QA personnel and provide for the following, where applicable:

- o Identification of characteristics or activities to be inspected.
- o Identification of those responsible for performing the inspection operations.
- o Acceptance or rejection criteria.
- o Method of inspection.
- o Recording evidence of completing an inspection operation.
- o Identifying the inspection or data recorder and the results of the inspection operation.
- o Qualification requirements of individuals performing inspections and examinations. (Refer to Table 2-1 for the commitment to compliance with ANSI N45.2.6).
- o Specification of any mandatory inspection points beyond which work cannot proceed without appropriate inspector action.

Such information is documented in planning documents which are appropriate to the activity and have been issued for utilization by inspection or examination personnel.

Inspection results are documented and evaluated by QA personnel prior to release of a product for shipment to provide assurance that inspection requirements have been satisfied and that proper records have been prepared.

## 11 TEST CONTROL

### 11.1 PRODUCT TEST PROGRAM

A product test program is established to provide assurance that all testing required to demonstrate that the product will perform satisfactorily in service is identified, performed, and documented. Product testing is performed in accordance with QA or engineering test procedures which incorporate or reference the test requirements and acceptance limits contained in applicable engineering and QA documents. Test requirements and acceptance criteria are normally provided by the organization responsible for the design of the product. The product test program covers all required test, including, as appropriate: development testing, prototype qualification testing, calibration testing of instruments, hydrostatic testing of pressure boundary components, qualification testing of procured components, in-process testing of manufacture components, or final acceptance testing of completed products.

Test procedures for GENE manufactured equipment are normally developed by QC engineers and/or development engineers in accordance with specified test requirements and reviewed by the cognizant design engineer. These test procedures include provisions for assuring that prerequisites for the given test have been met for mandatory hold points (where applicable), for acceptance and rejection criteria, and for appropriate methods of documenting test results. Prerequisites include such items as appropriate and calibrated test equipment, trained test personnel, completion status of the item to be tested, suitable environmental conditions, and provisions for data acquisition and storage.

Test procedures for procured equipment are based on engineering design, ASME code, and other specified requirements and when prepared by the supplier, are approved by assigned GENE engineering or QA personnel.

Product test results are documented, reviewed, and evaluated by designated QA or engineering personnel prior to release for shipment to assure that test requirements have been satisfied.

### 11.2 PREOPERATIONAL TESTING

The nuclear system is made operational by the Owner with technical direction provided by GENE personnel. The GENE provides preoperational test specifications and instructions for GENE-supplied systems and components.

Preoperational test specifications identify the systems and components which must be tested and state the requirements of the tests necessary to assure safe performance during testing. Test specifications are reviewed and approved by the appropriate engineering component prior to release.

Preoperational test instructions provide the necessary information and the essential steps to be taken to fulfill the requirements of the preoperational test specifications.

The GENE supplies field engineers and technical specialists with extensive product knowledge and preoperational testing experience to provide technical direction of the preoperational tests.

Upon completion of preoperational tests, the GENE Resident Site Manager and the Owner's representative formally document that the tests have been completed and that the results are in accordance with applicable specifications and instructions.



### 11.3 STARTUP TESTING

Initial fuel loading, nuclear system startup, and operational testing are performed by the Owner with technical direction provided by GENE personnel. To facilitate technical direction of initial fuel loading and power testing, startup test specifications and instructions are provided by the GENE.

Startup test specifications define the minimum test program for safe and efficient startup and authorize and require the performance of the described tests. The specifications limit and define the freedom for changes during the startup test activities. The specifications are reviewed and approved by responsible GENE engineering personnel and each required test is performed to the extent specified.

Startup test instructions contain the recommended test method and describe the steps necessary to perform the test as required by the startup test specification. Other test methods may be employed; however, the resulting data must be equivalent in all respects to the data which would result from the recommended test method. The results of analyses made to facilitate startup testing activities required by the startup test specifications are included in the startup test instructions. The startup test instructions also contain criteria for judging the test results, where applicable, and data and calculation sheets for analysis of the data on the site.

The GENE supplies field engineers and technical specialists with extensive product knowledge and startup experience to provide technical direction for the startup test program. Results of the startup tests are analyzed at the reactor site as the data becomes available and periodic reports of the results of the program are issued during the course of testing activities.

Upon completion of startup testing, the GENE Resident Site Manager and the Owner's representative formally document that the startup tests have been completed and report that the results have met the intent of the specifications, calculations, and instructions.

## 12 CONTROL OF MEASURING AND TEST EQUIPMENT

A measuring and test equipment control program is established and documented to provide assurance that tools, gauges, instruments, and other inspection, measuring, and testing equipment and devices used in activities effecting or evaluating quality are of the proper range and type, with measurement error limitations necessary to verify conformance to established requirements. Documented instructions and procedures, which establish and specify the control program for measuring and test equipment, are prepared, maintained, and implemented by the responsible QA or engineering organizations.

Measuring and test equipment and reference standards are stored and calibrated in environments which will not adversely affect their accuracy. Environment factors which are considered include, but are not limited to: temperature, humidity, vibration, electromagnetic interference, background radiation, dust, cleanness, and fumes. To assure precision and accuracy, inspection, measuring and test equipment is identified and controlled in accordance with documented procedures. Certified standards having known valid relationships to national standards are utilized in performing the calibration and adjustment when such standards exist. If no national standards, exist, the basis for calibration is documented. Instrument calibration includes verification that the instrument works in accordance with the manufacturer's instruction manual when such manual exists. When practical and within the limitations of the state-of-the-art, the reference standards used for calibration of measuring and test equipment shall have tolerances no greater than 25% of the allowable tolerance for the equipment being calibrated. Reference standards shall be calibrated against higher level standards of closer tolerance. The accuracies of the measuring and test equipment and the reference standards are chosen such that the equipment being calibrated can be calibrated and maintained within the required tolerances. Calibration measures are not employed for rulers, tape measures, levels, and other such standard devices, since their use is limited to rough measuring functions.

Calibration and maintenance of measuring and test equipment are performed at appropriately specified intervals. The method and interval of calibration for each item of equipment is defined and documented and is based on the type of equipment, stability characteristics, required accuracy, and other conditions affecting measurement control. Special calibration is performed when accuracy of the equipment is suspect or when other conditions warrant it. When inspection, measuring, or test equipment is found to be significantly out of calibration (as determined by the responsible engineer from the area where the suspect equipment was last used), an evaluation is made and documented to determine the validity of previous inspection or test results and the disposition to be made of items previously inspected or tested. If any inspection, measuring, or test equipment is found to be worn and consistently out of calibration, it is repaired or replaced.

Records are maintained of calibration and maintenance activity, and items of measuring and test equipment are suitably and uniquely identified by the responsible QA organization to provide for the traceability to their calibration test data and for visual determination of their calibrations status. It is the responsibility of each person utilizing inspection or test equipment to assure himself that such equipment is within the calibration due date prior to performing an inspection or test operation. Test and inspection supervision is responsible for enforcement of this provision.

### 13 HANDLING, STORAGE AND SHIPPING

Procedures and practices are established, documented, and implemented in accordance with applicable codes, standards, and regulations to provide control of handling, storage, cleaning, packaging, preservation, shipping release, and shipping of material and equipment to prevent damage, deterioration, or loss during manufacture and shipment. When necessary for a particular item, special covering, special equipment, or special environmental conditions, such as inert gas atmosphere, specific moisture content levels, and temperature levels are specified by the cognizant engineering organization, and their existence is verified by QA. As required, special markings or instructions are supplied to identify, maintain, and preserve a shipment, including indication of the presence of special environments or the need for special control, such as shelf life limitations.

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Where necessary to control quality, instructions or guidance for site inspection, handling, preservation, storage, and special controls are prepared and are transmitted to the Owner prior to, or at the time of component shipment.

#### 14 INSPECTION, TEST, AND OPERATING STATUS

Procedures and practices are established and documented to assure identification of inspection and test status. These procedures and practices provide for assurance that required inspections and tests are performed and that the acceptability of items with regard to inspections and tests performed is readily apparent throughout the manufacturing cycle and is verified by QA prior to shipment to the Owner. Nonconforming items are segregated and/or clearly identified as such and are controlled in accordance with the nonconforming material control measures described in Section 15.

The inspection and test status of items is maintained through the use of separate physical locations or status indicators such as: tags, markings, shop travelers, stamps, or inspection records. Measures provide for assuring that only items that have successfully completed the required inspections and tests are used in manufacturing or are released for shipment. When operations or inspections are performed out of planned sequence, limit points are established beyond which work can not proceed until required operations or inspections have been performed. The instructions for control of status indicators, including the authority for application and removal of tags, markings, labels, or stamps are documented in manufacturing or QA procedures.

## 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

### 15.1 GENERAL

Procedures and practices are established and documented to provide for positive control of items which do not conform to specified requirements in order to prevent their inadvertent use during manufacturing, or their release for shipment. Procedures have been issued within the GENE to provide for determining the cause of significant nonconformances, for the identification, documentation, segregation, and disposition of such items, and for the notification of responsible and other affected organizations. These procedures also delineate the responsibility and authority for establishing disposition of nonconformances after appropriate review.

Nonconforming items are either accepted for use as is, repaired, reworked, returned to the supplier, or scrapped in accordance with a properly documented disposition. Nonconforming items dispositioned as "rework" or "repair" undergo reprocessing and reinspection in accordance with the original operational planning and inspection instructions or special planning approved by the responsible engineer and QA. Reworked material must fully comply with drawings and specifications and final acceptability documentation is required for items which have been reworked or repaired.

For procured engineered equipment provided by suppliers for direct-to-site shipment, deviations are processed on a Deviation Disposition Request (DDR) form, or an equivalent form approved by the GENE. The supplier describes the deviation on the DDR and recommends the GENE disposition. The deviations are reviewed by the cognizant Design Engineer, Quality Control Engineer, and Buyer, who cosign the DDR and indicate the GENE disposition.

Completed nonconformance reports identify the nonconforming item, describe the nonconformance, specify the disposition of the nonconformance, prescribe any special inspection or test requirements, and include signature approval of the disposition.

A disposition decision to "use as is" or "repair" a nonconforming item is made only after careful review and approval by a Material Review Board (MRB) consisting of a minimum of two technically competent persons selected by engineering and QA management. Before making disposition, the engineering representative must determine that utilization of the item in the "as is" or "repaired" condition will not infringe upon the capability of the item to satisfactorily perform its intended functions and must document the rationale for acceptance. Items dispositioned as scrap are deformed, defaced, or clearly identified as unfit for their intended use and removed from the processing area as soon as practicable.

