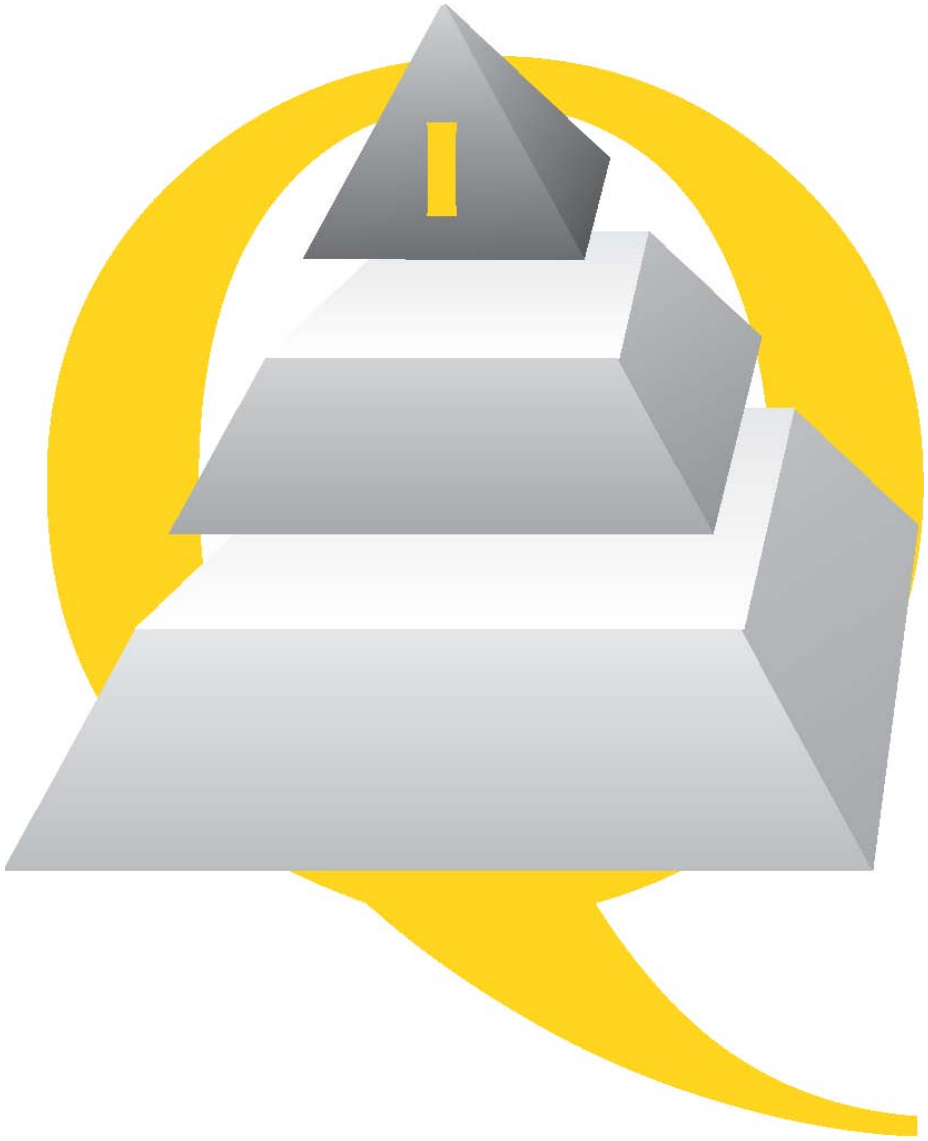
Enclosure 1

"Quality Management System (QMS)-A", Revision 8.0

(Non-Proprietary)

May 2020



Quality Management System-A

Revision 8.0

(NRC-approved Version)

Westinghouse

Westinghouse Electric Company
Quality Management System

Electronically Approved*

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

May 12, 2020

Ms. Camille Zozula, Manager
Infrastructure & Facilities Licensing
Westinghouse Electric Company
1000 Westinghouse Drive
Building 1, Suite 165
Cranberry Township PA 16066

SUBJECT: FINAL SAFETY EVALUATION FOR WESTINGHOUSE ELECTRIC COMPANY TOPICAL REPORT "QUALITY MANAGEMENT SYSTEM (QMS)," REVISION 8.0 (EPID L-2020-TOP-0022)

Dear Ms. Zozula:

By letter dated April 27, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20118C994), Westinghouse Electric Company (Westinghouse) submitted to U.S. Nuclear Regulatory Commission (NRC) Topical Report (TR) "Quality Management System (QMS)," Revision 8.0. By letter dated April 30, 2020 (ADAMS Accession No. ML20120A538), the NRC issued its request for additional information questions. By letter dated May 5, 2020, the NRC issued its draft safety evaluation (SE) for the TR "Quality Management System (QMS)," Revision 8.0. By letter dated May 7, 2020 (ADAMS Accession No. ML20129K029) Westinghouse provided comments on the draft SE.

The enclosed final SE addresses the applicability of the TR "Quality Management System (QMS)," Revision 8.0.

The NRC staff has found that "Quality Management System (QMS)," Revision 8.0, is acceptable for referencing in licensing applications to the extent specified and under the limitations delineated in the TR and the enclosed SE.

According to the guidance provided on the NRC website, we request that Westinghouse publish accepted proprietary and non-proprietary versions of these TRs within three months timeframe after non-proprietary version of this final SE is issued by NRC.

The accepted versions shall incorporate this letter and the enclosed final SE after the title page. Also, they must contain historical review information, including NRC RAI questions and your responses. The accepted versions shall include an "-A" (designating accepted) following the TRs identification symbol.

As an alternative to including the RAI questions and RAI responses behind the title page, if changes to the TRs were provided to the NRC staff to support the resolution of RAI responses, and the NRC staff reviewed and approved those changes as described in the RAI responses, there are two ways that the accepted version can capture the RAI questions:

1. The RAI questions and RAI responses can be included as an appendix to the accepted version.

2. The RAI questions and RAI responses can be captured in the form of a table (inserted after the final SE) which summarizes the changes as shown in the approved version of the TRs. The table should reference the specific RAI questions and RAI responses which resulted in any changes, as shown in the accepted version of the TRs.

If future changes to the NRC's regulatory requirements affect the acceptability of this TR, Westinghouse will be expected to revise the TR appropriately or justify its continued applicability for subsequent referencing. Licensees referencing this TR would be expected to justify its continued applicability or evaluate their plant using the revised TR.

Sincerely,

/RA/

Dennis C. Morey, Chief
Licensing Processes Branch
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Docket No. 99902038

Enclosure:
As stated

SUBJECT: FINAL SAFETY EVALUATION FOR WESTINGHOUSE ELECTRIC COMPANY TOPICAL REPORT "QUALITY MANAGEMENT SYSTEM (QMS)," REVISION 8.0 (EPID L-2020-TOP-0022) DATED MAY 12, 2020

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ADAMS Accession Nos.:
ML20132A017 (Package)
ML20132A303 (Letter)
ML20132A321 (SE Enclosure)
ML20132A325 (Comment Resolution Attachment) ***Via e-mail**

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UNITED STATES
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U. S. NUCLEAR REGULATORY COMMISSION

FINAL SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

WESTINGHOUSE ELECTRIC COMPANY TOPICAL REPORT

"QUALITY MANAGEMENT SYSTEM (QMS)," REVISION 8.0

(EPID L-2020-TOP-0022)

1.0 INTRODUCTION

By letter dated April 27, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20118C994), Westinghouse Electric Company (Westinghouse), requested approval of a proposed change to its "Quality Management System" (QMS) topical report (TR). In response to the United States Nuclear Regulatory Commission (NRC) staff's request for additional information (ADAMS Accession No. ML20120A538) to clarify the proposed changes, Westinghouse provided a supplemental submittal (ADAMS Accession No. ML20125A085) to include additional modifications to the QMS TR. The proposed change was considered a change to an NRC-accepted quality assurance (QA) TR from non-licensees (i.e., architect/engineers, nuclear steam supply system (NSSS) suppliers), in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," 50.4(b)(7)(ii). Westinghouse is also a 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," licensee holder and utilizes the same QMS TR to meet the requirements of Subpart H to 10 CFR Part 71. The proposed change extends the supplier audit frequency from once every three years (i.e., triennial) for the supplier audits and surveys affected by exigent conditions. The increased period between supplier audits and surveys will be supplemented by analysis or evaluations of supplier performance as prescribed in this safety evaluation (SE). The change is applicable to supplier audits implemented to meet the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 and Subpart H, "Quality Assurance," of 10 CFR Part 71 for supplier audit frequency for exigent conditions, for supplier audit frequency for exigent conditions, as described in the Westinghouse's QMS TR.

Currently, the Westinghouse QMS TR, Revision 7.1, Section 4.3.1, "General," under "Procurement," requires the following:

Suppliers of safety-related items and services are evaluated and approved by Quality prior to their designation as a qualified supplier, or placement of a purchase order. Active qualified suppliers (including suppliers accredited under national industry codes such as American Society of Mechanical Engineers (ASME)) of safety-related items are evaluated annually and audited at least every 3 years with the following exceptions:

For safety-related items and services, Quality determines the need to conduct supplier audits based on an evaluation that is conducted and documented in accordance with established procedures. Based on this evaluation Supplier audits need 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.

Audit programs for suppliers of items and services for nuclear power plants that are not subject to NRC regulations comply with requirements imposed by the governing regulatory agency or customer contract.

Westinghouse submitted the QMS TR, Revision 8.0 and requested the addition of a new Subsection 4.3.1.1, “Exigent Conditions” to this TR that states:

Under exigent conditions, the audit and/or survey interval may be extended up to 25%. This unique grace period can be applied if exigent conditions exist including but not limited to; a) declaration of a national emergency, b) severe localized or national weather conditions, or c) localized outbreak of a severe health concern to the public. Under these exigent conditions the audit clock resets when the audit and/or survey is performed. The 25% grace period extension is applicable to domestic and international suppliers.

During the use of the 25% extension, a supplier evaluation shall be performed, and results documented, including any necessary qualification adjustments. Suppliers in the 25% extension can be maintained on the Westinghouse Qualified Supplier List (QSL) provided the following actions (a-c) are taken and the results satisfactory:

a. Verification that:

(1) The supplier is still implementing a quality assurance program that meets Appendix B to 10 CFR Part 50 OR
(2) Commercial suppliers surveyed are still maintaining adequate documented programmatic controls for the activities affecting quality.

b. Monitoring ongoing and previous supplier performance promptly considering impacts of these following types of information:

1. Results of receipt inspection activities or other operating experience.
2. Review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions.

