71-0170

HITACHI

GE Hitachi Nuclear Energy

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10 October 2012

Michael Waters, Chief
Licensing Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

ATTN: Document Control Desk

Ltr. No.: DRK-2012-20

SUBJECT: Submission for Approval of the Vallecitos Quality Assurance Program for Radioactive Material Package, Revision 10, Docket 71-0170; Dated September 2012.

Dear Mr. Waters:

GE Hitachi Nuclear Energy Americas, LLC ("GEH"), with operations at the Vallecitos Nuclear Center (VNC), Sunol, California is submitting for approval and renewal, the Vallecitos Quality Assurance Program for Shipping Packages for Radioactive Material, Revision 10, Docket 71-0170.

Changes made in Revision 10 to QAP-1 reflect changes in GEH or Vallecitos Organization or are editorial. None of these changes reduce the effectiveness of the program.

If there are any questions on this request, or additional information is required, please contact me at (925) 862-4360 or our Quality Assurance contact: Mr. Gaby Francis at (408) 209-2976.

Sincerely,

Donald R. Krause
2012.10.10
09:32:06 -07'00'

Donald R. Krause
Mgr., Regulatory Compliance,
Radiation Safety Officer

bcc: Gaby Francis (GEH)
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Q004

HITACHI

QUALITY ASSURANCE PROGRAM FOR SHIPPING PACKAGES FOR RADIOACTIVE MATERIAL

(DOCKET 71-0170)

DOCUMENT NO. QAP-1

REVISION 10

DATE ISSUED: September 2012

ISSUED BY: Gaby Francis

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Quality Assurance Manager

APPROVED BY:

Digitally signed by Anthony McFadden
Date: 2012.09.20 16:01:43 -07'00'

Manager, Vallecitos Nuclear Center

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LIST OF ABBREVIATIONS

CFR	Code of Federal Regulations
DOT	Department of Transportation
DR	Deviation Report
ECN	Engineering Change Notice
FM	Facilities Maintenance
GEH	GE Hitachi Nuclear Energy
IR	Inspection Report
MR	Material Request
MRB	Material Review Board
NRC	Nuclear Regulatory Commission
NS	Nuclear Safety
QA	Quality Assurance
QP	Quality Procedure
RC	Regulatory Compliance
RD	Radiation Dosimetry
RM	Radiation Monitoring
SOP	Standard Operating Procedure
VNC	Vallecitos Nuclear Center
VSS	VNC Safety Standard

INTRODUCTION

A quality assurance program is provided by GE Hitachi Nuclear Energy (GEH), Vallecitos Nuclear Center (VNC), to assure compliance with the requirements of 10CFR71, Subpart H. The program will assure the required management efforts, equipment and procedures are directed toward satisfying the quality objectives of GEH of providing safe and reliable systems and components, and assuring compliance with applicable codes and regulations of governing regulatory agencies. It is structured in accordance with the 18 criteria of 10CFR71, Subpart H.

Packaging and shipments for quantities of licensed materials in excess of Type A quantities or fissile materials exceeding fifteen (15) grams are governed by this program (refer to 10CFR71 for specific exemptions and definitions of terms). The program will be applied to activities affecting the packaging in a graded approach to an extent consistent with the importance to radiological safety and performance of the packaging. Those activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, assembling, inspecting, testing, operating, maintaining, repairing, and modifying.

Changes to this program are initiated by the QA function of VNC and require approval by the same organizations as for origination.

1. ORGANIZATION

1.1 GENERAL

This section describes the organizational structure and functional responsibilities for the Quality Assurance Program. Persons and organizations assigned quality-related responsibilities have sufficient authority and organizational freedom to: identify, evaluate, and recommend solutions to quality- and safety-related problems; verify implementation of corrective action; and stop unsatisfactory work and control further processing, delivery, installation or utilization of nonconforming items until proper disposition has been established.

The program is implemented by or at the direction of GEH-VNC. Activities such as design, fabrication, testing or others, as appropriate, may be performed by contractors to GEH specifications. GEH assigns appropriately trained and qualified personnel to determine that those functions performed by contractors are accomplished properly.

The organizational structure and functional responsibility assignments are such that: (1) attainment of quality objectives is accomplished by individuals responsible for specifying quality or performing work to specifications; and (2) verification of quality requirements is accomplished through audits performed by Quality Assurance per Section 18 of this program.

An abbreviated organization chart showing those components concerned with implementing this program is presented in Figure 1-1.

1.2 STAFF ORGANIZATION FUNCTIONS

The President of GEH is responsible for establishing the QA policies, goals, and objectives. In order to assure compliance with those policies, the Manager, VNC, has been delegated the overall responsibility and authority for establishment and execution of this QA program.

