



August 3, 2006
SHP-4011

Attention: Document Control Desk
Director, Spent Fuel Project Office
Office of Nuclear Material, Safety & Safeguards
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: **Docket No. 71-0030**; Submittal of Bound Copies of General Atomics' QA Program Topical Report with NRC Approval Letter Incorporated.

Reference: Asmussen, Keith E., GA Letter No. 3978 to Director, Spent Fuel Project Office, dated April 13, 2006, "Request for Renewal of General Atomics' QA Program; Submittal of Amended General Atomics Quality Assurance Topical Report."

Dear Director:

By letter dated April 13, 2006, General Atomics (GA) requested renewal of its QA Program. In support of that request, GA submitted three copies of Amendment 15 to General Atomics' Topical Report, GA-A13010 "General Atomics Quality Assurance Program." By letter dated June 1, 2006, NRC provided approval of GA's QA Program for Radioactive Material Packages No. 0030, Revision No.8.

In the referenced letter, GA stated that upon NRC approval, GA would incorporate the NRC approval document into bound copies of the report and distribute them to the NRC. Accordingly, the NRC approval has been incorporated into the subject topical report and three bound copies are enclosed.

Should you have any questions regarding this matter, please do not hesitate to contact me at (858) 455-2823 or at keith.asmussen@gat.com.

Very truly yours,

Keith E. Asmussen, Ph.D., Director
Licensing, Safety and Nuclear Compliance

Enclosure: GA-A13010A / GA-LTR-11 / Amendment 15, dated June 2006 (3 copies)

*DMSS01
1/3
2 Copies
Forwarded to
Michele DeBose*



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Director, Spent Fuel Project Office
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Should you have any questions regarding this matter, please do not hesitate to contact me at (858) 455-2823 or at keith.asmussen@gat.com.

Very truly yours,

A handwritten signature in black ink that reads "Keith E. Asmussen".

Keith E. Asmussen, Ph.D., Director
Licensing, Safety and Nuclear Compliance

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AMSD
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Forwarded to
Michele DeBose

**GA-A13010A
GA-LTR-11
AMMENDMENT 15**

**GENERAL ATOMICS
QUALITY ASSURANCE PROGRAM**

JUNE 2006



**GA-A13010A
GA-LTR-11
AMMENDMENT 15**

**GENERAL ATOMICS
QUALITY ASSURANCE PROGRAM**

**GENERAL ATOMICS PROJECT 09123
JUNE 2006**





UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

June 1, 2006

Mr. Keith E. Asmussen, Ph.D.
Director Licensing, Safety and Nuclear Compliance
General Atomics
3550 General Atomics Court
San Diego, CA 92121-1122

**SUBJECT: QUALITY ASSURANCE PROGRAM APPROVAL FOR RADIOACTIVE
MATERIAL PACKAGES NO. 0030, REVISION 8**

Dear Mr. Asmussen:

Enclosed is the Quality Assurance (QA) Program Approval for Radioactive Material Packages No. 0030, Revision No. 8. This Approval satisfies the requirements of 10 CFR 71.17(b) and 71.101(c)(1) for a QA Program approved by the U. S. Nuclear Regulatory Commission.

This Approval will remain in effect until the expiration date, indicated in Block No. 3. Termination of your materials license does not cause this Approval to be automatically terminated. If you wish to renew, amend, or terminate this Approval, please request it in writing.

This letter also serves as a reminder that if you are using or planning to use an NRC-approved packaging, you must be registered for use of that packaging with NRC. Registration for use of NRC-approved packagings should be made pursuant to 10 CFR 71.17(c)(3).

Sincerely,

A handwritten signature in cursive script that reads "Melanie C. Wong".

Melanie C. Wong, Acting Chief
Transportation and Storage Safety
and Inspection Section
Spent Fuel Project Office
Office of Nuclear Material Safety
and Safeguards

Docket No.: 71-0030

Enclosure: QA Program Approval No. 0030, Rev. 8

0030

**QUALITY ASSURANCE PROGRAM APPROVAL
FOR RADIOACTIVE MATERIAL PACKAGES**

REVISION NUMBER

08

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Title 10, Code of Federal Regulations, Chapter 1, Part 71, and in reliance on statements and representations heretofore made in Item 5 by the organization named in Item 2, the Quality Assurance Program identified in Item 5 is hereby approved. This approval is issued to satisfy the requirements of Section 71.101 of 10 CFR Part 71. This approval is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

2. NAME

General Atomics

3. EXPIRATION DATE

June 30, 2016

STREET ADDRESS

3550 General Atomics Court

4. DOCKET NUMBER

71-0030

CITY

San Diego

STATE

CA

ZIP CODE

92121-122

5. QUALITY ASSURANCE PROGRAM APPLICATION DATE(S)

November 3, 1993, May 20, 1996, April 20, 2001, April 13, 2006

6. CONDITIONS

1. Activities conducted regarding transportation packagings are to be executed under applicable criteria of 10 CFR Part 71, Subpart H. Authorized activities include: design, procurement, fabrication, assembly, testing, modification, maintenance, repair, and use of transportation packagings.
2. Records shall be maintained in accordance with the provisions of 10 CFR Part 71. Specifically:
 - a. Records of each shipment of licensed material shall be maintained for 3 years after that shipment [10 CFR 71.91(a)].
 - b. Records providing evidence of packaging quality shall be maintained for 3 years after the life of the packaging [10 CFR 71.91(d)].
 - c. Records describing activities affecting packaging quality shall be maintained for 3 years after this Quality Assurance Program Approval is terminated [10 CFR 71.135]
3. Planned and periodic audits of all aspects of the Quality Assurance Program shall be conducted in accordance with written procedures or checklists, by appropriately trained personnel not having direct responsibility in the areas being audited, in accordance with 10 CFR 71.137.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

SIGNATURE



DATE

6/1/06

MELANIE C. WONG, ACTING CHIEF
TRANSPORTATION AND STORAGE SAFETY AND INSPECTION SECTION
SPENT FUEL PROJECT OFFICE
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

ABSTRACT

This topical report has been prepared using 10CFR50 Appendix B, 10CFR71, and NRC Regulatory Guides and regulations as documented in accordance with Regulatory Guide 1.70, Revision 3. It is in compliance with the requirements specified in 10CFR50 Appendix B; ANSI/ASME NQA-1-1983 and the NQA-1-1a-1983 addenda as endorsed by NRC Regulatory Guide 1.28, Revision 3; and additional requirements in ASME NQA-1-1989 through the NQA-1c-1992 addenda (that are not yet endorsed by the NRC).

It is also in compliance with the requirements specified in 10CFR71 Subpart H for Shipping Packages for Radioactive Materials applicable during the design, fabrication, assembly, testing, licensing, use, and maintenance of such packages; and to the United States Nuclear Regulatory Commission's Regulatory Guide 7.10, Revision 1.

This topical report describes the General Atomics (GA) Quality Assurance Program under which the GA Quality Assurance Manual has been prepared and implemented at General Atomics for the design, procurement, fabrication, testing, repair, and maintenance of United States Nuclear Regulatory Commission licensed shipping packages.

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INTRODUCTION

General Atomics is a California corporation owned by General Atomic Technologies Corporation. The shareholder of General Atomic Technologies Corporation elects the Board of Directors of General Atomics. The Board of Directors elects the Chairman of the Board and Chief Executive Officer. The Chairman of General Atomics has the full authority to establish and implement all Quality Assurance policies for the company. The General Atomics Company Policy Manual, which is prepared under the direction of the Chairman, establishes the basic policy concerning the Quality Assurance Program and the quality of General Atomics' products and services. The Chairman of General Atomics is the highest level from which this Quality Assurance policy emanates.

When changes in the General Atomics Quality Assurance Program are made, they are incorporated in revisions or amendments to the Quality Assurance Manual. Changes that affect this Topical Report are forwarded to the Nuclear Regulatory Commission for review in the form of an amended Topical Report. Notification of General Atomics organizational changes that affect the Quality Assurance Program are provided to the Nuclear Regulatory Commission within 30 days of their effectivity, either through an amended Topical Report or by separate communication.

17.0 QUALITY ASSURANCE DURING DESIGN AND CONSTRUCTION

17.1 ORGANIZATION

17.1.1 Quality Assurance Program Responsibility

The General Atomics' Company Policy Manual documents the following policy statement concerning Quality Assurance:

"The quality of General Atomics' products and services shall be of acceptable workmanship and performance consistent with General Atomics and customer requirements. Each organization performing work is responsible for the quality of its products or services.

It is the policy of General Atomics that all hardware to be delivered to a customer shall be produced with sufficient controls to achieve a satisfactory level of quality. This will be achieved by implementing common, industrial codes and standards appropriate to the nature and application of the hardware. Where no company imposed standards have been adopted for this product in the past or where the customer is not specific on quality requirements, the Quality Assurance (QA) organization that supports that division or subsidiary shall be consulted by the proposal manager in the assessment of applicable requirements at the proposal phase of all potential projects that could result in deliverable hardware. This policy shall apply unless specifically revoked for a particular item or project by a senior vice president of General Atomics.

The quality of a General Atomics product or service shall be defined in applicable instructions, procedures, drawings, and specifications. The fulfillment of the requirements contained in these documents is demonstrated by documented objective evidence of compliance with the requirements.

Work performed and products produced by or for all organizational units of General Atomics are subject to audit by Quality Assurance to verify compliance with the requirements. The General Atomics QA manuals are the basis for the quality program throughout General Atomics. Related subtier manuals which implement the General Atomics quality program shall be reviewed by QA for compatibility with the requirements specified in the QA Manual. The appropriate Quality organization will implement the QA

policies through appropriate quality engineering, development of inspection procedures, and product and services inspections.

QA personnel are to be contacted in a timely manner for their quality-related input to the planning, development and performance of activities involving General Atomics products and services. QA will be consulted on all quality-related matters associated with customers, regulatory agencies, and internal General Atomics quality policy. Quality-related matters pertaining to suppliers and industry code interpretations shall be coordinated with QA.

QA personnel have the authority and responsibility to independently stop work, suspend operations, or stop shipments for lack of compliance with quality requirements. Resumption of work will occur only after correction of the nonconforming activities by management and approval of QA.

Any proposed deviations from this policy require a written plan indicating the exceptions, approved by the President or a vice president."

NOTE: For this report President is synonymous with Chairman.

This policy is summarized by the Chairman of General Atomics in the Statement of Authority in GA's Quality Assurance Manual. The Statement of Authority commits the QA Program to meeting the requirements of 10CFR71 Subpart H, and 10CFR50 Appendix B.

To implement this policy, the Chairman, General Atomics has reporting to him, through a Vice Chairman and Sr. Vice Presidents, the organizations responsible for the design, fabrication, and use of transport packages and dry storage containers for radioactive materials. These organizations are shown in Figure 17-1. Project management for each project reports through a Sr. Vice President to the Chairman, General Atomics. This topical report applies to those activities affecting the quality of transport packages for radioactive materials.

The Director of Quality Assurance, reporting to the Senior Vice President of the Advanced Technologies Group, has been assigned the responsibility for establishing and enforcing the provisions of the Quality Assurance (QA) Program for the packaging and handling of radioactive materials. He derives his authority from the Chairman of GA through the Senior Vice President, Advanced Technologies Group. This authority includes the right to stop unsatisfactory work or to stop further processing of unsatisfactory

material. The authority is delegated down through all levels of the Quality Assurance organization. The QA organization is separate from, and independent of, other organizations of GA, as shown in Figure 17-1.