Procedures and instructions are in place, which prevent or limit further processing of nonconforming items pending a decision on their disposition. The QA managers have authority for stopping work in process when such action is necessary to assure requisite quality.

Physical segregation of nonconforming items within hold areas is used where practical until disposition is made; otherwise, tagging, marking, or other positive means of identification are used to effect control and to prevent inadvertent use.

A system is established by each QA organization to periodically or continuously analyze nonconformances through review of MRB action and scrap and rework, to determine trends. Appropriate action is taken relative to recurring defects and their cause, and the effect of corrective actions taken. Reports of these analyses are documented and submitted to appropriate management.

## 15.2 REPORTING OF NONCONFORMANCES

For safety-related equipment manufactured or purchased by the GENE, the GENE will identify and report to the Owner at the time of shipment, through completion of the FQC (or equivalent) and attachments, those nonconformances to procurement requirements affecting end use of modules or shippable components which are dispositioned "use-as-is" or "repair". For criteria and definitions for obtaining customer approval for such nonconformances refer to the GENE position for NRC Regulatory Guide 1.123, Rev. 1, July 1977 (Table 2-1, page 2-11).

Modules or components of modules which are fabricated according to the requirements of applicable codes must satisfy the requirements of the codes and applicable code cases. Identification and description of nonconformances of these parts are furnished to the Owner in accordance with code requirements.

## 16 CORRECTIVE ACTION

Procedures and practices are established and documented which provide assurance that conditions adverse to quality or nonconformance such as: failures, malfunctions, deficiencies, and deviations in material and equipment are promptly identified, documented, and corrected or otherwise handled in accordance with established procedures. Corrective action followup and closeout procedures provide for assuring that corrective action commitments are implemented in a systematic and timely manner. Results of such followup and closeout activities are periodically reported to appropriate levels of management. Corrective action documentation and request forms or formal letters are used to document the corrective-action-related requests, responses and followup.

Procedures provide for significant conditions adverse to quality to be identified, their causes to be determined, and for corrective action to be taken. Pertinent information is then documented to responsible management through established communication systems.

Each cognizant GENE QA organization is responsible for the following:

- o Identifying, diagnosing, and determining the cause of chronic quality problems.
- o Transmitting relevant information to the individual responsible for taking corrective action.
- o Verifying to assure that corrective action is taken which will preclude repetition of the problem or satisfactorily control the cause of the problem.

Continuous surveillance of operating BWR performance is maintained. Periodic contact by GENE personnel with plant operations personnel provides detailed information on statistical performance of the plant, as well as narrative reports of equipment malfunctions or failures. Automatic data handling systems record and analyze the statistical information. This information is analyzed by the cognizant design components and carefully monitored for significant or generic equipment weakness. This provides feedback to the responsible design component to avoid repetition of the same problems. Prompt communication to all operators of similar equipment is provided whenever significant or avoidable problems are discovered. Implementation of appropriate design changes to assure corrective action on GENE products is accomplished with procedures described in Subsection 3.10, "Design Change Control," and Subsection 3.11, "Field Change Control", as applicable.

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## 17 QUALITY ASSURANCE RECORDS

Procedures and practices are established and documented to provide assurance that sufficient records are prepared and accumulated as work is performed to furnish documentary evidence that the product quality is satisfactory and that other closely related activities have been performed satisfactorily. Requirements and responsibilities for record generation, accumulation, transmittal, retention, and maintenance are documented in these procedures. The QA records are consistent with the requirements of applicable codes, standards, regulations, specification, and contract requirements and are adequate for use in effective management of the QA Program.

The QA records include such documentation as the results of design reviews, inspections, tests, material analyses, etc. These records also include closely-related data such as qualifications of personnel, procedures, and equipment and other documentation required by applicable codes and regulations. Inspection and test records, as a minimum, identify the completion date of the inspection or test, the inspector or data recorder, the type of observation, the results, the acceptability of the item, and the action taken in connection with any nonconformance noted. The QA records are identified, collected, stored, and maintained in a systematic and controlled manner and are retrievable consistent with the applicable GENE and regulatory requirements.

Each GENE business organization is responsible for collecting, filling, transmitting, and/or maintaining and controlling these quality-related records which they generate or cause to be generated in accordance with documented procedures. Nonconformance reports (such as IRs and DDRs) are filed and maintained by the cognizant line QA organization. Corrective action reports and audit reports prepared by NQA are filed and maintained by NQA. These reports are made available to the Owner and NRC personnel for audit and review at GENE facilities upon request. | 8

For those items for which there are no code requirements for record retention of transmittal, designated QA records, such as outline drawings, purchase specifications, material property records or inspection and test data are provided to the Owner or maintained for him in accordance with the contractual agreement with the Owner.

Records which identify the "as built" condition of safety-related items as furnished by GENE shall be transmitted to, or retained for, the Owner for the life of the items.

Reference GENE position on NRC Reg Guide 1.88, Table 2-1, for commitment to collection, storage and maintenance of QA records and its supplement (pages 2-13 to 2-16) for the types of QA records and their respective retention times. | 8



## 18 AUDITS

A comprehensive system of planned and documented audits is carried out to verify product quality and compliance with the QA Program. This audit program is designed to assure compliance with all aspects of 10CFR50, Appendix B, including, as a minimum, the quality-related aspects of design, procurement, manufacture, storage, shipment and GENE supplied services. These audits are conducted at scheduled intervals as documented in audit schedule planning or on a random unscheduled basis, or both, as appropriate. The GENE instructions require that QA audits be conducted using pre-established written procedures or check lists by appropriately trained personnel not having direct responsibilities in the area being audited. Audit results are documented by the auditors and transmitted for review and commitment of corrective action by management having responsibility in the area audited. Audit data are periodically analyzed and reports indicating performance trends and the effectiveness of the QA Program are prepared and issued to responsible management for review and assessment. | 8

After evaluation and agreement on audit findings, the responsible managers take whatever action is necessary to correct any noncompliance revealed by the audit. The audit program provides for follow up action, including any necessary reaudit of deficient areas, to assure that corrective action has been taken. Audits are performed to determine the following, as appropriate:

- o The adequacy of documented QA-related policies, procedures, instructions and practices to meet their intended purpose of assuring product quality.
- o Compliance with quality-related policies, procedures, instructions, and practices.
- o The adequacy of work areas, activities, processes, items of equipment, documents, and records.
- o Product compliance with applicable engineering drawings and specifications.
- o Implementation of corrective action in accordance with applicable procedures.

The NQA, by delegation from the GENE Vice President and General Manager through the GENE P&Ps, has the responsibility for conducting QA audits of each of the Staff-level organizations\* that affect product quality for the purpose of appraising the quality of the products and the effectiveness of the quality systems. The NQA is required to prepare plans each year, for the conduct of audits which will assure that the quality systems established by such Staff-level organizations is audited at least annually. | 8

GENE Staff-level organizations are required by the GENE P&P to perform annual self-audits to determine the effectiveness of, and verify compliance with, assigned portions of the QA Program. Each organization prepares plans for the conduct of internal audits prior to February 1 of each year so that during the course of each year all aspects of the QA Program are included in at least one self-audit. More frequent audits or measurements may be conducted when dictated by any of the following circumstances: (1) When significant changes are made in functional areas of the QA Program; (2) when a systematic, independent assessment of program effectiveness or product quality or both is considered necessary; or (3) when it is necessary to verify implementation of required corrective actions.

\* Staff-level organizations are organizations, other than NQA, reporting to General Manager, Nuclear Operations or Vice President & General Manager, GENE; or equivalent. | 8

The GENE suppliers' quality-related systems, procedures, processes, operations, in-process and finished products, and documentation are subject to audit by the cognizant line-QA organizations. Audits are used to assess the adequacy of quality-related systems and procedures and compliance thereto, and to evaluate the effectiveness of inspection operations and other product controls. "QA Requirements" which are included as part of the purchase specifications for engineered equipment important to safety, require GENE suppliers to grant access to the GENE QC Representative for audit and review of applicable design, manufacturing, and quality control records, reports, and documents.

Audits of GENE suppliers of safety-related engineered equipment are conducted by QA Representatives at least every 3 years, or more frequently, based on the following: (1) Importance, complexity, and quality requirements of item or service; (2) the results of previous audits; (3) history of performance of product and/or purchased service; or (4) effectiveness of implementation of the suppliers QA Program. For those years when an audit is not planned, a formal evaluation of the supplier is performed to determine if a re-audit is required during the upcoming year (refer to Section 7, "Control of Purchased Material, Equipment, and Services").

## **APPENDIX A**

### **NRC APPROVED ORGANIZATIONAL CHANGES**



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

March 16, 1994

Mr. P. W. Sick, Manager  
Nuclear Quality Assurance  
GE Nuclear Energy  
General Electric Company  
175 Curtner Avenue  
San Jose, CA 95125

Dear Mr. Sick:

SUBJECT: GE NUCLEAR ENERGY ORGANIZATIONAL CHANGE

This letter is in response to your letter of January 24, 1994, which, in accordance with the requirements of 10 CFR 50.4(b)(7)(ii), notified the NRC of proposed organizational changes affecting the GE Nuclear Energy Quality Assurance (QA) Program Description.

Since the changes described in your letter will not effect a reduction of the commitments made in GE's Licensing Topical Report NEDO-11209-04A, Revision 8, dated March 31, 1989, and all quality assurance functions and their required organizational independence have been retained, we have determined that the proposed changes are acceptable and that the revised QA program incorporating such changes will continue to meet the criteria of Appendix B to 10 CFR 50.

As you noted on your letter, these changes should be reflected in your next revision to NEDO-11209-04A. Please issue the organizational changes described in your letter of January 24, 1994, together with this acceptance letter, to all holders of your Licensing Topical Report NEDO-11209-04A.

Any questions should be addressed to Juan Peralta of my staff on (301) 504-1052.

A handwritten signature in cursive script, reading "Gary G. Zech".

