December 29, 2014

Mr. James A. Gresham, Manager
Regulatory Compliance and Plant Licensing
Westinghouse Electric Company
1000 Westinghouse Drive
Cranberry Township, PA 16066

SUBJECT: FINAL SAFETY EVALUATION FOR WESTINGHOUSE ELECTRIC COMPANY (WESTINGHOUSE) TOPICAL REPORT QUALITY MANAGEMENT SYSTEM, REVISION 7 (TAC NO. MF2833)

Dear Mr. Gresham:

By letter dated August 28, 2013 (Agencywide Documents Access and Management System Accession No. ML13246A105), Westinghouse submitted for U.S. Nuclear Regulatory Commission (NRC) staff review Topical Report (TR) Quality Management System (QMS), Revision 7.

By letter dated October 30, 2014 (ADAMS No. ML14280A275), an NRC draft safety evaluation (SE) regarding our approval of TR Westinghouse QMS, Revision 7, was provided for your review and comments. By email dated December 2, 2014, Westinghouse indicated that they have no comments on the draft SE and stated that SE does not contain any proprietary information.

The NRC staff has found that TR Westinghouse QMS, Revision 7, is acceptable for use by Westinghouse for engineering, procurement, and construction activities affecting the quality and performance of safety-related structures, systems, and components.

Our acceptance applies only to material provided in the subject TR. We do not intend to repeat our review of the acceptable material described in the TR. When the TR appears as a reference in license applications, our review will ensure that the material presented applies to the specific plant involved. License amendment requests that deviate from this TR will be subject to a plant-specific review in accordance with applicable review standards.

In accordance with the guidance provided on the NRC website, we request that Westinghouse publish accepted proprietary and non-proprietary versions of this TR within three months of receipt of this letter. 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 requests for additional information (RAIs) and your responses. The accepted versions shall include an "-A" (designating accepted) following the TR identification symbol.

As an alternative to including the RAIs and RAI responses behind the title page, if changes to the TR 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 RAIs:

1. The RAIs and RAI responses can be included as an Appendix to the accepted version.
2. The RAIs 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 TR. The table should reference the specific RAIs and RAI responses which resulted in any changes, as shown in the accepted version of the TR.

If future changes to the NRC's regulatory requirements affect the acceptability of this TR, Westinghouse and/or licensees referencing it will be expected to revise the TR appropriately, or justify its continued applicability for subsequent referencing.

Sincerely,

/RA/

Aby Mohseni, Deputy Director
Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation

Project No. 700

Enclosure:
Final Safety Evaluation

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/RA/

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Enclosure:
Final Safety Evaluation

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U. S NUCLEAR REGULATORY COMMISSION

FINAL SAFETY EVALUATION

FOR WESTINGHOUSE ELECTRIC COMPANY TOPICAL REPORT

"QUALITY MANAGEMENT SYSTEM," REVISION 7

(TAC NO. MF2833)

1.0 INTRODUCTION

By letter dated August 28, 2013, Westinghouse Electric Company (Westinghouse) submitted for U.S. Nuclear Regulatory Commission (NRC) staff review Topical Report (TR) "Quality Management System," Revision 7 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13246A105) (hereafter referred to as the QMS) for NRC review and acceptance, pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50.4(b)(7)(ii). Westinghouse provided additional information by letter dated July 10, 2014, in response to an NRC request for additional information dated June 12, 2014 (ADAMS Accession No. ML14230A680).

2.0 REGULATORY EVALUATION

The Commission's regulatory requirements related to quality assurance (QA) programs for non-licensees are set forth in 10 CFR 50.4(b)(7)(ii). This regulation requires that a change to an NRC-accepted QA program description (QAPD) from non-licensees (i.e., architect/engineers, nuclear steam system suppliers (NSSSs), fuel suppliers, constructors, etc.) must be submitted to the NRC. The NRC will review the proposed QAPD for acceptability to ensure the applicable requirements of Appendix B to 10 CFR Part 50 will be satisfied.

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 establishes QA requirements for the design, fabrication, construction, testing, and operation of structures, systems, and components (SSCs) for the facility. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of those SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying SSCs.

3.0 EVALUATION

The proposed QMS is similar in many respects to previous submittals approved for licensees for the purpose of meeting NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Standard Review Plan (SRP) Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants," (hereafter referred to as Section 17.5).

ENCLOSURE

In evaluating the adequacy of the QMS, the NRC staff utilized the guidance contained in Section 17.5, which provides acceptance criteria for design certification, early site permit, combined operating license, construction permit, and operating license applicants. Section 17.5 is based on the American Society of Mechanical Engineers (ASME) Standard NQA-1-1994 Edition, as supplemented by additional regulatory and industry guidance for nuclear operating facilities. The ASME Standard NQA-1-2008 Edition and NQA-1a-2009 Addenda, upon which the Westinghouse QMS is based, incorporates the supplemental guidance into a single document, and is therefore, in alignment with Section 17.5, therefore is acceptable. In addition, NQA-1-2008 Edition and NQA-1a-2009 Addenda is endorsed by NRC Regulatory Guide (RG) 1.28, Revision 4.