3. Results of audits and inspections from other sources (e.g., customer, ASME, NIAC audits or NRC inspections)

c. In the case of a new procurement activity or changes to existing procurements that significantly enlarges the scope or changes the method/controls for activities performed by the supplier, the evaluation shall document the justification that the change(s) are adequately addressed by the supplier's quality assurance program or mitigating actions are being taken by Westinghouse.

Exigent conditions, such as the national emergency caused by COVID-19, impacts Westinghouse's ability to complete external supplier audits and surveys within the frequency specified in its QA program that complies with Appendix B to 10 CFR Part 50. Exigent conditions have restricted both domestic and international travel and restricted access to supplier facilities. The proposed change to the Westinghouse's QMS TR would provide an extension of the external audit frequency for supplier audits and surveys that need to be completed during exigent conditions.

The NRC staff has reviewed the modification of Westinghouse's QMS TR that would be implemented in the event of exigent conditions for QA programs submitted under 10 CFR 50.4(b)(7)(ii).

Details of the NRC staff's evaluation are summarized below.

2.0 REGULATORY BASIS

The regulations at 10 CFR 50.4(b)(7)(ii), set forth the NRC's regulatory requirements regarding changes to an NRC-accepted QA TR from non-licensees (i.e., architect/engineers, NSSS suppliers, fuel suppliers, constructors, etc.) that must be submitted to the NRC's Document Control Desk. Similarly, 10 CFR 71.106 sets forth the NRC's regulatory requirements regarding changes to NRC-approved QA programs that will reduce commitments in the program description as approved by the NRC.

The regulatory requirements for QA program audits of suppliers is set forth in Criterion VII, "Control of Purchased Material, Equipment, and Services," and Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50, and in 10 CFR Part 71.115, "Control of Purchase Material, Equipment, and Services and 10 CFR 71.137, "Audits." Licensees contractually impose these requirements upon their suppliers. Criterion VII of Appendix B to 10 CFR Part 50 and 10 CFR 71.115 require establishing measures for assuring that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear power plant or fuel reprocessing plant site prior to installation or use of such material and equipment. Criterion XVIII of Appendix B to 10 CFR Part 50 and 10 CFR 71.137 require a comprehensive system of planned and periodic audits to be carried out to verify compliance with all aspects of the QA program and to determine the effectiveness of the program.

Regulatory Guide (RG) 1.28, "Quality Assurance Program Criteria (Design and Construction)," Revision 4 (ADAMS Accession No. ML100160003) and RG 7.10, "Establishing Quality

Assurance Programs for Packaging Used in Transport of Radioactive Material," Revision 3 (ADAMS Accession No. ML14064A505), identify the ASME's Standard, NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications," as an adequate basis for complying with the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 71 Subpart H. RG 1.28 identifies some exceptions which are discussed in the Regulatory Position section of RG 1.28, Revision 4. Both RGs state that the audits and surveys are to be conducted on a triennial basis. RG 1.28, Revision 4, Section C.2.b.5 allows a general grace period to be taken for a supplier audit that must be performed on a triennial basis. Further, the grace period does not allow the supplier audit "clock" to be reset forward. However, the "clock" can be reset backwards by the supplier audit activity being performed early.

3.0 TECHNICAL EVALUATION

In evaluating the adequacy of the proposed change, the NRC staff considered the guidance of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Chapter 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," RG 1.28, Revision 4, and ASME NQA-1. The guidance in RG 1.28, Regulatory Position 2.b, "External Audits," states in part, that audits of supplier's QA program should be performed on a triennial basis.

The extension of the audit frequency during exigent conditions as proposed by Westinghouse will provide for greater flexibility in its consideration of other similar events, such as the ongoing COVID-19 pandemic. The current national emergency limiting domestic and international travel, is resulting in Westinghouse not meeting its contractual commitment imposed by licensees associated with the external audit frequency. As the duration of the current national emergency is unknown, the NRC agrees an overall extension of 25 percent to the triennial audit frequency for impacted supplier audits and surveys may be implemented for exigent conditions.

During the exigent conditions, Westinghouse may continue to use suppliers that have exceeded the maximum allowed audit or survey time based on the conditions set forth in the new Subsection 4.3.1.1, "Exigent Conditions," within the QMS TR, Revision 8.0. The NRC staff found that the descriptions provided in Subsection 4.3.1.1 are consistent with the following NRC staff's considerations for allowing extensions to the periodicity of audits and surveys for suppliers during exigent conditions:

a. Westinghouse should prioritize completing audits or surveys of affected suppliers based on safety significance and any issues with the supplier. However, the audit or survey shall be completed within the 25 percent grace period.
b. There is verification that the supplier is still implementing a quality assurance program that meets Appendix B to 10 CFR Part 50.
    i. For suppliers with delinquent surveys, the entity shall ensure that the suppliers have maintained adequate documented programmatic controls in place for the activity affecting quality.
c. The alternative method of the 25 percent extension discussed above is applicable to domestic and international suppliers.
d. Receipt inspection and industry operating experience are reviewed on an ongoing basis as the information becomes available and documented. The results of the review are promptly considered for the effects on a supplier's continued qualification and adjustments made as necessary, including corrective actions.

e. If there is no ongoing receipt inspection or operating experience with which to analyze the supplier for a period of 12 months since the last audit or survey, an annual documented evaluation shall be performed and include, as appropriate, the following:
    i. Review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions.
    ii. Results of previous source verifications, audits, survey and receiving inspection activities.
    iii. Operating experience of identical or similar products furnished by the same supplier.
    iv. Results of audits and inspections from other sources (e.g., customer, ASME, or NRC inspection).
f. If the contract or a contract modification significantly enlarges the scope or changes the methods or controls for activities performed by the same supplier, the supplier will provide documented justification the change(s) are adequately addressed by its quality assurance program controls.

The overall 25 percent extension for audits or surveys would only be applicable to exigent conditions. A determination of exigent conditions would be based on Westinghouse's prudent judgement.

The above frequency extension for supplier audits or surveys during exigent conditions is a different alternative to the 90-day grace period allowed under RG 1.28, Revision 4, Section C.2.b.5. The general 90-day grace period alternative will remain unchanged for conditions of a minor nature. Examples of conditions of a minor nature would include, but not limited to: 1) staffing limitations preventing a timely audit to be completed and 2) scheduling conflicts by either the vendor, supplier, or sub-tier supplier.

As previously stated, the expectation for the use of the 25 percent frequency extension would be limited to implementation for exigent conditions. The expectation would be that Westinghouse attempts to maintain the current triennial audit or survey period. Unlike the existing alternative on the use of a grace period, Westinghouse would not have to reset the "clock" backwards when the audit or survey is finally performed to the original date the audit or survey should have been performed. The date that the audit or survey is finally performed would be the start of the new triennial audit or survey frequency. The NRC staff considered that should events of a severe nature occur closely together, the requirement for not allowing the "clock" to be reset forward would result in an additional potential scheduling constraint on completing audits or surveys in a timely manner.

The NRC staff considered the maturity of Westinghouse's QA program and its supply chain oversight in determining this allowance of a 25 percent extension for audits and surveys to be completed from the date of the expiration of the triennial audit or survey frequency. The NRC staff also considered the potential risk significance of extending the audit and survey frequency by 25 percent. Based on the maturity of Westinghouse's QA program, the expected short duration that Westinghouse will be under an exigent condition, and Westinghouse's continuous monitoring of ongoing and previous supplier performance, the NRC staff determined that there is minimal risk associated with implementing the extended audit and survey frequencies during exigent conditions. Therefore, the NRC concluded that the conditions stated above ensure that reasonable assurance of the quality of items and services will continue to be maintained during this extension period.

4.0 CONCLUSION

The NRC staff reviewed Westinghouse's QMS TR, Revision 8.0, submittal. As stated above, the NRC staff concluded that there is reasonable assurance that Westinghouse's QMS TR will continue to meet the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 71 Subpart H while implementing the 25 percent extension of audit and survey frequencies during exigent conditions. Therefore, the NRC staff found Westinghouse's proposed changes in the QMS TR, Revision 8.0, to be an acceptable method for extending audit frequencies during exigent conditions.

Principal Contributor: Deanna Zhang

Date: May 12, 2020

RESOLUTION OF COMMENTS ON DRAFT SAFETY EVALUATION FOR

TOPICAL REPORT "QUALITY MANAGEMENT SYSTEM (QMS)," REVISION 8.0

WESTINGHOUSE ELECTRIC COMPANY

By letter dated May 7, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20129K029), Westinghouse Electric Company (Westinghouse) provided comments on the draft safety evaluation (SE) for Topical Report "Quality Management System (QMS)," Revision 8.0. Westinghouse stated that there is no proprietary information in the draft SE. The NRC staff has reviewed two clarification comments provided by Westinghouse and agrees that the proposed changes provide additional clarification. The NRC staff reviewed nine editorial comments provided by Westinghouse and finds them acceptable because the changes are editorial in nature.

Comment Number	Comment Location	Comment Type	Comment	NRC
1	Page 1/Line 15	Editorial	ML20118C993 is the non-proprietary package. ML20118C994 is the actual transmittal letter. Suggest referencing ML20118C994 to be consistent with the SE cover letter.	Change accepted
2	Page 1/Line 36	Editorial	"Revision 7.0" should be changed to "Revision 7.1." Westinghouse QMS Revision 7.1 was accepted by the U.S. NRC on September 19, 2019 (ML19246A008)	Change accepted
3	Page 1/Line 36	Editorial	The quoted QMS text is in Section 4.3.1, "General," under "Procurement." Therefore, 'Section 4.3, "Procurement,"' should be changed to 'Section 4.3.1, "General," under "Procurement."'	Change accepted
4	Page 1/Line 46	Editorial	The quoted QMS text is missing the following paragraphs: "For safety-related items and services, Quality determines the need to conduct supplier audits based on an evaluation that is conducted and documented in accordance with established procedures. Based on this evaluation Supplier audits need not be conducted for suppliers of safety-related items which are:" "Audit programs for suppliers of items and services for nuclear power plants that are not subject to NRC regulations comply with requirements imposed by the governing regulatory agency or customer contract."	Change accepted

Comment Number	Comment Location	Comment Type	Comment	NRC Response
5	Page 2/Line 27	Editorial	“type” should be changed to “types”	Change accepted
6	Page 2/Line 42	Editorial	“the” should be deleted	Change accepted
7	Page 2/Line 43	Editorial	“supplier audits” should be changed to “supplier audits and surveys” to be consistent with the last sentence in the paragraph.	Change accepted
8	Page 3/Line 41-42	Clarification	It is unclear to Westinghouse the applicability of the SE reference to Westinghouse, when the QMS cites RG 1.28, Revision 4, Section C.2.b.5 which allows the 90-day grace period.	Change made. Final SE references RG 1.28, Rev. 4, Section C.2.b.5 and not the SE.
9	Page 4/Line 10	Editorial	“length” should be changed to “duration”	Change accepted
10	Page 5/Line 7	Clarification	It is unclear to Westinghouse the applicability of the SE reference to Westinghouse, when the QMS cites RG 1.28, Revision 4, Section C.2.b.5 which allows the 90-day grace period.	Change made. Final SE references RG 1.28, Rev. 4, Section C.2.b.5 and not the SE.
11	Page 5/ Line 7	Editorial	“ML101830108” should be changed to “ML101820108”	Change made. Final SE references RG 1.28, Rev. 4 when discussing the 90-day grace period. SE reference deleted.

