Westinghouse
Electric Corporation

P. O. Box 355
Pittsburgh, PA 15230

May 27, 1997

QS-97-0864

Ms. Suzanne C. Black
U. S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation
Washington, DC 20555

Dear Ms. Black:

Subject: Westinghouse Electric Corporation, Energy Systems Business Unit, Quality Management System, Revision 2

Attached for your reference use is Revision 2 of the Westinghouse Electric Corporation, Energy Systems Business Unit, Quality Management System (QMS). The QMS was approved by USNRC letter, Suzanne C. Black to N. J. Liparulo, dated April 10, 1997. The QMS is being forwarded in accordance with that letter.

If you have any questions, please contact me at 412-374-6664.

Sincerely,

WESTINGHOUSE ELECTRIC CORPORATION

Dale A. Harmon
Supervisory Quality Engineer

ts
Attachment

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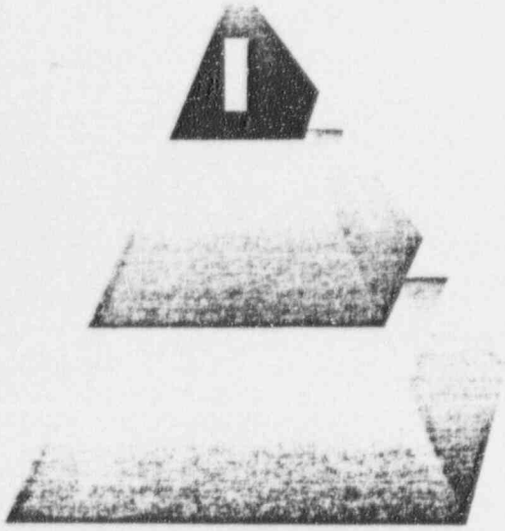
c N. J. Liparulo

97-110

ESBU

Quality Management System



REVISION 2

WESTINGHOUSE CLASS 3

QMS
Revision 2

Westinghouse Electric Corporation

Energy Systems Business Unit

Quality Management System

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Energy Systems Business Unit

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

April 10, 1997

N.J. Liparulo, Manager
Equipment Design and Regulatory Engineering
Westinghouse Electric Corporation
Energy Systems
P. O. Box 355
Pittsburgh, Pennsylvania 15230-0355

SUBJECT: QUALITY MANAGEMENT SYSTEM (QMS), REVISION 2

Dear Mr. Liparulo:

We have completed our review of the proposed Revision 2 to the Westinghouse Energy Systems Business Unit (ESBU) Quality Management System (QMS) quality assurance topical report submitted by letter dated February 20, 1997. QMS, Revision 2, describes the Westinghouse quality assurance program and attendant commitments to address the requirements of both 10 CFR 50, Appendix B, and the International Organization for Standardization (ISO) 9001. The revision primarily described the recent ESBU organizational changes in Section 1.0, Management Responsibility. Several other changes were delineated in Revision 2 including:

1. A description of the quality commitments for ESBU and the Westinghouse Pensacola Plant (WPP), and an amendment to include the Process Control Division (PCD) and the Government Technical Services Division (GTSD).

2. A generic organization description and clarification of the duties and responsibilities of the ESBU Quality Systems Director.

3. The QMS was updated to include the requirements of the 1994 revision of ISO 9001.

Your original QMS, Revision 2, submittal was supplemented by a second submittal dated April 1, 1997 that, in response to a March 25, 1997 telephone conference with the staff, provided clarification pages to address issues of independence of engineering design reviewers in Sections 4.1, Design Control; an explicit statement requiring approval of design inputs for adequacy by engineering organizations in Section 4.3, Design Input; amended wording to remove the conditional phrase "as applicable" from Section 9.1, Process Control; and corrected typographical errors regarding paragraph and page numbering. A page replacement submittal was also provided by facsimile on March 27, 1997.

Based on our review of the information provided, we have concluded that QMS, Revision 2, continues to meet the requirements of 10 CFR 50, Appendix B, and can be utilized to control the quality of items and services provided by Westinghouse ESBU, the Pensacola Plant, the Process Control Division, and the Government Technical Services Division.

Please incorporate a copy of this letter into the published edition of QMS, Revision 2, and forward one copy to the NRC in accordance with 10 CFR 50.4. Any questions on the above should be directed to Edward J. Ford of my staff on (301) 415-1149.

Sincerely,

Suzanne C. Black

Suzanne C. Black, Chief
Quality Assurance and Maintenance Branch
Division of Reactor Controls and Human Factors
Office of Nuclear Reactor Regulation

cc: Mr. Dale Harmon
Westinghouse Electric Corporation
Energy Systems
P.O. Box 355
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Docket No. 99900900

FOREWORD

Westinghouse Electric Corporation will comply with the requirements of 10CFR50, Appendix B as prescribed in Regulatory Guide 1.28 when supplying items and services to nuclear power plants. Changes that reduce the commitments contained herein for safety related items and services will be submitted to the NRC for review and approval prior to implementation. Changes that do not reduce the commitments will be submitted to the NRC for information within 90 days. NRC notification is in accordance with the requirements contained in 10CFR50.55 (f) (3).

This document is controlled and issued to designated personnel. Uncontrolled copies are made available to customers and clients on an as-needed basis.

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INTRODUCTION

The Quality Management System (hereafter known as the QMS) describes the Westinghouse Energy Systems Business Unit (ESBU) commitment to the requirements of 10CFR50, Appendix B; International Organization for Standardization (ISO) 9001; ISO 9000-3 (TickIT); and American Society of Mechanical Engineers (ASME) NQA-1. ESBU is a functionally organized group of divisions and supporting organizations responsible for the marketing, design, procurement, manufacture, installation, inspection, testing, and operation of certain nuclear power plant items; non-nuclear items; service of those items, and management of projects. ESBU also offers engineering services such as life-extension studies, diagnostics, service analyses, and product and service testing. The QMS has been developed to comply with regulatory, industry, and customer quality requirements for items and services provided by ESBU.

Commitments contained in this QMS are also applied by the Westinghouse Process Control Division (PCD). Commitments that comply with 10CFR50, Appendix B are also applied by the Power Generation Business Unit (PGBU) for nuclear application at the Westinghouse Pensacola Plant (WPP); and by the Westinghouse Government and Environmental Services Company (GESCO) for application by the Government Technical Services Division (GTSD).

WPP is a functional unit within the PGBU, responsible for the design, procurement, fabrication, inspection and/or testing of certain nuclear plant items.

PCD is a division of Westinghouse responsible for the design and manufacture of process control systems for nuclear and fossil power generation and other commercial and industrial processes.

GTSD is a functional unit within the GESCO responsible for the design, procurement, manufacture and use of radioactive material transportation packaging in accordance with 10CFR71.

The ESBU organization, PCD, PGBU-WPP, and GESCO-GTSD are responsive to energy industry, utility, and government needs. Manufacturing, installation, construction, engineering, service, project management, and engineering activities for ESBU and PCD are headquartered in Pittsburgh, Pennsylvania, and for WPP, activities are located in Pensacola, Florida. Manufacturing, engineering, and project management activities for GESCO-GTSD are located in Carlsbad, New Mexico with additional engineering activities located in San Jose, California. Sales, marketing, and services are implemented through a network of locations throughout the United States and other countries.

APPLICABILITY

The QMS applies to activities that affect the quality of supplied items and services. It defines the basic requirements applicable to customer contracts and is a commitment to our customers. It serves as a directive for all functions in establishing policies and procedures that comply with the requirements of ISO 9001-1994; 10CFR50, Appendix B; and ASME NQA-1-1994 Edition, and provides for specific international and domestic contractual quality program requirements when applicable. Westinghouse positions and clarifications to Regulatory Guides and ASME NQA-1 are stated in Appendix A.

1.0 MANAGEMENT RESPONSIBILITY

1.1 Quality Policy

It is our policy to provide products and services that fully satisfy customer and regulatory requirements. Management is responsible for ensuring that this policy is communicated, understood, and implemented at all levels of the organization.

All employees are expected to perform their responsibilities in accordance with applicable quality requirements and to strive for continuous performance improvement. Maintaining an atmosphere of integrity and responsiveness is one of the most important attributes of the work environment. To seat this philosophy, all employees are encouraged to openly express all safety and quality concerns that may arise during the course of their work.

1.2 Organizational Structure

Organizations are assigned responsibilities to ensure that contractual requirements are met, provide a focal point for timely resolution of customer concerns, and ensure the quality of items and services. These organizations include functions such as Engineering, Manufacturing, Quality, Marketing, and Purchasing. Figure 1 (page 6) shows a typical organizational reporting structure designed to satisfy the commitments of the QMS. Specific organizational details, including authority, responsibilities and interfaces is established and the achievement of quality is the responsibility of each individual performing work. Verification of the achievement of quality is accomplished by individuals or groups not directly responsible for performing the work.

The management of each organization that endorses this QMS is responsible for the quality program activities described throughout this document and ensuring that appropriate systems, processes, procedures, and work instructions are implemented. Management is also responsible for ensuring that instances of noncompliances and opportunities for improvement are addressed in a timely manner and that personnel are indoctrinated and trained in the applicable quality system requirements.

1.2.1 General Manager

The General Manager, or equivalent, is responsible for establishing and implementing a quality assurance program that complies with the commitments of the QMS.

1.2.2 Quality

The responsibility for documenting the quality program is assigned to a Quality Manager(s) (or similar title). The Quality Manager is sufficiently free from direct pressure for cost/schedule and has the authority to stop work and delivery or installation of nonconforming items and services. The Quality Manager has access to higher management levels, including the General Manager, for all quality related issues. This access ensures the authority of the Quality Manager to identify quality problems, initiate actions, make recommendations and verify implementation of solutions. Quality is responsible for verifying that the quality program is established and effectively implemented. Results of this verification are reported to management.

1.2.3 Operational Organizations

Operational organizations, such as Manufacturing and Engineering, are responsible for performing and controlling activities to ensure that items and services supplied meet specified quality requirements. Engineering is responsible for performing the various technical functions associated with the specification, design, servicing and replacement of items. Manufacturing is responsible for the manufacture, fabrication, construction, testing, and/or servicing of items.

1.2.4 Support Organizations

Support organizations include activities such as Purchasing and Marketing. Purchasing is responsible for all procurement services and serves as the primary interface with suppliers. Marketing is responsible for the preparation of offers, receipt of customer orders, and managing customer communications.