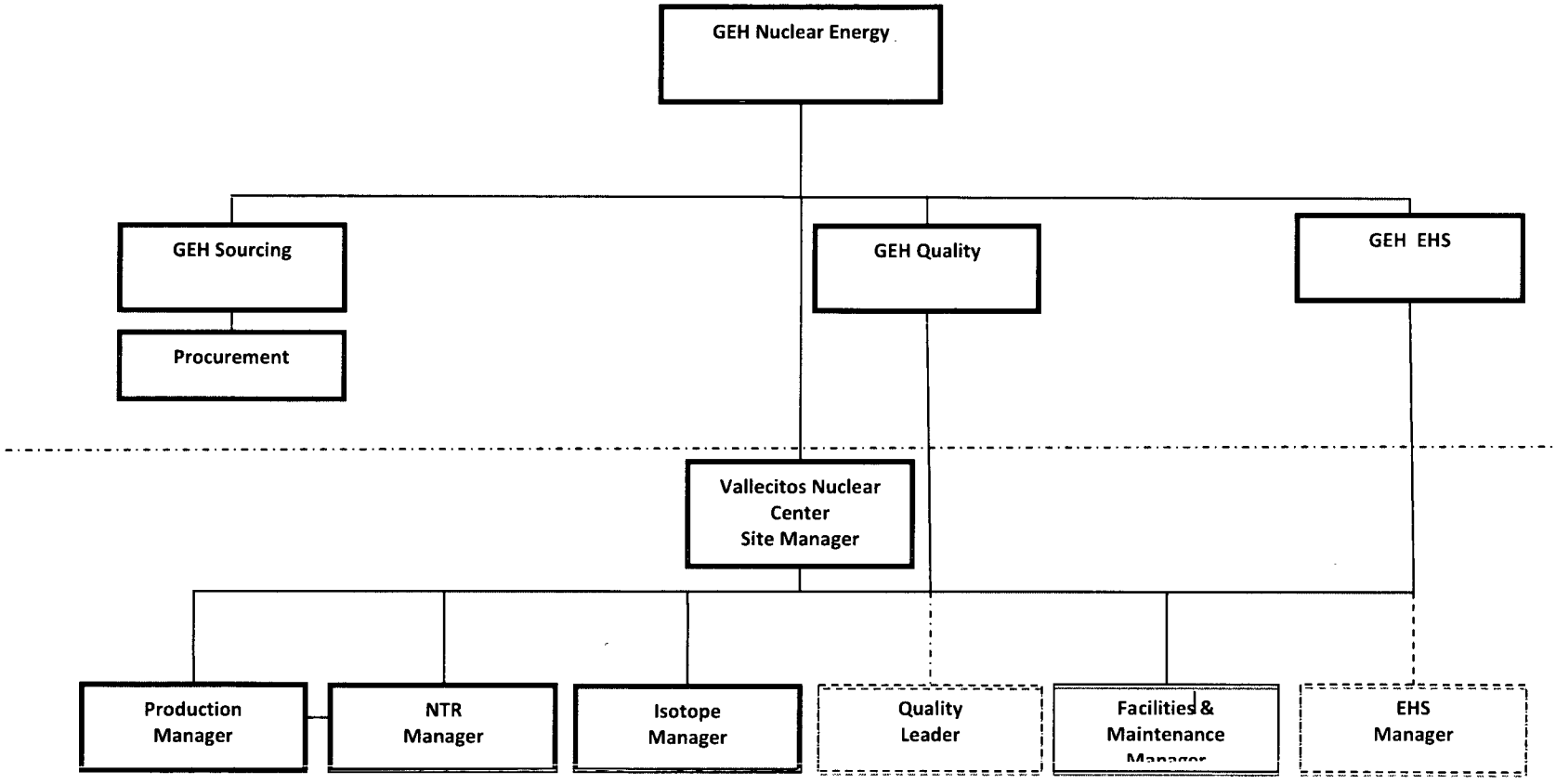

FIGURE 1-1. PARTIAL ORGANIZATION CHART

(OPERATIONS BELOW DOTTED LINE ARE REPRESENTED AT VALLECITOS NUCLEAR CENTER)

1.3 LINE ORGANIZATION FUNCTIONS

1.3.1 Production

Production has overall responsibility for routine operations, handling, maintenance, shipping and receiving activities for VNC containers that fall within the scope of this program. These responsibilities include:

a. Preparation and issuance of procedures for routine handling, maintenance and use of shipping containers.
b. Inspection of containers prior to each use in shipment.
c. Assembly of containers in preparation for shipment.
d. Verification of shipping documents, package labeling and marking before the shipments leave the site.
e. Performance of routine maintenance.
f. Receipt and storage of materials.
g. Recordkeeping relative to operations, maintenance, material receipt, in-service inspection, shipping and receiving.

1.3 LINE ORGANIZATION FUNCTIONS (Continued)

1.3.2 Facilities and Maintenance (FM)

FM provides assistance, as requested, in performance of those functions related to VNC shipping containers that fall within the scope of this program. The primary services provided by this organization are calibration of instruments, and providing personnel for inspection, maintenance and assembly of containers in preparation of shipment.