TABLE OF CONTENTS

INTRODUCTION

The Westinghouse Electric Company (Westinghouse) Quality Management System (hereafter known as the QMS) has been developed to comply with statutory, regulatory, industry, and customer quality requirements that are applicable to items (i.e., structure, system, or component, or part thereof) and services provided by Westinghouse's world-wide operations. The QMS describes Westinghouse's commitment to quality assurance (QA) requirements that ensure the highest levels of customer satisfaction.

As a provider of nuclear technology items and services, Westinghouse recognizes that nuclear technology is special and unique and that its deliverables must be safe and reliable. These deliverables require compliance to quality assurance requirements and standards through management organizations that possess a strong nuclear safety culture with core values that are consistent with the corresponding enabling principles, and behaviors that reinforce them. The Westinghouse QMS provides the necessary quality assurance framework for an environment that enables and sustains those nuclear safety culture core values.

Nuclear Safety Culture is defined by the Institute of Nuclear Power Operations (INPO) as: "***The core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.***" Westinghouse is committed to the embodiment of the INPO Traits of a Healthy Nuclear Safety Culture as the overriding principle behind the decisions made, and the actions taken by our organization.

Westinghouse has operations located throughout the world that are responsive to energy industry utilities, and government needs; and global nuclear safety culture requirements and expectations. Westinghouse operations are made up of organizations that are responsible for marketing, design, procurement, manufacture, construction, installation, inspection, testing, servicing, project management, operation and decommissioning of nuclear power plants, including structures, systems, and components, as well as, radioactive material packaging and transportation. Westinghouse also offers engineering services such as life-extension studies, diagnostics, analyses, and testing.

APPLICABILITY

The QMS and implementing procedures apply to activities that affect the quality of items and services supplied by Westinghouse. It defines the basic requirements and commitments applicable to customer contracts.

Westinghouse complies with the regulatory requirements applicable to the items and services it provides for use in nuclear power plants, as imposed by the governing regulatory agency. For nuclear power plants subject to U.S. Nuclear Regulatory Commission (NRC) regulations, Westinghouse complies with the requirements of 10CFR50, Appendix B by implementing the guidance in NRC Regulatory Guide 1.28 which endorses ASME NQA-1-2008 Edition, including NQA-1a-2009 Addenda (hereafter known as NQA-1). For nuclear steam supply systems and pressure-retaining components and related services, Westinghouse supplements the QMS by implementing quality assurance program requirements such as WCAP-12308 "ASME Quality

Assurance Program" or WCAP-17281, "Quality Assurance Program for N1 Pressure Equipment and their Components under ESPN Regulation and RCC-M Code," or similar programs based on the applicable governing regulations or customer contract requirements.

Safety-related items, services and activities are those that may impact those nuclear power plant structures, systems and components that are relied upon to remain functional during and following design basis events to assure: 1) the integrity of the reactor coolant pressure boundary, 2) the capability to shut down the reactor and maintain it in a safe shutdown condition; or 3) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set by the governing regulatory agency, if applicable. In addition, safety-related items, services, and activities may be those defined by a governing regulatory agency or contract.

The QMS also serves as a directive for all organizational functions in establishing the necessary policies and procedures that comply with the requirements of ISO 9001. Westinghouse will comply with the most recent edition of the ISO 9001 standard prior to the required compliance date.

Westinghouse utilizes the Project Quality Plan (PQP) (Section 1.1.2.2) process to describe how QMS requirements will be adapted or adjusted as necessary to meet unique customer/contract requirements that are not explicitly addressed in the QMS. See Appendix B for a non-exhaustive list of examples of requirements/regulations and standards for which Westinghouse would employ the use of a PQP to address customer-unique or contract-specific regulatory requirements.

Westinghouse positions and clarifications to NQA-1 and the applicable NRC Regulatory Guides are described in Appendix A to this document.

The QMS may be submitted to a governing regulatory agency, as needed. Westinghouse submits the QMS to the NRC for review and acceptance prior to implementation of any changes that reduce commitments contained herein for safety-related items and services subject to 10CFR50, Appendix B, ASME NQA-1 or applicable NRC Regulatory Guides. Westinghouse informs the NRC within ninety days of any implemented QMS changes that do not reduce QMS commitments in accordance with 10CFR 50.4(b)(7)(ii) requirements.

1.0 QUALITY MANAGEMENT SYSTEM

The QMS incorporates quality planning, provides a framework for managing the activities that enable the company to create items and services which consistently satisfy the customer and regulatory requirements, and is a tool for achieving enhanced customer satisfaction. The QMS also provides for continual improvement by monitoring processes based on their significance, measuring their effectiveness against objectives, and managing processes for improvement.

1.1 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:

- Level 1. QMS
- Level 2. Westinghouse Level 2 Policies and Procedures
- Level 3. Functional/Department/Plant Procedures and Work Instructions

1.1.1 Quality Management System (Level 1)

The QMS is structured around interlinked processes that provide the necessary implementation controls to ensure customer and regulatory requirements are met, and continual process improvement occurs. It provides the basis for policies and procedures that implement a comprehensive quality management system. These processes are those that define activities that are directly necessary to create the item or service, and those that provide the supporting infrastructure to enable the direct processes to operate under the required controls, and continually improve.

Figure 1 illustrates the continuous improvement model of the Westinghouse QMS. This model is a process-based quality management system that illustrates the process linkages as described in this manual. The model emphasizes the important role of the customer and regulator in defining the input requirements, and the importance of evaluating the product outputs and customer satisfaction to ensure the requirements are met with the goal of continual improvement.

The model illustrates the importance of Management Responsibility, Resource Management, Product Realization, and the Measurement System Analysis & Improvement Systems in achieving continual improvement. Product realization involves many individual processes that include (but are not limited to) the activities and functions shown in Figure 1 (Marketing, Contract Review, Project Management, Planning, Design & Development, Engineering, Purchasing [Supply Chain Management], Production [Manufacturing], Inspection, Measuring, Testing, Construction, Services, and Decommissioning).

The QMS is the foundation for the overall continual improvement model. The Environmental Health & Safety, Information Technology, and Finance Systems are key in supporting the overall operation of the company, but are not governed by the QMS. The implementing policies and procedures (Levels 2 and 3) provide the details of interaction and the sequence for the processes.

The QMS includes commitments to address quality standards and regulatory requirements as indicated in the Applicability section. The QMS provides for, and organizations comply with, applicable QA requirements imposed by the governing regulatory agency and/or customer contract.

The QMS and changes thereto are reviewed and approved by Westinghouse management. The control of the QMS is the responsibility of the Management Representative, or designee.

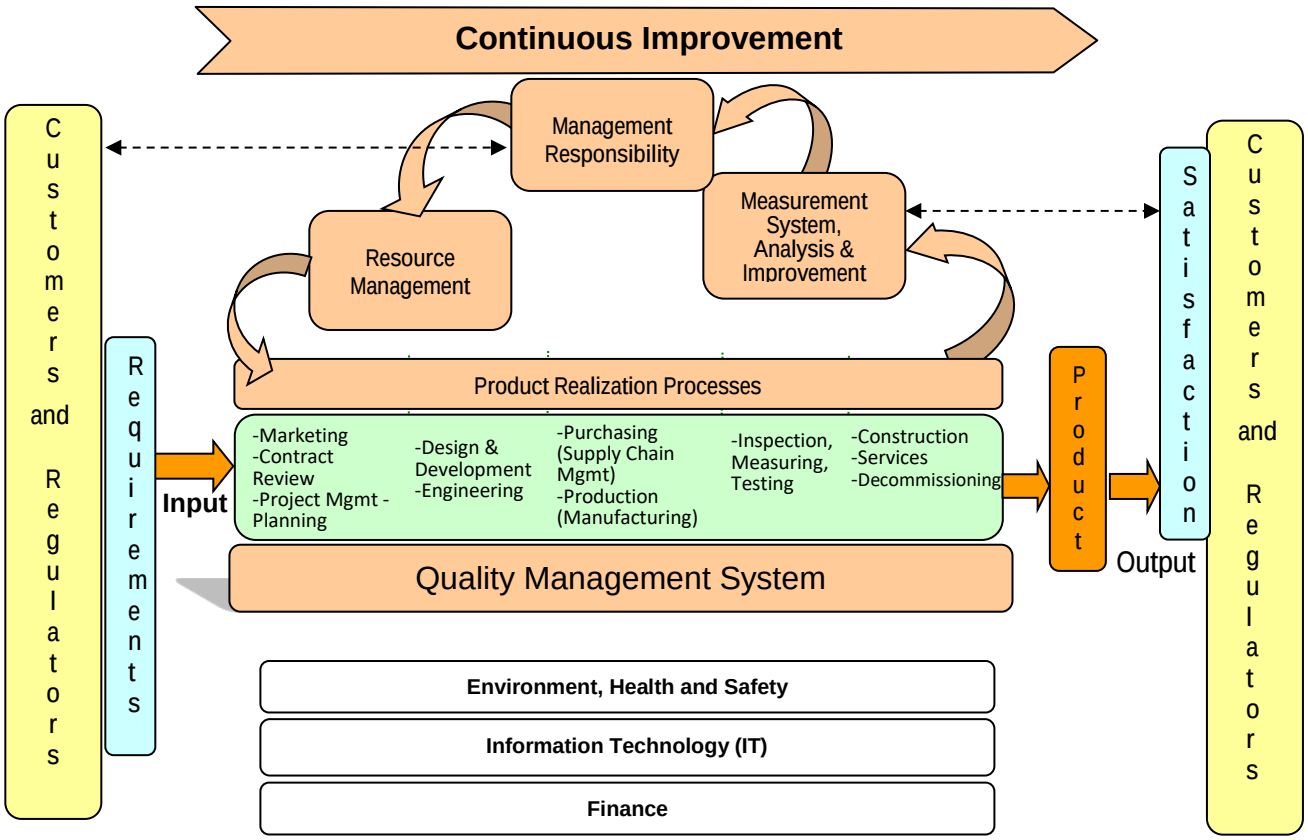


FIGURE 1
QUALITY MANAGEMENT SYSTEM
PROCESS INTERACTION

1.1.1.1 10CFR50.55a/Appendix B to 10CFR50

All organizations performing safety-related activities that impact pressure-retaining components or services subject to NRC regulatory requirements comply with the requirements of 10CFR50.55a, with the specific editions of the ASME Boiler and Pressure Vessel Code and Standards identified in the applicable customer's Safety Analysis Reports (SAR), and Appendix B to 10CFR50.