1.3 Management Review

The General Manager and staff are responsible for reviewing the QMS at defined intervals to ensure its continuing effectiveness and suitability in satisfying the applicable international and regulatory standards and specific quality objectives. Such reviews include, as necessary, audit performance data, customer satisfaction and feedback data, supplier performance data, and other key performance indicators. Records of these reviews shall be maintained.

1.4 ESBU Organization Structure

The ESBU President fulfills the responsibilities assigned to the General Manager in 1.2.1. Reporting to the ESBU President is a staff comprised of operational and support organizations. Quality Systems fulfills the responsibilities of the quality organization for ESBU. Figure 2 (page 7) provides the organizational structure for ESBU. Additional responsibilities for ESBU personnel are described in the following paragraphs.

1.4.1 President

The ESBU President defines the overall quality policy and promotes a culture of conformance to requirements and continuous improvement. The ESBU President ensures that appropriate resources are allocated to satisfy quality requirements, assigns priorities, and identifies key quality issues affecting all business unit activities. The ESBU President authorizes and endorses the QMS, and appoints and supports a Management Representative to coordinate development, implementation, and maintenance of the QMS.

1.4.2 ESBU Staff

The staff reporting to the ESBU President is primarily responsible for meeting business objectives and for directing the activities within their organizational charters. The staff includes division General Managers, Quality Systems, Commercial Operations, and the Chief Financial Officer. They have overall responsibility and are accountable for the quality of items and services supplied by their organizations and for the effectiveness of the QMS as applicable to their activities.

1.4.3 Division General Managers

Division General Managers are responsible for managing the operational activities in their organizations to comply with the QMS. The operating divisions in ESBU are the Nuclear Services Division, Commercial Nuclear Fuel Division, Electro-Mechanical Division and Nuclear Projects Division.

1.4.4 Commercial Operations (CO)

Commercial Operations is responsible for the business unit marketing efforts including offer preparation and development of pricing policies. CO coordinates the ESBU order entry process for reviewing and processing customer orders to the lead technical group and also has overall responsibility for managing the communication interface with customers.

1.4.5 Chief Financial Officer (CFO)

The CFO directs the collection and analysis of financial data and prepares financial plans, reports, and forecasts. The CFO also manages the ESBU Supply Management organization, which provides procurement services for the business unit. In this role, Supply Management serves as the interface between the divisions and suppliers and establishes systems to ensure effective control of procurement processes.

1.4.6 Quality Systems (QS)

Quality Systems directs ESBU quality policy and monitors the overall quality performance of the QMS. Quality Systems coordinates business unit-wide quality assurance activities, including customer satisfaction, and reports critical quality issues to the ESBU President. Quality organizations at the division manufacturing plant level responsible for product assurance report on a matrix basis to the QS organization.

1.4.7 Interfaces

ESBU organizational interface agreements reflecting responsibilities of interfacing divisions are documented and controlled in accordance with approved procedures.

1.5 Management Representative

The Management Representative is responsible for monitoring the implementation of the QMS within the organization. This responsibility includes guidance and direction to other internal organizations in the implementation of the QMS. This role is also established as a focal point for any employee to report issues concerning the QMS and for coordinating action with ESBU for changes and improvements. The Director, Quality Systems is the ESBU Management representative and has lead responsibility regarding ESBU ISO 9001 registration.

1.6 ESBU/PGBU-WPP Quality Program Interface

WPP management is responsible for quality through the commitment of the PGBU President to this QMS. Activities, responsibilities, authority, acceptance of work and interfaces are established and documented in WPP Quality Assurance Program documents for nuclear items

and services received through the ESBU order entry process. WPP provides the ESBU Quality Systems Director with a copy of the annual management assessment report.

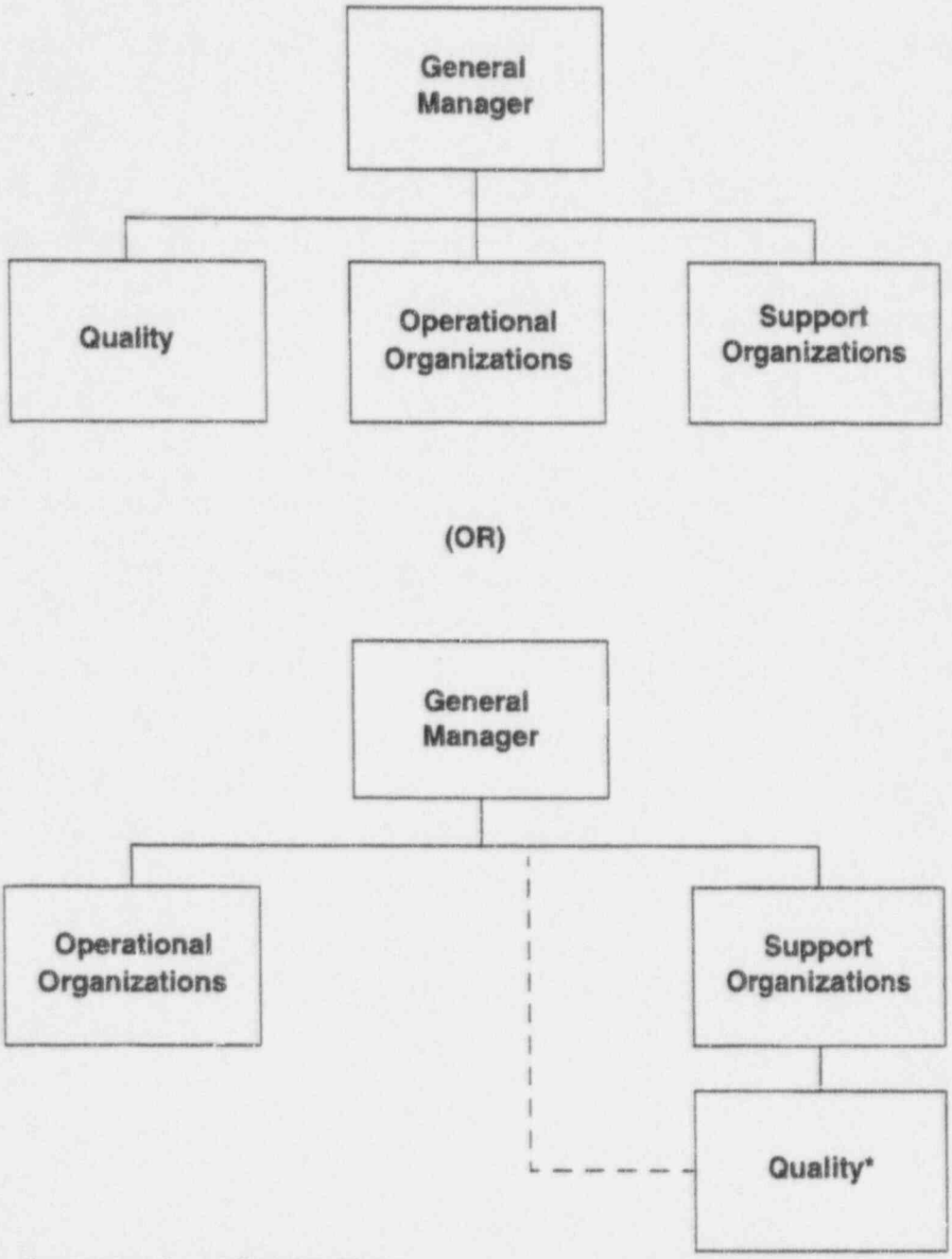
The ESBU Quality Systems Director is responsible for taking appropriate action with WPP management to resolve any identified issues that may have an adverse impact on ESBU/WPP commitments.

1.7 ESBU/GESCO-GTSD Quality Program Interface

GTSD management is responsible for quality through the commitment of the GESCO President to this QMS. Activities, responsibilities, authority, acceptance of work and interfaces are established and documented in GTSD Quality Assurance Program documents.

1.8 ESBU/PCD Quality Program Interface

PCD management is responsible for quality through the commitment of the PCD General Manager to this QMS. Activities, responsibilities, authority, acceptance of work and interfaces are established and documented in PCD Quality Assurance Program documents for nuclear items and services received through the ESBU order entry process. ESBU Quality Systems provides PCD with support for satisfying quality commitments as defined in a documented interface agreement.



*Quality has direct access for quality related issues.

FIGURE 1
TYPICAL ORGANIZATION REPORTING STRUCTURES

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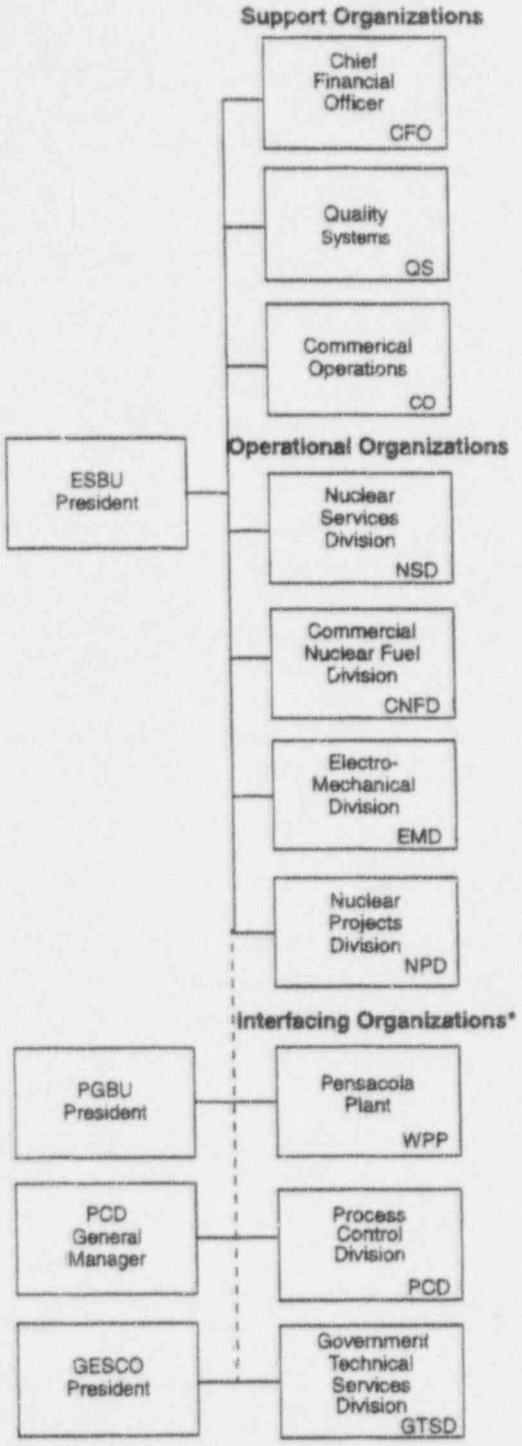

*Interfacing organizations are described in Section 1.0 of the QMS

FIGURE 2
ESBU AND INTERFACING ORGANIZATIONS

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2.0 QUALITY SYSTEM

Activities affecting quality are documented in accordance with written manuals, procedures, instructions, specifications, and drawings that contain appropriate criteria for determining whether prescribed activities have been satisfactorily accomplished. The documentation is established in the following three distinct levels that integrate the policies, procedures, and working documents:

1. QMS
2. Business unit and division level policies and procedures
3. Functional/Department procedures, working instructions, etc.