Further, FM has overall responsibility for engineering, and repair of VNC-owned Type B and/or fissile shipping containers used for radioactive material shipments that fall within the scope of this program. Those responsibilities include:

h. Issuance of new designs and changes to existing designs. This includes interfacing with regulatory agencies, through RC, on technical issues.
i. Ensuring that new designs and changes to existing designs are verified as required in Section 3 of this program.
j. Review of maintenance procedures.
k. Preparation of fabrication, procurement and/or process specifications and performance of technical liaison with suppliers.
l. Identification, preparation, issuance and maintenance of applicable documents or procedures required in Section 5 of this program.
m. Maintenance of design and fabrication records.
n. Engineering evaluation of radioactive material shipments that fall within the scope of this program utilizing VNC-owned Type B or fissile shipping containers.
o. Act as alternate engineering component responsible for evaluation of packaging designs for DOT specification containers that fall within the scope of this program.

1.3.3 Quality Assurance (QA)

The QA function is responsible for establishing overall quality programs and for assuring that quality-related activities are performed in accordance with these programs. QA is organizationally independent of the operating functions and has delegated authority and responsibility to identify and evaluate quality problems; to recommend and assure implementation of corrective actions; and to stop unsatisfactory work and control further processing, delivery, installation or utilization of nonconforming items until proper disposition is established. Responsibilities include:

a- Interpret quality requirements and issue QA plans. Review and approve procedures and specifications of performing components to assure inclusion of quality requirements.

b- Issue procedures for inspection work performed by QA.

c- Provide inspection services when specified by governing procedures or as requested.

d- Conduct Material Review Board evaluations on nonconforming items.

e- Perform audits of the quality system and follow up to verify completion of committed actions.

f- Approve procurement documents as required by this program to ensure that quality requirements are specified as appropriate.

g- Perform evaluations and maintain records of supplier quality capability.

h- As appropriate, approve supplier-furnished documents and witness or verify supplier activities to assure conformance with procurement requirements.

1.3.4 GEH Environmental Health & Safety (EHS)

EHS overall responsibility for Nuclear Safety (NS), Radiation Monitoring (RM), Radiation Dosimetry (RD), and Licensing functions which include but is not limited to:

a. Interface with regulatory agencies on matters pertaining to licensing and nuclear safety.

b. Review radioactive material shipping container designs for compliance with the appropriate regulations, license requirements, and GEH policies; and recommend the necessary corrective action to resolve areas of conflict.

c. Review operating procedures to ensure applicable radiological safety requirements are included.

d. Survey packaged products to assure that external radiation and contamination levels do not exceed limits established by regulatory agencies for shipping radioactive materials. Survey results are documented in appropriate records.

e. Perform audits, as necessary, to assure compliance with established radiological safety requirements.

1.3.5 GEH Quality Assurance

Certain activities are delegated to GEH Wilmington QA and Engineering. These activities are delegated in writing and require that they be conducted per the applicable requirements of this Quality Assurance Plan. The delegated activities are summarized as follows:

a. Certification of NDE personnel.

b. Review of NDE procedures.

c. Qualification of suppliers.
d. Procurement document review and issuance.
e. Safety-related component dedication.
f. Source inspection.
g. Shielding and engineering calculations.
h. Engineering activity verification.
i. Quality record archival.
j. Administration and maintenance of quality-related software.

1.4 QUALITY ASSURANCE PERSONNEL QUALIFICATIONS

Following are the minimum qualifications for principal QA personnel: technical degree or ten years experience in engineering, manufacturing, and/or quality assurance.

2. QUALITY ASSURANCE PROGRAM

An overall QA program is established, documented and implemented which encompasses those activities which are necessary to meet quality objectives. This program is applicable to GEH-VNC licensed containers used for shipping materials in excess of Type A quantities or fissile materials in excess of fifteen (15) grams. The program applies to activities affecting the components of the identified packaging to an extent consistent with their importance to safety. Those activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, assembling, inspecting, testing, operating, maintaining, repairing, and modifying.

QA policy and system documentation is structured from the GEH company-wide quality policy down to implementation in VNC. Figure 2-1 identifies the key policies, procedures, and instructions which are established to meet this objective.

GE company-wide Policy No. 20.1, "Quality", states quality considerations and requirements applicable to all GE business components. The policy specifically requires that each direct report to the Corporate Executive Office operate in accordance with the company-wide quality policy.

GEH Policy & Procedure No. 70-11, "GEH Nuclear Energy Quality Policy and Quality System Requirements", interprets the GEH Quality Policy and provides implementing direction to the GEH organizations. It is the policy of GEH to achieve and maintain a reputation in the nuclear energy business for timely and effective compliance with all applicable quality requirements.

GEH Policy & Procedure No. 70-14, "GEH Nuclear Energy Quality Assurance Audit Requirements", establishes Quality Audit requirements. This includes requirements for qualification and proficiency of lead auditors.