1.1.1.2 10CFR21/10CFR50.55(e)

Requirements imposed by a governing regulatory agency, law, or contract for reporting defects and noncompliance are addressed when applicable. Westinghouse maintains procedures that provide for the evaluation of reported conditions that may require NRC notification under United States law in accordance with the requirements of 10CFR21, Reporting of Defects & Noncompliance; and when imposed by customer contract, licensee notification under 10CFR50.55 (e), Conditions of Construction Permits.

1.1.1.3 Employee Safety Concerns

Free and open expression of safety concerns is an essential attribute of the Westinghouse safety-conscious work environment. It is Westinghouse's policy that all employees and all personnel of Westinghouse contractors working at Westinghouse facilities or its customers' sites are free and encouraged to raise safety concerns and that such concerns are promptly reviewed, investigated as necessary and resolved with timely feedback to the concerned individual. Any issues relating to safety can be raised by employees of Westinghouse and personnel of its contractors without fear of discrimination, intimidation, harassment or retaliation and that those issues receive prompt and appropriate attention.

1.1.2 Westinghouse Policies and Procedures (Level 2)

1.1.2.1 Policies and Procedures

Organizations with impact on customer contractual or regulatory 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 Westinghouse Level 2 Policies and Procedures address regulatory requirements and QMS commitments, as applicable. These procedures are reviewed and approved by Executive Management, or designee, and each applicable organization. Adoption of these policies and procedures by other organizations for implementation will be subject to review by those organizations.

1.1.2.2 Project Quality Plans

The quality requirements contained in the QMS may not explicitly address all quality system requirements invoked by customer contracts, or required by a governing regulatory agency, for each Westinghouse project. To define and implement an alternate quality system for specific projects, it may be necessary to create a Project Quality Plan (PQP) to specify supplemental quality requirements, identify supplemental/revised procedures, or provide recognition and compliance with alternative quality standards. When a PQP is necessary to address these needs, or to provide more detailed information required for specific customers, regulators, or market acceptance, the PQP may take the form of a complete quality assurance program manual based on the commitments of this document. For the project to which it is applicable, a PQP, in the language it is written, is the definitive quality system description and applies to activities that affect the quality of items and services supplied by Westinghouse.

A PQP is developed, issued, revised, and controlled in accordance with established procedures; it is reviewed and approved by the responsible functional organization or project management with Quality concurrence.

1.1.2.3 Graded Quality

Requirements are applied as necessary to achieve the level of quality specified (i.e., Design Specifications, Contract Requirements, etc.). 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 classification of items is documented and approved by responsible management.

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

1.1.3.1 Functional/Department/Plant Procedures

Procedures are established to implement local responsibilities in accordance with Level 2 policies and procedures or the QMS. Responsible managers ensure the preparation, approval, distribution, and revision of these procedures.

1.1.3.2 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.

1.2 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, drawings, and controlled data such as customer order requirements and documents of external origin. These documents describe the activity to a level of detail commensurate with the complexity of the activity to assure consistent and acceptable results, and contain appropriate criteria for determining whether prescribed activities have been completed satisfactorily. Procedures are established which provide for document review, approval, issuance, 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.

1.2.1 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, 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 or 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 that have access to the original data.

Change 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.

1.2.2 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.

1.2.3 Computer Software Control

Procedures are established to govern the development and maintenance of computer software applications, and to control changes to configured computer software. The development and maintenance of computer software includes planning, requirements specification, design, implementation, acquisition, verification and validation testing, configuration control, and error reporting and handling. These activities are documented in accordance with established procedures. Organizations developing, acquiring, or supplying computer software are required to use policies and procedures that comply with the applicable requirements of the QMS.

1.2.4 Translation of Documents

Translations of documents applicable to safety-related items or services from or to a language other than English will be translated by a qualified translator. These translations will be verified and certified in accordance with established procedures.

1.2.5 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.

1.3 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. Quality records may also include articles such as materials or test specimens when required. Quality records are retained, reviewed, and provided to the customer in accordance with applicable contractual and regulatory requirements. In manufacturing and service organizations, product-related records are not considered complete until the time of shipment.

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. 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. Procedures are established to ensure that no degradation of the electronic record media occurs during the established retention period and that they remain retrievable after hardware, software, or technology changes. When records are duplicated or transferred to the same media or to different media for the purposes of maintenance or storage, the following apply:

- Duplication or transfer is appropriately authorized
- Record content, legibility, and retrievability are maintained

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.

1.3.1 Classification and Retention of Nuclear Power Plant Records

Records are generated in accordance with the QMS for items and services supplied to nuclear power plants. Westinghouse classifies records as lifetime or nonpermanent and retains them in accordance with the guidance provided in NRC Regulatory Guide 1.28, or the requirements in 10CFR21, or 10CFR50.55 (e), as applicable. For nuclear power plants subject to a governing regulatory agency other than the NRC, Westinghouse classifies and retains records in accordance with the applicable regulatory requirements.

1.3.1.1 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.

1.3.1.2 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.

2.0 MANAGEMENT RESPONSIBILITY

2.1 Quality Policy

The Westinghouse Quality Policy is 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 customer satisfaction and continual improvement. Maintaining an atmosphere of integrity and responsiveness is one of the most important attributes of the work environment. All employees are encouraged to openly express all concerns for the safety and quality of Westinghouse items and services.

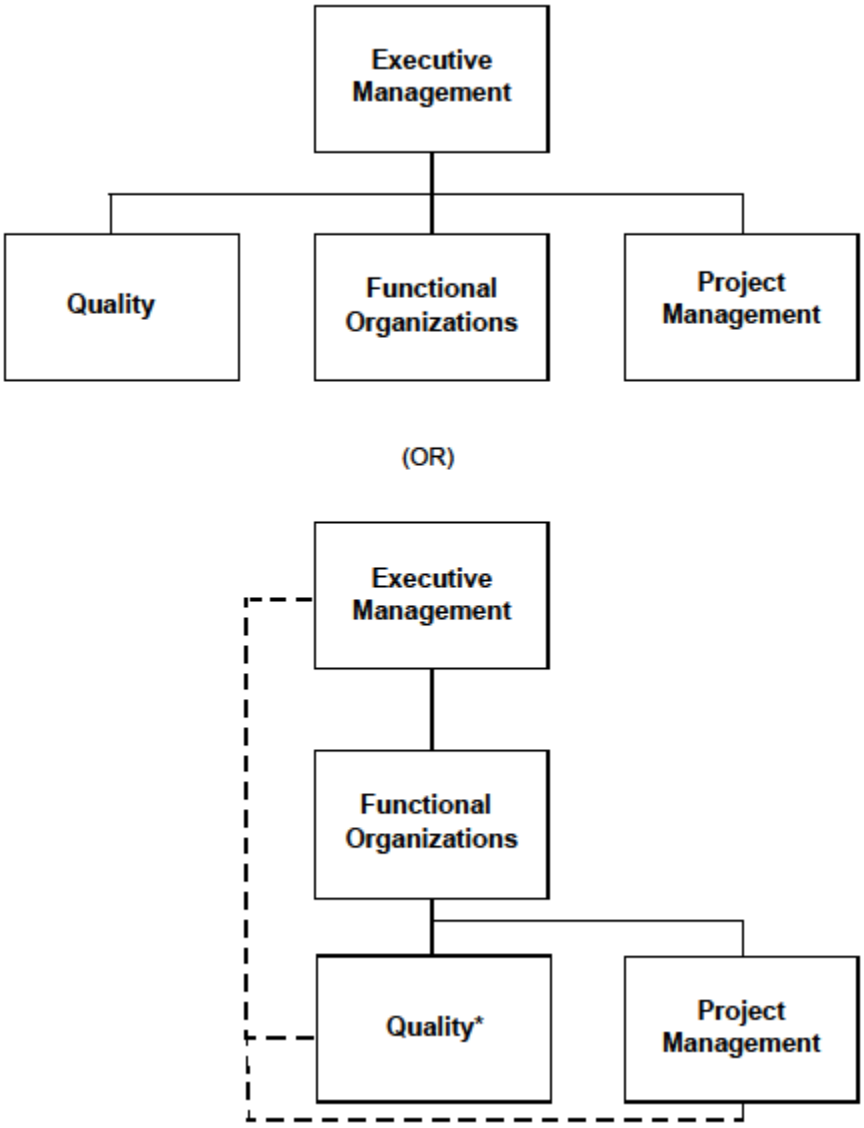
2.2 Westinghouse President and CEO

The Westinghouse President and CEO defines the overall quality policy and promotes a culture of excellence and continuous improvement that ensures compliance to requirements and customer satisfaction. The President and CEO authorizes and endorses the QMS, and appoints and supports a Management Representative to coordinate development, implementation, and maintenance of the QMS. Figure 2 illustrates the typical Westinghouse operational organization reporting structures that meet the requirements and commitments of this QMS.

2.3 Operational Organization

Organizations reporting to the Westinghouse President and CEO are assigned responsibilities to ensure contractual requirements are identified and met, a focal point for assuring customer satisfaction, and the quality of items and services. These organizations include functions such as Engineering, Manufacturing, Project Management, Quality, Marketing, and Purchasing. Specific organizational details, including authority, responsibilities, and interfaces are established. 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 operational organization 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.



***Quality has direct access for quality-related issues.**

FIGURE 2
TYPICAL OPERATIONAL ORGANIZATION REPORTING STRUCTURES

2.3.1 Executive Management

Executive Management is assigned responsibility for operational organizations. Senior Management establishes overall expectations for effective implementation of the QA program and is responsible for obtaining the desired end result. They are responsible for establishing and implementing a quality assurance program that complies with the commitments of the QMS, and for appointing a Quality Manager(s). Executive Management has overall responsibility and is accountable for:

1. The quality of items and services supplied,
2. The effective implementation of the QMS for applicable activities,
3. Ensuring QMS planning is carried out in order to meet the requirements given in Section 1.0, as well as the quality objectives,
4. Maintaining QMS integrity when changes to the quality management system are planned and implemented,
5. Ensuring the allocation of appropriate resources to satisfy quality requirements,
6. The identification of measurable quality objectives,
7. The availability of information necessary to monitor, measure, and analyze selected processes,
8. The continuous improvement of selected significant processes, and
9. Ensuring that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QMS.