The relationship between these documents is shown in Figure 3 (page 10).

2.1 Quality Management System (Level 1)

Implementation of the QMS ensures that customer quality assurance requirements and related quality standards are met. It is structured to the requirements of ISO 9001 and serves as a directive to organizations for implementing a comprehensive quality management system that complies with ISO 9001. For safety-related activities, the QMS provides for, and organizations comply with, applicable regulatory guides and ASME NQA-1. The QMS and changes thereto are reviewed and approved by ESBU management. As applicable, American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, and ASME NQA-1 requirements are supplemented with the guidance of the Regulatory Guides as described in Appendix A.

2.1.1 10CFR50.55a/Criterion 1 of 10CFR50 APP. A.

All organizations covered by this QMS for safety related activities comply with the requirements of 10CFR50.55a (with the specific editions of the Codes and Standards identified in the applicable Safety Analysis Reports (SAR) and Criterion 1 of 10CFR50, App. A.

2.1.2 10CFR21/10CFR50.55

Procedures provide for the evaluation of reported conditions that may require NRC notification in accordance with the requirements of 10CFR21, Reporting of Defects & Noncompliance, and 10CFR50.55(e), Conditions of Construction Permits.

2.2 Business Unit and Division Policies and Procedures (Level 2)

2.2.1 Policies and Procedures

Operational, support, and quality organizations with impact on customer contractual commitments are responsible for establishing procedures that comply with the requirements of the QMS. They are responsible for ensuring that lower-tier procedures are established as necessary to implement applicable requirements.

The procedures governing ESBU quality-related activities are contained in the ESBU Policy/Procedures Manual. Quality Systems coordinates the generation and review of these

procedures and is responsible for ensuring that regulatory requirements and the policies of the QMS are included, as applicable. These procedures are reviewed and approved by the General Manager, or designee, of each applicable organization. ESBU policies and procedures that are adopted by external organizations for implementation will be subjected to review by that organization.

2.2.2 Project Quality Plans

Project Quality Plans (PQPs) are developed to satisfy customer contracts when existing procedures do not address all of the contract requirements, or when supplemental or additional procedures are necessary. A PQP is developed and authorized by engineering with concurrence by the designated quality organization assigned to the project. The PQP will be issued, revised, and controlled by engineering.

When required, Project Quality Plans may take the form of a complete Quality Assurance Program manual based on the commitments of this document and other specific requirements which are based on local government regulations and customer contracts.

2.2.3 Graded Quality

Procedures identify control requirements for items and services based on the complexity of the work and safety-related function of the item or service. To ensure consistency the classification process, including safety classes, is documented in procedures. The safety class of items is documented and approved by responsible management.

For all items meeting the definition of a basic component per 10CFR21, all applicable requirements of this QMS are implemented. For items not meeting the definition of a basic component, selected quality requirements are applied, as appropriate, to achieve the level of quality specified.

2.3 Functional/Department/Plant Procedures and Work Instructions (Level 3)

2.3.1 Functional/Department/Plant Procedures

Procedures are established to implement individual departmental responsibilities in accordance with division level policies and procedures. Department managers are responsible for the preparation, approval, distribution, and revision of these procedures.

2.3.2 Work Instructions

Work instructions provide detailed steps to conduct specific work activities. Work instructions are prepared as needed to supplement procedure requirements and to ensure that critical work scopes are carried out in a consistent manner. Managers are responsible for determining where work instructions are required in their areas of responsibility and for establishing systems for the generation, review, distribution, revision, and control of work instructions.

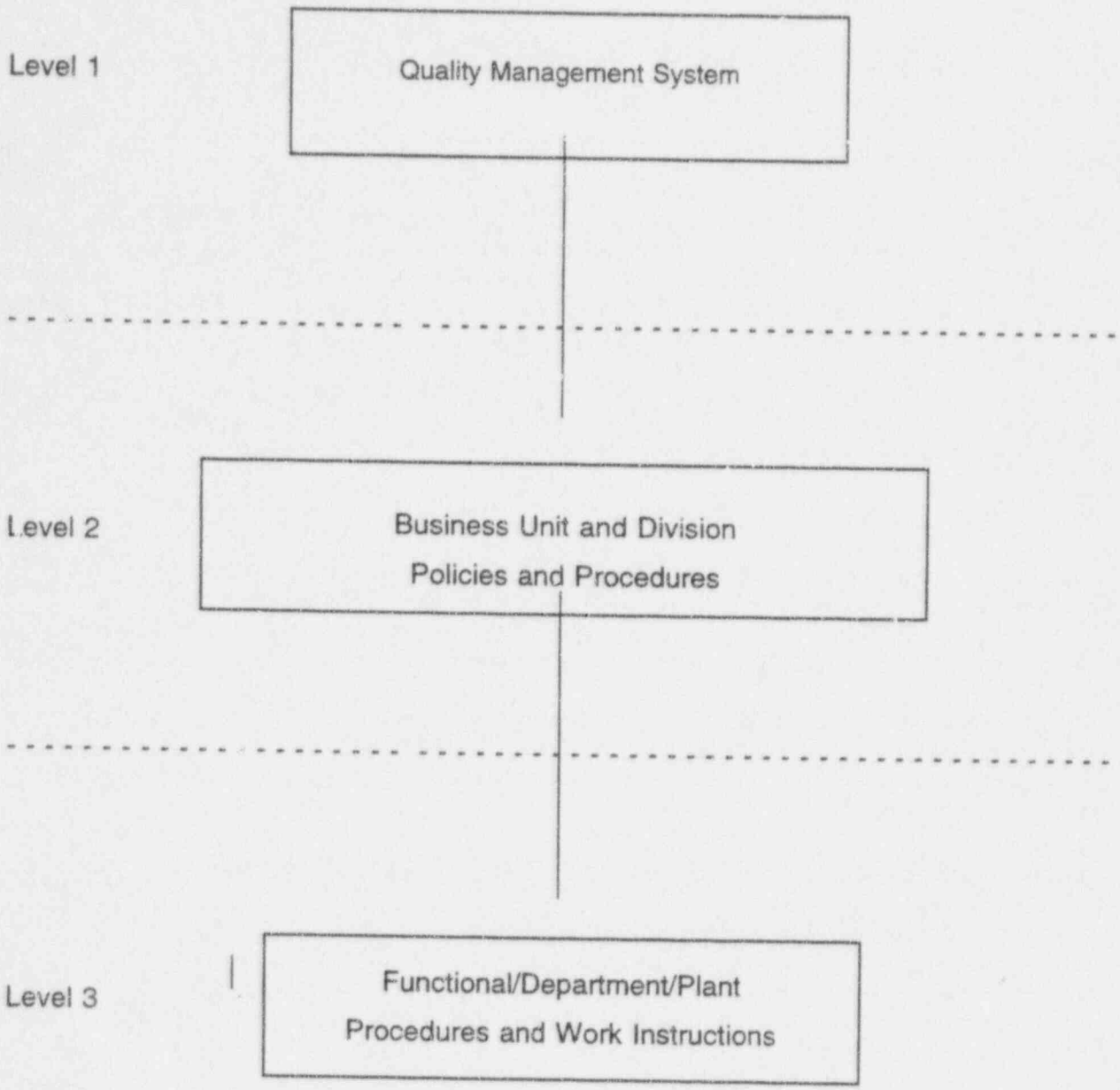

FIGURE 3

POLICY AND PROCEDURE STRUCTURE

3.0 CONTRACT REVIEW

Marketing and/or contract administration organizations are responsible for coordinating negotiation and contract review activities.

3.1 Negotiation

Marketing and/or contract administration organizations distribute copies of customer specifications and subsequent changes regarding technical, administrative, and quality requirements to appropriate functional groups for review and comment prior to proposal submittal. This review is performed to ensure that customer requirements are adequately defined and understood, and that the capability exists to meet these requirements. During the review, marketing and/or contract administration organizations coordinate all communication with the customer. A record of the review is maintained.

3.2 Contract Review

All customer orders received are formally reviewed by marketing and/or contract administration organizations and other designated functional organizations at the time of entry to ensure that all requirements are adequately defined and documented, and that the capability exists to meet all customer requirements. Requirements that differ from those in the final proposal are communicated to the customer and resolved. Documentation of this review is maintained in accordance with established procedures. After acceptance, the customer order and subsequent changes are distributed to appropriate functional organizations.

4.0 DESIGN CONTROL

4.1 General

Engineering controls the design process to ensure that the design and associated documentation meet applicable requirements and that design changes are properly evaluated prior to implementation.

Activities are performed by engineering organizations in support of new or modified product and/or specific customer projects. Engineering organizations are responsible for developing and maintaining procedures that comply with the requirements of the QMS. These engineering organizations are also responsible for complying with the applicable design-related requirements in division and department procedures.

Engineering organizations are responsible for performing design activities in accordance with established requirements and for preparing, reviewing, and approving design specifications, drawings, and other design documentation. These documents direct the work of purchasing, manufacturing, installation, servicing, quality, and other activities. Quality requirements are specified by engineering and are reviewed by an independent organization to ensure that inspection, test, acceptance, and documentation requirements are incorporated. Professional engineers performing ASME code certification activities are qualified in accordance with ASME N626.3.

4.2 Design and Development Planning

Engineering organizations are responsible for establishing and documenting a plan for a specific development or design activity. The plan shall provide a description of the design scope, verification methodology, the identification of qualified personnel responsible for the design activity, key milestones, and design interfaces necessary to accomplish the design activity. Plans shall be maintained and implemented throughout the design activity.

4.2.1 Activity Assignment

Engineering management is responsible for ensuring and documenting that personnel are qualified to perform assigned design work, including consideration for new capabilities that may be required as work scopes expand and/or change.