3.1 Quality Assurance Program Overview

TR "Quality Management System," Revision 7, and supporting documentation provides Westinghouse's QAPD for engineering, design, procurement, construction, modification, repair, and decommissioning of nuclear facilities. The TR is divided into six parts: I) Quality Management System; II) Management Responsibility; III) Resource Management; IV) Product Realization; V) Measurement, Analysis and Improvement; and VI) Regulatory Commitments.

The significant changes to the QA program for Westinghouse since the previously approved TR are: 1) a commitment to NQA-1-2008 and NQA-1a-2009 as the basis for the QA program; 2) incorporation of alternatives to NQA-1-2008 and NQA-1a-2009 that have been approved by NRC in safety evaluations or RG 1.28; 3) clarifications of requirements for computer software/hardware; and 4) clarification of requirements for commercial-grade items and services.

The format used for the following evaluation follows the sequence of the 18 criteria of Appendix B and corresponding provisions of NQA-1-2008 and NQA-a-2009 (hereafter referred to as NQA-1).

3.1.1 Organization

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.A, for providing an organizational description that includes the organizational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying Westinghouse QA program implementation. The Westinghouse QMS establishes independence between the organization performing checking functions related to the QA program and the organization responsible for performing the function. In addition, the Westinghouse QMS provides for applicable management to be responsible to size the QA organization commensurate with the duties and responsibilities assigned. Finally, responsibility and authority for planning, establishing, and implementing an effective overall QA program are clearly described and defined.

The Westinghouse QMS commits to implement the quality standards described in NQA-1, Requirement 1, without further clarifications or exceptions. The staff's review of the organizational controls finds that it is consistent with the quality requirements in NQA-1 and Section 17.5, and is therefore acceptable.

3.1.2 Quality Assurance Program

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.B, for establishing the necessary measures to implement a QA program.

A list or system identifying the SSCs and activities to which the Westinghouse QA program applies is maintained for the design certification project. Westinghouse may delegate all or part of the activities for which they are responsible to others, but retains overall responsibility for the QA program's effectiveness.

The Westinghouse QMS provides for measures to assess the adequacy of the QA program and to ensure its effective implementation, at least once each year or at least once during the life of the activity, whichever is shorter, using a continuous improvement process.

The Westinghouse QMS follows the guidance of Section 17.5, Paragraphs II.S and II.T, for describing the necessary measures to establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the QA program to assure that suitable proficiency is achieved and maintained. The Westinghouse QMS discusses the minimum training requirements for all personnel responsible for planning, implementing, and maintaining the Westinghouse QA program.

The Westinghouse QMS commits to implement the quality requirements described in NQA-1, Requirement 2, with the following clarifications and exceptions:

- Section 301, Nondestructive Examination (NDE)
  Westinghouse follows Section 301 for qualification of NDE personnel, except that organizations holding an ASME Certificate of Authorization may qualify NDE personnel as required by ASME Boiler and Pressure Vessel (BPV) Code. Westinghouse will follow the applicable standard cited in the versions(s) of Section III and Section XI of the ASME BPV Code approved by the NRC for use at Westinghouse sites for the scope of activities governed by these cited standards.

The regulation in 10 CFR 50.55a, "Codes and standards," requires use of the latest edition and addenda of Section III and Section XI endorsed in 10 CFR 50.55a. Therefore, the staff finds the use of Sections III and XI of the ASME BPV Code for qualification of nondestructive examination personnel acceptable.

The staff's review of this alternative finds that there is no conflict with the quality standards described in NQA-1, Section 17.5, or the ASME BPV Code requirements, and are therefore acceptable.

- Section 202, Training
  Section 202 states in part, "Training shall be provided, if needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities." Westinghouse includes the following 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 job function/responsibility is changed.

  The staff finds this clarification acceptable since it provides additional detail specific to manufacturing organizations and is consistent with NQA-1.

- Section 500, Records
  Section 500 states in part, "Records of implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records." Westinghouse includes the following clarification for manufacturing organizations, "In manufacturing organizations, training records for personnel performing fabrication, handling, shipping, storing, and cleaning activities are available for review; however, they are not maintained as nonpermanent QA records."

  The staff finds this clarification acceptable since it provides additional detail specific to manufacturing organizations and is consistent with NQA-1.