GEH Policy & Procedure No. 70-30, "Personnel Proficiency on Quality Related Activities", establishes the proficiency requirements for individuals performing activities, including testing and inspection, affecting quality in GEH.

QA procedures, quality plans, and performing component plans and procedures are documents which implement the GEH policy on quality.

Distribution of QA policies and procedures is accomplished in accordance with formal document control systems. This provides for communicating to responsible organizations and individuals the mandatory requirements of quality policies, manuals, and procedures. Table 2-1 is a cross-index showing the relationship of the key quality-related document system, manuals, plans or procedures with each of the criteria of 10CFR71, Subpart H.

Should any portion of the QA program be delegated to others, the agreement is documented to provide assurance that the applicable portions of 10CFR71, Subpart H, will be implemented.

In the event differences of opinion involving quality arise between QA personnel and other personnel, the issue(s) is brought to the attention of appropriate levels of management for resolution. GEH also is committed to 10CFR21, "Reporting of Defects and Noncompliance", which includes the posting requirements of 10CFR21.6. This provides individuals with the opportunity to have quality issues evaluated independently.

Training and experience qualifications are defined for each position in GEH. 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 are carried out through various documented procedures, personnel contacts, and meetings. 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. Personnel performing quality-related activities are trained and qualified in the principles and techniques of the activity being performed.

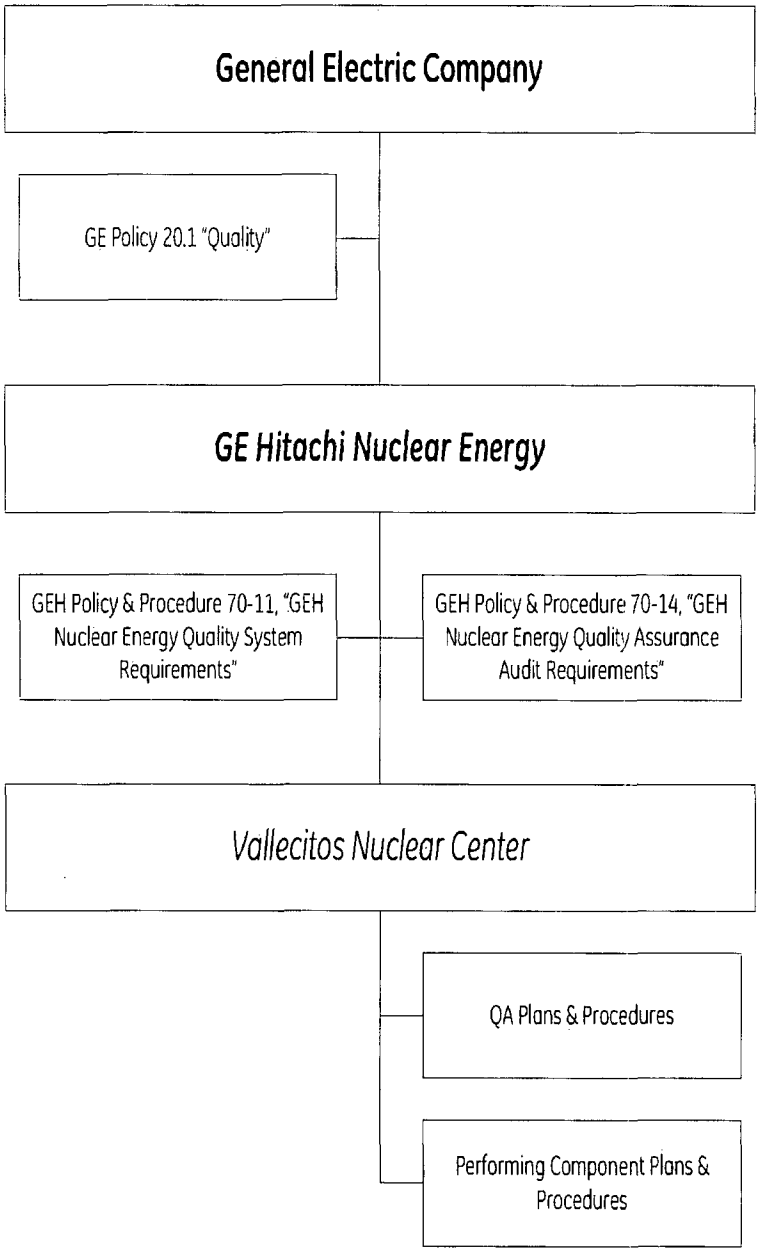

FIGURE 2-1. QUALITY ASSURANCE COMPLIANCE TREE
POLICIES, PROCEDURES, AND INSTRUCTIONS THAT GOVERN QUALITY-RELATED ACTIVITIES