4.2.2 Organizational and Technical Interfaces

Engineering organizations are responsible for establishing design interfaces with other organizations necessary to accomplish design project objectives and for documenting the identified interfaces. Design interfaces for safety related items are identified, documented and controlled. These interface controls include the assignment of responsibility and the procedures to be used for the review, approval, release, distribution and revision of documents involving safety related design interfaces. Transmittal of design information is documented and controlled, and the status of the information is identified.

Design interface considerations may include:

- Customers, to ensure understanding of requirements
- Marketing and/or contracts administration organizations, to address contractual requirements and changes
- Other internal and external engineering organizations, to identify technical support, review, approval, release, and distribution of documents and changes thereto
- Purchasing, to ensure the availability of suppliers to meet design requirements
- Manufacturing, to assess manufacturing capability to meet design needs
- Quality, to ensure inspection capability and understanding of acceptance criteria

4.3 Design Input

Engineering organizations are responsible for identifying and documenting the design inputs to specified design projects. Engineering organizations are responsible for the resolution of incomplete, ambiguous, or conflicting design inputs. Sources of design input may include, as applicable:

- Customer specifications
- Performance requirements
- Functional requirements
- Industry codes and standards
- Regulatory and statutory requirements
- Technical requirements

Engineering organizations are responsible for reviewing and approving the selected design inputs for adequacy.

4.4 Design Analysis

Design analysis documents are legible, reproducible, and describe the purpose, method, assumptions, design input, and references such that the analysis can be reviewed and verified by a person technically qualified in the subject without recourse to the preparer. Computer software is controlled, verified, and validated in accordance with established procedures.

Documentation of design analyses on safety related items includes, either directly or by reference, the objective of the analysis; design inputs and their sources; results of literature searches or other applicable background data; assumptions and identification of those that require verification as the design proceeds; identification of computer calculations, including computer type, computer program name, revision, inputs, outputs, evidence of, or reference to, computer program verification, and the bases or reference to supporting application of the computer program to the specific physical problem; and review and approval.

4.5 Design Output

Engineering organizations are responsible for design output, including computer software, in the form that meets contract requirements. Typical design output includes analyses, design reports, drawings, and specifications. Engineering is responsible for ensuring that the design

output complies with design input requirements, customer and regulatory requirements, and considers the safe and proper functioning of the designed items.

A commercial-grade item that is modified, inspected, and/or tested to requirements more restrictive than the supplier's published product description is identified as different from the commercial-grade item and traceable to the documented difference.

4.6 Design Verification

4.6.1 Verification Process

Engineering organizations are responsible for ensuring that design verification is performed and documented. Design verification is conducted by individuals, not directly responsible for the design scope, with expertise in various aspects of the design scope. Verification by the originator's supervisor may be permitted if the supervisor did not specify a single design approach or establish specific design inputs. Design verification activities for projects are based on such factors as the complexity of the design, effects of failure or malfunction, regulatory requirements, similarity to previous designs, and contractual requirements. Design validation, such as qualification or final product testing, is performed to ensure that the product conforms to the specified user requirements. When it is appropriate to do so, validation is performed during earlier stages of the design process such as the use of in process testing, validated software or independent review. The methods of design verification used are documented and include one or more of the following:

- Tests or demonstrations
- Alternate calculations
- Design reviews

4.6.2 Verification Documentation

Engineering is responsible for ensuring that design verification, including any software used in the design verification process, is performed in accordance with written procedures. Engineering is responsible for providing evidence that the design and design verification were performed in accordance with procedural requirements and ensuring that records are collected, stored, and maintained.

4.6.3 Design Verification of Safety-Related Items

Verification is accomplished using design reviews, alternate calculations, or qualification tests as described in procedures.

Engineering managers determine the extent of design verification required as a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with proven designs. Designs and changes are verified prior to release of design documents for procurement, manufacture, construction, and/or service except where timing cannot be met. In all cases, procedures require that design verification is completed prior to relying on the item to perform its intended function and before its installation becomes irreversible. Unverified design documentation is identified and controlled.

4.6.4 Design Verification by Design Review for Safety-Related Items

Design reviews are performed on safety-related items by individuals or multi-disciplined design review teams. Engineering is responsible for specifying in written procedures when design reviews using multi-disciplined teams are required. These reviews are performed by competent personnel and address the following, as applicable:

- Design input selection correct
- Design output reasonable compared to design input
- Design input and verification requirements for interfacing organizations specified
- Design methods appropriate
- Design inputs correctly incorporated into the design
- Adequately described, reasonable, and identified assumptions

4.6.5 Design Verification by Alternate Calculations for Safety-Related Items

The requirements for verification by alternate calculations are described in procedures that include the review of appropriateness of assumptions, input data, and computer program or other calculation method used.

4.6.6 Design Verification by Qualification Tests for Safety-Related Items

Qualification testing is performed to ensure that products conform to defined user needs and/or requirements. Qualification tests of safety-related items validate and demonstrate the adequacy of performance under conditions that simulate the most severe design conditions in accordance with written test procedures and test specifications. Test specifications are reviewed and approved by the responsible engineering group. Results of the qualification tests are approved by the engineering group responsible for the design. For tests performed on models or mockups, scaling laws are established and verified. Test results obtained for model or mockup test work are subject to error analysis, where applicable, prior to use in final design work. Information regarding verification that is incomplete, including incomplete qualification tests, is available to the customer prior to installation of equipment.

4.7 Design Changes

The need for changes to designs and design documentation may originate from many sources, including customers, suppliers, manufacturing and quality organizations. Design changes are evaluated to determine their effect on the overall design and on any analysis upon which the design is based.

The engineering organization responsible for the original design is responsible for controlling design changes, unless another organization has been designated in writing. Changes to approved design documents, including field changes, are subject to the same review and approval process as the original design. Unless specifically authorized by procedures, changes are performed and verified by the same process or by a similar process with the same degree of discipline.

Engineering organizations are responsible for maintaining records of changes, including the reasons for the change and effects on existing products. Design changes are initiated and documented in accordance with written procedures.

4.8 Technical Information

4.8.1 Bulletins

Notification to customers of problems or issues that relate to supplied items are communicated via technical bulletins in accordance with an established procedure.

4.8.2 Instruction Manuals

Instruction manuals that are used for proper and safe installation, operation, maintenance or repair of original safety related items are provided as specified by engineering organizations.

4.9 Computer Software

Computer software developed as a deliverable nuclear product or used in the design, analysis, or operation of components, structures, and systems, is developed, controlled, and maintained in accordance with procedures and instructions that comply with (ASME) NQA-1, (e.g., Part I Supplement 11S-2, Part II, Subpart 2.7) and ISO 9001 (using the guidelines described in ISO 9000-3 (TickIT). These procedures include provisions for the validation and acceptance of software obtained from external sources. Engineering organizations developing or utilizing computer software are responsible for establishing these procedures. Computer software developed for non-nuclear applications will be processed in accordance with procedures that meet specific contract and other requirements, including ISO 9000-3, as appropriate.

4.9.1 Computer Software Development

Any suitable software life cycle model may be adopted, provided that it encompasses the activities associated with requirements definition, design, code implementation and testing, installation, operation and maintenance, and retirement. Functional requirements, design documents, test requirements, and test results are verified in accordance with written procedures. Verification is performed at the completion of each phase to ensure that the output of a given phase fulfills the requirements established by previous phases. Validation is performed upon completion of software development to ensure that the code satisfies all identified requirements and produces correct results.

4.9.2 Computer Software Change Control

Changes to software are documented, approved, and controlled by authorized personnel in accordance with established procedures.

4.9.3 Computer Software Testing

Computer software is tested for all intended applications. The degree of testing is dependent on the importance of the computer software to safety, complexity of the program, and prior

documented performance. Acceptance criteria may be based on hand calculations, documented results from other validated computer programs, empirical data, published data in technical literature, or performance standards established through use. Testing is conducted in accordance with written procedures, and the results are documented. For nuclear applications, testing is independently verified.

4.10 Computer Hardware Systems

In-use test problems will be run whenever the computer program is installed on a different computer, or when significant hardware or operating system configuration changes are made. Periodic in-use manual or automatic self-check routines will be prescribed and performed for those applications where computer failures or drift can affect required performance. Procedures will be established that identify the controls for non-nuclear hardware systems based on specific customer and other requirements.

5.0 DOCUMENT AND DATA CONTROL

Managers are responsible for ensuring that all activities affecting the quality of items and services are accomplished in accordance with controlled documents such as quality system manuals, procedures, work instructions, and controlled data such as customer order requirements. These documents contain appropriate criteria for determining whether prescribed activities have been completed satisfactorily. Procedures are established which provide for document review, approval, issue, and changes to ensure inclusion of customer technical and quality requirements prior to implementation. All personnel are responsible for ensuring that the correct revisions of applicable industry codes and standards are used, in accordance with customer requirements.

5.1 Document Approval and Issue

Each manager with lead responsibility for a document or document series is responsible for establishing controls that define responsibility, authority, issue, use, and revision and control of the document or document series. Document control procedures identify (as applicable):

- Format and content guidelines;
- Requirements to ensure that documents are complete, correct, current, and in compliance with all applicable technical, quality, and administrative requirements;
- Individuals or organizations responsible for review and approval of documents, and revisions thereto;
- Requirements for the release and issue of approved documents to ensure that responsible personnel are promptly provided with current document revisions at the location where the document is used;
- Requirements for document effective and/or issue dates;
- Requirements for identifying what has been revised;
- Requirements for maintaining document master lists and controlled distribution lists; and
- Provisions for reissuing drawings after a practical number of changes have been identified/approved for inclusion.

During the document preparation and review cycle, designated personnel review documents to ensure that the requirements can be met within a timely manner once the document is formally issued. Review and approval of changes are performed by the same organizations that reviewed and approved the original documents, or by designated alternate organizations who have access to the original data.

Changes to procedures, instructions, and drawings are approved and documented prior to implementation and are made available at the location where the activity will be performed prior to commencing work.

5.2 Quality Management System Document Control

All levels of management are responsible for assigning responsibilities to ensure that documents and data are controlled in accordance with established procedures and resolving issues pertaining to policy and procedure content, application, and use.

The control of the QMS is the responsibility of the ESBU Management Representative, or designee.

5.3 Computer Software Control

Documented procedures are established to control changes to the approved configuration of computer software used on product-related applications. The development and maintenance of computer software include documentation describing computer software requirements, computer software design, verification and validation (testing), configuration control, and error reporting and resolution. Organizations developing or supplying computer software are required to use policies and procedures that comply with the applicable requirements of the QMS.