Lower levels of executive management responsible for specific operational organization business areas may share these responsibilities.

2.3.2 Quality

The responsibility for documenting the quality program is assigned to a Quality Manager(s) (or similar title). The Quality Manager has sufficient authority and organizational freedom from cost/schedule pressures, and has the authority to stop work, delivery, or installation of nonconforming items and services. The Quality Manager has direct access to higher management levels, including the President and CEO, and other Executive Management, 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 providing quality assurance program management and support, monitoring QMS performance, and coordinating quality assurance activities.

2.3.3 Functional Organizations

Functional 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. Each functional organization is responsible for ensuring, to the degree necessary, that its personnel are aware of organizational quality objectives that their activities may support.

2.3.4 Project Management

For accomplishment of a specific project or task, management may assign an individual to be responsible for all aspects of the job and to manage the efforts of personnel working on the project, whether they report directly to or through a functional organization. The title of such an individual may be Project Manager, Task Manager, Site Manager, Project Coordinator, Task Leader, Lead Engineer, Job Superintendent, or other similar titles.

The organizational structure for a project may vary depending upon the nature, scale, and complexity of the work, and assigned personnel may be located at a headquarters location, regional facility, supplier facility, or remote site location, wherever the work is to be performed.

2.3.5 Purchasing and Marketing

Purchasing (Supply Chain Management) and Marketing provide support in accordance with the requirements of this QMS. Purchasing is responsible for all procurement services and serves as the primary interface with suppliers. Marketing is responsible for the preparation of offers and for managing customer communications.

2.3.6 Interfaces

Westinghouse organizational interface agreements are implemented, as necessary, to reflect agreed upon responsibilities. They are documented and controlled in accordance with approved procedures.

2.4 Management Review

Executive Management and staff are responsible for reviewing the implementation of the requirements set forth in the QMS. This review is conducted at defined intervals to communicate the continuing process effectiveness and suitability in satisfying the applicable quality and regulatory standards, continual improvement by attaining specific, measurable quality objectives, and assessment of potential opportunities for improvement.

Review input includes information on audit performance, customer satisfaction, performance of selected processes, delivered item and service conformance, the status of corrective and preventive actions, supplier performance, prior review's action items, known changes that may significantly affect the QMS, and any substantial recommendations for improvement.

Review output includes any decisions and actions related to improving quality management system and process effectiveness, significant product improvements to address customer requirements, and resource needs.

Records of the management review are maintained.

2.5 Management Representative

The Chief Quality Officer (CQO) is the Management Representative. The CQO is responsible to and has direct access to the President and CEO, and has direct access to Executive Management, for all quality issues. The Management Representative has responsibility for 1) the QMS, including Quality Policy, assessment of QMS effectiveness, and supplier quality, and 2) monitoring the overall QMS performance, and assuring that the QMS provides for customer focus. Quality Managers throughout the organization report either directly, or on a matrix basis, to the Management Representative for quality policy matters. This role is also established as a focal point for any employee to report issues concerning the QMS and for coordinating action for changes and improvements.

3.0 RESOURCE MANAGEMENT

Necessary resources are provided to implement, maintain, and continually improve the effectiveness of the QMS, and to satisfy customer and regulatory requirements. Personnel performing or managing activities affecting quality receive indoctrination, training, and qualification as necessary to ensure that suitable proficiency is achieved and maintained. Personnel are aware how their activities support achievement of their organization's quality objectives. Adequate facilities, equipment, services, information, and work environment are provided and managed to support the delivery of items and services in compliance with customer and regulatory requirements.

Managers of activities affecting quality are responsible for 1) determining the personnel competencies necessary for the assigned activities and assessing associated needs, 2) ensuring necessary actions (e.g., training) are taken to satisfy these needs, and 3) evaluating these actions to confirm that personnel are adequately trained, competent, and qualified to manage and perform assigned work activities. These actions include indoctrination to and familiarization with the applicable QA program and procedure requirements, and any special skills training required for the performance of job activities. The extent of such actions is commensurate with the scope, nature, and complexity of the activity, as well as the education, experience, and proficiency of the individual. Historical records of personnel education and experience may serve as documentation of competency, when supplemented by applicable training records. Actions to build or maintain necessary competencies are documented, and records are maintained in accordance with applicable records procedures.

Personnel performing inspection, test, nondestructive examination (NDE), 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. Personnel 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.

4.0 PRODUCT REALIZATION

4.1 Contract Review

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

4.1.1 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.

4.1.2 Contract Review

All customer orders and amendments received are formally reviewed by marketing and/or contract administration organizations and other designated functional organizations at the time of entry. This review is performed to enhance customer satisfaction by ensuring that 1) all stated customer requirements are adequately defined and documented, 2) that other requirements necessary for the application (e.g., regulatory) are determined and considered, and 3) 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 amendments are distributed to the appropriate functional organizations.

4.2 Design Control

4.2.1 General

Engineering organizations control 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 items, services, 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 established 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 define and communicate requirements for procurement, manufacturing, installation, servicing, quality, and other activities.

Quality requirements are specified by engineering organizations and are reviewed by an independent organization to ensure that inspection, test, acceptance, and documentation requirements are incorporated.

Professional engineers performing certification activities are qualified in accordance with appropriate code section requirements (e.g., ASME B&PV Code Section III, Appendix XXIII), in compliance with applicable governing regulations or customer contract requirements.

4.2.2 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 and validation 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.

Westinghouse may subcontract the performance of design work to a supplier approved for such services. For example, such subcontracted services may include preparation of Design Specifications and Design Reports for ASME B&PV Code Section III components. Westinghouse responsibilities as the Owner's Designee, or similar designation under other national or international industry codes, when assigned by contract, shall not be delegated.

4.2.2.1 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.

4.2.2.2 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 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. 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 contract 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

4.2.3 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
- Information derived from previous similar designs
- Manufacturing process capability

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

4.2.4 Design Analysis

Design analysis activities are performed in accordance with established procedures which address selection of design inputs, selection of methodologies and assumptions, and performance of analyses.

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.

Documentation of design analyses 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 (hardware and operating system), computer program name, revision, inputs, outputs, evidence of or reference to computer program verification, validation, and control, and the bases or reference to the bases, supporting application of the computer program to the specific physical problem; and review and approval.

4.2.5 Design Output

Engineering organizations are responsible for design output in the form that meets contractual 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. *Design outputs shall also provide appropriate information for purchasing, production, and service provision, and contain or reference product acceptance criteria.*

4.2.6 Design Verification

4.2.6.1 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

4.2.6.2 Verification Documentation

Engineering is responsible for ensuring that design verification 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.

4.2.6.3 Design Verification of Safety-Related Items

Verification is accomplished using design reviews, alternate calculations, or qualification tests as described in Westinghouse Level 2 Policies and 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 the release of design documents for procurement, manufacture, construction, and/or service. If a schedule

conflict should exist, procedures require that in all cases design verification is completed prior to relying on the item to perform its intended function and before its installation becomes practically irreversible. Unverified design documentation is identified and controlled.

4.2.6.4 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:

- Correct selection of design input
- Reasonable design output compared to design input
- Specification of design input and verification requirements for interfacing organizations
- Appropriate design methods
- Design inputs correctly incorporated into the design
- Adequately described, reasonable, and identified assumptions
- Suitable materials, parts, processes, and inspection and test criteria

Records of design review results and any necessary actions shall be maintained.

4.2.6.5 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 the appropriateness of assumptions; input data used; and the computer program or other calculation method used.

4.2.6.6 Design Verification by Qualification Tests for Safety-Related Items

Qualification testing is performed to ensure that items 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.

4.2.7 Design Changes

Changes to designs and design documentation may originate from many sources, including customers, suppliers, manufacturers, internal or external quality organizations, etc. Design changes are evaluated to determine their effect on the overall design, on any analysis upon which the design is based, and the changes effects on the design inputs. The evaluation shall

include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities.

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 items. Design changes are initiated and documented in accordance with written procedures.

4.2.8 Technical Information

4.2.8.1 Bulletins

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

4.2.8.2 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.

4.2.9 Computer Software

Development, acquisition, control, and maintenance of computer software will be performed in accordance with established procedures and instructions that meet the requirements of ISO-9001. The guidelines contained in ISO 90003 will be used as a reference in the establishment of software-related procedures. Organizations developing computer software are responsible for establishing these procedures. Organizations using computer software are responsible for establishing procedures controlling the use of software.

In addition, computer software used in the design, analysis, monitoring, operation, or control of a safety-related structure, system or component, including software delivered to a customer for the same purposes, will be developed, acquired, controlled, and maintained in accordance with procedures that comply with the software quality assurance-related requirements of ASME NQA-1, Part I, Requirement 3 and Part II, Subpart 2.7. These procedures include provisions for the validation of software acquired or procured from external sources.

4.2.9.1 Computer Software Development

Any suitable software development life cycle may be adopted, provided that it encompasses the activities associated with planning, requirements specification, design, code implementation, testing, configuration, installation, operation, maintenance, and retirement. The software

development procedures ensure that these software life cycle activities are planned and performed in a traceable and orderly manner. Requirements specifications, designs, test plans, test requirements, and test results are documented and verified in accordance with established procedures. Verification is performed to ensure that the output of an activity fulfills the requirements established by previously executed activities. For computer software that performs calculations associated with a mathematical model of a physical phenomenon, the software will be verified to show that it produces correct solutions within its defined range. In addition, the mathematical model shall be shown to produce a valid solution to the associated physical problem. Software validation is performed to ensure that the computer software satisfies all identified requirements and is correct and appropriate for use in its intended application.

4.2.9.2 Computer Software Change Control

Changes to configured software are documented, approved, and controlled by authorized personnel in accordance with established procedures. The documentation shall include:

- A description of the change
- The rationale for the change
- The identification of affected software baselines

The change shall be formally evaluated and approved by the organization responsible for the original design, unless an alternate organization has been given the authority to approve the change(s).

4.2.9.3 Computer Software Testing

Computer software is tested for all intended applications. Testing is conducted in accordance with established procedures. All software testing is traceable to documented requirements, and all documented requirements will be tested. The degree of testing is dependent on the importance of the computer software to safety, the complexity of the program, and prior documented performance.

For computer software used in design analysis activities, test plans and procedures will provide assurance that the software produces correct and accurate results. For computer software used for operational control, test plans and procedures will provide for demonstrating required performance over the range of operation of the controlled function or process.

Expected results and acceptance criteria will be established. Acceptance criteria may be based on hand calculations, documented results from other validated computer programs, empirical data, published data in the technical literature, performance standards established through use, or expected function documented in the requirements. Tests are defined to demonstrate that the software will properly handle abnormal conditions and will not perform adverse unintended functions.