TABLE 2-1

CROSS-INDEX TABLE OF QUALITY-RELATED DOCUMENTS TO EACH CRITERION OF 10CFR71, SUBPART H

1.	ORGANIZATION	
	GEH Policies & Procedures	Section 150, Organization Section 160, Functional Directives
	QA Program	Section 1, Organization
2.	QUALITY ASSURANCE PROGRAM	
	QA Program	All Sections
3.	DESIGN CONTROL	
	Performing Components	SOP's
	QA Program	Section 3, Design Control
4.	PROCUREMENT DOCUMENT CONTROL	
	QA Manual	No. QP 40.1, Procurement Document Control
	QA Program	Section 4, Procurement Document Control
5.	INSTRUCTIONS, PROCEDURES, AND DRAWINGS	
	VNC Safety Standards	No. VSS 25.1, Document Control
	Performing Components	SOP's
	QA Program	Section 5; Instructions, Procedures and Drawings
6.	DOCUMENT CONTROL	
	VNC Safety Standards	No. VSS 25.1, Document Control
	Performing Components	SOP's
	QA Program	Section 6, Document Control
7.	CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES	
	QA Manual	No. QP 40.1, Procurement Document Control
	QA Manual	No. QP 40.2, Supplier Quality Capability
8.	IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS	
	QA Manual	No. QP 10.3, Inspection Reporting
	QA Manual	No. QP 20.1, Receiving Inspection
	Performing Components	SOP's
	QA Program	Section 8; Identification and Control of Materials, Parts, and Components

TABLE 2-1

CROSS-INDEX TABLE OF QUALITY-RELATED DOCUMENTS TO EACH CRITERION OF 10CFR71, SUBPART H

9.	CONTROL OF SPECIAL PROCESSES	
	Performing Components	SOP's
	QA Program	Section 9, Control of Special Processes
10.	INSPECTION	
	QA Manual	Instructions for QA Inspection
	QA Program	Section 10, Inspection
11.	TEST CONTROL	
	QA Program	Section 11, Test Control
12.	CONTROL OF MEASURING AND TEST EQUIPMENT	
	QA Manual	No. QP 30.1, Gage and Instrument Control
	QA Program	Section 12, Control of Measuring and Test Equipment
13.	HANDLING, STORAGE AND SHIPPING	
	Performing Component	SOP's
	QA Program	Section 13; Handling, Storage and Shipping
14.	INSPECTION, TEST AND OPERATING STATUS	
	QA Manual	Instructions for QA Inspection
	Performing Component	SOP's
	QA Program	Section 14; Inspection, Test and Operating Status
15.	NONCONFORMING MATERIAL, PARTS OR COMPONENTS	
	QA Manual	No. QP 50.1, Nonconformances
16.	CORRECTIVE ACTION	
	QA Manual	No. QP 60.3, Corrective Action Request
17.	QUALITY ASSURANCE RECORDS	
	QA Program	Section 17, QA Records
18.	AUDITS	
	QA Manual	No. QP 70.1, QA Audit System

3. DESIGN CONTROL

3.1 GENERAL

Design control applies to the following items: criticality physics; radiation shielding; stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for in-service inspection, maintenance and repair; features to facilitate decontamination; and delineation of acceptance criteria for inspection and tests. Quality standards are specified in the design documents, and deviations and changes from these quality standards are controlled. Regulatory requirements which provide the bases for design methods, material evaluation and process control are identified in the design specifications.

Measures are established for the selection of suitable materials, parts, equipment and processes for safety-related structures, systems, and components which include the use of valid industry standards and specifications. Materials, parts, and equipment which are standard, commercial (off the shelf), or which have been approved previously for a different application are reviewed for suitability prior to selection.

Errors and deficiencies in the design, including the design process, that could adversely affect safety-related structures, systems, and components are documented; and corrective action is taken to preclude repetition.

3.2 DESIGN VERIFICATION

Verification or checking of design adequacy is performed using one or more of the following: design review, the use of alternate or simplified calculation methods, or the performance of a suitable qualification test.

Design reviews normally include representatives from engineering and quality assurance. Individuals or groups responsible for design verification are other than the original designer and the designer's immediate supervisor, but who may be from the same organization.

When a test program is used to verify the adequacy of a design, a qualification test under adverse design conditions is used. A prototype unit is used, or actual components may be tested if the test does not cause degradation.

3.3 DESIGN CHANGE CONTROL

Design and specification changes are subject to design control measures commensurate with those applied to the original design. NRC approval is obtained for changes which result in conditions different from those specified in the certificate of compliance.

4. PROCUREMENT DOCUMENT CONTROL

Material and services purchased from outside suppliers are requested on a Material Request (MR) form. Review and approval of MR's for safety-related material and services are performed by QA prior to release and are available for verification.

Review of procurement documents for safety-related material and services determines that quality requirements are stated correctly, inspect able, and controllable; there are adequate acceptance and rejection criteria; and the procurement document has been prepared, reviewed and approved in accordance with QA program requirements.

Procurement documents for spare or replacement parts of safety-related structures, systems, and components are subject to controls commensurate with those used for the original equipment.