5.4 Translation of Documents

Translations of documents from or to a language other than English, which could have an effect on safety-related products or services, will be translated by a qualified translator. These translations will be verified and certified in accordance with established procedures.

5.5 Specifications and Drawings

Specifications and drawings are prepared to define design and process characteristics of items and services. The organization responsible for the design or process is responsible for determining the specification and drawings necessary to ensure compliance with customer and regulatory requirements. The organization that initiates specifications or drawings is responsible for ensuring that these documents are maintained and controlled.

6.0 PURCHASING

6.1 General

Controls of purchased items and services are established to ensure that applicable technical and quality requirements are met. Spare or replacement parts are procured to requirements which are equal to or greater than the original requirements. Purchasing activities are controlled through documented procedures and instructions that include requirements for bid evaluation, selection of suppliers, communication of requirements to suppliers, evaluation of supplier performance, and resolution of nonconformances. Suppliers of safety-related items are evaluated and approved by Quality prior to placement of a purchase order. Commitments to resolve unacceptable conditions are obtained from the supplier prior to contract award. Active suppliers (including ASME-accredited suppliers) of safety-related items are evaluated annually and audited at least every 3 years except as described below. Procurement documents are reviewed in accordance with established procedures to ensure that technical and quality requirements are correctly specified.

Based on an evaluation that is conducted and documented in accordance with ASME NQA-1, Section 5.1 of Appendix 4A-1, supplier audits may not be conducted for suppliers of safety-related items which are:

1. Relatively simple and standard in design, manufacturing, and testing, and
2. Adaptable to standard or automated inspections or tests of the end product to verify quality characteristics upon receipt.

6.2 Supplier Selection

The purchasing organization is responsible for placing orders only with qualified suppliers. Documentation of the acceptability of suppliers is maintained and identifies the items and/or services to be supplied. This documentation is maintained and is available to organizations as defined in established procedures. Procedures also describe requirements for the evaluation and selection of suppliers, as well as monitoring of supplier performance, in accordance with quality requirements.

Procedures are established to describe methods for evaluating supplier performance and for initiating corrective action. Evaluations of suppliers consider the historical quality performance data and audit/survey reports to the extent applicable to the equipment or service being procured. Evaluation and selection methods for suppliers of safety related items and services include one or more of the following: (a) evaluation of the supplier's history (including current capability) of providing the same or similar product in accordance with specified requirements; (b) review of supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated; and/or (c) supplier's technical and quality capability determined by a source evaluation of their facilities, personnel, and the content and implementation of their quality program. Failure of suppliers to correct problems contributing to unacceptable performance constitutes a basis for disqualification.

6.3 Surveillance

Quality conducts surveillance of suppliers during fabrication, inspection, testing, and release of items, as appropriate, and as specified in procurement documents. Surveillance planning for complex items is performed by Quality, and special emphasis is placed on aspects of manufacture and inspection that could affect equipment performance and reliability. The frequency and scope of surveillance vary with the importance to safety, complexity of an item or service, and supplier performance.

In addition to item verification, the surveillance representative verifies supplier activities such as the following:

- Written instructions are maintained current.
- Supplier certificates are correct and based upon objective evidence.
- Corrective action is implemented, when required.

Supplier management is informed of problems, and commitments for corrective action are obtained. Reports are provided to management, as appropriate, for information and resolution of significant problems. Nonconformances and/or deviations are documented by the supplier and are reported and dispositioned in accordance with requirements of the procurement document.

6.4 Procurement Documents

Procurement documents for safety-related procurements require qualified suppliers to have a quality program consistent with the applicable portions of 10CFR50, Appendix B as evaluated in accordance with ANSI standards or ASME NQA-1.

Procurement documents (for example, purchase requisitions, purchase orders, supplier quality requirements, engineering drawings, specifications, etc.) are controlled to ensure that applicable technical and quality requirements are communicated to suppliers.

Engineering organizations define technical and quality requirements for purchased items and services. Quality requirements are incorporated into procurement documents in accordance with the QMS, regulatory, and customer contractual requirements. Organizations responsible for original requirements documentation submitted to Purchasing are also responsible for processing changes to that information, submitting the changes to Purchasing and revising standard documents, as appropriate, to incorporate the changes. Purchasing organizations are responsible for formally communicating changes to suppliers.

6.4.1 Supplier Design Controls

Design controls required of suppliers include:

- Measures to ensure that design bases are correctly translated into drawings, specifications, procedures, and instructions
- Documented review of designs to ensure that appropriate quality standards are specified
- Control of design changes commensurate with those applied to the original design

- Review and approval of changes to quality documents by the group responsible for originating the documents
- Independent verification of designs by review, testing, or alternate calculations
- Design-related computer software control

6.4.2 Customer Access to Suppliers

Customers may require access to suppliers' locations for surveillance, audit, and/or verification purposes. Such requirements specified in customer contracts are identified during the contract review process and communicated to the applicable quality and purchasing organizations for coordination with the customer and supplier. Records of customer involvement are maintained in accordance with established procedures.

6.4.3 Document Submittal

When suppliers are required to submit drawings, specifications, and procedures for review, approval, or other informational purposes, these requirements are specified in procurement documents.

6.5 Computer Software Procurement

Organizations responsible for developing or supplying software, or providing software services, utilize established policies and procedures that meet the applicable requirements of the QMS. Procured software that has not been developed in accordance with the requirements of the QMS shall be controlled, evaluated, and tested prior to use, as described in documented procedures.

6.6 Documentation

Supplier submittals of documents are evaluated against approved acceptance criteria for technical correctness, adequacy of inspection methods, and completeness of test data. Items with contingent conditions that require additional action after delivery are documented and monitored until resolution is complete and documented.

6.7 Acceptance

6.7.1 Quality Releases

Quality Releases are prepared and issued for items shipped to the customer, based on the item's importance to safety and/or complexity of item, in accordance with established procedures. The Quality Release is a document that provides for:

- The specific identification of the procured item by purchase order number, appropriate item designation, and serial number.
- Certification that the equipment meets requirements of the purchase order, drawings, and specifications.
- Identification of any deviations to the procurement requirements, including requirements that have been deferred and are to be accomplished at the site. Approved Deviation Notices are listed on the Quality Release.

Audits, surveillance, and inspections are performed, as appropriate, to verify the supplier's compliance with procurement documents.

6.7.2 Engineering Services

When engineering services are procured for safety-related items, they will be subject to technical verification, audit of the activity, or other objective evidence reviewed to ensure conformance with procurement requirements.

6.7.3 Certificates of Conformance

Certificates of Conformance (C of Cs) are issued in accordance with customer requirements and with established procedures. C of Cs are signed by designated personnel based on documented acceptance records.

6.7.4 Post-Installation Testing

When post-installation testing is required for acceptance of safety-related components, the responsible division and the applicant/licensee or agent will mutually establish the test requirements and acceptance documentation.

6.8 ASME Supplied Items

Items required to meet ASME Section III, Division 1 requirements are supplied as follows:

- Obtained from suppliers holding the proper certificates of authorization
- Supplied under an independent Westinghouse quality program accredited by the ASME

No repair, replacement, modification, or alteration activities are performed on ASME Section III stamped items purchased under this program.

6.9 Commercial-Grade Items

Commercial-grade items intended for safety-related applications are subjected to a dedication process that is defined and authorized by engineering in accordance with procedures that meet the requirements of Generic Letter 89-02 [NRC endorsement of EPRI NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety Related Applications" (NCIG-07].

7.0 CONTROL OF CUSTOMER-SUPPLIED PRODUCT

When customer items and material are supplied in accordance with contractual requirements, the applicable marketing and/or contract administration organization communicates the appropriate customer requirements to the responsible organizations.

Procedures provide for the identification, inspection, and protection of customer-supplied items and material and for the application of such material in the manufactured item or services. Any customer-supplied item or material that is lost, damaged or otherwise unsuitable for use is documented and reported to the customer.

8.0 PRODUCT IDENTIFICATION AND TRACEABILITY

Procedures are established to specify the methods and extent of identification and traceability of items to ensure that defective or incorrect items are not installed or used in products.

8.1 Identification Requirements

Engineering is responsible for specifying the requirements for the identification, traceability, and control of items. The identification may be on the item itself, on documents attached to the item, or on containers in which the items are handled.

8.2 Identification of Items

Identification of items is maintained, as necessary, to provide confidence that the correct items are used. Suppliers are required to identify all supplied items in accordance with the requirements of procurement documents.

8.3 Traceability of Items

When regulatory or customer requirements include traceability of items, procedures are established to provide identification, traceability, and records. Engineering organizations define the traceability requirements in drawings or specifications and provide specific instructions for accomplishing the required identification. If the requirements impact suppliers, purchasing includes the requirements in the procurement documentation. Items including consumable materials and items identified as having limited calendar, shelf, or operating lives or cycles are traceable and controlled. Procedures identify the organization responsible for storing and controlling these items in a manner that precludes use after the shelf life or operating life has expired.

The loss of identification on traceable items is documented and the items dispositioned in accordance with established procedures.

Records of item traceability are maintained in accordance with established procedures.

9.0 PROCESS CONTROL

9.1 General

Manufacturing, service, and installation activities are planned and performed under controlled conditions that ensure conformance to customer requirements, quality system requirements, and applicable standards and regulations. Management is responsible for ensuring that only properly trained and qualified personnel are assigned to accomplish work activities and that they are provided adequate facilities, equipment, tools, and information to perform their work in compliance with requirements.

Processes affecting the quality of items and services are controlled by instructions, procedures, drawings, checklists, process control documents, computer software, and/or other appropriate methods. When required, process parameters and environmental conditions are specified and maintained. Typical elements of process control include but are not limited to:

- Work instructions
- Quality workmanship standards
- Routings
- Acceptance criteria
- Process monitoring
- Process and equipment approval as appropriate
- Checklists
- Process control documents
- Validation and control of computer software used for process control
- Maintenance of equipment

9.2 Special Processes

Special processes, the results of which, are highly dependent on the control of the process or the skill of the operator, or both, are controlled through written procedures, and records are established and maintained. Special processes include nondestructive examination (NDE), welding, brazing, cleaning, heat treating, etc. Nondestructive examination is in accordance with ASNT-TC-1A or other specified requirements.

Special process controls are developed, as appropriate, with sufficient demonstration runs to ensure that the special process will yield acceptable results. Personnel, equipment, and procedures used to perform special processes are qualified in accordance with established procedures. Documentation of personnel, equipment, and process qualifications is maintained.