Gary G. Zech, Chief  
Performance and Quality Evaluation Branch  
Division of Reactor Inspection  
and Licensee Performance  
Office of Nuclear Reactor Regulation



General Electric Company  
175 Curtner Ave  
San Jose, CA 95125

July 25, 1994

cc: Distribution of Controlled Copies of  
Licensing Topical Report NEDO-  
11209-04A

Document Control Desk  
United States Nuclear Regulatory Commission  
Washington, D.C. 20555

**SUBJECT: GE NUCLEAR ENERGY ORGANIZATIONAL CHANGE**

Reference: "GE Nuclear Energy Organization Change", dated January 24, 1994

Pursuant to the public meeting of July 19, 1994, held with NRC Staff at the NRC offices, the following is being provided as an update to the GE-NE organization.

In Licensing Topical Report NEDO-11209-04A, Revision 8, GE Nuclear Energy committed to notify the Nuclear Regulatory Commission of organizational changes affecting the GE Nuclear Energy Quality Program within thirty days of implementation. In compliance with that commitment, notification of organizational changes within GE Nuclear Energy is transmitted herein.

These organizational changes are directed to our changing business needs and do not degrade the GE Nuclear Energy quality system or impact commitments contained in our Licensing Topical Report NEDO-1109-04A, Revision 8. All quality functions and their associated organizational independence per Criteria 1 of 10CFR50, Appendix B, have been retained.

In October 1992, the Nuclear Services and Projects Department (NS&PD) implemented a project organization. In the projectized organization, the businesses within NS&PD obtain Project Managers, Engineers and other required personnel to work on projects from Engineering. The Engineering organization is divided into rosters by discipline and the personnel on the roster report to an Engineering Manager. The Engineering Manager is responsible for the administrative aspects of the employees such as hiring, training, career development, and salary forecasting and action. The Engineering Manager does not perform engineering work within the Engineering organization and is independent of responsibility for schedules and profit or loss. The Project and Business Managers are responsible for business strategies, schedules, and profit or loss. At the time the engineering roster concept was put in place, some functional groups were excluded such as Quality.

The following summarizes organizational changes effective June 27, 1994:

The personnel within the Services & Projects Quality organization are being transferred to rosters within the Engineering organization. The Quality Project Managers are being placed in the Project Management and Support roster and the Quality personnel will be placed in the Quality roster. The Quality personnel will report to an Engineering Manager who is responsible for administrative tasks such as hiring, training, career development, and salary forecasting and action. The Quality Project Managers will be assigned back to the Manager of Services & Projects Quality. Likewise, the Quality personnel will be assigned back to the Quality Project Managers to perform the same quality functions they were performing before the reorganization.

The performance appraisals for the Quality personnel will be performed as they are currently being

performed; the appraisal will be given by the Quality Project Mangers. The Quality Project Mangers are appraised by the Manager of Services and Quality Projects. The appraisal ratings are then turned over to the Engineering Manager for salary forecasting and action.

The project organization concept allows the employees to integrate their career interests and act on them through project assignments, and there is more emphasis on training and development. The business gains the flexibility to respond rapidly to project needs, more consistency in the salary planning processes which brings more equity and fairness across the organization, and better utilization of resources.

Services and Projects Quality continues to perform the same quality functions and provide quality oversight for NS&PD and other assigned organizations. The Manager of Services and Projects Quality retains the authority, independence, and organization freedom to identify quality-related problems; initiate recommend, or provide solutions to conditions adverse to quality; and verify implementation of such solutions. The Manager of Services and Projects Quality has a direct line of communication with the NS&PD Department General Manager. Overall administrative control (salary review, hire/fire, position assignments and QA direction is the responsibility of the NS&PD Department General Manager.

With this organization change there is no need to change to the organization chart submitted with the Reference letter.

These organizational changes will be addressed in the next revision of Licensing Topical Report NEDO-11209-04A.

Sincerely,

*L. W. Brayman for Paul Sick*

P. W. Sick, Manager  
Nuclear Quality Assurance



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

September 30, 1994

Mr. P. W. Sick, Manager  
Nuclear Quality Assurance  
GE Nuclear Energy  
General Electric Company  
175 Curtner Avenue  
San Jose, CA 95125

Dear Mr. Sick:

SUBJECT: GE NUCLEAR ENERGY ORGANIZATIONAL CHANGE

This letter is in response to your letter of July 25, 1994, which, in accordance with the requirements of 10 CFR 50.4(b)(7)(ii), notified the NRC of proposed organizational changes affecting the GE Nuclear Energy Quality Assurance (QA) Program Description.

Since the change described in your letter will not effect a reduction of the commitments made in GE's licensing Topical Report NEDO-11209-04A, Revision 8, dated March 31, 1989, and all quality assurance functions and their required organizational independence have been retained, we have determined that the proposed changes are acceptable and that the revised QA program incorporating such changes will continue to meet the criteria of Appendix B to 10 CFR 50.

As you noted on your letter, these changes should be reflected in your next revision to NEDO-11209-04A. Please issue the organizational changes described in your letter of July 25, 1994, together with this acceptance letter, to all holders of your Licensing Topical Report NEDO-11209-04A.

Any questions should be addressed to Mike Payne of my staff on (301) 504-1024.

A handwritten signature in cursive script that reads "Suzanne C. Black".

Suzanne C. Black, Chief  
Performance and Quality Evaluation Branch  
Division of Reactor Inspection  
and Licensee Performance  
Office of Nuclear Reactor Regulation



January 24, 1994

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Licensing Topical Report NEDO-  
11209-04A

Document Control Desk  
United States Nuclear Regulatory Commission  
Washington, D.C. 20555

**SUBJECT: GE NUCLEAR ENERGY ORGANIZATIONAL CHANGE**

Gentlemen:

In Licensing Topical Report NEDO-11209-04A, Revision 8, GE Nuclear Energy committed to notify the Nuclear Regulatory Commission of organizational changes affecting the GE Nuclear Energy Quality Program within thirty days of implementation. In compliance with that commitment, notification of organizational changes within GE Nuclear Energy is transmitted herein.

These organizational changes are directed to our changing business needs and do not degrade the GE Nuclear Energy quality system or impact commitments contained in our Licensing Topical Report NEDO-1109-04A, Revision 8. All quality functions and their associated organizational independence per Criteria 1 of 10CFR50, Appendix B, have been retained.

The following summarizes organizational changes effective January 1, 1994:

The Nuclear Quality Assurance organization continues to perform the independent Staff Quality Assurance function, and was expanded to include the Nuclear Fuel Quality Assurance function and the Production Quality Assurance function. These last two quality assurance functions support the Nuclear Fuel and Nuclear Energy Production departments respectively.

The following summarizes organizational changes effective January 4, 1994:

A new organization, GE Nuclear Energy Sourcing and Support will report directly to the Vice President and General Manager of GE Nuclear Energy. The new organization will include Purchasing, Sourcing Support, Shipping, Receiving, Licensing, Traffic, and Materials Control for all of GE Nuclear Energy.

In addition, the name of the Fuel Engineering organization has been changed to the Nuclear Fuel Department and the name of the Fuel & Components Manufacturing organization has been changed to Nuclear Energy Production Department.

The Manager of Nuclear Quality Assurance retains unrestricted access, at his determination, to the GE Nuclear Energy Vice President & General Manager regarding quality-related matters. These organizational changes will be addressed in the next revision of Licensing Topical Report NEDO-11209-04A.

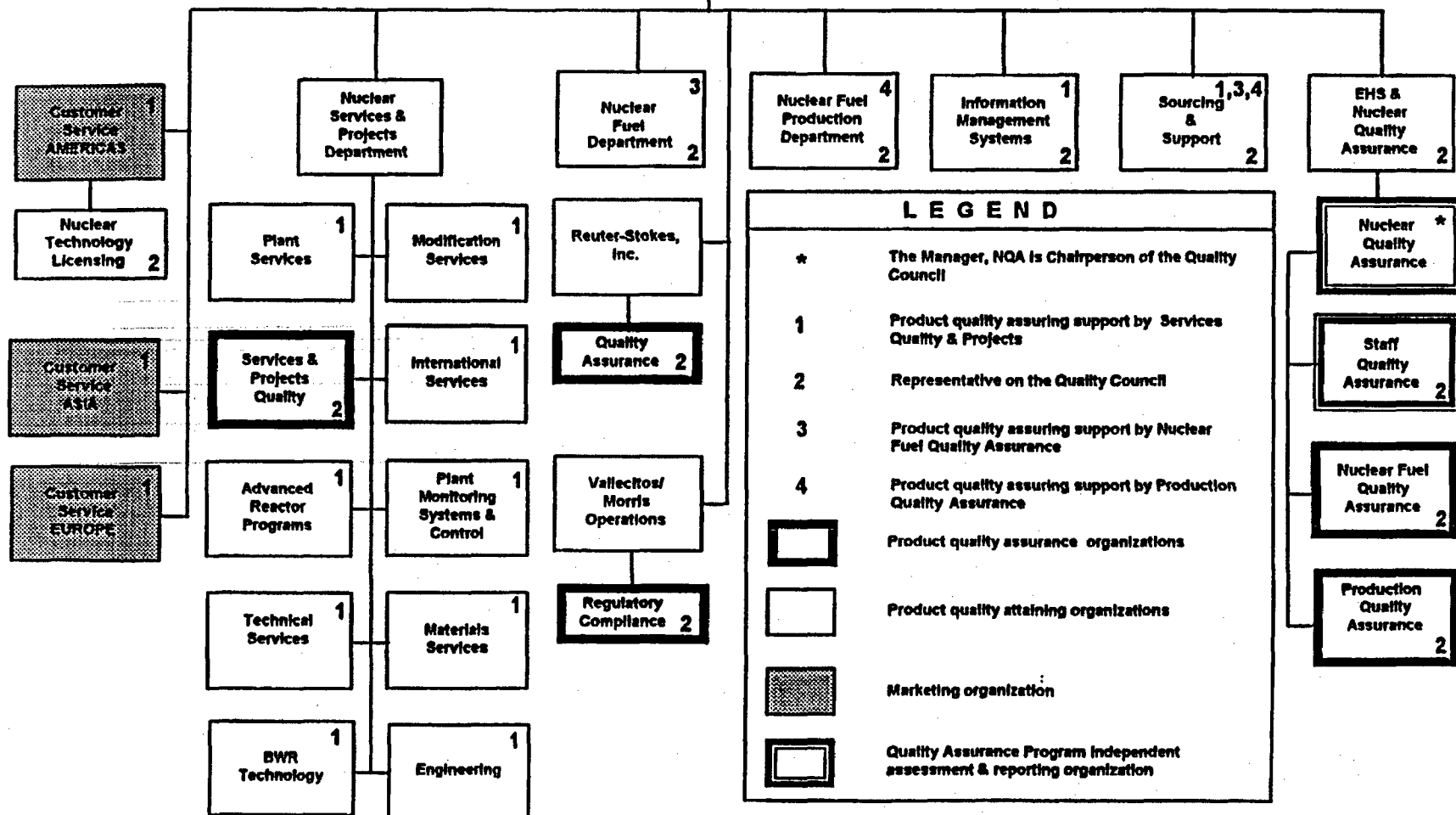
Sincerely,

P. W. Sick, Manager  
Nuclear Quality Assurance

att:



**GE NUCLEAR ENERGY**  
 -----  
**VP & General Manager**



NEDO-33181 Revision 1

**ATTACHMENT 2**  
**GE Nuclear Energy**  
**Quality System Description for ISO-9001:2000**  
**NEDO-32280**



**GE Nuclear Energy**

**UNCONTROLLED COPY**

NEDO-32280  
March 25, 2003

# **GE Nuclear Energy**

## **ISO-9001 Quality Management System Description**

**Current controlled copy resides at GE-NE San Jose shared drive:**  
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GE NUCLEAR ENERGY

**Nuclear Services and Nuclear Plant Projects**  
**ISO 9001 Quality System Description**

**NEDO-32280**

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**Approvals**

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Quality Engineering and Services

3/25/2003

Date

Approved By:

Louis M. Quintana, Manager  
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3/25/2003

Date

**Certificate of Approval**  
Lloyd's Register Quality Assurance  
Current Date: March 17, 2000 — Expiry Date: March 31, 2003



**CERTIFICATE OF APPROVAL**

*This is to certify that the Quality Management System of:*

**GE Nuclear Energy  
San Jose, California, USA**

*has been approved by Lloyd's Register Quality Assurance Limited  
to the following Quality Management System Standards:*

**ISO 9001:1994,  
ANSI/ISO/ASQ Q9001-1994**

*The Quality Management System is applicable to:*

**Design, Procurement, Supply, and Servicing of Nuclear Power  
Plants and Related Systems and Components, including the  
Development of Control Instrumentation Software and Maintenance of  
Plant Monitoring Software in Accordance with TickIT**

**Approval  
Certificate No: 100503**

**Original Approval: March 3, 1994  
Current Certificate: March 17, 2000  
Certificate Expiry: March 31, 2003**

  
on behalf of LRQA Houston



This approval is subject to the company maintaining its system to the required standards, which will be monitored by LRQA.  
The use of the UKAS Accreditation Mark indicates Accreditation in respect of those activities covered by the Accreditation Certificate Number 001

Issue No. 0



## ***GE Nuclear Energy***

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March 25, 2003

### **STATEMENT OF POLICY & AUTHORITY**

GE Nuclear Energy is committed to setting the industry standard of excellence for customer satisfaction. Inherent in this objective is our continuing determination to perform every function and every process to the highest quality standards, from the way we develop and apply technologies, to the way we manufacture products and provide services.

In terms of quality, what really counts is our customers' perception of how well we meet their requirements and our quality objectives and goals. Therefore, our quality measurements and procedures are constantly monitored, evaluated against our customers' needs and our own high standards and, as necessary, revised to respond to changing parameters. Another dimension of attaining quality excellence is our continuous quality improvement programs.

I have charged each person in GE Nuclear Energy with the responsibility for delivering the highest quality products and services to our customers. With each employee focused on satisfying customers in everything we do, we will meet our quality and customer satisfaction objectives and retain our reputation as the world's leading supplier of Boiling Water Reactors and related services.

The implementation of this program as described in NEDO-32280 has my unqualified endorsement and support.

**Andrew C. White**



GE NUCLEAR ENERGY

***Nuclear Services and Nuclear Plant Projects***  
***ISO 9001 Quality Management System Description***

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## **PREFACE**

The Quality Management System described herein assures the required personnel, equipment, procedures, management, and other resources are directed toward satisfying the quality policy and commitments, and complying with the elements of ISO-9001:2000, Quality Management Systems – Requirements. The Quality Management System defines minimum requirements which shall be followed in all cases irrespective of contract, recognizing that contract requirements specified are additional.

The Quality System herein described is structured in accordance with the outline of the ISO-9001:2000 standard.

This document describes the Quality Management System, which is applied to the following locations:

- San Jose, California facility including its off-site locations at Huntersville, North Carolina and Vineland, New Jersey.

The applicable elements of the Quality System and the procedures which implement the Quality System elements will apply to each organization based upon their scope of work.



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## **1.0 INTRODUCTION**

GE Nuclear Energy, San Jose has developed and implemented a Quality Management System 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 Quality Management System of GE Nuclear Energy meets the requirements of the international standard ISO 9001:2000, Quality Management Systems - Requirements. This quality system addresses the design, development, procurement, supply and servicing of nuclear power plants and related structures, systems and components.

This document is divided into eight sections that correlate to the quality management system sections of ISO 9001:2000 standard. Each section describes the quality system requirements and provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard. The procedures delineate responsibilities, authorities and inter relationships of the personnel responsible for performing within the system.

This document is used internally to guide the Company employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, quality objectives, continuous improvement and provide the necessary instructions that create an empowered work force within the business segments of GE Nuclear Energy (GE-NE).

## **2.0 BUSINESS SCOPE AND ORGANIZATION DESCRIPTION**

### **2.1 Business Scope**

The scope and application of the Quality Management System as described in this document NEDO-32280, GE Nuclear Energy ISO-9001 Quality Management System Description apply to: Nuclear Services and Nuclear Plant Projects organizations located at San Jose, California facility including its off-site locations at Huntersville, North Carolina and Vineland, New Jersey, and applicable field service activities.

Nuclear Services (NS) include business segments: Engineering and Technology, Technical Services, Parts Services, and Reactor Services. Nuclear Services business segments are responsible for the marketing and delivery of all parts and services to our nuclear power plant customers world wide including: design and engineering, replacements, in-vessel service inspections and modified/repared products provided to comply with regulatory requirements, support continued plant operation, or to improve plant performance. Additionally, field service is provided and performed whether at the client's site or at a GE-NE authorized service facility. Activities performed at the customer site locations or GE-NE's authorized service facilities are controlled by quality programs/procedures as noted in section 4.2.1 of this document.





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Nuclear Plant Projects (NPP) has the primary responsibility to manage development, design, analysis, procurement and construction of advanced boiling water reactors for customers throughout the world. It also has the responsibility to design, analyze and certify the advanced boiling water reactor and the simplified boiling water reactor in the United States. In addition, it has the responsibility to provide hardware and software products and services for plant monitoring instrumentation and control.

## **2.2 Organization Description**

### **2.2.1 GE-NE has the following business organizations:**

- Nuclear Plant Projects
- Quality
- Engineering and Technology
- Technical Services
- Parts Services
- Reactor Services
- Sourcing
- Global Sales/Marketing

2.2.1.1 EOP 20-2.00 provides reference to the Organization Charts. Typical organization structure and functional descriptions are included in the applicable documents noted in section 4.2.1 of this manual, and in project procedures/plans of the specific work/project to be performed.

## **3.0 PROCESS FLOW**

3.1 The process flow for NPP products typically begins with proposals developed jointly with the applicable GE-NE customer interface (Americas, Europe, or Asia Pole) organization. Customer acceptance is documented in a contract, and the management of the contract becomes the responsibility of a NPP project group. Quality assurance overview is provided by the NPP Quality organization.

3.2 The process flow for NS products and services typically begins with proposals developed in conjunction with the appropriate Pole organization. The proposal is entered into a sales tracking system. Customer acceptance is documented via a contract or Purchase Order, which is managed by the assigned NS business Project/Program Manager. Each project is staffed with personnel having the appropriate skills to complete the project. Quality assurance overview is provided by the Nuclear Services Quality organization.



## **4.0 QUALITY MANAGEMENT SYSTEM**

### **4.1 General requirements**

GE Nuclear Energy (GE-NE) has established, documented and implemented Quality Management System to ensure that products conform to specified requirements, and to meet the requirements of ISO-9001:2000. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement this Quality Management System, GE-NE 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 documented them in quality plans and work instructions,
- 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, and
- established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes.

GE-NE exercises control over any outsourced processes that affect product conformity with requirements.

### **4.2 Documentation requirements**

#### **4.2.1 General**

The documentation, implementation and maintenance of the GE-NE ISO-9001 Quality Management System is based upon the following manuals and procedures:

- NEDO-32280, ISO-9001 Quality Management System
- GE-NE Procedure 70-11, GE-NE Quality Policy and Quality System Requirements
- NEDE 21109, Engineering Operating Procedures (EOP)
- NEDE-20387, ASME Quality Assurance Program Manual
- NEDC-32286, Quality Assurance Manual for International Nuclear Services
- Lungmen Quality Assurance Program #31113-0A18-0001
- QAM-001, Quality Assurance program for Modification, Maintenance, Repair or Replacement Projects
- QAM-003, Quality Assurance program for In-service Inspection



Other documents required for planning, operation and control of processes are referenced in the related sections of this manual.

#### **4.2.2 Quality manual**

Within ISO documentation requirements, Quality Management System as described in this manual is the top-tier document. This manual covers all requirements of ISO 9001:2000, references the related procedures, and describes the interactions between the processes of the quality management system. No exclusions have been identified.

#### **4.2.3 Control of documents**

Procedures to control documents and data that relate to the requirements of ISO-9001 including, to the extent applicable, documents of external origin such as standards and customer drawings are established and maintained. Document control at plant sites is controlled in accordance with the requirements specified in the applicable quality assurance manuals.

Procedures associated with approval, issuance, and changes of engineering drawings and specifications are as follows:

- EOP 42-8.00, Document Initiation or Change by ERM/ECN
- EOP 55-2.00, Engineering Change Control
- EOP 60-3.10, Engineering Records and Document Distribution
- EOP 60-5.00, GE Designated Proprietary and Sensitive Information
- EOP 60-5.10, Proprietary and Sensitive Information Received from Companies Outside GE

Control and administration of Quality Management System procedures and manuals are specified in the respective manuals referenced in section 4.2.1. Control of instructions, procedures and plans are specified in EOP 10-2.10. Requirements for control of Reactor Services field documentation are specified in QAM-001, QAM-003, and NEDC-32286 manuals. Requirements for control and administration include:

- approving documents for adequacy prior to issue,
- reviewing and updating as necessary and re-approving documents,
- ensuring that changes and current revision status of documents are identified,
- ensuring that latest versions of applicable documents are issued and available at points of use,
- ensuring that documents of external origin are identified and their distribution controlled, and
- preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose.