17.1.2 Organizational Relationships

General Atomics' lines of authority and responsibilities of all organizations involved in the implementation of the QA Program are described in Section 17.1.3 and shown in Figures 17-1 and 17-2. Direct interface relationships are required and necessary between the QA organization, and GA customers for coordination of the QA Program, for investigation of quality problems, and for implementation of any required remedial actions. Similar direct interfaces with the Nuclear Regulatory Commission (NRC) is maintained for packaging items.

Licensing, Safety and Nuclear Compliance is responsible for obtaining licenses for shipping packages for radioactive materials, where GA is the organization shipping the materials, and for compliance with licensing requirements regarding GA facilities and radioactive materials in GA custody. Quality Assurance is responsible for verifying implementation of an adequate QA Program for all such licensed activities.

All organizations indicated in Figures 17-1 and 17-2 are located in San Diego, California.

It is GA's policy that all personnel whose activities affect the quality of deliverable or NRC licensed items will have sufficient authority, access to work areas, and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions to quality problems through designated channels; to verify implementation of solutions; and to assure that further processing, delivery, installation or use of an item is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. This delegation of authority and responsibility is implemented in the GA Quality Assurance Manual. The QA organization has been assigned the responsibility and the authority to assure implementation of the QA Program as described herein.

17.1.3 Organizational Responsibilities for Implementation of the GA Quality Assurance Program on Shipping Packages

17.1.3.1 Advanced Technologies Group. Advanced Technologies Group organizations report to the Senior Vice President of the Advanced Technologies Group. The following Advanced Technologies

Group organizations have 10CFR71 Subpart H, contractual requirements and implement the applicable sections of the QA program:

17.1.3.1.1 Nuclear Waste Management. Nuclear Waste Management under Advanced Process Systems reports to the Senior Vice President, Advanced Technologies Group and is responsible for the design and manufacture of transport packagings and dry storage containers for radioactive materials including design verification and interface control. Nuclear Waste Management assures responsiveness to Nuclear Regulatory Commission (NRC), and Department of Transportation (DOT) requirements and is responsible for obtaining required QA approvals.

17.1.3.1.2 Quality Assurance. The GA Quality Assurance organization reports to the Senior Vice President of the Advanced Technologies Group and is responsible for establishing and documenting the GA QA Program in accordance with Corporate policies, this topical report, 10CFR71 Subpart H, and ASME NQA-1-1989 through the ASME NQA-1c-1992 addenda; and for enforcing the requirements of the QA Program. The Quality Assurance organization is shown in Figure 17-2. The technical and administrative (hire/fire/salary review) authority of Quality Assurance organization personnel is indicated by the solid lines of this figure. The dashed line represents communication of QA policy, practices, and problems. Detailed responsibilities of the Quality Assurance organization are described in Appendix 17-1.

Minimum qualification requirements for Quality Assurance management, technical, and administrative positions are contained in General Atomics Job Descriptions. The functional responsibilities of the GA organizations involved in implementing the QA Program are implemented as described in the QA Manual. The results of their activities that affect product quality are subject to review for adequacy by QA. Examples of such QA action are the review and/or approval of design documents, procurement documents, and fabrication/manufacturing documents and audits of these activities.

17.1.3.2 Administration/Legal. The Vice President, Secretary, and General Counsel reports to the Chairman and Chief Executive Officer. The following organizations report to the Vice President, Secretary, and General Counsel and implement the QA Manual:

17.1.3.2.1 Licensing, Safety and Nuclear Compliance (LSNC). LSNC has the overall responsibility for control of radioactive material in GA custody, the licensed GA-operated facilities, and the licensing and controlled use of shipping packages for radioactive material.

17.1.3.3 Administration and Finance. The Senior Vice President of Administration and Finance, Chief Financial Officer, and Treasurer reports to the Chairman and Chief Executive Officer. The following organizations report to the Senior Vice President, Administration and Finance and implement the QA Manual:

17.1.3.3.1 Contracts and Purchasing. Contracts and Purchasing is responsible for issuing Work Project Notifications (WPN) when work is authorized by the customer, for coordinating and monitoring services required by such authorized work, and for communicating all QA requirements involved with such authorized work. Contracts and Purchasing also provides procurement services for materials, components, and services; and coordinates and monitors activities related to GA-placed procurements.

17.1.3.3.2 Facilities. Facilities provides welders, brazers, and machinists, as necessary.

17.1.3.3.3 Information Services. Information Resources provides maintenance services for computer programs and equipment.

17.1.3.3.4 Configuration/Records Management. Configuration/Records Management reports to Financial Services and is responsible for maintenance of engineering data bases and configuration control; technical reports management; technical correspondence; maintenance of engineering design drawings/documents and project control documents; inactive records storage and retrieval; and maintenance of GA's Licensing Library.

17.2 QUALITY ASSURANCE PROGRAM

17.2.1 Applicability of QA Program

The GA QA program, the basic provisions of which are contained herein, applies to all activities that affect the quality of shipping packages licensed under 10CFR71. A specific list of safety-related equipment will be compiled for each shipping package in the applicable Project Quality Assurance Program Document (QAPD).

17.2.2 GA QA Program Description

The procedures that implement the GA QA Program controls presented in this report are contained in the GA Quality Assurance Manual and the Quality Assurance Program Document for the specific project. These documents cover all work performed at GA on shipping packages and make provision for work done by others on behalf of GA. Changes to this report will be implemented in the GA Quality Assurance Manual and the Quality Assurance Program Document for the project when they affect these documents.

GA Quality Assurance Manual. The GA Quality Assurance Manual establishes the measures to achieve compliance with the requirements of this report. A listing of applicable Regulatory Guides and GA's position on these documents is provided in Table 17-2. The GA Quality Assurance Manual covers the criteria of 10CFR71 Subpart H, ASME NQA-1-1989 through the ASME NQA-1c-1992 addenda, and applicable Regulatory Guides and industry codes to implement the requirements within all organizations of GA.

Quality Assurance Program Document. The Quality Assurance Program Document is a Quality Assurance planning document issued for specific projects. It invokes the Quality Assurance Manual and establishes authority and responsibility for quality assurance activities for individual projects, including mandatory supplementary requirements unique to a customer, and exceptions or modifications to QA Manual requirements. Requirements are imposed on shipping packages for radioactive materials licensed pursuant to 10CFR71.

Relationship of Procedures to Criteria of 10CFR71 Subpart H, and ASME NQA-1-1989 through the ASME NQA-1c-1992 addenda. Table 17-1 of this report relates the quality procedures in effect at the date of this submittal and contained within the GA Quality Assurance Manual to the applicable criteria of

10CFR71 Subpart H, and the requirements of ASME NQA-1-1989 through the ASME NQA-1c-1992 addenda.

17.2.3 Changes in the GA QA Program Description

Regulatory Guides are reviewed by the QA organization for impact on the GA QA Program. This topical report will be updated as required to reflect applicable changes or provide acceptable alternatives.

17.2.4 Specifications for Supplier Quality Assurance Requirements

Measures for imposing the applicable GA QA Program requirements on suppliers are described in Section 17.4.

17.2.5 Training

GA Directors and cognizant Sr. Vice Presidents, or their designees, are responsible for providing indoctrination and training, as required, to personnel under their cognizance. Training is conducted and documented prior to the start of work and provides personnel with the tools, skills, and information to properly perform assigned tasks. Training also provides personnel with an adequate working knowledge of those quality assurance requirements that affect their work. Project managers assure that project personnel are trained as a minimum in the basic requirements of the QA Manual, QA Manual requirements specified by the project QAPD, and the specific customer requirements identified in the project QAPD.

Quality assurance and technical indoctrination and training is planned by the cognizant manager. The extent of indoctrination and training is commensurate with the scope, complexity, and nature of the activity; and the education, experience, and proficiency of the person(s) to be trained. As applicable to a particular function, personnel are initially indoctrinated in general criteria, including applicable codes, standards, and company procedures; applicable quality assurance program elements; and job responsibilities and authority. Indoctrination of QA personnel is documented. Subsequent training assures that personnel, as necessary, achieve initial proficiency in their assigned tasks, maintain that proficiency, and adapt to changes in technology, methods, procedures, and job responsibilities.

The QA managers are responsible for indoctrinating, training, evaluating, qualifying, and certifying personnel performing inspection and test activities. Qualification is based on an individual's education, experience, indoctrination, training, and either test results or capability demonstration. Qualification

records are maintained in QA. Proficiency is maintained by experience, retraining, reexamining, and recertifying. The QA managers are also responsible for planning, developing, and staffing an adequate number of personnel to perform the required inspections, examinations, and tests.

The cognizant QA manager is responsible for training and certifying personnel to adequately perform, operate, or otherwise control special process operations in accordance with applicable Government and contractually imposed specifications. Special process training and examination comply with the recommendations of SNT-TC-1A, 2001 edition for NDE processes covered by that document, and are accomplished in accordance with specially developed process qualification procedures for processes not covered by SNT-TC-1A, 2001 edition. Qualification records are maintained in QA.

When there are changes to the Quality Assurance Manual or any supporting procedure, retraining is provided and documented.

The Quality Assurance Director is responsible to assure that such training programs are functioning effectively through audits as described in Section 17.18.

Records are maintained of quality assurance indoctrination and training activities. These records include the training schedule, training duration, course outline, dated attendance rosters, subjects of the courses, name of instructor, and any special notes considered germane. Document review training records include project, document title, and revision or date.

17.2.6 Management Assessment of the QA Program

On a routine basis, reports of audits and corrective actions are disseminated to appropriate Sr. Vice Presidents, and other management levels of organizations involved in the activities of the QA Program. The Quality Assurance Director compiles for the Senior Vice President of the Advanced Technologies Group a monthly report of quality-related activities, performance trends, and significant problems, if any.

Management of other organizations participating in the QA Program assess the adequacy of that part of the program for which they are responsible and assure its effective implementation. Assessments may be performed by a combination of several methods including, but not limited to, readiness reviews; project and staff meetings; review of QA, customer, and regulatory agency audit reports; corrective action requests, and nonconformance reports; personnel interviews; etc.

17.2.7 Written Policies, Procedures and Instructions

The policies, procedures, and instructions that implement the QA program described in this report are contained in the GA Quality Assurance Manual which is prepared by Quality Assurance and reviewed and approved by the signature of the Director, Quality Assurance and the Senior Vice President of the Advanced Technologies Group. Changes to the procedures contained in the GA Quality Assurance Manual are processed and approved in the same manner. Distribution and control of the GA Quality Assurance Manual, and changes thereto, are accomplished by the Quality Systems organization. The GA Quality Assurance Manual is issued by copy number to control distribution and updating of changes. A receipt is obtained from addressees for each controlled GA Quality Assurance Manual, and for all subsequent changes.

The GA Quality Assurance Manual provides for a Quality Assurance Program Document for each project, in which specific functional assignments are shown for the positions of responsibility within the project. Additionally, coordination and operating details for the project are described, and the items to which the program applies are identified. The Quality Assurance Program Document is approved by the Quality Assurance Director and the project director/manager. When required by contract, approval of the GA Quality Assurance Program Document by the customer will constitute approval of the GA QA Program for that project. NRC licensing approval is required for packaging designs that are subject to 10CFR71 requirements. The subsections of this report describe the contents of policies, procedures, and instructions contained in the GA Quality Assurance Manual which assure that quality-related activities are performed with specified equipment and under suitable environmental conditions, and that all prerequisites have been satisfied prior to commencement of any such activity.

The Chairman, General Atomics has directed that compliance with the procedures of the GA Quality Assurance Manual is mandatory for all personnel performing activities affecting the quality of transport packaging and dry storage container items at General Atomics. This is communicated to GA personnel through the Company Policy Manual and the GA Quality Assurance Manual which contains a Statement of Authority signed by the Chairman of General Atomics. These Manuals are available to all personnel.