Qualification of processes and personnel for welding is in accordance with the ASME Boiler and Pressure Vessel Code or other specified requirements. Welding to the requirements of ASME Code Section IX, when performed by Westinghouse organizations, is performed in accordance with written welding procedures and utilizing welding personnel of the organization who are qualified and have been certified in accordance with the organization's approved quality program as permitted by Section IX of the ASME Code. The organization utilizing the applicable welding procedures or personnel is responsible for reviewing certifications for compliance with the specific job requirements prior to use. In addition, organizations/

subsidiaries may utilize welding procedures and personnel qualified by other Westinghouse divisions if the procedures and personnel have been qualified and certified in accordance with a quality program that has been approved by the user organization.

Subcontractors performing special processes at operating nuclear plant sites and other locations are managed by the responsible Westinghouse organization in accordance with approved field service procedures.

10.0 INSPECTION AND TESTING

Inspection and testing are performed on both purchased and manufactured items, as applicable, to verify compliance with acceptance criteria. Tests for safety-related items may include proof tests before installation, post-modification tests; prototype qualification tests, production tests, construction tests, and pre-operational tests. Sources of criteria include drawings, specifications, industry codes and standards, and contractual requirements that are provided or approved by the organization responsible for the design.

Inspections and tests are performed by personnel checking their own work or by qualified inspection and test personnel independent of those performing the work, when required by contractual or regulatory requirements. For safety related items, inspections or tests will be performed by qualified personnel who are independent of those performing the work.

Inspections are performed in accordance with written procedures or inspection plans. These may include checklists, forms, steps integrated into other process control documents, or work instructions. If hold points are required, they are identified in applicable documents. Work shall not proceed beyond hold points without authorization from the organization that established the hold point(s). This authorization is documented. Inspection procedures/plans include, as a minimum:

- Organization performing the inspection
- Characteristics being inspected
- Specification of inspection method on safety related items
- Acceptance criteria
- Sampling plans, if applicable
- Records to be maintained

Tests are performed in accordance with written procedures or instructions which include, as a minimum:

- What is being tested
- Prerequisites
- Acceptance criteria
- Calibration requirements
- Mandatory hold points
- Test conditions
- Test equipment
- Test personnel requirements
- Requirements for recording test data
- Records to be maintained

Procedures provide for identifying nonconforming items and for identifying, documenting, and controlling unverified items to permit recall and replacement in the event of a nonconformance to specified requirements.

10.1 Receiving Inspection and Testing

Procedures are established to ensure:

- Incoming items are not used or processed until they have been accepted for use, except in those cases in which a subsequent test or inspection will verify acceptability. Methods of acceptance include Certificate of Conformance, source verification, and receiving inspection.
- Acceptance is performed in accordance with written checklists, plans, or procedures.
- Items released for urgent production purposes are identified, documented, and controlled to permit recall until acceptance is completed.

10.2 In-Process Inspection and Testing

Items in process are inspected commensurate with their complexity and importance to nuclear safety.

Procedures are established to ensure:

- Identification and disposition of nonconforming items;
- Items are held until completion of required in-process inspections and testing;
- Positive recall measures are applied to ensure that the required inspections and tests are satisfied if process inspection and test points are bypassed; and
- Process monitoring and control methods are employed using qualified processes and people. Process monitoring and inspections may be used in combination to ensure that specified requirements for control of the process and quality of the item are being achieved. These activities are documented when required, for acceptance of safety-related items.

10.3 Final Inspection and Testing

Procedures are established to ensure that required final inspections and tests, including associated documentation, have been completed and results accepted before items are released. Final inspection and testing include the resolution of any nonconformances.

10.4 Inspection and Test Records

Procedures establish provisions for generation of quality records of planned inspection and test activities, as appropriate, to document that items satisfy established criteria.

Inspection and test records for safety-related items shall, as a minimum, identify: item, date, inspector/tester or data recorder, type of observation, results and acceptability, action taken for deviations noted, and person(s) evaluating test results.

11.0 CONTROL OF INSPECTION, MEASURING, AND TEST EQUIPMENT

Inspection, measuring, and test equipment is calibrated and controlled in accordance with established procedures to ensure the accuracy of measurements. Each device is properly controlled, calibrated, and adjusted at specified intervals to maintain its accuracy within the necessary limits. Jigs, fixtures, templates, inspection software, and test software are also controlled to ensure accuracy. Inspection and test software is validated prior to use. Process controllers, microprocessors, and software, when used as an integral part of the measuring and test equipment system, are not interchanged without recalibration of the test system. Personnel using measuring and test equipment are responsible for ensuring that the equipment is calibrated.

Procedures have been established for control of inspection, measuring, and test equipment, including tools, as appropriate, to ensure that such devices fit the purpose and are of the proper type, range, accuracy, and tolerance to accomplish the function of determining conformance to specified requirements. Selection of equipment type takes into account factors that may affect the known measurement uncertainty, including equipment accuracy, environmental effects, skills of personnel using the equipment, and condition of the item being verified. Handling and storage of measuring and test equipment are controlled to ensure that the accuracy of the equipment is maintained.

Inspection, measuring, and test equipment utilization is controlled. A record system, including a description of the device, the unique device identifier, calibration intervals, next due date, the calibration standard used, and results of the calibration, is maintained. Calibration is performed at specified intervals in accordance with written procedures using standards traceable to national recognized standards. Calibration standards have a higher accuracy level than the equipment being calibrated. Where no national standards exist, the basis used for calibration shall be documented. Each inspection, measuring, and test device is given a calibration status indicator based upon the latest calibration records. Out-of-calibration devices are tagged or segregated until repaired and recalibrated, or replaced. Systems and practices provide for the safeguarding of inspection, measuring, and test equipment from adjustments that would invalidate the calibration settings.

Documentation is maintained to support an evaluation of the validity of previous measurements when measuring and test equipment is found to be out of calibration.

12.0 INSPECTION AND TEST STATUS

The organization responsible for a work scope ensures that the status of inspections, tests, and operations can be determined at any point throughout the process. Altering the sequence of tests, inspections or other operations requires the authorization of personnel responsible for the function being altered. Status indicators are used on items or in documents traceable to the item to ensure that required inspections, tests, and operations have been performed before release in accordance with established procedures and instructions. Procedures are established to ensure that an item has satisfactorily passed required inspection and tests, and to prevent the use of defective material in production.

Some examples of status indicators include:

- Color-coded markings
- Tags
- Authorized inspection stamps
- Nonconformance reports/tags
- Labels
- Routings
- Bar codes on worksheet routings
- Inspection records
- Test records
- Physical location
- Labeling of software

Authorized personnel are responsible for ensuring that only product conforming to specified requirements is released for shipment. The authority for applying and removing status indicators is specified.

13.0 CONTROL OF NONCONFORMING PRODUCT

Nonconforming items and services are controlled to ensure proper disposition. A nonconformance is defined as a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

All personnel are responsible for reporting nonconformances in accordance with established procedures.

Procedures are established for the identification, documentation, evaluation, segregation (if practical), review, corrective action, and notification to affected organizations. Disposition may include rework, accept as-is, repair, or reject and scrap. Repaired and reworked items are reverified in accordance with the original criteria or as specified in the disposition. In the disposition of a safety-related item, technical justification for the acceptability of a nonconforming item that is to be repaired or used as-is will be documented. Nonconformances of these items will be subject to control measures commensurate with those applied to the original design. When required by contract, customer approval of the final disposition is obtained.

14.0 CORRECTIVE AND PREVENTIVE ACTION

14.1 General

Conditions adverse to the quality of items and services are identified, documented, analyzed, and corrected in accordance with established procedures. For significant conditions adverse to quality, these procedures provide for identification; assignment of responsibility for corrective action; documentation of the cause and corrective action taken; implementation, evaluation, and verification of corrective action to prevent recurrence; and reporting to the appropriate levels of management.

14.2 Corrective Action

The need for corrective action is identified through sources such as nonconformances, failures, malfunctions, audits, inspections, surveillance, and customer complaints. Organizations performing quality/product assurance functions participate in evaluating and verifying corrective action implementation. They have the authority to stop work or ensure adequate controls are in place until effective corrective action has been taken and any applicable changes have been incorporated in procedures and communicated to appropriate personnel.

Provisions are contained in procedures to ensure that corrective actions are reviewed and not inadvertently nullified by subsequent actions. For significant conditions adverse to quality, the causes are determined and documented and the impact on items and services is evaluated. Reports, including actions to prevent recurrence, are provided to the appropriate level of management.

14.3 Preventive Action

Quality data is analyzed for trends in products, processes, and systems that may require action to eliminate causes of potential conditions adverse to quality. The results of these analyses are provided to management to determine the preventive action required to prevent occurrence. When necessary, this action will include the application of controls to ensure that it is effective.

15.0 HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY

15.1 General

Systems are established to ensure that parts and material are received, handled, stored, packaged, and delivered in accordance with codes, standards, regulations, designs, and customer requirements. Procedures require that items shipped from suppliers, items processed internally, and product shipped directly to customers are received in acceptable condition. Procedures also provide for:

- Storage requirements, such as shelf life and environmental control;
- Special material handling requirements; and
- Standard and nonstandard shipping requirements.

15.2 Handling

Engineering and user organizations are responsible for specifications and procedures for the use of handling equipment. Periodic equipment examinations verify conformance to required codes and/or standards. Procedures also provide for the handling of items to prevent damage or deterioration.

When items are shipped to a plant site or storage facility, special handling, storage, and shipping instructions will be provided in accordance with the requirements of the customer.

15.3 Storage

All stored items are properly identified and located in areas that provide adequate control of access. When necessary, special coverings, equipment, and protective environments are specified for storage by engineering organizations. Engineering organizations are also responsible for identifying shelf-life characteristics and preservation and storage requirements, and systems are established to protect against deterioration or expiration of shelf life.

Purchasing organizations are responsible for transmitting storage requirements to suppliers and determining their capability to meet them.

Storage areas are monitored at planned frequencies to ensure adequacy of the storage system and the status of stored items.

15.4 Packaging

Cleaning, packaging, and preservation for shipment and delivery are performed in accordance with documented instructions, procedures, or drawings, as specified by the responsible engineering organization. These requirements include packaging and preservation provisions for both long-term and short-term storage and are implemented by the organization responsible for accomplishing the work, including cleaning, packaging, marking, labeling, and preserving.

15.5 Delivery

Each organization is responsible for defining transportation requirements to ensure integrity of products during delivery to their destination and for monitoring conformance to established methods. Purchasing is responsible for transmitting shipping requirements to suppliers and determining their capability to meet them.