The following information is included in procurement documents as deemed appropriate by QA or the responsible engineer:

- Identification of the applicable QA requirements which must be complied with and described in the supplier's QA program. This includes specifying, as necessary, that the requirements of 10CFR21 apply. As necessary, the supplier's QA program or a portion thereof is reviewed and concurred with by qualified personnel in QA prior to initiation of activities affected by the program.
- Design basis technical requirements including the applicable regulatory requirements; material and component identification requirements; drawings, specifications, codes and industrial standards; test and inspection requirements; and special process instructions.
- Identification of the documentation (e.g., drawings, specifications, procedures, inspection and fabrication plans, inspection test records, personnel and procedure qualifications, and chemical and physical test results of material) to be prepared, maintained, and submitted to GEH for review and approval.
- Identification of those records to be retained, controlled, and maintained by the supplier, and those delivered to GEH prior to use or installation of the hardware.
- Provisions for access to the supplier's facilities and records for source inspection and audit.

5. INSTRUCTIONS, PROCEDURES AND DRAWINGS

The design, fabrication, assembly, testing, use and maintenance of applicable shipping containers for radioactive material are performed in accordance with approved instructions, procedures, or specifications. These instructions, procedures, or specifications include the appropriate quantitative or qualitative acceptance criteria as a basis to evaluate the satisfactory performance of specified activities.

Provisions are established which clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of instructions, procedures and drawings. Activities affecting quality, including methods of complying with 10CFR71, Subpart H, are specified in instructions, procedures and drawings.

6. DOCUMENT CONTROL

Each of the organizations listed in Section 1 generates documents in the course of performing their assigned tasks. Procedures are established describing the document control system in each organization. These measures provide assurance that documents, including changes, are reviewed and approved prior to implementation and are distributed for use at the location where the prescribed activity is performed. Changes to documents are reviewed and approved by the same organizations that approved the original document unless other organizations are designated specifically by appropriate management.

QA concurrence is obtained for inspection plans, test calibration and special process procedures, drawings and specifications, and changes thereto. This is accomplished by such QA actions as participation in design reviews; issuance of QA procedures and instructions; and review of operating component procedures, fabrication plans, or procurement documents.

Through established distribution and communication systems, those participating in an activity are apprised of current applicable instructions for performing the activity. These measures are established to assure use of the proper documents and to preclude use of superseded documents.

Table 2-1 and Table 6-1 identify the types of quality-related documents controlled under this program.

TABLE 6-1

*KEY QA PROGRAM DOCUMENTATION APPROVAL AND ISSUANCE AUTHORITY**

Document Type	GEH President	Business-Level Managers	Engr. Managers	Quality Manager	Oper./Manuf. Component Managers
GEH Policy & Instructions	X				
Business-Level Procedures		X			
QA Program		X			
QA Procedures & Instructions				X	
Design Criteria			X		
Design Documentation			X		
Procurement Documents					X
Manufacturing/Operating Procedures					X
Inspection & Nonconformance Reports				X	

*Approval and issuance authority may be delegated by the respective managers.

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

Procedures and practices are established to provide assurance that purchased items and services conform to procurement documents. Qualified personnel evaluate the supplier's capability to provide acceptable quality services and products before the award of the purchase order or contract. As appropriate, QA, engineering and/or manufacturing personnel will participate in the evaluation of those suppliers providing safety-related components. The evaluations are documented and filed.

Evaluation of suppliers is based on one or more of the following:

- The supplier's capability to comply with the elements of 10 CFR Part 71, Subpart H, that are applicable to the type of material, equipment or service being procured.
- A review of previous records and performance of suppliers who have provided similar articles of the type being procured.
- A survey of the supplier's facilities and QA program to determine his capability to supply a product which meets the design, manufacturing, and quality requirements.

Source inspection or surveillance is performed as necessary during fabrication, inspection, testing, and shipment of materials, equipment, and components to assure conformance to the purchase order requirements. These are performed in accordance with written procedures or instructions which specify the characteristics or processes to be witnessed, inspected or verified, and accepted; the method of audit or surveillance and the extent of documentation required; and those responsible for implementation. Source inspection or surveillance is performed on those items where verification of specific procurement requirements is necessary but which cannot be determined upon receipt.

As a minimum, supplier-furnished documentation includes:

- Identification of the purchased material or equipment and the specific procurement requirements which have been met.
- Identification of procurement requirements which have not been met, together with a description of those nonconformances dispositioned "accept as is" or "repair".

Receiving inspection is the responsibility of the QA function and provides assurance that:

- Supplier-furnished documents meet specified requirements.
- Material, component, or equipment is identified properly and corresponds with the identification on receiving documentation.
- Inspection records or certificates of conformance attesting to the acceptance of material, components, and equipment are available at Vallecitos prior to installation or use.
- Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for installation, use, or further work.

Periodically, supplier's certificates of conformance are evaluated by audits, independent inspections, or tests to assure they are valid. The effectiveness of the control of quality by suppliers is assessed by GEH at intervals consistent with the importance, complexity, and quantity of the item.