17.2.8 Controlled Conditions

Activities affecting quality are accomplished under controlled conditions. Controlled Conditions include the use of appropriate equipment and work instructions, suitable environmental conditions, and assurance that all prerequisites for a given activity have been satisfied.

17.2.9 Unresolved Issues

Unresolved issues or disputes involving quality matters are elevated to successively higher levels of management, culminating with the GA Chairman for resolution, or with the customer when external interfaces are involved.

17.3 DESIGN CONTROL

17.3.1 Design Responsibility

The GA Quality Assurance Manual establishes procedures applicable to all phases of design activity to assure controlled design of products supplied or specified by General Atomics within the scope of the program described in this report.

17.3.2 Design Input

The responsible design engineer defines and documents criteria stating the requirements to be satisfied by the design specification. These criteria include design bases, such as criticality physics, cooling, and decontamination of an item; project performance requirements; operating conditions; regulatory requirements, codes, and standards; and requirements for materials, fabrication, construction, controlled conditions, testing, operation, maintenance, rework, and quality assurance. The selection of the design input is reviewed and approved by the responsible design organization on a timely basis.

17.3.2.1 Design input is specified to the level of detail necessary to assure correct design processes and to provide a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.

17.3.2.2 Changes from approved design inputs, including the reasons for the changes, are identified, approved, documented, and controlled.

17.3.3 Design Analyses

Design analyses are performed and documented in a planned, controlled, timely manner. The documents are sufficiently detailed in the methods used to permit a technically qualified person to verify adequacy of the analyses without recourse to the originator. Documentation of design analyses includes definition of the objective of the analyses, definition of design inputs and their sources, results of literature searches, identification of assumptions, and identification of those assumptions that require verification, identification of any computer calculations and the bases supporting application of the computer program to the specific physical problem, identification of other design calculations, identification of applicable quality standards, and evidence of review and approval.

17.3.4 Identification and Control of External Design Interfaces

GA Management coordinates with the customer in identifying the interfaces between that portion of item design for which GA is responsible and those portions for which other organizations have design responsibility. GA Program/Resource Procedures Manual procedures are established for the control and documentation of technical communications across such interfaces, to assure timely and accurate transmittal and receipt of information affecting such design interfaces, to provide for appropriately scheduled design interface reviews, and to assure timely completion of review action items.

17.3.5 Identification and Control of Internal Design Interfaces

An internal design interface control function has been established which provides overall direction for design control system activities, with the authority to review and approve specified product design documents during the design phase of a project or item. The review includes coordination with representatives of Project Management; Licensing, Safety and Nuclear Compliance; and Quality Assurance, as applicable. The designated interface control function is responsible for assuring additional coordination with other representatives, who reflect different product areas, skills, and responsibilities, as deemed appropriate.

The designated interface control function is responsible for:

1. Establishing the design baselines beginning after the conceptual design phase and through final design.
2. Reviewing and approving the prime design documents for all systems and equipment items.
3. Verifying during review of prime design documents that all systems and equipment items are complete and producible; are within the scope of supply and cost parameters; and meet the established criteria for performance capability, interface compatibility, reliability, safety, and product support.
4. Reviewing, approving, and documenting all recommended additions or modifications submitted for incorporation into an established design baseline.

5. Reviewing, with the cognizant engineer, conformance of test program justification documents, test specifications, and related documents to established design baselines. They shall identify those documents that require their review.

Procedures are provided for the identification and control of interfaces relating to configuration and dimensions, processes and performance, materials, control and readout indication, testing, operation, and safety through design, fabrication, testing, and operation.

The procedures specify the level of detail to be controlled, the method of control, the control responsibility, the manner of feedback and documentation, and means of resolving incompatibilities.

The procedures cover interfaces and documentation for items supplied by GA and by its subcontractors.

The procedures provide for the action required to maintain compatibility when any interface characteristic is altered.

17.3.6 Translation of Basic Requirements Into Design Documents

It is the responsibility of the design organization to provide design criteria and system description documents that meet all safety and functional requirements. The design organization is responsible for correctly translating these requirements into specifications, drawings, diagrams, procedures, and instructions, all of which are used to control the fabrication/manufacture, testing, use, and maintenance of the products.

It is the responsibility of the cognizant design engineer to assure that all quality assurance requirements are included in the design documents to meet the applicable codes, functional requirements, and safety and licensing requirements.

The cognizant licensing engineer is responsible for coordinating licensing activities within the project. The licensing engineer reviews the safety-related aspects of the design and changes to assure conformance with NRC licensing criteria and regulations. The Licensing, Safety and Nuclear Compliance organization performs the above functions.

The cognizant engineering organization is responsible for the analysis of the design for safety and reliability. Engineering develops the safety-oriented material for the safety analysis reports, including the license technical specifications.

Quality Assurance provides review and approval of design documents to verify that:

1. Appropriate accept and reject criteria are specified.
2. The QA Level is specified.
3. Safety-related design characteristics can be inspected and controlled.

17.3.7 Application of Materials, Processes, and Parts

Materials, processes, and parts, including off-the-shelf and commercial items used in a design, are considered for suitability of application prior to selection. This is the responsibility of the cognizant design engineer or process engineer. An independent review of the materials and processes to be used in safety-related applications is provided by draft review or a design review board. All design documents for safety-related systems, structures, and components, including off-the-shelf commercial items, are reviewed and/or approved by Quality Assurance and comments are resolved with the cognizant engineer/originator. Procurement requisitions for these items are reviewed and approved by Quality Assurance.

Commercial grade or off-the-shelf items which have been upgraded and dedicated for a safety-related application are identified with a GA part number which is traceable to the upgrade documentation.

The suitability of all parts, materials, and processes is reviewed during the independent review of the design.

17.3.8 Verification of Design Adequacy

The adequacy of the design of transport packages licensed in accordance with 10CFR71, is independently verified. Verification of design adequacy may be accomplished by any one (or combination) of the following methods: design review; checking of analyses by alternative calculation methods, or by performance of qualification testing. When a test program is used to verify the adequacy of a design, a qualification test of a prototype unit under the most adverse design conditions will be used. The method of independent verification is specified for review in the review transmittal form by the cognizant design engineer; for alternate calculations, a calculation review report is used; and for qualification testing, by a

test specification. Verification addresses adequacy in such areas as stress, thermal, health physics, accident analysis, compatibility of materials, accessibility for inservice inspection, maintenance and repair, and delineation of acceptance criteria for inspection and tests.

Persons or organizations performing the independent verification of design adequacy are technically qualified individual(s) or group(s) who have an adequate understanding of the requirements and intent of the design and are independent of those who performed or directed the original design, but may be from the same organization. The design engineer's immediate supervisor may perform the verification, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or, provided the Supervisor is the only individual in the organization competent to perform the verification. (See Table 17-2, Note 1b).

Independent verification reports and supporting attachments become part of the approval package and of the permanent record. Any deficiencies reported in the verification are resolved by the cognizant engineer to the satisfaction of the verifier and the cognizant engineering manager, with appropriate corrective action taken.

17.3.9 Quality Assurance Classifications

As a part of the design control process, the cognizant design engineer will note the Quality Assurance Level (QAL) designation on design documents used for the procurement, fabrication/manufacturing, installation, test, and/or inspection of safety-related and nonsafety-related items. The decision process for selecting and applying the necessary and appropriate QA Program requirements and procedural controls for achievement of quality is accomplished using a multi-level QA classification system based on 1) classifying each component, structure and system as safety-related or non-safety-related ("Q" or "non Q"), 2) grouping items classified as safety-related into quality categories, and 3) specifying a level of quality assurance effort applicable to each category.

Components, structures, and systems appearing in the latest design documents are analyzed to determine whether their functions or physical characteristics are essential to safety. Quality categories are established based on the relative safety significance of each "Q" item and its appropriate subcomponent parts. Categories are identified as QA Level (QAL) I-A for items that are critical to safe operation, QAL IB for items with a major impact on safety, and QAL IC for items with a minor impact on safety. QAL II is for items that are non-safety-related, but have a high economic or reliability impact on performance. QAL III is for all other items with a non-critical application.

QAL IA (Critical) – Packaging items whose failure or malfunction could result directly in a significant condition adversely affecting public health and safety. This includes such conditions as loss of primary containment with subsequent release of radioactive materials, loss of shielding or an unsafe geometry compromising criticality control.

QAL IB (Major) – Packaging items whose failure or malfunction could lead to circumstances that could require QAL IA items to perform their safety-related function. Failure or malfunction could indirectly result in a condition adversely affecting public health and safety. An unsafe condition could result only if the primary event occurs in conjunction with a secondary event or other failure or environmental occurrence.

QAL IC (Minor) – Packaging items whose failure or malfunction would not significantly reduce the package effectiveness and would be unlikely to create a condition adversely affecting public health and safety.

QAL II – Any non-safety-related item where failure or malfunction could cause a significant reduction in the required performance. (Economic and Reliability). Items selectively chosen because of special programmatic importance other than radiological safety.

QAL III – All other items non-critical applications.

Quality Assurance reviews the classifications applied by Engineering to design documents.

17.3.10 **Design Changes**

Changes to all released design documents, including field changes and modifications, are processed by controls commensurate with those implemented for the original release, including an evaluation of the effects of the changes on the overall design.

All changes to released design documents, except non-technical changes such as spelling corrections, require approval of Quality Assurance. This approval signifies that the necessary quality requirements associated with the change have been provided or planned for.

Approval and release of changes to released design documents are based on the following guidelines:

1. The necessary interface requirements have been evaluated.

2. The necessary engineering analysis and review actions have been performed.
3. The documented evidence of the above has been completed and is included in the document review report or approved change notice file.
4. The necessary quality requirements associated with the changes have been provided.
5. All configuration control lists affected by the change will be revised.

17.3.11 Design Document Errors and Deficiencies

Errors or deficiencies discovered in design documents prior to their release are documented on review forms and may be supplemented by markups of the draft documents. Resolution of such items is required before the document or drawing is released. When a significant design change is necessary because of an incorrect design, the design process is reviewed for corrective action, as described in Section 17.16. Deficiencies that result from design document errors and that are identified during fabrication/manufacture or installation are documented, and initial corrective action is taken by revision and approval of the appropriate design documents and procedures, as described in Sections 17.15 and 17.16, respectively. Additionally, prompt corrective action to rectify design control system deficiencies documented during Quality Assurance audits, as described in Section 17.18, is provided by the organization responsible for the deficiency.

17.3.12 Design Document Release and Configuration Control

The release of all design documents is the responsibility of the releasing function of the cognizant engineering organization. A "Release" stamp on design documents signifies that the design, as represented on the document, is authorized for procurement, fabrication, or test.

All design documents, including changes, required to define the project configuration are recorded in a listing of required design documents. The design document listing, communicated to all working levels on a periodic basis as changes occur, represents the official basis for monitoring, fabrication/manufacturing, and constructing. The design documents comprising the design of a transport package for radioactive materials subject to requirements of 10CFR71 are indicated in the associated licensing documentation. Incorporation of approved changes in the design document listing is accomplished by the designated release authority. Appropriate task sections of the design document

listing in which design changes are reflected are distributed to organizations whose work is affected by the changes.

17.3.13 Documentation and Records

Design documentation and records which provide evidence that the design and design verification processes were performed in accordance with specified requirements, are collected, stored, and maintained in accordance with Section 17.17.

Suppliers and subcontractors are required to establish and implement applicable controls equivalent to those described in this section.