Testing activities and results are documented and verified. Independence of the verifier is required for safety-related software.

4.2.10 Computer Hardware Systems

Procedures will be established that identify necessary controls for computer hardware systems. Controls will be based on how the hardware system is used (e.g., for design analysis of safety-related structures, systems and components; as part of monitoring and control systems) and on specific customer and other requirements.

Installation testing, that is, the execution of a defined set of test problems, will be performed when a computer software product is installed on a computer system different than the system on which it was validated. Installation testing will be performed when there are significant changes to the underlying hardware or operating system.

For plant monitoring or control system applications where computer program errors, data errors, computer failures, or instrument drift can affect required performance, periodic in-use manual or automatic self-check steps will be prescribed and performed.

4.3 Procurement

4.3.1 General

Controls of purchased items and services are established to ensure that applicable technical and quality requirements are met. Procurement 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. Commitments to resolve unacceptable conditions are obtained from the supplier prior to contract award. Spare or replacement parts are procured to requirements which are equivalent to or exceed the original requirements.

Suppliers of safety-related items and services are evaluated and approved by Quality prior to their designation as a qualified supplier, or placement of a purchase order. Active qualified suppliers (including suppliers accredited under national industry codes such as ASME) of safety-related items are evaluated annually and audited at least every 3 years with the following exceptions:

For safety-related items and services, Quality determines the need to conduct supplier audits based on an evaluation that is conducted and documented in accordance with established procedures. Based on this evaluation Supplier audits need 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.

Audit programs for suppliers of items and services for nuclear power plants that are not subject to NRC regulations comply with requirements imposed by the governing regulatory agency or customer contract.

4.3.1.1 Exigent Conditions

Under exigent conditions, the audit and/or survey interval may be extended up to 25%. This unique grace period can be applied if exigent conditions exist including but not limited to; a) declaration of a national emergency, b) severe localized or national weather conditions, or c) localized outbreak of a severe health concern to the public. Under these exigent conditions the audit clock resets when the audit and/or survey is performed. The 25% grace period extension is applicable to domestic and international suppliers.

During the use of the 25% extension, a supplier evaluation shall be performed and results documented, including any necessary qualification adjustments. Suppliers in the 25% extension can be maintained on the Westinghouse QSL provided the following actions (a - c) are taken and the results satisfactory:

a. Verification that;
   (1) the supplier is still implementing a quality assurance program that meets Appendix B to 10 CFR Part 50 **OR**
   (2) commercial suppliers surveyed are still maintaining adequate documented programmatic controls for the activities affecting quality.

b. Monitor ongoing and previous supplier performance promptly considering impacts of the following types of information:
   1. Results of receipt inspection activities or other operating experience.
   2. Review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions.
   3. Results of audits and inspections from other sources (e.g., customer, American Society of Mechanical Engineers (ASME), NIAC audits or NRC inspections)

c. In the case of a new procurement activity or changes to existing procurements that significantly enlarges the scope or changes the method / controls for activities performed by the supplier, the evaluation shall document the justification that the change(s) are adequately addressed by the supplier's quality assurance program or mitigating actions are being taken by Westinghouse.

4.3.2 Supplier Selection

The purchasing organization is responsible for placing orders only with suppliers that have been found acceptable in accordance with established procedures. 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.

Suppliers are evaluated and selected considering the historical quality performance data and audit/survey reports to the extent applicable to the item or service being procured. Procedures 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. Failure

of suppliers to correct problems contributing to unacceptable performance constitutes a basis for disqualification.

Suppliers of safety-related items and services are evaluated and selected prior to their designation as a qualified supplier. These methods include one or more of the following: (a) evaluation of the supplier's history (including current capability) of providing the same or similar item in accordance with specified requirements; (b) review of the supplier's current quality records supported by documented qualitative and quantitative information which can be objectively evaluated; and/or (c) the supplier's technical and quality capability determined by a source evaluation of their facilities, personnel interviews, and the content and implementation of their quality program. Suppliers of safety-related items and services for nuclear power plants not subject to NRC regulations are evaluated and qualified in accordance with the requirements of the governing regulatory agency or customer contract.

4.3.3 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.

4.3.4 Procurement Documents

Procurement documents (e.g., purchase requisitions, purchase orders, supplier quality requirements, engineering drawings, and specifications) are controlled to ensure that applicable technical and quality requirements are communicated to suppliers. The procurement documents shall provide for access to the Supplier's and subtier Supplier's facilities and records for surveillance, inspection, or audit by Westinghouse, its designated representative, and others authorized by Westinghouse.

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.

Procurement documents for safety-related items or services require qualified suppliers to have a quality program consistent with the quality standards required by the governing regulatory agency and/or customer contracts. Suppliers of safety-related items and services for nuclear power plants not subject to NRC regulations are evaluated and qualified in accordance with the requirements of the governing regulatory agency or customer contract.

4.3.4.1 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

4.3.4.2 Customer Access to Suppliers

Customers may require access to suppliers' locations (including subtier suppliers) 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.

4.3.4.3 Document Submittal

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

4.3.5 Computer Software Acquisition

Sections 4.3.1 through 4.3.4 and Section 4.3.6 through 4.3.8 apply to the procurement of software and software services from qualified suppliers.

Acquired software from a non-qualified supplier (i.e., software that has not been developed under a program consistent with the QMS for use in its intended application) shall be identified, controlled, and dedicated prior to use, in accordance with Section 4.3.9, and as described in documented procedures. The dedication process will include identification of critical characteristics, including capabilities and limitations for intended use; use of test plans and test cases as the method of acceptance; and documentation of instructions for use within the limits of the dedicated capabilities. If the software does not meet the definition of a commercial grade item, then it will be controlled, evaluated, and tested prior to use, as described in documented procedures.

4.3.6 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.

4.3.7 Acceptance

4.3.7.1 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 source verification, receiving inspection, and review of source documents attesting to acceptability.

- 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.

4.3.7.2 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.

4.3.7.3 Post-Installation Testing

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

4.3.7.4 Quality Releases

Quality releases are prepared and issued for items that will not otherwise have their acceptance documented by Westinghouse prior to being shipped to the customer, based on the item's importance to safety and/or complexity of the item, in accordance with established procedures. The quality release is a document that provides for:

- The specific identification of the procured item by a 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, inspections, and document reviews are performed, as appropriate, to verify the supplier's compliance with procurement documents.

4.3.7.5 Statement of Conformance

A statement of conformance is documented for items and services in accordance with customer requirements and applicable procedures. These documents are authenticated by designated personnel based on documented acceptance records. Examples of these include Certificate of Compliance, Inspection Certificate, or Certified Material Test Report (CMTR).

4.3.8 Industry Code-Supplied Items

Items required to meet national industry code (e.g., ASME B&PV Code Section III, Division 1) requirements are supplied as follows:

- Obtained from suppliers holding the proper industry code certificates of authorization, or

- Supplied under an independent Westinghouse quality program accredited by the national code agency.

Repair, replacement, modification, or alteration activities performed on items procured under the QMS when supplied in accordance with a national code (e.g., ASME B&PV Code Section III stamped items) are subject to approval from the design authority for that item.

4.3.9 Dedication of Commercial-Grade Items

Commercial-grade items (items not originally 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 the governing regulatory agency, before the items are approved for safety-related applications. Commercial grade dedication also applies to a commercial grade service that was not intended to be relied upon as an activity affecting safety or was not considered part of a basic component (e.g., safety-related design, analysis,

inspection, testing, or fabrication that is associated with a basic component). Procedures are established to describe the responsibilities for Engineering to perform a technical evaluation, select applicable critical characteristics, and determine an appropriate dedication method for acceptance. Procedures are also established to enhance the detection of counterfeit and fraudulent items and to minimize the likelihood of the introduction of such items in safety-related applications.

For nuclear power plants subject to NRC regulatory requirements, Westinghouse may utilize commercial-grade items or services in its supply of basic components in compliance with the guidance in Generic Letter 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products.” Generic Letter 89-02 documents the NRC’s endorsement of EPRI NP-5652, “Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety Related Applications” (NCIG-07).” Westinghouse utilizes a commercial grade dedication process consistent with Generic Letter 89-02 and 10CFR21, for the supply of basic components. For radioactive materials transport packaging subject to NRC requirements, commercial-grade items are utilized in accordance with NRC Regulatory Guide 7.10, “Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Materials,” as appropriate.

When a commercial-grade item is modified, inspected, and/or tested to demonstrate compliance to requirements more restrictive than the manufacturer’s original specifications it is uniquely identified as different from the commercial-grade item and traceable to documents that record the difference.

When purchasing commercial-grade calibration services from a United States calibration laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met:

- The purchase documents impose additional technical and administrative requirements, as necessary, to comply with the Westinghouse QA program and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report include identification of the laboratory equipment/standard used.

- The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.

- A documented review of the supplier’s accreditation is performed and includes a verification of the following:

    — The calibration laboratory holds a domestic (United States) accreditation by an NRC-approved accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). The accreditation encompasses ANS/ISO/IEC 17025, “General Requirements for the Competence of Testing and Calibration Laboratories.”

    — The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, range, and uncertainties.

4.4 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 service. Any customer-supplied item or material that is lost, damaged, or otherwise unsuitable for use is documented and reported to the customer.

4.5 Product Identification and Traceability

Procedures are established to specify the methods and extent of identification and traceability of items to ensure that only correct and acceptable items are installed or used in items and services.

4.5.1 Identification Requirements

Engineering is responsible for specifying identification requirements 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.

4.5.2 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.

4.5.3 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, appropriate requirements are included 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.

4.6 Process Control

4.6.1 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/or 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

4.6.2 Special Processes

Special processes are those processes where the results are highly dependent on the control of the process or the skill of the operator, or both, and in which the specified quality cannot be readily determined by inspection or testing of the product. Special processes include, but are not limited to, nondestructive examination (NDE), welding, brazing, cleaning, and heat treating. Special processes that could affect the quality of items or services shall be performed by qualified personnel using qualified procedures in accordance with applicable industry codes, standards, and regulatory requirements.

Qualification of process controls is performed, as appropriate, to ensure that the special process will yield acceptable results. Personnel, equipment, and procedures used to perform special processes are qualified and controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. Documentation of personnel, equipment, and process qualifications is maintained.

Qualification of processes and personnel for welding and NDE is in accordance with the applicable national industry code (e.g., ASME Boiler and Pressure Vessel B&PV Code) or other specified requirements. Welding and NDE are performed in accordance with written procedures, utilizing personnel of the organization who are qualified and certified in accordance with the organization’s approved quality program. The organization utilizing the applicable procedures or personnel is responsible for reviewing certifications for compliance with the specific job

requirements prior to use. In addition, organizations/subsidiaries may utilize procedures and personnel qualified by other Westinghouse organizations 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 procedures.