16.0 CONTROL OF QUALITY RECORDS

Quality records are completed documents that furnish evidence of the quality of items, services, and/or activities affecting quality and compliance with the QMS. These quality records will be controlled in accordance with established procedures. These procedures identify the requirements and responsibilities for records classification, legibility, identification, collection, filing, indexing, storage, distribution, retention, retrieval, and disposition. At manufacturing divisions, product-related records are not considered complete until the time of product shipment.

Quality records are retained, reviewed, and provided to the customer in accordance with applicable contractual and regulatory requirements. Documents are considered valid records when they are validated by stamp, initialed, or signed and dated, by authorized personnel. Handwritten signatures are not required if the document is clearly certified or otherwise authenticated as a statement by the reporting individual or organization. Correction of quality records is in accordance with established procedures.

Records requirements for suppliers of items and services are specified in procurement documents, as required. Suppliers' records systems are verified and monitored during surveillance and audits.

Quality records are protected against deterioration, damage, and/or loss in accordance with established procedures, and safety-related records requiring long-term storage are maintained either at an approved single storage facility or by storage of duplicate copies at separate geographical locations.

16.1 Classification of Nuclear Records

Records that are generated in accordance with the QMS for items and services supplied to nuclear power plants are classified as lifetime or nonpermanent. These records are classified in accordance with Reg. Guide 1.28 and stored in accordance with ASME NQA-1, Supplement 17S-1.

16.1.1 Lifetime Records

Quality records are classified as lifetime if they meet one or more of the following:

- Records that would be of significant value in demonstrating capability for safe operation of a nuclear power plant.
- Records that would be of significant value in maintaining, reworking, repairing, replacing, or modifying a safety-related item.
- Records that would be of significant value in determining the cause of an accident or malfunction of a safety-related item.
- Records that provide required baseline data for in-service inspection of a nuclear power plant.

16.1.2 Nonpermanent Records

Quality records are classified as nonpermanent when they show evidence that an activity was performed in accordance with applicable requirements, but do not meet any of the criteria for lifetime records.

17.0 INTERNAL QUALITY ASSESSMENTS

17.1 Internal Assessments

The quality organization is responsible for implementing and maintaining an internal assessment program to examine and evaluate objective evidence for compliance with the QMS and evaluating the effectiveness of implementation. Internal assessments of activities affecting the quality of items and services are scheduled, planned, and conducted at least annually in accordance with established procedures.

Assessments are scheduled based on the status and importance of an activity, and schedules are updated as necessary to ensure that adequate coverage is maintained. Supplemental assessments are performed when necessary to verify specific activities, processes, and/or implementation of corrective actions.

Assessments are performed by qualified personnel, independent of the activity being assessed, using written procedures and/or checklists, as appropriate. Reports documenting results are prepared upon completion of the assessment and distributed to appropriate management. Assessment reports require the assessed organizations to provide a response within a specified time period to identify planned corrective actions and a schedule for completion thereof, when applicable. Quality is responsible for evaluating, following, and verifying corrective action implementation. Reported conditions that become overdue are escalated to higher management for resolution, as necessary.

Auditors are trained on quality standards, regulatory requirements, and internal practices. Lead auditors are qualified in accordance with ASME NQA-1, Supplement 2S-3 and qualification records are maintained by Quality.

Assessment records include assessment plans, checklists, assessment reports, written replies, and documentation of completed corrective actions.

17.2 Assessments at Field Locations

Field services are conducted and controlled in accordance with specific contractual requirements. Assessments will be conducted on service activities at customer sites when specifically identified in the contractual agreements and will be scheduled with the following considerations, when contractually required:

- As early in the life of the activity as practical
- At intervals consistent with the schedule for accomplishing the activity
- Commensurate with the status and importance of the activity

17.3 Self-Assessments

Self-assessments are performed for nuclear projects when an organization is a licensee or participates as an applicant for new plant design/construction and implements 10CFR50, Appendix B quality program requirements. Procedures for implementing the self-assessment process are developed in detail commensurate with the complexity of the activity and importance to safety.

18.0 TRAINING

Managers of activities affecting quality are responsible for assessing their organizations' training needs and ensuring that personnel are adequately trained and qualified to manage and perform work activities. This includes indoctrination to and familiarization with applicable quality assurance program and procedure requirements and any special skills training required for the performance of job activities. The extent of such training is commensurate with the scope, nature, and complexity of the activity, as well as the education, experience, and proficiency of the individual. Training and indoctrination are documented, and records are maintained in accordance with applicable records procedures.

Historical records of personnel education and experience may serve as documentation of job proficiency, when supplemented by applicable training records.

Personnel performing surveillance/inspection, test, NDE examination, and audit activities are qualified in accordance with applicable requirements, including specific provisions for education and experience. Qualification programs include documentation of capability through either written tests or physical demonstrations of skill, as well as evidence of maintenance of proficiency based on retraining or continued satisfactory performance. Documentation in the form of certificates of qualification, or other similar records, specifies activities for which the individual is qualified, the basis for certification, and the period for which the certification is valid.

19.0 SERVICING

Organizations have engineering and service capabilities that ensure proper installation, on-line start-up testing, and acceptance of supplied systems and items, as well as other similar systems. Organizations involved in maintenance programs, reliability, and field test programs provide training on systems and products to customers upon request. Interfaces are identified and maintained to provide support as necessary to meet servicing work scopes.

19.1 Servicing Requirements

Engineering organizations responsible for field services determine the applicable requirements by reviewing customer contracts and technical documentation that define the system or products in the service work scope. Responsible organizations provide technical direction to customer personnel, customer subcontractors, or specific planned services provided to the customer.

19.2 Performing Services

Services (including repair services) are performed by each organization in a controlled manner that ensures conformance to the organizations' procedures and customer requirements. Procedures and work instructions are used to ensure that the servicing work is performed under a degree of control consistent with the original manufacture and/or installation of the systems and products.

Engineers from appropriate organizations participate in the process for returning components, materials, or assemblies to the manufacturing plant for either warranty repair or regular repair and for service in the field when appropriate.

20.0 STATISTICAL TECHNIQUES

Organizations are responsible for incorporating statistical techniques into operations to the extent necessary to ensure that acceptable items and services are provided in an acceptable manner. Each organization identifies the statistical techniques that are adequate to ensure that quality and technical requirements are achieved. The procedures that describe this application are implemented when specified requirements, process capability, or product performance characteristics can be evaluated using statistical techniques to determine product or service acceptability or to identify improvement opportunities.

Each organization identifies the responsibilities for approving the application of statistical techniques and evaluation of results. Organizations utilizing statistical techniques in activities establish procedures for analyzing the results of the statistical information and initiating changes to controls when appropriate.

APPENDIX A
POSITIONS ON REGULATORY GUIDES AND ASME NQA-1

ESBU organizations comply with the regulatory positions listed below, when applicable. Additional positions on Regulatory Guides and ASME NQA-1 may be given in individual Safety Analysis Reports (SARs).

1.0 REGULATORY GUIDES

1.1 Reg. Guide 1.8, Rev 2, "Qualification and Training of Personnel for Nuclear Power Plants" - Not applicable to scope of work.

1.2 Reg. Guide 1.26, Rev 3, "Quality Group Classifications and Standards for Water - Steam - and Radioactive-Waste - Containing Components of Nuclear Power Plants" - See specific SAR.

1.3 Reg. Guide 1.28, Rev 3, "Quality Assurance Program Requirements (Design and Construction)" - ESBU follows NRC Regulatory positions with the following clarifications:

Section C.1, Appendix 2A-1, "Nonmandatory Guidance on the Qualification of Inspection and Test Personnel" provides guidance on the qualification of inspection and test personnel.

Position (Alternate) - Where high school graduation is specified in (Appendix 2A-1), paragraph 3.0, a General Education Development (GED) equivalent of a high school diploma is considered acceptable.

Where three levels of qualification are to be utilized depending on the complexity of the function involved, specific level designations for personnel involved in inspection, examination, and testing activities may not necessarily be used. A combination of position descriptions and pre-determined qualification requirements for a position define the level of capability required to perform the function. These methods are used to identify levels of capability that include the comparable requirements of the levels identified in Appendix 2A-1.

Section C.3, "Audits"

Position (Clarification)

The regulatory position in Section C.3 along with alternatives to NQA-1, which are compatible with Reg. Guide 1.28, Rev. 3 will be followed.

1.4 Reg. Guide 1.29, Rev 3, "Seismic Design Classification" - See specific SAR.

1.5 Reg. Guide 1.33, Rev 2, "Quality Assurance Program Requirements (Operation)" - Not applicable to scope of work.

1.6 Reg. Guide 1.36, Rev -, "Nonmetallic Thermal Insulation for Austenitic Stainless Steel" - Quality Assurance controls are applicable, see specific SAR.

1.7 Reg. Guide 1.54, Rev -, "Quality Assurance Requirements for Protective Coatings Applied to Water-Cooled Nuclear Power Plants - See specific SAR.

1.8 Reg. Guide 1.143, Rev 1, "Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants" - See specific SAR.

1.9 Reg. Guide 1.152, Rev -, "Criteria for Programmable Digital Computer Systems Software in Safety-Related Systems of Nuclear Power Plants" - ESBU organizations follow NRC regulatory positions.

1.10 Reg. Guide 2.5, Rev -, "Quality Assurance Program Requirements for Research Reactors" - Not applicable to scope of work.

1.11 Reg. Guide 3.3, Rev 1, "Quality Assurance Program Requirements for Fuel Reprocessing Plants and for Plutonium Processing and Fuel Fabrication Plants" - Not applicable to scope of work.

1.12 Reg. Guide 3.21, Rev -, "Quality Assurance Requirements for Protective Coatings Applied to Fuel Reprocessing and to Plutonium Processing and Fuel Fabrication Plants" - Not applicable to scope of work.

1.13 Reg. Guide 4.15, Rev 1, "Quality Assurance for Radiological Monitoring Programs (Normal Operation) - Effluent Streams and the Environment" - Not applicable to scope of work.

1.14 Reg. Guide 7.10, Rev 1, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Materials" - ESBU organizations follow the NRC regulatory positions.

1.15 ASME Boiler & Pressure Vessel Code, Section III - For safety class items covered by Section III of the ASME B&P Code the quality assurance requirements (NCA 4000) are supplemented by Reg. Guides 1.8, 1.26, 1.28, 1.29, 1.33, 1.152 and Generic Letter 89-02, as applicable.