17.4 PROCUREMENT DOCUMENT CONTROL

Supplier bids are reviewed by the Project and QA to evaluate technical considerations; quality assurance requirements; the supplier's production capability, past performance and personnel; changes recommended and exceptions taken by the supplier; and effects of the changes and recommendations on the procurement. Unacceptable issues are resolved prior to award.

The procurement of items and services is initiated by Purchasing for deliverable items upon receipt of a Procurement Requisition (PR) under controlled procedures. To assure that the scope of work, applicable regulatory requirements, design basis technical requirements, and quality assurance requirements are included in the procurement documents, all identifiable requirements applicable to a procurement are included by the originator, either by reference or on the face of the PR. The extent of 10CFR71 Subpart H requirements depends on the type, use, and safety attributes of the item or service being procured. Commercial off-the-shelf or catalog items procured for a safety-related application are upgraded to safety-related by a dedication process of inspections, evaluations, and/or tests pertinent to the item's intended use. Such items are procured as nonsafety-related items and identified as safety-related after successful completion of the dedication process.

Test and inspection, objective evidence documentation, supplier nonconformance dispositions, and other QA requirements relative to GA design documents are prescribed in procurement specifications or directly on the procurement document and indicate those records to be retained, controlled, and maintained by the supplier and those to be delivered to GA prior to use or installation of the item.

Requirements for GA's and the customer's access to the supplier's facility and records for source inspection, surveillance, and audits are prescribed in procurement specifications or on the procurement documents.

Prior to transmittal to Purchasing, all safety-related PR's for items and services, including safety-related replacement parts, are approved by signature and/or stamp of a representative of Quality Assurance who is knowledgeable of the procurement requirements. The purpose of this review is to (1) verify that the referenced design document(s) and/or specification(s) are released prior to work being performed on the item, and (2) assure that all necessary quality assurance requirements are accurately stated. Documentary evidence of Quality Assurance review of QAL IA safety-related procurement documents is maintained by Quality Assurance. All identification, regulatory, technical, and QA requirements are transcribed to procurement documents under the direction of the assigned Buyer. Prior to

release to the supplier, the applicable buyer assures that the PR information is accurately transcribed to the Purchase Order (PO).

Written QA programs are required from suppliers of QAL IA & IB safety-related items and services under conditions described in Section 17.7 of this report, and are reviewed and approved by Quality Assurance for the requirements applicable to the supplier's scope of activity.

Changes to the requirements imposed on a supplier are initiated by describing the change or referencing a changed product description document (such as a drawing and/or specification) on a PR Change Order. The PR's that make changes to the technical or QA requirements are reviewed and approved by the same organizations that reviewed and approved the original PR. The applicable Buyer verifies that the PR change is accordingly transcribed to a PO Change Order. GA procurement personnel do not have the authority to change the technical or quality requirements contained in procurement documents, *without the approvals specified above.*

Suppliers and subcontractors are required to establish and implement applicable controls equivalent to those described in this section.

17.5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting the quality of GA products and services within the scope of the Quality Assurance Program described in this report are accomplished in accordance with written procedures, instructions, or drawings appropriate to the type of work. The GA Quality Assurance Manual (QAM) describes the controls that apply to each category of work, in terms of quality assurance levels. The procedures in the QAM describe the methods established at GA for complying with each of the criteria of 10CFR71 Subpart H, ASME NQA-1, and this report. Table 17-1 identifies the procedure that implements each criterion.

The Quality Assurance Program Document (QAPD) for each specific project identifies which level of controls applies to which items and services being produced by the project, what procedures and/or sections of procedures are to be used, where responsibility lies for each of the controls, and what unique contractual requirements may exist. QAPDs are approved as indicated in Section 17.2.7 of this report.

As key documents in the system, product-description documents, work-authorizing documents, and instruction documents define or reference the nature and sequence of operations as well as quantitative and/or qualitative acceptance criteria for each component, system, and structure. The purpose and controls of these documents are further described in Section 17.6 of this report. The use of these key documents is assured by Quality Assurance personnel who verify compliance. Assurance that all activities affecting quality are documented and performed as documented is achieved by audit of the QA Program by the Quality Systems organization of QA, as well as by the customers or their agents.

Suppliers and subcontractors are required to establish and implement applicable controls equivalent to those described in this section.

17.6 DOCUMENT CONTROL

Documents that establish the product or service description and quality requirements, or that prescribe operations to determine compliance of products or services with those requirements are subject to control measures implemented by procedures contained in the GA Quality Assurance Manual.

Document types subject to these controls include:

1. QA manuals and procedures.
2. Design documents (e.g., drawings, specifications, calculations, computer programs and associated documentation, etc.) and design change notices.
3. Fabrication/manufacturing and inspection instructions.
4. Procurement documents.
5. Test specifications, procedures, and reports.
6. Nonconformance reports.
7. Corrective action requests.
8. Maintenance and modification procedures.
9. Loading and unloading procedures.
10. Packaging for transport procedures.

To assure that it is clear, accurate, and authorized, each document is reviewed for adequacy by knowledgeable personnel in the originating organization and is approved for release by the appropriate authorized individual(s). In addition, prior to release, each such document is reviewed and/or approved by Quality Assurance personnel who are cognizant of the applicable quality requirements, to verify accuracy and completeness of quality requirements in the document, identification of safety-related characteristics, presence of acceptance criteria, unique identification, etc. Review comments are resolved prior to release of the document, and the comments and their resolutions are documented for the record.

Approval of the document by Quality Assurance signifies that the control requirements applicable to the document have been satisfied and that the document is acceptable for its intended use. Review and/or approval is indicated by signature or stamp on the document, or on the design review transmittal for drawings and specifications as described in Section 17.3 of this report. Changes to the documents are accomplished in accordance with configuration control procedures and are reviewed and/or approved by the same organizations, including Quality Assurance that performed the original review and/or approval. Reviewing organizations have access to pertinent background data or information upon which to base their review and approval.

Planning documents which provide instruction for fabrication/manufacturing operations are reviewed by the cognizant quality engineer. Such review assures that the document identifies all applicable quality requirements and the governing design documents.

The initial release and distribution of these documents and their changes to the location where the activity is performed are the responsibility of a designated releasing authority. The releasing authority is also responsible for directing the user as to the disposition of obsolete or superseded documents previously issued. The user is responsible for verifying that he is using the correct version, as follows:

Each document, which is uniquely numbered, is identified on a controlled list or lists that indicate the current revision letter or number to facilitate, in a timely manner, verification of use of the correct revision of a document. The lists are updated as documents are changed and reissued. Design document changes that occur between issues of the lists are permitted when supported by approved change notices.

Use of released documents is verified by QA during routine inspection operations and by conducting periodic audits or surveillances.

Suppliers and subcontractors are required to establish and implement applicable controls equivalent to those described in this section.

17.7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

Procurement planning is accomplished as early as practicable in order to assure interface compatibility and a uniform approach to the procurement process.

The supplier's QA organization shall have the authority and responsibility for establishing, planning, and implementing the required quality program. No single organizational pattern is mandatory. However, an organized approach that clearly defines the authority and duties of all persons involved in the quality program is required.

The supplier's QA personnel shall have sufficient organizational freedom to identify quality problems; initiate, recommend, or provide solutions; and verify implementation of solutions. This freedom shall include authority to control further processing, delivery, or installation of a nonconforming item, deficiency, or unsatisfactory condition until proper dispositioning has occurred.

In addition, the person or organization responsible for the quality program shall have direct access to responsible management at a level where action can be taken, shall be independent from the pressures of production, and shall report periodically to responsible management on the effectiveness of the program.

17.7.1 Evaluation of Supplier Capabilities

Suppliers¹ of safety-related materials, items, equipment, or services must be approved by QA as capable of complying with the requirements that are applicable to the procurement. Such approval must precede placement of the procurement action, and consists of one of the following:

For QAL IA Items:

1. Pre-award survey of the supplier's facilities and QA program by qualified GA QA personnel to determine the supplier's capability to comply with applicable elements of 10CFR71 Subpart H. Surveys evaluate the supplier's facilities, personnel, and QA Program implementation.

¹ Suppliers in this section include licensees and co-developers who provide services and/or test data for GA use and who have a contractual agreement with GA. Other licensees and co-developers are controlled by our mutual customer and their services and data are accepted by GA as customer-furnished information.

2. Evaluation of the supplier's previous performance. If GA has actively procured a supplier's hardware or services involving GA QA requirements from a supplier's plant during the year preceding the expected date of award of a new order for procurement actions requiring supplier evaluation, the performance demonstrated by the supplier during the period is evaluated by the responsible quality engineer for applicability to the hardware or service to be procured.

3. Existence of an appropriate ASME Certificate of Authorization. For ASME Code stamped items, a Certificate of Authorization by ASME, applicable to the item to be procured, with an expiration date consistent with the procurement time frame, is used as the basis for supplier selection. For Material Manufacturers or Suppliers, an ASME Quality System Certificate (Materials) may be used for selection of suppliers of materials within the scope of the certificate.

Evaluations described in the foregoing paragraphs include the supplier's compliance with requirements relating to such operations as calibration, welding, nondestructive and properties testing, inspection, personnel and procedure qualification, heat treating, quality assurance records, and auditing. These documented evaluations are used as a basis for the selection of the supplier and listing the supplier on the QA Approved Suppliers List. The status of each supplier is updated at least annually based on supplier performance revealed through inspection results, re-evaluation of the supplier's QA Program, or audit of the supplier's implementation of his GA-approved QA Program.

In the event it is necessary to process procurement documents to a supplier who is not fully approved, specific provisions to assure full quality requirements compliance must be specified in the procurement documents. Such procurement documents must be approved by the GA Quality Assurance Director.

For QAL IB Items:

1. Procurement of materials and services shall be from a supplier whose QA Program has been verified by the Project QE, or designee, to meet the applicable sections of 10CFR71 Subpart H as commensurate with the items or services rendered.

For QAL IC Items:

1. Suppliers and Sub-tier suppliers should have a QA Program commensurate with the item or services rendered.

17.7.2 Source Quality Assurance Operations

GA's quality assurance activities at suppliers, when required, are planned, witnessed, and audited by Quality Assurance to verify continued and proper use of the required quality assurance capabilities as well as to assure conformance of supplier products to procurement document requirements. Depending on the complexity, quantity, or relative importance or application of the end use of the supplier's product, QA source activities are defined in a source inspection planning document written and approved by the cognizant quality engineer. This document identifies the characteristics to be inspected or tested, the methods to be employed, and documentation required. Mandatory quality assurance activities at the source are established with the supplier to assure that planned coverage is accomplished prior to formal release of the product for shipment. Source activities performed by GA personnel do not relieve the supplier of his responsibility to verify quality achievement. Quality Assurance audit activities at the supplier's plant, as described in Section 17.18 of this report, include verification that the supplier's quality assurance activities produce documented evidence of compliance with requirements of the procurement documents and compliance with the documented procedures that control the operations performed. GA QA activities at a supplier's plant are performed by QA inspectors, QA representatives, or quality engineers. On occasion, other personnel who have been appropriately trained and qualified are utilized for QA activities if GA QA has determined that they can and will be able to operate independent from management pressure. GA may use approved consultants to perform activities at its suppliers when deemed appropriate.

Prior to release of the supplier's product for shipment, or during receiving inspection at GA, the supplier's quality records are reviewed for compliance with requirements of the procurement documents. Where supplier certificates of conformance are the specified documentation, validity of the certificates and effectiveness of the supplier's certification system are verified at intervals by independent inspection or test of items that have been so certified, or by GA audits of the supplier in accordance with Section 17.18 of this report. Intervals are determined on the basis of the supplier's past quality performance.