8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

Procedures and systems are established for the identification, inventory, control related to shelf life or operating life, and traceability of raw materials, in-process materials, and finished components. Identification of materials and parts important to the function of safety-related structures, systems, and components is traceable to the appropriate documentation such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, and physical and chemical mill test reports.

Measures are taken to assure that the location and method of identification do not affect the fit, function or quality of the item being identified. Correct identification of material, parts, and components is verified and documented prior to release for fabrication, assembly, shipping, and installation to prevent inadvertent use of unsuitable items.

9. CONTROL OF SPECIAL PROCESSES

When required by engineering specifications or planning documents, fabrication processes are accomplished under controlled conditions in accordance with applicable codes, standards, specifications, or other engineering criteria using appropriately qualified personnel and procedures. Special processes as a minimum include welding, heat treating, and nondestructive testing.

9.1 PROCEDURE QUALIFICATION

Qualification of a production process is achieved by performing the process under controlled conditions on samples and then analyzing the output to determine acceptability. When the process can be duplicated on a repetitive basis by holding essential variables constant, the process is considered qualified. Qualifications are performed to written instructions (or an appropriately issued standard operating procedure) based upon engineering specifications and include essential variables. Process procedures derived from qualification specifications then may be issued for

routine production use. Appropriately issued standard operating procedures are considered to be qualified.

9.2 PERSONNEL QUALIFICATION

The management of each organization ensures personnel capabilities at all levels in each specific organization are adequate to perform assigned duties. Where personnel evaluation is delegated, the management ensures adequate instructions are conveyed properly to assure qualification review is commensurate with assigned responsibilities. Where personnel qualification includes quality-related activities and specialties, each organization maintains current, auditable records of such qualifications.

10. INSPECTION

Inspection is performed for each work operation where it is necessary to assure quality and is executed in accordance with QA-approved plans, procedures, or instructions. This includes inspection activities for fabrication of new and modification, repair or routine in-service inspection of packaging.

Inspection personnel for fabrication of new and modification or repair of existing shipping containers are independent from the individuals performing the activity being inspected. Personnel performing routine in-service or maintenance inspection may be from the same organization responsible for the activity. They are qualified in accordance with applicable codes, standards, or company training programs; and their qualifications and certifications are kept current.

An annual inspection is performed by the QA function, which includes, but is not limited to:

- Assuring that storage areas (e.g., bins, cages, etc.) are labeled properly and that acceptance tags are present on the storage areas and/or the individual parts, as appropriate.
- Assuring that parts are not damaged.
- Assuring that identification numbers on individual parts are logged when appropriate.

Note: Metallic parts are considered to have an unlimited shelf life. For non-metallic parts, the identification number is checked against the log to assure that the part is within shelf life.

The QA-approved plans, procedures, or instructions provide for the following, where applicable:

- Identification of characteristics or activities to be inspected.
- A check list of requirements to be met prior to release of the package(s) to a carrier for transport.

- Identification of the individuals or groups responsible for performing the inspection operation.
- The method of inspection.
- Recording evidence of completing or verifying a manufacturing, inspection, or test operation.
- Recording inspector or data recorder and the results of the inspection operation.
- Mandatory hold points beyond which work cannot proceed without appropriate inspector action.

Modifications, repairs, and replacements are inspected in accordance with the original design and inspection requirements or acceptable alternatives. Where it is not possible to perform direct inspection, provisions are established for indirect control by monitoring processing methods, equipment and personnel.

11. TEST CONTROL

Written test programs are established to assure all testing required is performed to demonstrate that the packaging components perform satisfactorily. As required, modifications, repairs and replacements are tested in accordance with the original design and testing requirements or acceptable alternatives.

Test procedures incorporate or reference, as appropriate:

- The requirements and acceptance limits contained in applicable design and procurement documents.
- The requirements of 10CFR71.
- Acceptance limits contained in the package approval.
- Instructions for performing the test.
- Test prerequisites such as:
  - ◊ Calibrated instrumentation
  - ◊ Adequate and appropriate equipment
  - ◊ Trained, qualified, and licensed or certified personnel
  - ◊ Completeness of item to be tested
  - ◊ Provisions for data collection and storage
- Mandatory inspection hold points for witness by owner, contractor, or inspector.
- Acceptance and rejection criteria.
- Methods of documenting or recording test data and results.

Test results are evaluated by engineering to determine acceptability.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

Each component or subcontractor responsible for measuring quality parameters is responsible for the inventory, identification, and calibration of all gages and instruments used for such inspections.

Procedures describe the calibration technique and frequency, maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) which is used in the measurement, inspection, and monitoring of safety-related components, systems, and structures.

Calibration and maintenance of measuring and test equipment are performed at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement. Measuring and test equipment is labeled, tagged, or otherwise identified to provide traceability to the calibration test data and to indicate the next calibration date. Calibration measures are not employed for rulers, tape measures, and other such devices where their use is limited to rough measuring functions.