#### **4.2.4 Control of records**

Quality assurance records are maintained to provide evidence of conformity to product specifications, and of the effective operation of the Quality Management System. EOPs 42-10.00, Design Record File, 60-3.10, Engineering Records and Document Distribution, and 75-6.00, Quality Assurance Records, are used to identify, collect, index, file, sort, maintain, and dispose of quality records. The procedures specify requirements for legibility and reproduction of QA records. Quality records for the Reactor Services activities are controlled in accordance with QAM-001, QAM-003, or NEDC-32286 quality assurance manual.

### **5.0 MANAGEMENT RESPONSIBILITY**

#### **5.1 Management Commitment**

GE-NE Policy 70.11 defines the quality policy of GE Nuclear Energy (GE-NE). The businesses shall implement this Quality Policy and demonstrate, by performance outside and inside the Company, total dedication to the attainment of quality leadership.

GE-NE management is committed to implement and maintain Quality Management System, and continually improve its effectiveness by:

- communicating to the organization the importance of meeting customer, statutory and regulatory requirements,
- implementing GE-NE quality policy,
- establishing quality objectives,
- conducting management reviews, and
- providing adequate resources.

#### **5.2 Customer focus**

GE-NE strives to identify current and future customer needs to meet current requirements and exceed customer expectations.

Customer requirements are determined, converted into internal requirements if needed, communicated to the appropriate personnel, and are met with the aim of enhancing customer satisfaction. The further details are covered in sections 7.2.1 and 8.2.1. GE-NE Procedure 70-11, GE-NE Quality Policy and Quality System Requirements, and EOPs 25-5.00, Work Planning and Scheduling, 25-5.10, Customer Technical Requirements and Design Inputs, and 70-3.00, Spare and Renewal Parts, address process to capture customer requirements.



### **5.3 Quality Policy**

GE-NE Procedure 70.11 defines the quality policy of GE Nuclear Energy. The requirements of this policy apply to all components and employees of GE Nuclear Energy. This policy is subject to management review to ensure its continual improvement and suitability.

Top management ensures that the quality policy is communicated to all employees. To achieve this, any or all of the following may be used: GE-NE Bulletins, all employee meetings, staff meetings, internal memos and training.

The GE-NE President has established a forum for 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 score-cards, delivered product defects, corrective actions, trends and process improvements)
- Quarterly Quality Council sessions (a forum for review of quality policy, objectives, problems, corrective actions and improvements)
- Annual management review of the status and adequacy of the GE-NE Quality Management System.

### **5.4 Planning**

#### **5.4.1 Quality Objectives**

Quality objectives are established throughout the organization to implement the quality policy, to meet process and product requirements, and to facilitate continual improvement (refer to GE-NE Procedure 70-11). During management review meetings, quality objectives are reviewed against set goals and past performance.

#### **5.4.2 Quality management system planning**

Quality system processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. Various quality objectives and documents comprising quality management system are periodically reviewed and appropriate changes are made (refer to GE-NE Procedure 70-11). These changes may be in response to changing circumstances such as process, or organizational change; or to improve the effectiveness and efficiency of the quality system. Before implementing, each quality assurance programmatic change is reviewed to ensure that it does not conflict with the integrity of the quality management system.



## **5.5 Responsibility, authority and communication**

### **5.5.1 Responsibility and authority**

The organizations and functional lines of authority of GE-NE, NPP and NS is described in EOP 20-2.00, Organizational Directory, and QAM-001, QAM-003, or NEDC-32286 QA manual. Functional responsibilities are defined in detail in the GE-NE Procedure 70-11 and the implementing EOPs and Manuals (QAM-001, QAM-003 and NEDC-32286). Procedures, manuals and the organizational charts are reviewed and approved by responsible management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities.

The GE-NE President has established a Quality Council to aid the Manager, GE-NE Quality in fulfilling assigned integration and quality assurance communication responsibilities and to provide a communications medium within GE-NE and to the GE-NE President on quality-related matters. One of the primary objectives of the Council is to assure total quality management system coverage, uniformity, consistency, and continuity, while eliminating system deficiencies and redundancies. The Council is chaired by the Manager, GE-NE Quality and consists of the managers in each of the major business organizations within GE-NE. The Council normally meets quarterly to review the status of quality-related programs and projects and to plan future efforts. The Council provides QA and line managers in the business organizations with direct access to top-level management and provides a forum for the review of quality problems and corrective actions.

All NPP and NS managers are responsible to provide leadership and to ensure that the company policies on quality and customer satisfaction (section 5.3) are communicated to, and understood by all personnel.

All NPP and NS managers are responsible to make certain that up-to-date procedures are in place for the performance of activities affecting quality in their assigned areas.

### **5.5.2 Management representative**

The GE-NE President has executive responsibilities for the total quality of all GE-NE products and services and will, as required and appropriate, set quality measurements and objectives, conduct quality reviews, and initiate continuous quality improvement.

Responsibility for total quality is assigned to each direct report to the GE-NE President. These representatives are accountable for improving the total quality of their business output, including their interfaces with other functions, suppliers or customers as appropriate and facilitating continuous quality improvement. Irrespective of other responsibilities each of the assigned representatives is responsible for:



- ensuring that the established quality system is implemented and maintained in accordance with ISO-9001,
- ensuring that processes needed are established to assure effective implementation of the quality system, and
- reporting the performance of the quality system to the GE-NE President for review and as a basis for continuous quality improvement.

The Manager, GE-NE Quality has the authority and responsibility to assure that ISO-9001 requirements are implemented and maintained, and awareness of customer focus is promoted throughout the organization.

### **5.5.3 Internal communication**

To achieve the effectiveness of the quality management system, the following internal communication channels are established within GE-NE:

- GE-NE Bulletins (new or revised procedures, manuals, system/processes),
- Indoctrination sessions or staff meetings (review of new or revised procedures/manuals),
- Quarterly sessions of Quality Council (to review, integrate and communicate quality related matters, problems, corrective actions, and annual reports on the status and adequacy of the quality management system to the top level management),
- Periodic sessions of Continuous Improvement Council (amongst quality organization management to review the status and effectiveness of assigned projects for continuous improvement processes).

The subject matter discussed may include performance and/or improvements against quality objectives, customer feedback, customer/regulatory requirements, and adequacy of quality system, processes and procedures. The distribution of meeting minutes from management review and internal audit closing meeting etc. are also used as communication tools regarding the effectiveness of the quality management system.

## **5.6 Management review**

### **5.6.1 General**

Top management reviews GE-NE Quality Management System to ensure its continuing suitability and effectiveness. Other periodic management reviews are conducted as described in section 5.3. These reviews identify opportunities for improvement and needed changes. Records are maintained for management review meetings. GE-NE Procedure 70-11, GE-NE Quality Policy and Quality System Requirements, defines requirements for the management reviews.



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### **5.6.2 Review input**

During management reviews, typical input includes the following:

- 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, and
- Recommendations for improvement.

### **5.6.3 Review output**

Review 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, and
- Resource needs to assure proper implementation of quality management system, and assignment of responsibilities for completing actions.

Records of management reviews shall be maintained for at least three years.

## **6.0 RESOURCE MANAGEMENT**

### **6.1 Provision of resources**

The GE-NE business segments have the responsibility for planning and implementing the quality assurance functions performed within their area of responsibility. Procedures require that the detailed quality assurance program planning and implementation performed by these business segments comply with the overall quality management system requirements. 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.

The business segments are responsible for identifying quality requirements, quality related activities to be performed, and providing adequate resources to:

- plan, develop processes, implement requirements and deliver products to customer satisfaction,
- maintain and continually improve the quality management system, and





- enhance delivered quality and customer satisfaction.

Refer to GE-NE Procedure 70-11, GE-NE Quality Policy and Quality System Requirements.

## **6.2 Human Resources**

### **6.2.1 General**

To ensure competence of personnel, the functional managers shall identify the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with required training in accordance with GE-NE Procedure 70-30, provide the competence required for each position.

Design reviews and verifications, and self-assessments of the quality system, processes, and/or product are carried out by competent personnel. Supplier quality audits are performed by trained auditors.

### **6.2.2 Competence, awareness and training**

Training requirements are identified in GE-NE Procedure 70-30, Personnel Proficiency in Quality Related Activities, and EOP 75-5.00, Quality and Technical Training. Training at the sites is controlled in accordance with QAM-001, QAM-003, or NEDC-32286 QA manual.

GE-NE Procedure 70-30 requires managers to ensure that personnel are proficient in the procedures and technical capabilities required for the activities for which they are assigned. Training and qualification of personnel for inspection, tests, nondestructive examinations, auditors and lead auditor certification are performed in accordance with EOP 75-2.00, Qualification and Certification of Personnel.

Training program includes appropriate means to:

- evaluate the effectiveness of training,
- determine qualification prior to certification,
- ensure that employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

## **6.3 Infrastructure**

GE provides and maintains suitable workspace, utilities, equipment (hardware and software), and other supporting services to achieve conformity to product requirements.

EOP 40-12.00, Materials & Processes Engineering Control, includes requirements to provide control of materials and processes applied to GE supplied design, hardware, and services.



## **6.4 Work Environment**

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. GE-NE Policy 70-4, Employee Health and Safety and Environmental Protection, defines implementation of requirements for adequate and safe facilities and plant activities.

## **7.0 PRODUCT REALIZATION**

### **7.1 Planning of product realization**

The processes needed for product realization have been developed and are consistent with the requirements of the other processes of the quality management system. GE-NE Procedure 70-11 defines quality management system requirements that shall be implemented for all GE-NE products.

EOP 25-5.00, Work Planning and Scheduling, requires 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. EOP 35-1.00, New Product Introduction, describes the detailed process for the development and introduction of new products.

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, specs., procedures, plans, instructions),
- resources (personnel with appropriate skills and qualifications),
- verification, validation, monitoring, inspection and test requirements (evidence of results, certifications and quality assurance records), and
- acceptance criteria.

Product realization planning and requirements for site work are addressed in QAM-001, QAM-003, or NEDC-32286 QA manual.