Copies of quality records are obtained, or record delivery commitment dates are established, to provide assurance that the records are available at GA prior to installation or use of the supplier's product. The supplier's product is released on a GA Work Release form, prepared and approved by the GA QA representative, which signifies GA's approval for shipment to the receiving organization. Omitted or incomplete operations and documentation are identified on the Work Release directly or by reference to a

Nonconformance Report (NR) or Supplier's Disposition Request (SDR). NRs or SDRs with GA QA approved disposition actions not completed at the supplier's plant are also referenced on the Work Release to assure completion at the point of delivery. A copy of the Work Release form is sent to the QA organization (GA or other) at the point of delivery to assure that the open items are identified and accomplished prior to use.

As a minimum, the Work Release form accompanying the item to the point of delivery will provide the following information:

1. The procurement document and change order to which the item was manufactured.
2. The engineering design document and applicable revision that defines the product.
3. A listing of all undispositioned and "open" NRs and SDRs, if applicable.
4. A unique identifier of the specific source inspection plan(s) used.
5. The GA QA representative's signature, which provides certification and approval that all the required GA operations have been performed, or omitted operations and documentation are as noted on the Work Release.

17.7.3 Destination Quality Assurance Operations

As a minimum, materials, parts, components, and systems are inspected at the point of delivery for identification, damage, and documented evidence of prior source acceptance of the item by a GA QA representative according to instructions specified and documented by the cognizant quality engineer. If not previously reviewed by GA at the source as evidenced on a Work Release form, the records prescribed by the procurement document and documents referenced therein are reviewed at the point of delivery to assure that the results show compliance with the applicable acceptance criteria. Prior to release of the supplied item for use, the receiving inspector documents on a controlled receiving inspection plan the operations he performed, as well as his acceptance of the item delivered. Accepted items are tagged or otherwise identified to indicate the inspection status and are forwarded to a controlled storage area or released for installation or further work. Whenever possible, nonconforming items are held in a segregated or controlled area, their status clearly identified by tagging or other appropriate means, and with the appropriate documentation, until final disposition is made.

Suppliers and subcontractors are required to establish and implement applicable controls as described in this section.

17.8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

Requirements for the identification of materials, parts, and components are established during design and are recorded or referenced on the drawing or specification. Methods and materials that provide legible markings not detrimental to the item are used.

The degree of identification, such as heat number, lot number, serial number, part number, or specification number, provided on the drawing or in the specification is such as to assure material or item traceability to drawings, specifications, or work documents from receipt of raw material through fabrication, final inspection, receipt inspection, delivery, end use, or until the item is consumed, as applicable.

Compliance with identification requirements is verified and documented by receiving, in-process, and source inspection personnel, according to QA instructions. Documents referenced or requirements contained in the procurement documents require suppliers of QAL IA & IB safety-related equipment to establish and implement methods for the identification and control of materials, parts, and components consistent with 10CFR71 Subpart H, and GA requirements.

17.8.1 Materials

For GA-fabricated/manufactured items, raw materials such as metal sheets, plates, bars, forgings, and castings are identified by heat number or heat code marked on the material, when required by drawing or specification. Virtually all such raw materials are procured to an end-use part number, which is identifiable on the Purchase Order. Similarly, welding filler materials and brazing materials are controlled and identified.

Age-sensitive materials, such as elastomers or epoxies, are marked to indicate the date when useful life began and/or the date when useful life will expire. Such materials are preserved and stored in accordance with governing specifications and the expiration date shall be controlled by the cognizant quality engineer.

The activities associated with material identification are inspected and audited by Quality Assurance to assure proper implementation of the requirements.

17.8.2 **Parts and Components**

GA-fabricated/manufactured items, parts, and components are identified with unique part numbers marked on the item or in documents traceable to the item, as prescribed on the drawing or specifications. Each level of assembly completed is identified by a part number. Fabrication, process, and inspection documentation is identified by the batch, part, component, serial, and/or heat numbers and traveler numbers, where such identification is necessary to provide traceability to the specific item fabricated, processed, or inspected. These activities are inspected and audited by Quality Assurance to assure proper implementation of the requirements.

Suppliers and subcontractors are required to establish and implement applicable controls equivalent to those described in this section.

17.9 CONTROL OF SPECIAL PROCESSES

Special processes, such as welding, brazing, heat treating, and nondestructive testing are controlled, as required, by the applicable GA process specifications. Where the design requires the use of a special process, the applicable design document specifies the process and the acceptance criteria. Special processes will be performed in accordance with written controlled procedures which specify process parameter controls, applicable environmental conditions, acceptance criteria, the equipment to be used when specific equipment is required, and personnel, process, or equipment qualifications necessary for special processes not covered by existing codes and standards, or where quality requirements for an item exceed those of existing codes and standards. Procedures or instructions are reviewed and approved by cognizant Quality Assurance personnel, as indicated by signature or stamp, and means are provided for recording evidence of verification of compliance in the application of these processes.

Personnel who perform special processes are qualified and certified as indicated in Section 17.2.5 of this report. Results of examinations and other data demonstrating that GA's special process procedures, equipment, and personnel satisfy established qualification criteria are maintained in active, current files by Quality Assurance. The Quality Systems organization monitors and accumulates the records of annual eye examinations for all inspection personnel, monitors and accumulates the triennial requalification records of NDE and inspection personnel, and provides notification of approaching re-examination dates.

Suppliers and subcontractors are required to establish and implement applicable controls equivalent to those described in this section.

17.10 INSPECTION

Inspection activities, including source inspections, are performed by Quality Assurance personnel or other independent personnel who have the experience or training commensurate with the scope, complexity, or special nature of the activity. All personnel performing acceptance inspections are qualified according to ASME NQA-1 as endorsed by Regulatory Guide 1.28, Revision 3. The inspector qualification and certification process is described in Section 17.2.5.

For GA procured items, the QA activities necessary to verify compliance with procurement documents are described in sequence in source inspection plans and receiving inspection plans prepared by the cognizant quality engineer. For GA fabricated items, detailed instructions or procedures (travelers or inspection plans) prepared and/or approved by Quality Assurance are used to integrate inspection operations with fabrication operations and provide the required in-process inspection and final inspection instructions.

These inspection planning documents provide for identification of the item and the quality characteristics to be inspected; verification that any prerequisites have been satisfied, including completion or receipt of required documentation; the accept or reject criteria; a description of the inspection method, when appropriate; recording objective evidence of inspection results; documenting serial numbers of Nonconformance Reports and Supplier's Disposition Requests for which discrepancies are noted, and their eventual clearance; customer or QA hold or witness points; identification of the inspector at each line item of the inspection planning document, and date the inspection was performed; and the acceptance status of the item.

The inspector checks to assure that the device or instrument to be used is of the proper type, range, and accuracy to accomplish the inspection and meets calibration interval requirements. Completed inspection planning documents are reviewed and approved by the cognizant quality engineer or QA Manager.

The Nonconformance Report, Supplier's Disposition Request, and Material Review Board (MRB) controls described in Section 17.15 of this report are used at the customer's facility, at GA, and by the supplier to assure proper disposition of discrepant items and to assure that the items are inspected and accepted to the appropriate design requirements.

Rework and repairs made after the initial inspection or test are inspected by QA personnel or tested by the responsible organization in accordance with the original method and acceptance criteria, or

as described in the disposition description on an approved Nonconformance Report or Supplier's Disposition Request (Section 17.15). Replacement items are inspected by QA personnel in accordance with methods and acceptance criteria specified for the original item. Modifications are inspected as prescribed by the released design documents for the modified items.

If direct inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel is conducted by Quality Assurance. Both inspection and process monitoring are used when control by one is inadequate, to assure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process.

Accepted items are tagged in accordance with Section 17.14 and controlled in accordance with Section 17.13 of this report until they are placed in stock or issued for use. Maintenance inspections are performed at established intervals in accordance with applicable procedures.

A Quality Assurance Work Release is used when GA inspection is required to verify that all quality requirements listed on the drawings, specifications, and purchase orders have been accomplished prior to product shipment to the customer. A QA Work Release is generated by cognizant GA QA personnel for all GA deliverable items to release them for shipment.

As a minimum, the Work Release form used to release deliverable items for shipment and accompanying the item(s) to the point of delivery will provide the following information:

1. The customer's procurement document number and/or contract number to which the item was fabricated/manufactured.
2. The engineering design document and applicable revision that defines the product.
3. A list of all unapproved discrepancy reports (customer concurrence to ship may be required by contract).
4. A list of all Nonconformance Reports or Supplier's Disposition Requests with a disposition of "Use-As-Is" or "Repair."
5. The final inspection condition of the item.

6. The cognizant GA QA person's signature.

Inspection records are controlled as described in Section 17.17 and identify the (1) item inspected; (2) date of inspection; (3) inspector; (4) type of observation; (5) results or acceptability; (6) reference to information on action taken in connection with nonconformances; and (7) applicable controlling document identification and revision.

Suppliers and subcontractors are required to establish and implement applicable equivalent controls as described in this section.

17.11 TEST CONTROL

17.11.1 Hardware Testing

Required testing is prescribed by the cognizant design engineer. The design engineer specifies the type of testing (e.g., design verification, qualification, or production acceptance) and the applicability to a design or design feature. Testing requirements are documented in test specifications and procedures. Testing is performed in compliance with released specifications, drawings, and procedures.

Test specifications contain the following, as appropriate:

1. Objectives of the test.
2. Quality Assurance Level.
3. Test data to be determined.
4. Points of measurements.
5. Ranges of measurements, accuracy required, and requirement that instruments be in current calibration.
6. Operating conditions and limitations.
7. Safety considerations.
8. Test specimen configuration.
9. Test environment and conditions.
10. Requirement that test results shall not be averaged, deleted nor omitted from the record (unless specifically required or allowed by the test specification).
11. Acceptance limits or an explanation of how test results are to be evaluated and reported as acceptable or not acceptable. For example, certain test results may be compared to stated acceptance limits and noted as acceptable by test personnel. Other test results may require calculations or evaluations by the design engineer. The requirements for evaluating and reporting final results and conclusions shall be included in the test specification.
12. Special skills or knowledge over and above that normally expected shall be identified, along with necessary training or qualification requirements.
13. Description of the test records to be submitted upon completion of the test. The records shall include the test performance copy of the test procedure, necessary supporting sketches and calculations, and if used, the test operation log. The test records shall be required to be adequate to demonstrate completion of the test and completion of evaluation of the results of the test.

Test procedures contain the following, as appropriate:

1. Reference to the applicable test specification.
2. Selected technical requirements, restraints, and acceptance limits contained in the applicable specification.
3. Pre-test inspections and/or testing.
4. Prerequisites for the test operations, including:
 - a. Appropriate equipment and adequate test instrumentation calibrated and of the required condition, range, and accuracy. Assurance that such instrumentation is available and is used.
 - b. Trained personnel.
 - c. Provisions for acquisition and documentation of required data.
 - d. Suitable environmental conditions.
 - e. Acceptable condition of the item to be tested.
5. Description of test rig setup, including:
 - a. A list of test articles, test equipment, facilities, instruments, cameras, etc. for the test rig.
 - b. Applicable reference documents such as instrumentation diagrams, calibration procedures, etc.
 - c. The method for checking out the test rig, including calibration of instruments and control settings.
6. The Quality Assurance Level.