4.7 Control of Inspection, Measuring, and Test Equipment

Inspection, measuring, and test equipment are 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. The 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, due date, the calibration standard used, and results of the calibration, is maintained. Calibration is performed at specified intervals in accordance with procedures using standards traceable to national recognized standards. Reference standards used for calibration have a minimum accuracy of four times greater than the measuring and test equipment being calibrated. Where this 4:1 ratio cannot be maintained, the basis for selection of the standard in question is technically justified. 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, during handling and storage, from adjustments that would invalidate the calibration settings. Measuring and test equipment are used and calibrated in environments that are controlled to the extent necessary to ensure that the required accuracy and precision are maintained.

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

4.8 Handling, Storage, Packaging, Preservation and Delivery

4.8.1 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 items 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.

4.8.2 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 nuclear power plant site or storage facility, special handling, storage, and shipping instructions will be provided in accordance with the requirements of the customer.

4.8.3 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. 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.

4.8.4 Packaging and Preservation

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.

4.8.5 Delivery

Each organization is responsible for defining transportation requirements to ensure integrity of items 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.

4.8.6 Shipment of Hazardous Goods

Assigned organizations are responsible to ensure that the packaging and shipment of hazardous goods and materials, such as radioactive, contaminated field service tooling, are performed according to national and international regulations, and contractual requirements, as applicable.

4.9 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, items, and services to customers upon request. Interfaces are identified and maintained to provide support as necessary to meet servicing work scopes.

4.9.1 Servicing Requirements

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

4.9.2 Performing Services

Services (including repair services) are performed by each organization in a controlled manner that ensures conformance to the organizations' procedures, and customer and regulatory 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 items.

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.

5.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

The QMS provides control over a system of interlinked individual processes. These processes are monitored and the resulting data is used to demonstrate conformance to specified requirements, and support corrective, preventive, or continual improvement actions. The management review process identifies the significant processes that were targeted for improvement and the associated quality objectives. This monitoring, measuring, and analysis are used to support the management review process in which executive management participates.

5.1 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 item performance characteristics can be evaluated using statistical techniques to determine item 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.

5.2 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, including computer program tests, are controlled under appropriate environmental conditions. Required tests (other than computer program tests) may include proof tests before installation, post-modification tests, prototype qualification tests, production tests, construction tests, and pre-operational tests. Sources of acceptance 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 other than those performing the work, when required by contractual or regulatory requirements. For safety-related items and services, inspections or tests will be performed by qualified personnel who are independent of those performing the work. Oversight is conducted by qualified personnel for individuals performing inspections during on-the-job training for qualification. Modifications, repairs, or replacements of items performed subsequent to final inspection are reinspected or retested, as appropriate, to verify acceptability.

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/procedures, if applicable*
- Records to be maintained

*Sampling plans/procedures when used are based upon standard statistical methods with engineering approval.

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

- Identification of item(s) 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.

5.2.1 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.

5.2.2 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.

5.2.3 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.

5.3 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

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

5.4 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 define responsibility and authority for the evaluation and disposition of nonconforming items. Further processing, delivery, installation, or use of nonconforming items are designated in writing. Procedures are established for the identification, documentation, evaluation, segregation (if practical), review, corrective action, and notification to affected organizations. Disposition may include rework, use as-is, repair, or reject and scrap. Repaired and reworked items are re-verified 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.

5.5 Corrective and Preventive Action

5.5.1 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.

5.5.2 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 and reviewing effectiveness of the corrective actions. 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 root 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.

5.5.3 Preventive Action

Quality data is analyzed for trends in items, services, 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.

Action to prevent adverse impact on customer satisfaction is based on information that comes from direct customer discussions, survey feedback on delivered items and services, and information captured in nonconformance tracking systems.

5.5.4 Self-Assessments

Organizational management is responsible for the implementation of a self-assessment program to identify gaps between current levels of performance and management expectations or industry standards. Self-assessments are a proactive performance monitoring activity, which involves identifying precursor-level problems for resolution before they become larger organizational issues. Gaps between actual performance and desired performance are captured in the corrective action system. Self-assessment identified improvements to current performance are tracked to completion.

Management oversees the planning and implementation of self-assessments to ensure they focus on key issues and that completed self-assessments are of high quality. Records of the self-assessments are maintained.

5.6 Internal Quality Audits

5.6.1 Internal Audits

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

Audit frequency is based on the status and importance of an activity, results of external audits, and internal quality performance monitoring and indicators. Schedules are updated as necessary to ensure that adequate oversight is maintained. Quality retains responsibility for the validity of external audits used as input to determine audit scopes and schedules. Supplemental audits are performed when necessary to verify specific activities, processes, and/or implementation of corrective actions.

Audits are performed by qualified personnel (including subject matter experts or technical specialists), independent of the activity being assessed, using written procedures and/or checklists, as appropriate. Reports documenting results are prepared upon completion of the audit and distributed to appropriate management. Audit reports require the audited 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 applicable standards. Westinghouse qualifies lead auditors in accordance with ASME NQA-1 and applicable procedures. For organizations subject to governing regulatory agencies other than the NRC, Westinghouse may also qualify lead auditors in accordance with regulatory or contractual requirements applicable to those organizations. Qualification records are maintained by Quality.

Audit records include audit plans, checklists, audit reports, written replies, and documentation of completed corrective actions.

5.6.2 Audits at Field Locations

Field services are conducted and controlled in accordance with specific contractual requirements. Audits 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

APPENDIX A
WESTINGHOUSE POSITIONS ON NRC REGULATORY GUIDES AND ASME NQA-1

Westinghouse organizations comply with regulatory requirements and ASME NQA-1 guidance. This appendix identifies clarifications, alternatives, and exceptions taken by Westinghouse to NRC Regulatory Guides and generic correspondence as well as ASME QA-related requirements. Additional positions on Regulatory Guides and ASME NQA-1 may be given in individual customers' Safety Analysis Reports (SARs).

1.0 REGULATORY GUIDES

1.1 Regulatory Guide 1.26, Rev. 4, "Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste -Containing Components of Nuclear Power Plants," See the specific SAR.

1.2 Regulatory Guide 1.28, Rev. 4, "Quality Assurance Program Criteria (Design and Construction)". Westinghouse follows NRC regulatory positions with the following clarifications:

NQA-1-2008(9a), Part III, Subpart 3.1 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 300, 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.

Part III, Subpart 3.1, Appendix 18A-1, Nonmandatory Guidance on Audits

Position (Clarification)

The regulatory position in Section C.3 along with alternatives to NQA-1, which are compatible with Regulatory Guide 1.28, Rev. 4, will be followed.

1.3 Regulatory Guide 1.29, Rev. 4, "Seismic Design Classification," See the specific SAR.

1.4 Regulatory Guide 1.36, "Nonmetallic Thermal Insulation for Austenitic Stainless Steel," Quality Assurance controls are applicable. See the specific SAR.

APPENDIX A (cont.)
WESTINGHOUSE POSITIONS ON NRC REGULATORY GUIDES AND ASME NQA-1

1.5 Regulatory Guide 1.54, Rev. 2, "Quality Assurance Requirements for Protective Coatings Applied to Water-Cooled Nuclear Power Plants," See the specific SAR.

1.6 Regulatory Guide 1.143, Rev. 2, "Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light-Water-Cooled Nuclear Power Plants," See the specific SAR.

1.7 Regulatory Guide 7.10, Rev. 2, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Materials," Westinghouse organizations follow the NRC regulatory positions.

1.8 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 implemented in accordance with this position.

1.9 Regulatory Position 6 of Regulatory Guide 1.143, Rev. 2, - Radioactive waste QA controls are to be implemented in accordance with this position.

APPENDIX A (cont.)
WESTINGHOUSE POSITIONS ON NRC REGULATORY GUIDES AND ASME NQA-1

2.0 ASME NQA-1, Part I

2.1 NQA-1, Requirement 2, Quality Assurance Program

2.1.1, Paragraph 301 – "The American society of Nondestructive Testing (ASNT) Recommended Practices or Standards provide acceptable qualification requirements for NDE personnel."

Position - Alternative

Organizations holding an ASME Certificate of Authorization may qualify NDE personnel as required by the ASME B&PV code.

2.1.2, Paragraph 202 – "Training shall be provided, if needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities."

Position - Clarification

Manufacturing organizations 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.

2.1.3, Paragraph 500, Records – "Records of the implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records."

Position - Clarification

In manufacturing organizations, training records for personnel performing fabricating, handling, shipping, storing, and cleaning activities are available for review; however, they are not maintained as nonpermanent QA records.

APPENDIX A (cont.)
WESTINGHOUSE POSITIONS ON NRC REGULATORY GUIDES AND ASME NQA-1

2.2 NQA-1, Requirement 7, Control of Purchased Items and Services

2.2.1, Paragraph 200, Supplier Evaluation and Selection – "Measures for evaluation and selection of procurement sources, and the results there from, 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 QA Program. Audits and annual evaluations are performed in accordance with the commitments and requirements of this Plan.

2.2.2, Paragraph 600, Control of Supplier Nonconformances – "(b). . .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 item or service. Thus, suppliers are not required to submit nonconformance reports on deviations from these procedures, unless they constitute deviations from the Westinghouse procurement requirements.

APPENDIX A (cont.)
WESTINGHOUSE POSITIONS ON NRC REGULATORY GUIDES AND ASME NQA-1

2.3 NQA-1, Requirement 17, Quality Assurance Records

2.3.1, Paragraph 500, Receipt Control of Records – "Receipt controls shall provide a method for identifying the 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.

2.3.2, Paragraph 600, Storage

Position - 1

Long-term records storage 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 NRC (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 (described as follows) 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 8-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/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 facility is located approximately 5 miles away and 100 feet above the nearest stream. Floor and roof drains are not necessary.

APPENDIX A (cont.)
WESTINGHOUSE POSITIONS ON NRC REGULATORY GUIDES AND ASME NQA-1

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 4 feet of limestone. The asphalt floors are coated with a sealant. Concrete floors are coated with hard, wearing deck enamel.

Position - 7

The foundation consists of a 4-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 a 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 tours inside the area every 4 hours during non-working hours. A volunteer fire department in a neighboring town is located within 1.5 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.

APPENDIX A (cont.)
WESTINGHOUSE POSITIONS ON NRC REGULATORY GUIDES AND ASME NQA-1

3.0 ASME NQA-1, PART II

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/operation 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 Facilities"

3.2.1, Paragraph 402.3, Special Shipments

Position - Exception

For special shipments, Westinghouse 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, Westinghouse does not consider it desirable or feasible to implement subsection 402.3 in all situations. For example, it may not always be possible to install impact recording meters prior to handling. In summary, Westinghouse implements controls for special shipments based upon engineering judgment and experience to assure proper transportation of the special shipment.