### **7.2 Customer-related processes**

#### **7.2.1 Determination of requirements related to the product**

Contracts are reviewed to determine customer requirements in accordance with GE-NE Procedure 10-27, Customer Requests, Proposals and Sales Contracts, and Order Processing, and



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EOPs 25-5.00, Work Planning and Scheduling, 25-5.10, Customer Technical Requirements and Design Inputs, and 70-3.00, Spare and Renewal Parts. This includes customer's stated requirements or intended expectations, regulatory requirements, product specification, and any other GE-NE identified requirements.

### **7.2.2 Review of requirements related to the product**

Prior to contract acceptance, various product-related requirements are reviewed in accordance with GE-NE Procedure 10-27, Customer Requests, Proposals and Sales Contracts, and Order Processing, to ensure that:

- product requirements are defined,
- contract requirements differing from those previously stated are resolved,
- GE-NE has the ability to meet the defined requirements, and
- where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance.

EOP 25-5.10 defines process and requirements for review and acceptance of customer technical requirements and design inputs for design and engineering services, and EOP 70-3.00 defines process and requirements for review and acceptance of requirements for spare and renewal parts.

These requirements are approved by a responsible business manager, project manager or commercial representative. Any changes in these requirements are documented and communicated to the personnel involved. These requirements, including any changes, are maintained as quality records.

### **7.2.3 Customer communication**

Direct Customer communications is accomplished utilizing media such as:

- Product Service Information letters (SIL),
- Web site for engineering services,
- Request for quote enquiries, and
- Customer feedback and/or complaints.

GE-NE Procedure 70-11 specifies the requirements for customer communication and feedback.

## **7.3 Design and development**

### **7.3.1 Design and development planning**

EOPs 42-1.00, Design Process, and 35-1.00, New Product Introduction, describe the details of:



- The design and development stages with responsibilities/authorities
- Appropriate review, verification and validation activities.

The necessary interfaces between different groups involved are identified with assigned responsibilities in the EOPs controlling design and development activities.

### **7.3.2 Design and development inputs**

EOPs 25-5.10, Customer Technical Requirements and Design Inputs, and 70-3.00, Spare and Renewal Parts, require the Project Manager to review and control design inputs. This review activity assures that incomplete, ambiguous, or conflicting requirements are resolved with the customer.

The inputs include customer specifications/acceptance criteria, industry standards, regulatory requirements, and safety classification, as appropriate.

### **7.3.3 Design and development outputs**

Design specifications and drawings are verified according to EOP 42-6.00, Independent Design Verification, to meet design inputs. Characteristics critical to the safe and proper functioning of the product are classified and designated on the appropriate drawings and specifications according to EOP 65-2.10, Safety-Related Classification, or appropriate international practices specified by the customer.

The outputs provide information for purchasing, production, product acceptance criteria, and include product characteristics necessary for its safe and proper use.

### **7.3.4 Design and development review**

The review activities planned in EOP 35-1.00, New Product Introduction, are performed according to EOP 40-7.00, Design Reviews. The review process:

- evaluates design outputs against input requirements, and
- provides an opportunity to take actions on any problems identified.

The review team consists of representatives of functions concerned with the activity.

### **7.3.5 Design and development verification**

EOP 42-6.00, Independent Design Verification, is used to plan the verification and select a verifier. It requires the responsible verifier to verify all task design analyses and final deliverables including application of previously verified results, and to document the verification



on an Engineering Services Verification Cover Sheet. This activity is documented and retained in a design record file according to EOP 42-10.00, Design Record File.

### **7.3.6 Design and development validation**

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 preop and startup testing, mock-up testing, etc

Refer to EOP 35-3.00 for requirements specified for Engineering Tests, and EOP 35-3.10 for Special Engineering Tests/Inspection at Operating Plants.

### **7.3.7 Control of design and development changes**

Design changes to engineering drawings and specifications are processed in accordance with EOP 55-2.00, Engineering Change Control.

Design change requests from the field are processed in accordance with EOP 55-3.00, Field Deviation Disposition Request, and EOP 55-3.20, Field Disposition Instructions, for the communication of instructions to the field to implement approved changes. Records of the changes, reviews and any necessary actions are maintained in accordance with EOP 42-10.00, Design Record File.

## **7.4 Purchasing**

### **7.4.1 Purchasing process**

EOP 45-1.00, Procurement Initiation and Control, specifies the process and requirements for procurement of direct material, equipment and services by GE-NE business segments. Suppliers are selected on the basis of their ability to meet all requirements applicable to the product or service to be delivered. Suppliers are selected and controlled per EOP 45-1.00, Procurement Initiation and Control, which specifies criteria for selection, evaluation, and re-evaluation. The GE-NE Procedure 70-11, GE-NE Quality Policy and Quality System Requirements, and EOPs 45-1.00, Procurement Initiation and Control, and 42-5.00, Material Requests, require that appropriate quality and customer unique requirements be incorporated into the procurement document to assure product/service conformance to GE-NE and customer specified requirements.

Suppliers that meet the requirements are placed in GE-NE's Approved Supplier List (ASL) and are subject to re-evaluation and assessments based on the established guidelines. The records of supplier audits and evaluations are maintained as QA Records.



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Procurement performed from sites is controlled in accordance with QAM-001, QAM-003, or NEDC-32286 QA manual.

#### **7.4.2 Purchasing information**

EOP 42-5.00, Material Requests and EOP 45-1.00, Procurement Initiation and Control, require that purchasing documents contain data which:

- clearly describe the product or service through use of GE-NE documentation released per EOP 42-8.00, Document Initiation or Change by ERM/ECN,
- specify requirements for approval of supplier's procedures per EOP 45-4.00, Supplier Services/Equipment Document Review,
- specify requirements for qualification of personnel, and
- specify quality assurance program requirements for control of quality related activities.

The purchasing documents are reviewed by engineering and QA personnel to ensure the adequacy of requirements before orders are placed with the supplier.

#### **7.4.3 Verification of purchased product**

EOP 75-4.00, Material Receipt, Acceptance and Shipping Inspection, is in place to ensure that purchased product meets specified requirements.

As part of the customer contract review, any special customer requirements, such as customer inspection of products at a supplier's facility, are identified and incorporated into purchasing requirements imposed on the supplier. This is in addition to any source-inspection requirements imposed by the GE-NE Quality organization. GE-NE Sourcing standard terms and conditions provide for inspection and test by the Buyer, or their designated representative, to the extent possible at all times and places.

EOP 42-6.00, Independent Design Verification, requires that all designs and analysis by suppliers and each application of or change to these be design verified.

### **7.5 Production and service provision**

#### **7.5.1 Control of production and service provision**

EOP 40-12.00, Materials & Processes Engineering Control, includes requirements to provide control of materials and processes applied to GE supplied design, hardware, and services. EOP 45-4.00, Supplier Services/Equipment Document Review, defines responsibilities and procedural requirements for review and acceptance of documents submitted by suppliers of equipment and



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services. EOP 75-4.20, Material Receipt, Handling, Storage, Packaging and Shipping, describes requirements for accumulation, packaging, release, and shipment of products.

Manufacturing suppliers are evaluated to assure 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.

Servicing of material/equipment is performed by the applicable business in accordance with the customer's contract.

Field services are provided under individual Quality Assurance programs, as applicable to the contract:

- NEDC-32286, Quality Assurance Manual for International Nuclear Services
- QAM-001, Quality Assurance program for Modification, Maintenance, Repair or Replacement Projects
- QAM-003, Quality Assurance program for In-service Inspection.

#### **7.5.2 Validation of processes for production and service provision**

Procedures and practices are established and documented to provide that special processes such as welding, heat treating, and nondestructive examination are accomplished under controlled conditions. These special processes are accomplished in accordance with applicable codes, standards, regulations, specifications, design criteria, and other special requirements using qualified personnel, procedures, and equipment.

Requirements for special processes such as welding, heat treating, and nondestructive examination are specified by the customer's procurement documentation, specifications or on design documentation by the GE-NE engineer responsible for the design. Appropriate inspections and tests to assure control of these special processes are designated in applicable test and inspection procedures.

EOP 70-9.00, Welding Control, defines validation requirements for welding process and qualification of personnel. Functional testing and qualification of new tooling/process are controlled by EOP 35-3.00, Engineering Tests. EOP 45-4.00, Supplier Services/Equipment Document Review, defines requirements for review and approval of procedures utilized by suppliers for production, process control, inspection and test. EOP 75-2.00, Qualification and Certification of Personnel, defines requirements for qualification and certification of NDE personnel.

#### **7.5.3 Identification and traceability**

All engineering drawings and specifications produced are controlled according to EOPs 30-3.00, Product Definition, 30-3.40, Engineering Information System, and the GE-NE Drafting Manual



which is controlled by EOP 60-6.00, Drafting Manual Control, to ensure that products are identified during all stages of production, delivery and installation and that they are traceable.

The Product Definition documentation is controlled as quality records per EOP 60-3.10, Engineering Records and Document Distribution.

EOP 42-12.20, Material and Equipment Traceability Requirements, is used to assure product identification and traceability.

EOP 75-4.00, Material Receipt, Acceptance and Shipping Inspection, ensures that inspected and tested products are identified appropriately to indicate monitoring and measurement status. Inspection and test status at the sites is controlled in accordance with QAM-001, QAM-003, or NEDC-32286 QA manual.

#### **7.5.4 Customer property**

EOP 75-4.30, Customer Supplied Material, ensures that customer supplied 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. EOP 60-5.10, Proprietary and Sensitive Information Received from Companies outside GE, ensures that customer supplied documents are protected and handled in a controlled manner.

#### **7.5.5 Preservation of product**

EOPs 75-4.00, Material Receipt, Acceptance and Shipping Inspection, and 75-4.20, Material Receipt, Handling, Storage, Packaging and Shipping, specify processes for the control of identifying, preserving, segregating, handling, storage, packaging, and delivery of product. The design of packaging and shipping containers is procedurally controlled by EOP 40-18.00, Packaging of GE-NE - Procured or Manufactured Items.

Handling and storage at the sites is controlled in accordance with QAM-001, QAM-003, or NEDC-32286 QA manual.

#### **7.6 Control of monitoring and measuring devices**

Measuring and test equipment has been identified and procedures have been developed to ensure that product testing is completed in consistent with the requirements.

EOP 35-3.20, Calibration Control, specifies the requirements and control of measuring and test equipment utilized for monitoring and/or product acceptance.