7. Requirement for producing records, in addition to the test operation log, such as data sheets, charts, notebooks, instrument recording methods, and photographic methods.
8. Test methods, including:
 - a. Procedural steps required to accomplish the test.
 - b. Lists of parameters to be recorded for each test condition.
 - c. Precautionary and safety measures to be taken by the test operator.
 - d. Post-test instrumentation calibration and parameters to be recorded.
 - e. Acceptance requirements for completion or termination of the test.
9. Quality Assurance participation, including appropriate "hold" points, necessary monitoring, and verification of test results.
10. Protective maintenance requirements.
11. Post-test inspections and/or tests.

The test procedure is prepared by the test engineer. Quality Assurance review assures the test procedure includes the appropriate items noted above.

Upon completion of the test, a test report is prepared to describe the results of the test. The test report may range from a one page data sheet for a routine production acceptance test to a voluminous report for a major test. However, as a minimum the test report contains:

1. A description of the test, referencing the test procedure number, revision, test equipment identification, and location.
2. The results of the test, such as required data sheets, graphs, charts, and nonconformance reports.
3. The approval signature of the test engineer.
4. Reference to pertinent GA lab notebooks, test records, equipment logs.
5. Description of the equipment used and serial numbers.

6. Description of the test parameters and test results.

The test report (or separate evaluator report) contains an evaluation of the test results. For example, if the test data must be evaluated by the design engineer, the test records must contain the results of his evaluation, indicating whether or not the results were acceptable. If not acceptable, a Nonconformance Report will be processed for qualification or acceptance tests.

Modifications and retesting are accomplished as necessary to assure satisfactory performance when testing indicates modification to an item is required in order to obtain acceptable performance. Further, such modifications and retesting follow the same control procedures as for the original test, and the test report includes a complete description of the modifications.

17.11.2 Computer Program Testing

Computer program test requirements and acceptance criteria are provided for existing computer programs, or approved for new computer programs by the computer program custodian and documented in the Validation Document for that computer program in accordance with the requirements of the Program/Resource Procedures Manual (P/RPM). Computer program tests including, as appropriate, verification tests, hardware integration tests, and in-use tests are controlled. Test requirements and acceptance criteria are based upon the computer program's applicable design or other pertinent technical documents.

Test Specifications and Procedures. Test specifications and/or procedures specify the following, as applicable:

1. Required validation tests and test sequence.
2. Required ranges of input parameters.
3. Rationale for establishing test cases.
4. Acceptance criteria.
5. Requirements for computer platform integration
6. Required reports and records.

Test Results. Test results are documented in the Test Report. Verification test results shall be evaluated by a responsible authority to assure that test requirements have been satisfied in accordance with the independent review requirements of the P/RPM.

The validation test results shall be documented in test reports and shall include:

1. PIN
2. Computer program name and version tested.
3. Computer platform used.
4. Validation test problems (input/output).
5. Results and acceptability.
6. Action taken in connection with any deviations noted.
7. Conclusions

Testing of Procured Computer Programs. The computer custodian or cognizant engineer evaluates the validation documentation, if available, to verify that it is comparable to the above requirements or that additional validation is necessary. The documentation review, evaluation, and test results are documented and include a record of comments and their resolution, deficiencies identified, and corrective action, if any.

Suppliers and subcontractors are required to establish and implement applicable controls equivalent to those described in this section.

17.12 CONTROL OF MEASURING AND TEST EQUIPMENT

Measuring and test equipment used for inspection acceptance of products fabricated/manufactured or tested by GA are identified with unique numbers which are recorded on calibration records maintained by the QA calibration laboratory. Each record documents the frequency of calibration specified in the controlling quality procedure, the calibration history, and maintenance actions taken. Items are calibrated periodically by the QA calibration laboratory or a QA-approved supplier of calibration services in accordance with predetermined calibration intervals based on frequency of use, required accuracy, stability characteristics, and other conditions affecting measurement control. The records are arranged by a computerized system to recall-for-calibration dates to effect recall of equipment not submitted at the specified intervals. When equipment size permits, a calibration sticker is attached as visual evidence of calibration and the due date of the next calibration; otherwise, the calibration sticker is affixed to the equipment container.

External suppliers of calibration services are evaluated for QA approval as described in Section 17.7 of this report (i.e., by facility survey) to determine if the facility has the required capability to meet the accuracy requirements and has a suitable control system in place to assure validity and traceability of its calibrations. Periodic audits verify that this capability is maintained.

External facilities that calibrate standards furnish a certification document that identifies the calibrating standards used and their accuracies. These documents are maintained by the QA calibration laboratory.

Calibration is performed against standards of known accuracy. Standards have an accuracy of at least four times the required accuracy of the equipment or standard being calibrated, or when this is not possible, have an accuracy that ensures the equipment or standard being calibrated will be within the required tolerance. Standards traceable to the National Institute of Standards and Technology (NIST), or other nationally recognized standards as appropriate, are used when they are reasonably available to industry. When such standards are not available, the method of calibration used is documented and retained in the calibration files. Calibration is performed under environmental conditions commensurate with equipment accuracy requirements.

If an instrument is found to be out of calibration, the responsible quality engineer or designee conducts and documents the results of an investigation to determine the validity of previous inspections, the quality status of items previously measured with the unacceptable instrument, and the need for performing additional inspections.

Suppliers and subcontractors are required to establish and implement applicable controls equivalent to those described in this section.

17.13 HANDLING, STORAGE, AND SHIPPING

Requirements for handling, storage, shipping, cleaning, and preservation are specified on drawings, specifications, and procurement documents during the design phase or prior to procurement of the item. Radioactive material transport containers are designed, tested, and licensed by the NRC in accordance with requirements stipulated in 10CFR71 and associated governing codes.

The cognizant design engineer is responsible for defining the measures for special packaging, shipping, storage, and handling of materials and products in accordance with governing code and regulatory requirements or other requirements which he determines will provide equivalent protection and control. These measures are intended to prevent loss, damage, deterioration, degradation, and substitution and specify any necessary provisions for special handling, lifting, markings, or protective environments.

Verification of inclusion of the appropriate quality requirements in design documents, procurement documents, packaging and handling procedures, shipping procedures, and instructions is accomplished by Quality Assurance review of the particular document involved as described in Sections 17.3, 17.4, and 17.6 of this report.

For GA fabricated/manufactured items, handling, storage, and shipping requirements are translated into appropriate work instruction documents such as travelers, inspection plans, and procedures by the appropriate organizations responsible for preparing them. The inspector or QA representative inspects those characteristics called out in the work instruction for compliance with procedures and design documents at GA or at the supplier's facility, during receiving inspection, or prior to shipment to the customer, as appropriate. For items containing radioactive material, the cognizant design engineer and Licensing, Safety, and Nuclear Compliance (LSNC) organization specify requirements in design documents. The appropriate procedure-preparing organization incorporates the requirements in the implementing instructions and procedures. Such documents comply with appropriate provisions of the governing state and federal regulations concerning the handling and transportation of radioactive material.

Suppliers and subcontractors are required to establish and implement applicable controls equivalent to those described in this section.

17.14 INSPECTION, TEST, AND OPERATING STATUS

The inspection, test, and operating status of items and materials is indicated by the application of appropriate dated stamps and/or attaching tags, where practicable, to the controlling documentation or item. The tags are imprinted "Accept" (final), "In-Process Acceptance," "Hold" or "Notice of Discrepancy" (for limited processing of discrepant items) or "Reject." Stamps and/or tags assure that the required inspections and tests are performed and that the items which have not passed the required inspections and tests are not inadvertently installed, used, or operated. Tags are validated by the cognizant QA inspector's signature and stamp, and the date it was applied. Completed work document (e.g., traveler) activities are validated by the cognizant QA inspector's stamp and the date it was applied.

"Accept", "In-Process Acceptance", and "Notice of Discrepancy" tags are applied only by QA personnel; "Hold" and "Reject" tags are applied and removed only by QA personnel.

Quality Systems is responsible for the design, control, and issuance of inspection, welders, machinists, manufacturing engineering personnel, and quality engineering stamps and inspection status tags.

Suppliers and subcontractors are required to establish and implement applicable controls equivalent to those described in this section.

17.15 CONTROL OF NONCONFORMING ITEMS

A nonconformance report system is used by GA under the control of Quality Assurance to document discrepancies and to obtain authorized dispositions when materials, items, activities, or associated documentation are found to deviate from drawings, specifications, Quality Assurance Manual, or contract requirements. The accountability of these reports is achieved by recording their serial numbers on the traveler, inspection plan, or other QA-approved work instruction documents.

When a nonconformance is first detected, Quality Assurance personnel immediately attach a Hold tag to the item(s), where practicable. The Hold tag identifies the item as being nonconforming and indicates that the nonconforming item is to be withheld from normal production channels to prevent installation or use. The discrepancy is recorded on a Nonconformance Report (NR) by Quality Assurance personnel. The cognizant inspection supervisor or quality engineer consults with predetermined qualified people of other departments to evaluate the discrepancy and arrive at an approved disposition. Personnel performing evaluations to determine a disposition have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information. Dispositions provided are "Use-As-Is," "Rework," "Repair," "Reject," and "Return to Supplier." The terms "Use-As-Is," "Repair," and "Rework," as used by GA, are as defined in ASME NQA-1 as endorsed by Regulatory Guide 1.28, Revision 3.

The Material Review Board (MRB) is a board of engineers chaired by a QA representative that must approve all "Use-As-Is" or "Repair" dispositions of nonconforming items. The Board is comprised of representatives technically qualified and knowledgeable in the engineering nature and end use of the nonconforming item(s).

The need for corrective action is determined on an individual basis by the cognizant quality engineer who documents the cause and corrective action on the NR. The quality engineer evaluates corrective action implementation and records the results in the applicable quality trend report.

Suppliers use the GA Supplier's Disposition Request (SDR) form to request GA review of "Use-As-Is" or "Repair" consideration of discrepant items, or to request modifications to design requirements. Suppliers forward the completed SDR to GA with supporting detail sufficient to permit a proper judgement to be made. Quality Assurance representatives may use the SDR to initiate action on nonconformances identified during their source inspection activities relative to procurements.

Rework and repair are accomplished in accordance with a Traveler, the NR disposition, or other work instruction. After the rework or repair has been accomplished, QA personnel reinspect or retest the item in accordance with the original requirements, or as stated or referenced in the NR/SDR disposition. When acceptable, QA personnel stamp or sign and date the NR/SDR, remove the Hold tag, and release the item for further processing.

NRs, SDRs, and other data are analyzed and quality trend reports generated by Quality Assurance to identify quality problems and improvements. Such reports are described in Section 17.16 of this report.

Suppliers and subcontractors are required to establish and implement applicable controls equivalent to those described in this section.

17.16 CORRECTIVE ACTION

GA implements a corrective action system for documenting significant conditions adverse to quality (including hardware nonconformances, design errors, and quality system deviations or deficiencies); determining the cause of and establishing corrective action for such problems; and informing appropriate levels of management of such significant conditions, their causes, and the corrective actions taken. Corrective action implemented as a result of nonconformance reports is described in Section 17.15 of this report; corrective action implemented as a result of audits is described in Section 17.18. As a part of the corrective action program, any GA employee may initiate a Corrective Action Request (CAR). Any significant GA or supplier conditions adverse to quality that are brought to the attention of GA QA are inputted to the CAR system for resolution and reporting.

Quality Systems maintains a CAR log, assigns CAR numbers, and maintains awareness and visibility of CAR status. Each CAR is transmitted to Quality Systems for logging and distribution to the organization(s) responsible for defining and implementing corrective action.

The CAR recipient documents the root cause, action taken to correct the observed deficiency, action to locate and correct any other deficiencies of the same nature, action to preclude recurrence, and the scheduled completion date for each kind of action on the CAR. The CAR is then returned to Quality Systems for evaluation of the adequacy of the proposed actions and schedules. Quality Systems, the CAR initiator, and the initiator's manager evaluate the actions and completion schedules shown in the CAR response. If the action or schedules are unacceptable, Quality Systems rejects them in writing, specifying the reasons for rejection. Disagreements are elevated to higher management levels for resolution.