Calibrations are traceable to nationally recognized standards. If no national standards exist, the basis for calibration is documented. Calibrating standards have an uncertainty (error) requirement of no more than 25% of the tolerance of the equipment being calibrated. A greater uncertainty may be acceptable when limited by the "state of the art".

When inspection, measuring, and 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), measures are taken and documented to determine the validity of measurements previously taken with the equipment.

The status of all items under the calibration system is recorded and maintained.

13. HANDLING, STORAGE AND SHIPPING

Procedures are prepared which control the cleaning, handling, storing, packaging, shipping, and preserving of materials, components and systems in accordance with design and specification conditions such as temperature or humidity.

Prior to delivery of a package to a carrier for transport, any special instructions needed to safely open the package are sent to or made available to the consignee. Procedures, instructions or other documentation as required by DOT regulations also are provided.

Established radiation safety requirements for handling, storing and shipping of packages containing radioactive material are followed. These packages are not released for shipment until all tests, certifications, final inspections and acceptance have been completed.

14. INSPECTION, TEST AND OPERATING STATUS

The inspection, test, and operating status are indicated by the use of markings such as stamps, tags, labels, routing cards, or other suitable means. Written instructions define which method is to be used. Bypassing of required inspections, tests, and other critical operations is controlled procedurally under the cognizance of QA personnel.

Measures also are established to indicate the operating status of components such as tagging valves and switches to prevent inadvertent operation.

15. NONCONFORMING MATERIALS, PARTS OR COMPONENTS

Procedures are established to provide for the identification, documentation, segregation, review, disposition, and notification to affected organizations of nonconforming materials, parts, components, or services. A Deviation Report is issued for nonconforming items which require convening of a Material Review Board. This provides the documentation which identifies the nonconforming item; describes the nonconformance, the disposition, and the inspection requirements; and includes signature approval of the disposition.

GEH Policy & Procedure No. 70-42, "Reporting of Defects and Noncompliances Under 10 CFR Part 21", is further established as a reporting mechanism for any employee or individual in the organization who becomes aware of a possible defect or noncompliance and for the evaluation of such as to reportability to the NRC.

Nonconforming items are segregated from acceptable items and are identified as discrepant until properly dispositioned. Re-work or repair of materials, parts, components, systems, and structures is verified by reinspecting and re-testing the item as originally inspected and tested or by a method which is at least equal to the original inspection and testing method. Inspection, testing, re-work, and repair procedures are documented. For procured items, nonconformances dispositioned *"use as is"* or *"repair"* are made part of the inspection records and evaluated by GEH prior to use of the item(s).

16. CORRECTIVE ACTION

Procedures are established for the evaluation of conditions adverse to quality (such as nonconformances, failures, malfunctions, deficiencies, deviations, and defective material and equipment) to determine the need for corrective action. Necessary corrective actions are identified, documented, and implemented in a manner appropriate to the cause and importance of the deficient condition. Documentation may be by formal letters, audit reports, or special forms such as that created by the GEH Commitment Tracking System The cause and corrective action for adverse quality conditions are reported to appropriate management and, when warranted, to customers or regulatory agencies. Follow-up reviews are conducted to verify proper implementation of corrective actions and to close out the corrective action documentation.

17. QUALITY ASSURANCE RECORDS

Procedures are established to provide assurance that sufficient records are maintained to furnish documentary evidence that the quality of items is satisfactory. The requirements and responsibilities for record transmittals, retention (such as duration, location, fire protection, and assigned responsibilities), and maintenance subsequent to completion of work are consistent with applicable codes and regulations.

The records include qualification of personnel, procedures and equipment and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports, nonconformance reports, and corrective action reports.

Facilities are provided to prevent destruction of the records by fire, flood, theft, and deterioration by environmental conditions such as temperature or humidity. Typically, records are maintained in metal file cabinets in rooms with fire suppression systems to assure retrievability and protection.

18. AUDITS

A system is provided for the performance of audits in accordance with pre-established written procedures or check lists and conducted by trained personnel not having direct responsibilities in the areas being audited. The audit plans and/or check lists are developed from approved QA programs, operating procedures and/or specifications. Audits are conducted on a scheduled or random, unscheduled basis, as appropriate. However, audits of safety-related activities are conducted at least on an annual basis. Audit results are documented and transmitted to responsible management in the area audited who then have sixty (60) days to respond to any findings so that necessary action to correct deficiencies can be taken. QA reviews the proposed corrective action(s) and re-audits deficient areas to verify implementation of committed corrective actions.

Audits are performed by QA to determine the following, as appropriate:

- The adequacy of quality-related practices, procedures and instructions.
- Compliance with the quality-related practices, procedures and instructions.
- The adequacy of work areas, activities, processes, items, and the review of documents and records.

Audits also are performed by GEH and its contractors to verify and evaluate suppliers' QA programs, procedures and activities.

Audit data are analyzed periodically; and the reports, which indicate quality trends and the effectiveness of the QA program, are reviewed and assessed by appropriate management.