Where necessary to ensure valid results, measuring equipment is:





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- calibrated or verified at specified intervals, or prior to use, against appropriate measurement standards,
- adjusted or re-adjusted as necessary,
- identified to enable the calibration status to be determined,
- safeguarded from adjustments that would invalidate the measurement result,
- protected from damage and deterioration during handling, maintenance and storage.

In addition, responsible QA organization assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Appropriate action is taken on the equipment and any product affected. Records of the results of calibration and verification are maintained.

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.

Measuring and test equipment at the sites is controlled in accordance with QAM-001, QAM-003, or NEDC-32286 QA manual.

## **8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT**

### **8.1 General**

GE-NE plans and implements periodic self-assessments and audits, performs measurement and analysis, and determines improvements as needed to:

- demonstrate conformity of the product,
- ensure conformity of the quality management system, and
- continually improve the effectiveness of the quality management system.

These requirements and methods are identified in documented procedures (GE-NE Procedure 70-11, GE-NE Quality Policy and Quality System Requirements, EOP 75-3.00, Self-Assessment, Corrective Action and Audits, EOP 75-7.00, Statistical Techniques) and include determination of applicable methods, including statistical techniques, and the extent of their use.

### **8.2 Monitoring and measurement**

#### **8.2.1 Customer satisfaction**

GE-NE Procedure 70-11 specifies the requirements for gathering and analyzing Customer Feedback information to gauge company performance against customer requirements. Direct communications are established with customers by the GE-NE's Customer Service



representatives to inquire, monitor and assure that customer requirements are fulfilled for delivered products.

### **8.2.2 Internal audit**

GE-NE conducts internal audits at planned intervals to determine whether the quality management system:

- conforms to the planned arrangements (see 7.1), to the requirements of ISO 9001 and to the quality management system requirements established by the organization, and
- is effectively implemented, and is adequate and maintained.

GE-NE Procedure 70-11, GE-NE Quality Policy and Quality System Requirements, and EOP 75-3.00, Self-Assessment, Corrective Action and Audits, specify a comprehensive system of planned and documented internal quality audits to determine the adequacy and effectiveness of the quality system.

This audit program identifies an audit schedule based on the importance of processes and related quality activities conducted in the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results are also covered in this program.

The management responsible for the area being audited is responsible for ensuring that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

### **8.2.3 Monitoring and measurement of process**

Self-assessments, in addition to self-audits and measurement methods, where applicable, are applied to demonstrate the ability of the processes of the quality management system to achieve planned results. GE-NE Procedure 70-11, GE-NE Quality Policy and Quality System Requirements, and EOP 75-3.00, Self-Assessment, Corrective Action and Audits, define activities such as: setting quality objectives, performing self assessments, initiating actions to correct identified deficiencies, and conducting management reviews.

EOP 75-4.10, Control of Nonconforming Material, details the process of documenting and controlling nonconforming products.

### **8.2.4 Monitoring and measurement of product**

Source inspections at supplier facilities are determined and controlled in accordance with EOP 42-5, Material Requests and 45-1.00, Procurement Initiation and Control. Receiving and final inspection/testing and release to ship is controlled in accordance with EOP 75-4.00, Material Receipt, Acceptance and Shipping Inspection. Release of product is authorized to ship by issuing a Product Quality Certificate.



For field services, in-process and final testing is controlled in accordance with QAM-001, QAM-003, or NEDC-32286 QA manual.

Filing, maintenance and retention of inspection and test records is controlled in accordance with EOP 75-6.00, Quality Assurance Records. Records generated at the sites are controlled in accordance with QAM-001, QAM-003, or NEDC-32286 QA manual.

### **8.3 Control of nonconforming product**

EOPs 75-4.10, Control of Nonconforming Material, and 50-3.00, Material Review Board, specify the responsibility for review and the authority for the disposition of nonconforming material. Control of nonconforming products at the sites is controlled in accordance with QAM-001, QAM-003, or NEDC-32286 QA manual.

When nonconformances in products manufactured by suppliers occur, they are dispositioned according to EOP 45-6.00, Deviation Disposition Requests from Suppliers.

When required by contract, the proposed disposition is submitted to the Customer for approval prior to acceptance for delivery or further processing.

Products, which are reworked or repaired, are re-inspected per the documented procedures. The description of the nonconformance and the disposition is recorded on the applicable nonconformance report, which is retained as a quality record per EOP 75-6.00, Quality Assurance Records.

EOP 75-4.10 specifies requirements for review of all nonconformances to determine if such nonconformity may exist in the delivered products. If so, a Potential Safety Concern is processed in accordance with GE-NE procedure 70-42, Reporting of Defects and Noncompliance Under 10CFR Part 21.

### **8.4 Analysis of data**

Data is collected and analyzed to demonstrate effectiveness of the quality management system and to evaluate the following:

- Customer satisfaction (complaints, feedback, score-cards)
- Conformity to product requirements (nonconformances, analyses and trends)
- Commitment tracking (corrective action requests, overdue, trends, affected procedures, processes)
- Suppliers (performance trend)

Data collected at various sources is analyzed to access and improve customer satisfaction, product quality, process trends, and supplier performance. In addition to standard data analysis



tools, Six-Sigma continuous process improvement techniques are incorporated. EOP 75-7.00, Statistical Techniques, lists various techniques for use by engineering personnel.

## **8.5 Improvement**

### **8.5.1 Continual improvement**

The GE-NE Procedure 70-11 specify responsibilities to Continuous Improvement Council to periodically review quality related GE-NE experience, trends and improvement opportunities, and provide a forum for the review of quality policies/objectives, problems, corrective actions and quality assurance technology.

In addition, the Quality Council reviews and provides a forum for the review of quality policies and objectives, problems, corrective actions and current quality assurance technology.

The information gathered from these discussions is used to continually improve the effectiveness of the quality management system. The results of management reviews also contribute to continuous improvement activities.

### **8.5.2 Corrective action**

Appropriate corrective actions are taken to prevent recurrence of nonconformities observed during internal or external audits.

GE-NE Procedure 70-11, GE-NE Quality Policy and Quality System Requirements and EOP 75-3.00, Self-Assessment, Corrective Action and Audits define the requirements for:

- reviewing nonconformities, 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, and
- reviewing corrective actions taken.

GE-NE Commitment Tracking System (CTS) is utilized to document, track status and maintain records of corrective and preventive action activities and results. EOP 75-6.00 requires retention of Corrective Action Requests (CARs) as QA Records.

EOP 50-3.00, Material Review Board, is used to ensure that corrective action is taken for repetitive deviations from technical requirements. EOP 70-6.00, Warranty Services, is used to ensure that customer complaints are resolved.



### **8.5.3 Preventive action**

GE-NE determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are taken as appropriate to the effects and extent of the potential problems.

GE-NE Procedure 70-11, EOP 75-3.00, Self Assessment, Corrective Action and Audits, EOP 50-3.00, Material Review Board, EOP 75-4.10, Control of Nonconforming Material, 45-6.00, Deviation Disposition Requests from Suppliers, and 55-3.00, Field Deviation Disposition Request, are used to ensure that:

- all corrective actions from audits and self-assessments, all nonconformances (GE and Supplier), and customer complaints are analyzed to detect conditions or potential conditions adverse to quality,
- changes in processes or procedures resulting from corrective and preventive actions are implemented and recorded to prevent recurrence of nonconformities, and
- conditions adverse to quality are evaluated for a potentially reportable condition per GE-NE Policies & Procedures 70-42, Reporting of Defects and Noncompliance Under 10CFR Part 21.

GE-NE Commitment Tracking System (CTS) is utilized to document, track status and maintain records of preventive actions taken in response to corrective actions as per section 8.5.2 of this document.



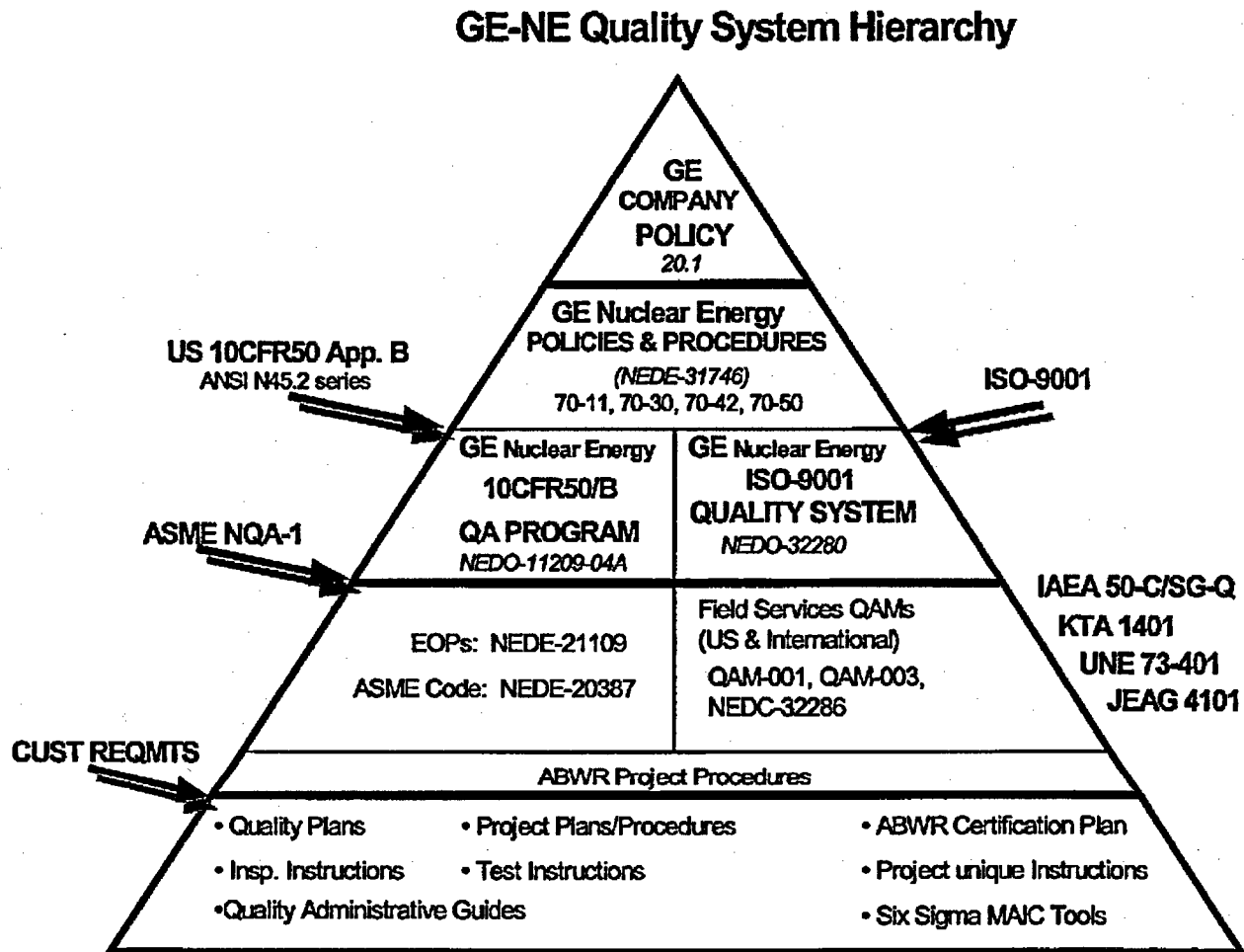
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Figure 2-1: GE Nuclear Energy Hierarchy Quality System