3.2.2, Paragraph 306.2, Vapor-Proof Barrier Material

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

Position - Alternate

Westinghouse 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 meets other physical and chemical requirements.

3.2.3, Paragraph 500, Receiving

Position - Clarification

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

APPENDIX A (cont.)
WESTINGHOUSE POSITIONS ON NRC REGULATORY GUIDES AND ASME NQA-1

3.2.4, Paragraph 600, Storage

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

3.2.5, Paragraph 700, Handling

Position - Alternate

Organizations and suppliers use conservative industrial engineering practices for controlling the lifting and moving of completed components 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/operation 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/operation 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"

Organizations follow the requirements of Subpart 2.5 to the extent specified in the contract for those portions of the site work within their scope.

3.6 Subpart 2.7, "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications"

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"

Organizations follow the requirements of Subpart 2.8 to the extent specified in the contract for those portions of the site work within their scope.

APPENDIX B
PROJECT QUALITY PLAN APPLICABILITY EXAMPLES

International Standard Examples (not all-inclusive):

- International Atomic Energy Agency (IAEA) GS-R-3, The Management System for Facilities and Activities
- ISO 14001, Environmental Management Systems Requirements
- Occupational Health and Safety Standard (OSHAS) 18001 (or similar)

Country-Specific Examples (not all-inclusive):

Belgium

- Transposition to Belgium of the Regulatory aspects of Section III, Division 1 of the ASME Code
- Transposition to Belgium of the Regulatory aspects of Section XI, Division 1 of the ASME Code

Canada

- Canadian Standards Association (CSA) N286, Management System Requirements for Nuclear Power Plants

China

- HAF 604, Regulations on Supervision and Management of Imported Civil Nuclear Safety Equipment
- HAF 003, Regulations on Nuclear Power Plant Quality Assurance and Safety
- HAD 003/04, Nuclear Power Plant Quality Assurance Records

France

- CEFRI SPE-E-0400 Indice 18: Specification concerning Companies Employing Category A or Personnel Working in Nuclear Facilities
- ACT No. 2006-686 of June 2006 on Transparency and Security in the Nuclear Field at the last applicable revision
- Order of 12 December 2005 concerning nuclear pressure equipment at the last applicable revision

APPENDIX B (cont.)
PROJECT QUALITY PLAN APPLICABILITY EXAMPLES

Germany

- Nuclear Safety Standards Commission (KTA) 1401 General Quality Requirements
- KTA 1201 Requirements for Documentation
- AVS 100/50 Quality Requirements for Manufacturer

Japan

- Japan Electric Association Code (JEAC) 4111, Quality Assurance Code for Safety in Nuclear Power Plants

South Africa

- RD-0034 Quality and Safety Management Requirements for Nuclear Installations

Spain

- Spanish QA Standard UNE 73 401, Quality Assurance Requirements for Nuclear Facilities

Spanish Safety Council as endorsed in Safety Guide GS-10.1 (Spanish Safety Guides are the equivalent to the United States Nuclear Regulatory Commission [NRC] Regulatory Guides)

Sweden

- Swedish Radiation Safety Authority Regulations

United Kingdom

- Health and Safety Executive (HSE) Safety Assessment Principles for Nuclear Facilities, United Kingdom Quality Standard

APPENDIX C
U.S NRC RAI AND WESTINGHOUSE RESPONSE

Westinghouse Non-Proprietary Class 3

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LTR-NRC-20-36

May 1, 2020

Subject: Submittal of "Westinghouse Responses to RAIs on Quality Management System Revision 8.0 (Non-Proprietary)

Enclosed is "Westinghouse Responses to RAIs on Quality Management System Revision 8.0". The enclosure provides changes to Quality Management System, Revision 8.0, which will be incorporated into the –A version of the Quality Management System.

The NRC RAIs and Westinghouse's responses do not contain proprietary information.

Correspondence with respect to the contents of this submittal should be addressed to Angela Zubroski at zubrosal@westinghouse.com.

Camille Zozula

Camille T. Zozula, Manager
Regulatory Compliance & Corporate Licensing

cc: Kerri Kavanagh (NRC)
Greg Galletti (NRC)
Ekaterina Lenning (NRC)
Dennis Morey (NRC)
Ngola Otto (NRC)

Enclosure:

1. Westinghouse Responses to RAIs on Quality Management System Revision 8.0 (Non-Proprietary)

APPENDIX C
U.S NRC RAI AND WESTINGHOUSE RESPONSE

Enclosure 1

Westinghouse Responses to RAIs on Quality Management System Revision 8.0

(Non-Proprietary)

April 2020

APPENDIX C
U.S NRC RAI AND WESTINGHOUSE RESPONSE

Westinghouse Non-Proprietary Class 3

LTR-NRC-20-36
Enclosure 1

REQUESTS FOR ADDITIONAL INFORMATION FOR TOPICAL REPORT, "QUALITY MANAGEMENT SYSTEM (QMS)," REVISION 8.0 WESTINGHOUSE ELECTRIC COMPANY

By letter dated April 27, 2020 (Agencywide Documents Access and Management System Package Accession No. ML20118C994), Westinghouse Electric Company (Westinghouse) submitted to the U.S. Nuclear Regulatory Commission (NRC) Topical Report, "Quality Management System (QMS)," Revision 8.0. Below are the NRC staff requests for additional information:

1) In Section 4.3.1, "General," of the QMS, Westinghouse proposes to include a 25 percent extension to the periodicities of audits or surveys when performance of such activities is not feasible under exigent conditions. Please describe how Westinghouse ensures the applicability of the 25 percent extension is only for exigent conditions and does not create confusion regarding the existing 36-month audit frequency and associated 90-day grace period afforded for emergent administrative issues.

   Westinghouse Response:

   Westinghouse will update the QMS to add Subsection 4.3.1.1, "Exigent Conditions". This section will contain the requirements for exigent conditions.

   Please see the attached markup.

2) In Section 4.3.1 of the QMS, Westinghouse states:

   > The grace period clock under Regulatory Guide 1.28 Rev. 4 can be extend if exigent conditions exist including but not limited to: a) declaration of a national emergency, b) severe localized or national weather conditions, or c) localized outbreak of a severe health concern to the public. In the case exigent conditions exist, an overall 25% extension to the periodicities of audits or surveys may be exercised when performance of such activities is not feasible.

   Please provide more information on the relevancy of referencing the grace period in Regulatory Guide 1.28, Revision 4, because the proposed 25 percent grace period is not an extension of the 90-day grace period for administrative issues, but rather a totally unique grace period to be used only during exigent conditions.

   Westinghouse Response:

   Westinghouse will update the QMS to remove the reference to RG 1.28, Revision 4 for exigent conditions.

   Please see the attached markup.

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U.S NRC RAI AND WESTINGHOUSE RESPONSE

Westinghouse Non-Proprietary Class 3

LTR-NRC-20-36
Enclosure 1

3) In Section 4.3.1 of the QMS, Westinghouse identifies three actions (a-c) that need to be taken in order for suppliers in the 25 percent extension to remain on the Westinghouse qualified supplier list. Action item b.3 states, "results of audits from other sources (e.g., customer, American Society of Mechanical Engineers (ASME), NIAC or NRC audits)." The NRC staff considers information from previous NRC inspections is more suitable for supporting the monitoring ongoing and previous supplier performance.

   Please provide why inspections were not included in Action item b.3.

   Westinghouse Response:

   Westinghouse will update the QMS to change item b.3 to include inspections.

   Please see the attached markup.

APPENDIX C
U.S NRC RAI AND WESTINGHOUSE RESPONSE

Westinghouse Non-Proprietary Class 3

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Enclosure 1

Attached Changes

APPENDIX C
U.S NRC RAI AND WESTINGHOUSE RESPONSE

4.3 Procurement

4.3.1 General

Controls of purchased items and services are established to ensure that applicable technical and quality requirements are met. Procurement 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. Commitments to resolve unacceptable conditions are obtained from the supplier prior to contract award. Spare or replacement parts are procured to requirements which are equivalent to or exceed the original requirements.

Suppliers of safety-related items and services are evaluated and approved by Quality prior to their designation as a qualified supplier, or placement of a purchase order. Active qualified suppliers (including suppliers accredited under national industry codes such as ASME) of safety-related items are evaluated annually and audited at least every 3 years with the following exceptions:

For safety-related items and services, Quality determines the need to conduct supplier audits based on an evaluation that is conducted and documented in accordance with established procedures. Based on this evaluation Supplier audits need 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.

Audit programs for suppliers of items and services for nuclear power plants that are not subject to NRC regulations comply with requirements imposed by the governing regulatory agency or customer contract.

4.3.1.1 Exigent Conditions

Under exigent conditions, the audit and/or survey interval may be extended up to 25%. This unique grace period ~~The grace period clock under Regulatory Guide 1.28 Rev. 4~~ can be applied ~~extended~~ if exigent conditions exist including but not limited to; a) declaration of a national emergency, b) severe localized or national weather conditions, or c) localized outbreak of a severe health concern to the public. ~~In the case exigent conditions exist, an overall 25% extension to the periodicities of audits or surveys may be exercised when performance of such activities is not feasible.~~ Under these exigent conditions the audit clock resets when the audit and/or survey is performed. ~~grace period clock reset under Regulatory Guide 1.28 Rev. 4 does not apply, the audit performed within this extension period resets the clock.~~ The 25% grace period extension is applicable to domestic and international suppliers.

During the use of the 25% extension, a supplier evaluation shall be performed and results documented, including any necessary qualification adjustments. Suppliers in the 25% extension can be maintained on the Westinghouse QSL provided the following actions (a - c) are taken

APPENDIX C
U.S NRC RAI AND WESTINGHOUSE RESPONSE

and the results satisfactory:

a. Verification that;
   (1) the supplier is still implementing a quality assurance program that meets Appendix B to 10 CFR Part 50 OR
   (2) commercial suppliers surveyed are still maintaining adequate documented programmatic controls for the activities affecting quality.

b. Monitor ongoing and previous supplier performance promptly considering impacts of the following types of information:
   1. Results of receipt inspection activities or other operating experience.
   2. Review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions.
   3. Results of audits and inspections from other sources (e.g., customer, American Society of Mechanical Engineers (ASME), NIAC audits or NRC inspections)

c. In the case of a new procurement activity or changes to existing procurements that significantly enlarges the scope or changes the method / controls for activities performed by the supplier, the evaluation shall document the justification that the change(s) are adequately addressed by the supplier's quality assurance program or mitigating actions are being taken by Westinghouse.