1.16 Generic Letter 89-02 endorsement of EPRI NP-5652, 'Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)" - ESBU organizations follows these guidelines.

1.17 Regulatory Positions 2 and 4 of Branch Technical Position CMEG 9.5-1 as given in SRP Section 9.5.1 - Fire protection QA controls are to be in accordance with this position.

1.18 Regulatory Position 6 of Reg. Guide 1.143, Rev 1, - Radioactive waste QA controls are to be in accordance with this position

2.0 ASME NQA-1, Part I

2.1 Introduction -Terms and Definitions - Quality Assurance Record: "A completed document that furnishes evidence of the quality of items and/or activities affecting quality."

Position - Prior to their delivery to the long-term storage facility, records are protected by normal office procedures, including either duplicate copies or the capability to reconstruct records lost during this period. At manufacturing divisions, product-related records are not considered complete until the time of product shipment.

2.2 Supplement 2S-2, Section 2.1 - "The American Society of Nondestructive Testing Recommended Practice No. SNT-TC-1A, June 1980 Edition and its applicable supplements shall apply as requirements to NDE personnel covered by this Supplement.

Position - Alternative

Organizations holding an ASME Certificate of Authorization may qualify nondestructive examination personnel as required by the ASME Code.

2.3 Supplement 2S-4, Section 4, Standard Paragraph

"Training shall be provided, if needed, to: (a) achieve initial proficiency; (b) maintain proficiency; and (c) adopt to changes in technology, methods, or job responsibilities."

Position - Clarification

Manufacturing divisions have programs for training personnel performing fabricating, handling, shipping, storing and cleaning activities to achieve initial proficiency. Maintenance of proficiency is accomplished through continued assignments in that activity. Additional training is performed, as needed, when the job function/responsibility is changed.

2.4 Supplement 2S-4, Section 5, Standard Paragraph

"Records of the implementation of indoctrination and training may take the form of: (a) attendance sheets; (b) training logs; or (c) personnel training records.

Position - Clarification

At manufacturing divisions training records for personnel performing fabricating, handling, shipping, storing and cleaning activities are available for review, however, they are not maintained as nonpermanent quality assurance records.

2.5 Supplement 3S-1, Section 6.0, Standard Paragraph

Interface Control: "Interface controls shall include the assignment of responsibility and the establishment of procedures among participating design organizations for the review, approval, release, distribution and revision of documents involving design interfaces."

Position - Clarification

The responsibilities and authority of persons involved in the design process are defined by organization charts, management appointment letters and internal procedures. These documents are available for audit but are not transmitted to external organizations. Various interface agreements are established among the design departments, suppliers, customers and architect-engineers to ensure the proper flow and control of design information among the participants, and are documented by correspondence procedures, memoranda of understanding or contract documents.

2.6 Supplement 7S-1, Section 2, Standard Paragraph

Procurement Planning: "Planning shall provide for the integration of;...(3) verification (surveillance, inspection or audits) activities by Purchaser, including notification of hold and witness points;"

Position - Alternative

Divisions routinely identify notification points in procurement documents when applicable. Such points are not always identified in pre- and post-award meetings. However, the required notification/hold points are specified by changes to the procurement documents in a reasonable time prior to their being accomplished to allow the Purchaser the opportunity to witness the event.

2.7 Supplement 7S-1, Section 3.1, Standard Paragraph

Source Evaluation and Selection: "Measures for evaluation and selection of procurement sources, and the results therefrom, shall be documented and shall include one or more of (a) through (c) below:"

Position - Clarification

In addition to methods (a), (b) and (c) for the evaluation and selection of procurement sources, ASME accredited certificate holders may be selected for the supply of ASME Section III code items and services as identified within the scope of their ASME certificates, based upon ASME acceptance of their Quality Assurance Program. Audits and annual evaluations are performed in accordance with the commitments and requirements of this Plan.

2.8 Supplement 7S-1, Section 9, Standard Paragraph

Control of Supplier Nonconformances: "Nonconformances to the procurement requirements or Purchaser-approved documents, which consist of one or more of the following, shall be submitted to the Purchaser for approval of the recommended disposition: (2) requirement in Supplier documents which has been approved by the Purchaser, is violated."

Position - Clarification

Suppliers are required to submit deviations from technical procurement requirements for approval. When suppliers are required to submit selected process or manufacturing procedures for approval, the term approval means a review to assure that the supplier understands the procurement requirements and is applying appropriate measures to assure compliance with these requirements. The approval action does not relieve the supplier of responsibility for assuring the acceptability of the product. Thus, suppliers are not required to submit nonconformance reports on deviations from these procedures, unless they constitute deviations from the Westinghouse procurement requirements.

2.9 Supplement 17S-1, Section 3.2, Standard Paragraph

Receipt Control: "As a Minimum, a receipt control system shall include the following:...(b) a method for identifying records received."

Position - Alternative

Receipt control systems are maintained to fit individual organizations' needs and requirements. Each system is defined in procedures and identifies the types of records to be processed. Files are established in accordance with these procedures establishing a separate file location for each category of record. When a record is received, it is filed in its pre-assigned location. The large volume of records and the diverse nature of the activities being performed preclude keeping a running inventory of each record received into an in-process/working file. The presence of the document itself serves as the record of what has been received. When action is completed for a particular activity or component, the in-process information is checked to assure that all appropriate records are available.

2.10 Supplement 17S-1, Section 4.4.1)

Position - 1

The Westinghouse Corporate Records Center (CRC) in Boyers, PA is utilized as a permanent records storage facility for inactive records which are stored in duplicate and/or single records as accepted by the U.S. Nuclear Regulatory Commission (6/02/80 and 3/08/79 letters from Mr. W. P. Haass and 4/23/81 letter from Mr. U. Potapovs). This facility is located in an underground limestone mine that is no longer being worked and is approximately 200 feet beneath the surface. Entry is made down a gradual graded hard surface roadway to a 24-hour guarded steel gate. This records storage facility provides an alternate to the construction criteria for a permanent records storage facility (as described below) which adequately protects records from possible destruction.

Position - 2

The walls which constitute the perimeter of this storage facility are limestone ribs, 15-20 feet thick with eight inch heavy duty concrete blocks constructed between the ribs from floor to ceiling with sealed expansion joints. Where there are doors in the perimeter to permit access, these doors are locked and monitored by video camera 24 hours a day.

Position - 3

The limestone mine, approximately 200 feet below ground level, is impervious to water and is 38 feet above the water table. Additionally, the entrance to the (CRC) is located approximately five miles away and 100 feet above the nearest stream. Floor and roof drains are not necessary.

Position - 4

All doors, frames and hardware are constructed of non-flammable materials such as steel or brass.

Position - 5

Aluminum enamel paint is applied to the walls and ceiling as a sealant.

Position - 6

Floors in the storage area are constructed of either asphalt or concrete over four feet of limestone. The asphalt floors are coated with a sealant. Concrete floors are coated with a hard wearing deck enamel.

Position - 7

The foundation consists of four-foot thick limestone base covered with concrete or asphalt acting as the foundation sealant. Because of the underground location and the fact that limestone is impervious to water, no foundation draining is necessary.

Position - 8

A natural draft of air flows through the mine and passes through forced-air circulation fans when entering and existing the storage areas. This air is also filtered as it enters the storage facility. This system assures adequate air circulation through the storage areas. The ventilation openings are equipped with fire rated dampers that close in guillotine fashion upon sensing heat.

Position - 9

A series of smoke detectors are located at strategic locations throughout the storage facility which would alert the fire crew at the first sign of a fire. This alarm system is tied into a central fire alarm board at the guard station located at the mine entrance. A volunteer fire crew with equipment is located at the storage facility. Additionally, fire extinguishers are located throughout the storage areas. A guard makes a tour inside the area every four hours during non-working hours. A volunteer fire department in a neighboring town is located within 1-1/2 miles of the mine entrance.

Position - 10

A single waterline is located within the storage facility to provide service water for sanitation and kitchen facilities. This line is equipped with shut-off valves both inside and outside the storage area. A drainage line is also located in the storage area to remove the discharge.

3.0 ASME NQA-1, PART II

Organizations follow ASME NQA-1, Part II identified in Appendix A with the following clarifications, alternatives and exceptions

3.1 Subpart 2.1 "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Power Plants"

Organizations follow the requirements of Subpart 2.1 for those portions of the construction site work within their scope.

3.2 Subpart 2.2 "Quality Assurance Requirements for Packaging, Shipping, Receiving Storage, and Handling of Items for Nuclear Power Plants"

Subsection 4.2.3 Special Shipments

Position - Exception

For special shipments, W implements requirements for bracing and tie down, identification of the shipment, use of impact recording meters and escorts, and investigation of the carrier and transportation route when appropriate. However, W does not consider it desirable or feasible to implement subsection 4.2.3 in all situations. For example it may not always be desirable to identify special shipments with large letters or it may not always be possible to install impact recording meters prior to handling. In summary, W implements controls for special shipments based upon engineering judgement and experience to assure proper transportation of the special shipment.

Subsection 3.6.2 Vaporproof Barrier Material

"Vaporproof barrier material should be colored to contrast with the material on which it is used."

Position - Alternate

W utilizes vapor barriers in packaging processes that contrast with the material being packaged when such packaging materials are commercially available. A variety of colors for these packaging materials is not readily available because of the limited supply of material which meet other physical and chemical requirements.

Section 5 Receiving (Requirements for receiving contained in Section 5)

Position - Clarification

Organizations follow this section for those portions of the construction site work within their scope.

Section 6 Storage (Requirements for storage contained in Section 6.)

Organizations follow this section for those portions of the construction site work within their scope.

Section 7 Handling (Requirements for handling contained in Section 7.)

Position - Alternate

Organizations and suppliers use conservative industrial engineering practices for controlling the lifting and moving of completed component during packaging and shipping operations.

3.3 Subpart 2.3 "Quality Assurance Requirements for Housekeeping for Nuclear Power Plants"

Organizations follow the requirements of Subpart 2.3 for those portions of the construction site work within their scope.

3.4 Subpart 2.4 "Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities"

Organizations follow the requirements of Subpart 2.4 for those portions of the construction site work within their scope.

3.5 Subpart 2.5 "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and foundations for Nuclear Power Plants"

Not applicable to the scope of work.

3.6 Subpart 2.7 "Quality Assurance Requirements of Computer Software for Nuclear Power Plants"

Organizations follow the requirements contained in Subpart 2.7

3.7 Subpart 2.8 "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems for Nuclear Power Plants"

Not applicable to the scope of work.