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ISO 9001:2000		ISO 9001:1994	GE-NE Procedures
Section Heading	Sec. No.	Corresponding sections	Referenced in ISO QMS manual
<b>Scope</b>	<b>1</b>	<b>1</b>	ISO QMS manual
<b>General</b>	<b>1.1</b>	<b>1</b>	
<b>Application</b>	<b>1.2</b>	<b>1</b>	ISO QMS manual
<b>Normative reference</b>	<b>2</b>	<b>2</b>	
<b>Terms and definitions</b>	<b>3</b>	<b>3</b>	Addressed in GE-NE procedures as appropriate
<b>Quality management system</b>	<b>4</b>		
<b>General requirements</b>	<b>4.1</b>	<b>4.2.1</b>	ISO QMS manual
<b>Documentation requirements</b>	<b>4.2</b>		
<b>General</b>	<b>4.2.1</b>	<b>4.2.1</b>	P&P 70-11 (sec. D 2.1), QAM-001, QAM-003, NEDC-32286, NEDE 20387, NEDE 21109, Lungmen QA Program #31113-0A18-0001
<b>Quality manual</b>	<b>4.2.2</b>	<b>4.2.1, 4.2.2</b>	ISO QMS manual
<b>Control of documents</b>	<b>4.2.3</b>	<b>4.5.1, 4.5.2, 4.5.3</b>	EOP 10-2.10, 42-8.00, 55-2.00, 60-3.10, 60-5.00, 60-5.10, QAM-001, QAM-003, NEDC-32286
<b>Control of records</b>	<b>4.2.4</b>	<b>4.16</b>	EOP 75-6.00, 42-10.00, 60-3.10, QAM-001, QAM-003, NEDC-32286
<b>Management responsibility</b>	<b>5</b>		
<b>Management commitment</b>	<b>5.1</b>	<b>4.1, 4.1.2.2, 4.2.1</b>	P&P 70-11 (sec. B, D 1.3, D 2.2)
<b>Customer focus</b>	<b>5.2</b>		P&P 70-11 (sec. D 3.5, D 3.17), EOP 25-5.00, 25-5.10, 70-3.00
<b>Quality policy</b>	<b>5.3</b>	<b>4.1.1</b>	P&P 70-11 (sec. B)
<b>Planning</b>	<b>5.4</b>		
<b>Quality objectives</b>	<b>5.4.1</b>	<b>4.1.1, 4.2.1</b>	P&P 70-11 (sec. D 2.2)
<b>Quality management system planning</b>	<b>5.4.2</b>	<b>4.2.3</b>	P&P 70-11 (sec. D 2.0, D 3.3)
<b>Responsibility, authority and communication</b>	<b>5.5</b>		
<b>Responsibility and authority</b>	<b>5.5.1</b>	<b>4.1.2</b>	P&P 70-11 (sec. D 3.4, D 3.5), EOP 20-2.00, EOPs QAM-001, QAM-003, NEDC-32286
<b>Management representative</b>	<b>5.5.2</b>	<b>4.1.2.3</b>	ISO QMS manual
<b>Internal communication</b>	<b>5.5.3</b>		ISO QMS manual
<b>Management review</b>	<b>5.6</b>		
<b>General</b>	<b>5.6.1</b>	<b>4.1.3</b>	P&P 70-11 (sec. D 3.18)
<b>Review input</b>	<b>5.6.2</b>	<b>4.1.3</b>	P&P 70-11 (sec. D 3.18.1)
<b>Review output</b>	<b>5.6.3</b>	<b>4.1.3</b>	P&P 70-11 (sec. D 3.18.2)



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ISO 9001:2000		ISO 9001:1994	GE-NE Procedures
Section Heading	Sec. No.	Corresponding sections	Referenced in ISO QMS manual
<b>Resource management</b>	<b>6</b>		
Provision of resources	6.1	4.1.2.2	P&P 70-11 (sec. D 3.3)
Human resources:	6.2		
General	6.2.1	4.1.2.2	P&P 70-30
Competence, awareness and training	6.2.2	4.18	P&P 70-30, EOP 75-2.00, 75-5.00, QAM-001, QAM-003, NEDC-32286
Infrastructure	6.3	4.9	ISO QMS manual, P&P 70-11 (sec. D 3.8), EOP 40-12.00
Work environment	6.4	4.9	P&P 70-4, ISO QMS manual
<b>Product realization</b>	<b>7</b>		
Planning of product realization	7.1	4.2.3, 4.9, 4.10, 4.15, 4.19	P&P 70-11 (sec. D 2.1.2, D 2.2, D 3.1), EOP 25-5.00, 35-1.00, QAM-001, QAM-003, NEDC-32286, ISO QMS manual
<b>Customer-related processes</b>	<b>7.2</b>		
Determination of requirements related to the product	7.2.1	4.3	P&P 10-27, EOP 25-5.00, 25-5.10, 70-3.00
Review of requirements related to the product	7.2.2	4.3	P&P 10-27, EOP 70-3.00, 25-5.10
Customer communication	7.2.3		ISO QMS manual, P&P 70-11 (Sec. D 3.17)
<b>Design and development</b>	<b>7.3</b>		
Design and development planning	7.3.1	4.4.2, 4.4.3	EOP 35-1.00, 42-1.00
Design and development inputs	7.3.2	4.4.4	EOP 25-5.10, 70-3.00
Design and development outputs	7.3.3	4.4.5	EOP 42-6.00, 65-2.10
Design and development review	7.3.4	4.4.6	EOP 35-1.00, 40-7.00
Design and development verification	7.3.5	4.4.7	EOP 42-6.00, 42-10.00
Design and development validation	7.3.6	4.4.8	ISO QMS manual, EOP 35-3.00, 35-3.10
Control of design and development changes	7.3.7	4.4.9	EOP 42-10.00, 55-2.00, 55-3.00, 55-3.20
<b>Purchasing</b>	<b>7.4</b>		
Purchasing process	7.4.1	4.6	EOP 45-1.00, 42-5.00, QAM-001, QAM-003, NEDC-32286, P&P 70-11 (sec. D 3.16)
Purchasing information	7.4.2	4.6	EOP 45-1.00, 42-5.00, 42-8.00, NEDC-32286, P&P 70-11 (sec. D 3.16)
Verification of purchased product	7.4.3	4.6	EOP 75-4.00, 42-6.00, NEDC-32286, P&P 70-11 (sec. D 3.16)





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ISO 9001:2000		ISO 9001:1994	GE-NE Procedures
Section Heading	Sec. No.	Corresponding sections	Referenced in ISO QMS manual
<b>Production and service provision</b>	<b>7.5</b>		
Control of production and service provision	7.5.1	4.9, 4.10, 4.12, 4.19	EOP 40-12.00, 45-4.00, 75-4.20, QAM-001, QAM-003, NEDC-32286
Validation of processes for production and service provision	7.5.2	4.9	EOP 35-3.00, 45-4.00, 70-9.00, 75-2.00
Identification and traceability	7.5.3	4.8	EOP 30-3.00, 30-3.40, 42-12.20, 60-3.10, 60-6.00, 75-4.00, QAM-001, QAM-003, NEDC-32286
Customer property	7.5.4	4.7	EOP 60-5.10, 75-4.30
Preservation of product	7.5.5	4.15	EOP 75-4.00, 75-4.20, 40-18.00, QAM-001, QAM-003, NEDC-32286
Control of monitoring and measuring devices	7.6	4.11	EOP 35-3.20, QAM-001, QAM-003, NEDC-32286
<b>Measurement, analysis and improvement</b>	<b>8</b>		
General	8.1	4.10, 4.20	ISO QMS manual, P&P 70-11 (sec. D 3.2, D 3.12, D 4.0), EOP 75-3.00, 75-7.00
<b>Monitoring and measurement</b>	<b>8.2</b>		
Customer satisfaction	8.2.1		P&P 70-11 (sec. D 3.17)
Internal audit	8.2.2	4.17	P&P 70-11 (Sec. D 4.0), EOP 75-3.00
Monitoring and measurement of processes	8.2.3	4.2	P&P 70-11 (Sec. D 4.0), EOP 75-3.00, 75-4.10
Monitoring and measurement of product	8.2.4	4.10, 4.20	EOP 42-5.00, 45-1.00, 75-4.00, 75-6.00, QAM-001, QAM-003, NEDC-32286, P&P 70-11 (sec. D 3.11)
Control of nonconforming product	8.3	4.13	P&P 70.11 (sec. D 3.15), 70-42, EOP 75-4.10, 50-3.00, 45-6.00, 75-6.00, QAM-001, QAM-003, NEDC-32286
Analysis of data	8.4	4.14, 4.20	ISO QMS manual, EOP 75-7.00 P&P 70.11 (sec. D 3.8)
<b>Improvement</b>	<b>8.5</b>		
Continual improvement	8.5.1	4.1.3, 4.9	P&P 70-11 (sec. D 3.2)
Corrective action	8.5.2	4.14	P&P 70-11 (sec. D 4.8.5 – D 4.8.11, D 4.10, Appendix II), EOP 75-3.00, 50-3.00, 70-6.00
Preventive action	8.5.3	4.14	P&P 70-11 (sec. D 4.8.5 – D 4.8.11, D4.10, Appendix II), 70-42, EOP 45-6.00, 50-3.00, 55-3.00, 75-3.00, 75-4.10