Each entry in the CAR log remains open until Quality Assurance verifies that the corrective action has been accomplished. Follow-up is accomplished as appropriate to verify the effectiveness of the implemented corrective action.

Regulatory agency and customer requests for corrective action of a quality nature are forwarded to the Director, Quality Assurance for investigation, corrective action, and reply.

Trending is performed on all 10CFR71 projects and NQA-1 Projects, and other Projects when contractually required. The cognizant quality engineer compiles quality data and issues quality trend reports. Corrective action for problems identified from these data or trends is initiated by the cognizant quality engineer or the responsible QA Manager using a CAR. Trend reports are distributed to the

applicable Sr. Vice President(s); responsible Division Director; responsible Project Manager; responsible QA Manager; and Director, Quality Assurance.

Corrective action system requirements are specified or referenced in procurement documents.

Any GA employee who becomes aware of what appears to be a defect in a basic component that has been supplied for use in an NRC-licensed facility, or a noncompliance within the meaning of 10CFR21 that relates to or could create a substantial safety hazard at an NRC-licensed facility, reports it immediately to his or her supervisor and to the Chairman, Nuclear Defects and Noncompliance Committee.

17.17 QUALITY ASSURANCE RECORDS

Specific records that are evidence of performance and acceptance of activities affecting quality are identified in the engineering design documents, inspection and test procedures, and/or inspection documents. Most records are microfilmed and indexed for computerized retrieval. Microfilm duplicates are stored in remotely separated facilities. Records that are not microfilmed, such as radiographs, are stored in facilities constructed to prevent record deterioration from theft, loss, damage, fire, and environmental conditions such as weather, contamination, pressure, or extremes of temperature and humidity.

Quality assurance records are categorized as "lifetime" or nonpermanent." Lifetime records are those which would be of significant value in:

1. Demonstrating capability for safe operation of an item.
2. Maintaining, reworking, repairing, replacing, or modifying an item.
3. Determining the cause of an accident or malfunction of an item.
4. Providing required baseline data for inservice inspection.

Nonpermanent records are those required to show evidence that an activity was performed in accordance with applicable requirements, but do not meet the criteria for lifetime records. Nonpermanent records for shipping containers under 10 CFR-71 are maintained for a minimum of three years.

The responsibility for delivery of the records to records management areas lies with the organizational unit which completes the record. The retention and disposition of the required quality assurance records is established by the customer.

Procedures govern the management of records within records management areas. The procedures provide receipt, storage, preservation, safekeeping, access, and retrieval information for quality assurance records. Typical examples of quality assurance records types include:

1. Design and Design Control Records such as drawings, specifications, change notices, design review records, etc.
2. Product Data Records such as Travelers, Nonconformance Reports, NDE reports, maintenance records, welding procedures, heat treating procedures, radiography, etc.

3. Purchasing and Supplier Records such as supplier evaluations, Purchase Orders, Source and Receiving Inspection Plans, Work Releases, etc.
4. General Quality Assurance Records such as QA training records, calibration records, audit records, QA procedures, qualification records, Corrective Action Requests, etc.
5. Test Control Records such as test specifications, test procedures, test reports, test operation logs, etc.

Prior to final item acceptance, QA personnel review work documents such as inspection and test procedures and fabrication/manufacturing travelers to verify that the documents are legible and that evidence exists for (1) the completion and/or verification of fabrication/manufacturing, inspection, or test operations; (2) results of the inspection or test; and (3) information related to nonconformances, inspector identification, and item acceptability.

Suppliers and subcontractors are required to establish and implement applicable controls equivalent to those described in this section.

17.18 AUDITS

The Manager, Quality Systems prepares, maintains, and approves the audit schedule. Planning for the schedule takes into account the complexity and status of the activities to be audited, their relative criticality to the program, and their nature in regard to the state-of-the-art. Each element of the QA program involved and each organization involved in safety-related activities is scheduled for audit at least once each year or at least once during the life of the activity, whichever is shorter. Audits of suppliers and subcontractors of safety-related items are performed by Quality Assurance on a triennial basis. Audits of 10CFR71 Projects are conducted annually. The frequency and scope of these audits are determined by the nature and phase of fabrication activity and by the criticality of the items involved.

Quality Assurance procedures for conducting audits of the activities affecting quality within GA and supplier organizations require that each audit be performed by Lead Auditors or by auditors/auditor trainees under the direct supervision of a Lead Auditor. Lead Auditors and Auditors are qualified and certified in accordance with ASME NQA-1 requirements. Audits are performed to an audit plan and audit checklist. The audit plan identifies the audit objective, scope, applicable documents or requirements, audit personnel, activities to be audited, organizations to be notified, any special concerns or notes and audit schedule. The audit checklist identifies the points that are to be checked during the audit to verify implementation of the controls described in this report and to verify compliance with the applicable policy directives and procedures. Each audit includes an evaluation of the adequacy of the applicable part of the established QA program and of the QA program's effectiveness in the audited areas.

Lead Auditors and auditors are selected for their knowledge of the Quality Assurance system as it affects the operations to be audited. Where specific knowledge of the technologies involved in an audit is necessary, technical specialists are included in the audit team. In every case, those selected to perform audit operations have no direct responsibility for the operations to be audited.

When an audit results in adverse findings, the auditor discusses the audit findings with responsible management during the post-audit conference to assure that the documented findings are concurred with and understood and that the necessary action is taken to correct the deficiencies revealed.

Audit reports are distributed by Quality Systems within 30 days of audit completion to the appropriate Senior Vice President(s) and the Director of Quality Assurance, as well as to the other cognizant GA managers. These audit reports, which may reflect quality trends or deficient areas, provide management with an indication of the effectiveness of GA's QA Program. The report includes the Lead

Auditor's assessment of the effectiveness of that part of the Quality Assurance program that was audited, adverse findings (if any), corrective action commitments, and planned corrective action completion dates.

Follow-up audits are performed to verify that the corrective actions have been effectively implemented within the committed time period.

Permanent audit files are maintained by Quality Systems. The files include documentation of audit scheduling and accomplishment; audit plans, audit checklists, findings, corrective action responses, records of corrective action completion, and reports; and records of auditor selection, qualification, and continued proficiency.

Quality Systems provides assistance to the cognizant quality engineer and/or the applicable QA Manager during all regulatory agency and customer audits and follows through to assure all corrective action commitments are completed.

Supplier and subcontractors are required to establish and implement applicable controls equivalent to those described in this section.

APPENDIX 17-1 QUALITY ASSURANCE ORGANIZATION RESPONSIBILITIES

Director, Quality Assurance. The Director of Quality Assurance reports to the Senior Vice President, Advanced Technology Group (see Figure 17-2) and is responsible for developing, directing, and implementing an effective quality assurance program. The prime role and responsibilities of the Director are to:

1. Establish and maintain policies and practices which are responsive to the needs of the Company in the functions of quality assurance and assure implementation of the requirements of the QA manual.
2. Develop and obtain budgetary needs to support an adequate Quality Assurance organization.
3. Assure adequate staffing of personnel to properly carry out the function of Quality Assurance.
4. Assure that procedures used within Quality Assurance implement the established policies and meet the requirements of applicable regulatory standards and result in a product or service that meets Customer quality requirements and, if applicable, ASME Code requirements.
5. Cooperate with agencies performing audits of QA operations to assure conformance to, and the effectiveness of, the established policies and procedures.
6. Assure that personnel within QA are qualified for their assigned responsibilities and establish such training as may be necessary to develop and maintain the required qualification.
7. Delegate authority within QA to carry out its responsibilities, including authority to stop unsatisfactory work or to stop further processing of unsatisfactory material.
8. Provide periodic reports to management indicating results of audits, quality trends, and overall Quality Assurance performance.
9. Maintain direct interface with QA managers of Customers. (May be delegated to the cognizant QA personnel.)
10. Avail himself of his direct access to the Chairman of GA for all areas concerning the implementation of the QA Program.

Manager, Quality Systems. The Manager, Quality Systems reports to the Director, Quality Assurance. Specifically, the Manager, Quality Systems:

1. Develops and monitors implementation of new or improved quality systems.
2. Implements the QA audit and corrective action system.

**APPENDIX 17-1 QUALITY ASSURANCE ORGANIZATION RESPONSIBILITIES
(CONTINUED)**

3. Coordinates the QA training program.
4. Manages the Quality Assurance Records Center.
5. Evaluates QA programs of GA suppliers.
6. Coordinates Quality Assurance surveys conducted by potential customers and provides resolution and corrective action responses for any survey deficiencies.
7. Prepares, or assists in the preparation of, the formal corrective action response to all customer and regulatory agency audit deficiencies of the QA Program.
8. Issues and controls quality assurance, machinists', welders', brazers', and fabrication/manufacturing engineers' stamps.
9. Maintains Quality Assurance personnel qualification and certification records.
10. Maintains communication for quality matters across internal and external organizational interfaces.
11. Processes and controls Quality Assurance documents which implement the QA program.

Manager, Electromagnetic Systems QA. The Manager, Electromagnetic Systems QA reports to the Director, Quality Assurance. Specifically, the Manager, Electromagnetic Systems QA:

1. Manages the Calibration and Inspection Laboratory. Provides calibration services for mechanical measuring and test equipment (M&TE), used by various groups at GA.
2. Defines the QA Program requirements for licensed transport package projects and manages the QA Program for each licensed shipping package project.
3. Performs quality engineering functions such as chairing the Material Review Board (MRB) and review of design, test, and procurement documents.
4. Translates quality assurance contractual and regulatory requirements into working documents. Also prepares inspection plans and provides inspection point input to integrated work instructions.
5. Performs receiving, in-process, and final inspection.
6. Performs source surveillance and source inspection.
7. Prepares quality records by documenting inspection work.
8. Assures use of qualified procedures and personnel for special processes.
9. Prepares, implements, and maintains Quality Assurance Program Documents (QAPDs).
10. Coordinates audits and surveys by the customer and regulatory agency representatives at GA or at GA suppliers' facilities and provides resolution and corrective action responses for any deficiencies.

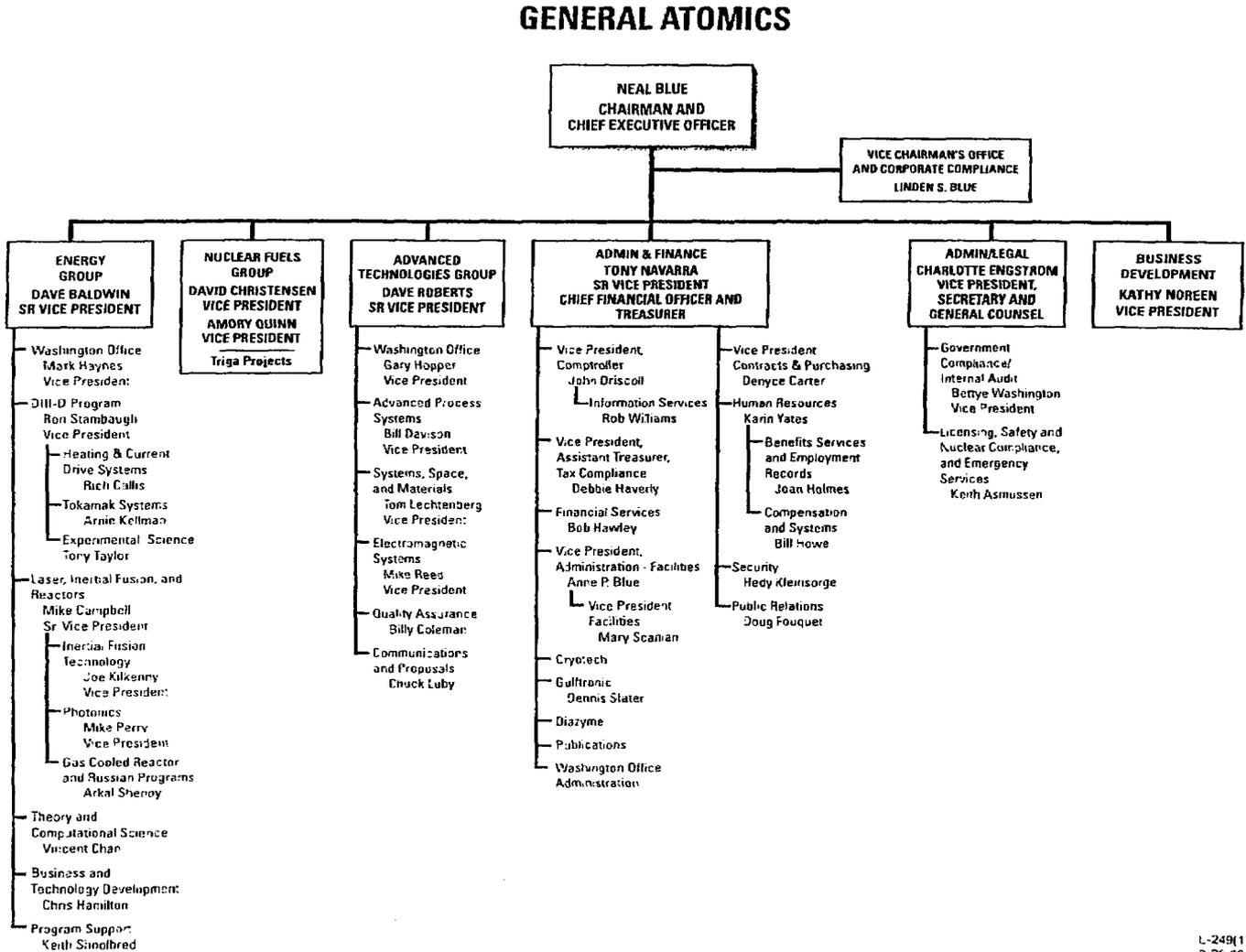
**APPENDIX 17-1 QUALITY ASSURANCE ORGANIZATION RESPONSIBILITIES
(CONTINUED)**

11. Maintains current knowledge of proposal activity in the area of responsibility to assure that proposals requiring QA approval are submitted in a timely manner.
12. Provides QA input and approval of proposals issued in area of responsibility, when required.
13. Prepares and coordinates QA input to all sections of Safety Analysis Reports for Packaging (SARP).
14. Maintains and monitors tools, gages, and equipment used for product acceptance.
15. Maintains communications for quality matters across internal and external organizational interfaces.
16. Performs trend analyses.

Manager, Advanced Process Systems QA. The Manager, Advanced Process Systems QA reports to the Director, Quality Assurance. His responsibilities are not part of the GA QA Program as it applies to licensed transport packages.

Manager, Fusion and Advanced Technologies QA. The Manager, Fusion and Advanced Technologies QA reports to the Director, Quality Assurance. His responsibilities are not part of the GA QA Program as it applies to licensed shipping packages.

FIGURE 17-1 GA OPERATING ORGANIZATION



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FIGURE 17-2 QUALITY ASSURANCE ORGANIZATION

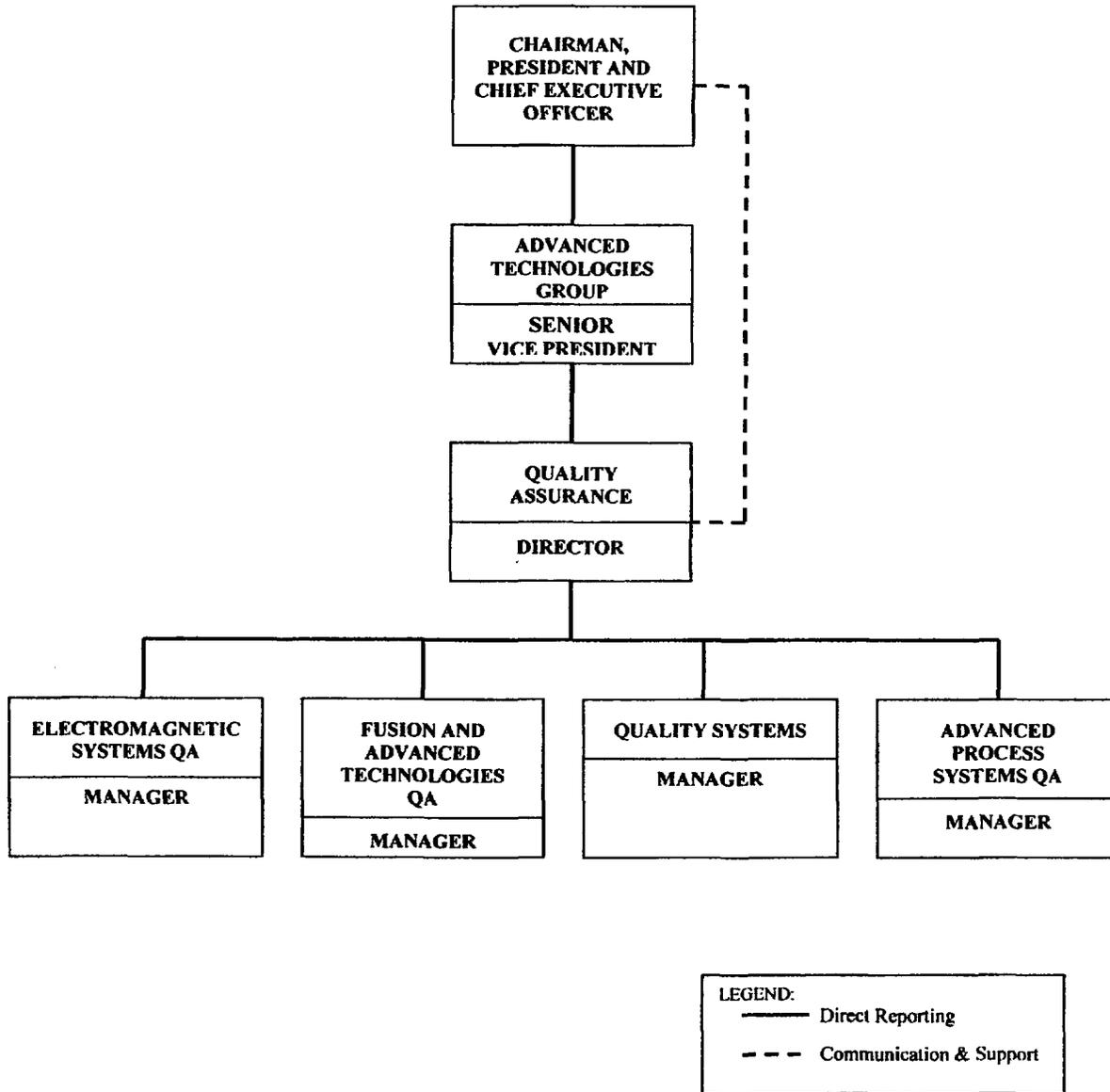


TABLE 17-1 GA IMPLEMENTING PROCEDURES

GA Implementing Document	Title	10CFR71 Subpart H Criteria and Corresponding ASME NQA-I Requirements	Description
GA Quality Assurance Manual (QAM), Quality Procedure (QP) No. 1	Organization	I	Identifies organizations and their relationships in performance of activities affecting quality.
QAM, QP No. 2	Quality Assurance	II	Describes basic methods for establishing a documented QA Program that implements requirements of 10CFR71 Subpart H, and contracts with customers. Also establishes responsibilities, and procedures for developing, implementing, and maintaining programs for indoctrination and training of personnel who perform activities affecting quality of GA products/services.
QAM, QP No. 3	Design Control	III	Describes design control measures established for structures, systems, and components to be delivered.
QAM, QP No. 4	Procurement Document Control	IV	Describes procedures for assuring that applicable regulatory requirements, design bases, and other requirements necessary to assure adequate quality are suitably included or referenced in documents for procurement of material, equipment, and services.
QAM, QP No. 5	Instructions, Procedures, and Drawings	V	Establishes measures for the preparation and implementation of detailed procedures for all organizational activities at GA that have an effect on requirements prescribed in the QAM.
QAM, QP No. 6	Document Control	VI	Establishes measures to control issuance of documents, and changes thereto, which prescribe requirements that establish or evaluate product quality. Such documents are those used directly as a basis for achieving or determining compliance of deliverable items with the requirements.
QAM, QP No. 7	Control of Purchased Items and Services	VII	Defines measures established to assure purchased material, equipment, and services conform to procurement documents.
QAM, QP No. 8	Identification and Control of Items	VIII	Establishes measures used to identify and control materials, manufacturing parts, components, and assemblies within GA scope of supply.
QAM, QP No. 9	Control of Processes	IX	Describes measures used to control special processes such as welding, heat treatment, cleaning, and nondestructive examination.
QAM, QP No. 10	Inspection	X	Establishes requirement that activities affecting quality of deliverable items be inspected to verify conformance with documented instructions, procedures, and drawings.

QAM, QP No. 11	Test Control	XI	Defines measures for control of tests performed prior to shipment to assure that equipment will perform satisfactorily in service. (Does not apply to nonoperational tests such as helium leak, radiographic, or other nondestructive tests. Such tests are controlled by requirements of Procedure No. 9.)
QAM, QP No. 12	Control of Measuring and Test Equipment	XII	Describes requirements and procedures for calibrating measuring and test equipment.
QAM, QP No. 13	Handling, Storage, and Shipping	XIII	Establishes procedures and responsibilities for assuring that proper methods, materials, and equipment are used in handling, preservation, storage, and shipping of products in compliance with applicable specifications and contractual requirements.
QAM, QP No. 14	Inspection, Test and Operating Status	XIV	Defines procedures and responsibilities for indicating inspection status of parts and materials throughout GA processing.
QAM, QP No. 15	Control of Nonconforming Items	XV	Establishes procedures and responsibilities for identification, segregation, review, and disposition of nonconforming parts and materials throughout GA processing.
QAM, QP No. 16	Corrective Action	XVI	Establishes requirements and procedures for corrective action within the General Atomics Quality Assurance program.
QAM, QP No. 17	Quality Assurance Records	XVII	Establishes measures for retention and retrieval of Quality Assurance records, defined as documents that furnish evidence of compliance of safety-related deliverable hardware and of activities affecting quality.
QAM, QP No. 18	Audits	XVIII	Establishes requirements and procedures for audits to verify effectiveness of GA QA Program.

TABLE 17-2 CODES AND REGULATION COMPLIANCE

GA's QA Program complies with the following documents except as noted.

Document No.	Title
Regulatory Guide 1.28 (Rev. 3, 8/1/85)	Quality Assurance Program Requirements Design and Construction
Regulatory Guide 7.10 (Rev. 1, 6/86)	Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material (See Note 1)

Notes:

- 1(a) As applicable, the guidance provided in Regulatory Guide 7.10 is specified in each specific project Quality Assurance Program Document that relates to packaging or shipping of radioactive material.
- (b) Design Verification may be performed by the designer's immediate supervisor under the conditions specified in NQA-1 as endorsed by Reg. Guide 1.28.



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