3.1.3 Design Control

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.C.1, for establishing the necessary measures to control the design, design verification, and analysis activities of safety-related items and services that are subject to the provisions of the QA program. The Westinghouse QA program design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces. These provisions ensure that the design inputs (such as design bases, performance and regulatory requirements, and codes and standards) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions). In addition, the Westinghouse QMS provides for design documents to be reviewed by individuals knowledgeable in QA to ensure that the documents contain the necessary QA requirements.

Consistent with Section 17.5, Paragraph II.C.2, the Westinghouse design processes provide for design verification to ensure that items and activities subject to the provisions of the QA program are suitable for their intended application and consistent with their effect on safety.

Design changes are subject to these controls, which include verification measures commensurate with those applied to original plant design. The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Design verification activities are completed before the design outputs are used by other organizations for design work; before they are used to support other activities such as procurement, manufacture, or construction; or when such timing cannot be achieved, before relying on the item to perform its intended design or safety function. Verification methods may include, but are not limited to, design reviews, alternative calculations, and qualification testing.

The Westinghouse QMS governs the development, procurement, testing, maintenance, and use of computer application and digital equipment software when used in safety-related applications and designated nonsafety-related applications. Westinghouse and its suppliers are responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The Westinghouse QMS states that the procedures shall require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification.

In establishing its program for design control and verification, Westinghouse commits to compliance with NQA-1, Requirement 3, Subpart 2.7 for computer software, and Subpart 2.14 for commercial grade items and services without further clarifications or exceptions. The staff's review of the design controls finds it consistent with the quality standards in NQA-1, and Section 17.5, and is therefore acceptable.

3.1.4 Procurement Document Control

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.D, for establishing the necessary administrative controls and processes to ensure that applicable regulatory, technical, and QA program requirements are included or referenced in procurement documents. Applicable technical, regulatory, administrative, quality, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21) are invoked for the procurement of items and services.

The Westinghouse QMS commits to implement the quality standards described in NQA-1, Requirement 4. The staff's review of the procurement document controls finds it consistent with the quality standards in NQA-1, and Section 17.5, and is therefore acceptable.

3.1.5 Instructions, Procedures, and Drawings

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.E, for establishing the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by, and performed in accordance with, documented instructions, procedures, or drawings of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QAPD.

The staff's review finds that in establishing its program for instructions, procedures, and drawings Westinghouse commits to implement the quality standards described in NQA-1,

Requirement 5 and the guidance in Section 17.5, without further clarifications or exceptions, and is therefore acceptable.

3.1.6 Document Control

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.F, for establishing the necessary measures and governing procedures to control the preparation, review, approval, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled. Measures are provided to assure that documents, including revisions or changes (other than those defined in implementing procedures as minor changes), are reviewed and approved by the same organization that performed the original review and approval, unless other organizations are specifically designated. A list of all controlled documents, identifying the current approved revision or date, is maintained so personnel can determine the appropriate document for use.

The staff's review finds that in establishing its program Westinghouse commits to implement the quality standards described in NQA-1, Requirement 6, and meets the guidance in Section 17.5 without further clarifications or exceptions, and is therefore acceptable.

3.1.7 Control of Purchased Material, Equipment, and Services

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.G, for establishing the necessary measures and governing procedures to control the procurement of items and services to ensure conformance with specified requirements. The controls include measures for evaluating prospective suppliers and selecting only those that are qualified. In addition, controls include auditing and evaluating suppliers to ensure that qualified suppliers continue to provide acceptable products and services.

The program provides measures for source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services. The Westinghouse QMS establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through contractors, at intervals and to a depth consistent with the item's or service's importance to safety, complexity, quantity, and frequency of procurement.

The Westinghouse QMS provides measures for evaluating prospective suppliers and selecting only qualified suppliers, as well as auditing and evaluating suppliers to ensure that qualified suppliers continue to provide acceptable products and services. The scope of procurement includes engineering, design, and testing services, as well as the procurement of safety-related software.

The Westinghouse QMS also outlines acceptance actions, such as source verification, receipt inspection, certificates of conformance, and review of documentation (e.g., Certified Material Test Reports/Certificates) to ensure that the procurement, inspection, and test requirements have been satisfied before relying on the item to perform its intended safety function.

In establishing procurement verification control, the Westinghouse QMS commits the applicant to the quality standards described in NQA-1, Requirement 7, with the following clarifications and exceptions:

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

  a) *The Westinghouse commercial-grade dedication process shall be followed.*

  b) *The performance of an evaluation to identify additional technical requirements and critical characteristics for the specific measuring and test equipment (M&TE) being calibrated.*

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

  d) *The purchase documents require reporting as-found calibration data and as-left data when the calibrated items are found to be out-of-tolerance.*

  e) *A documented review of the supplier's accreditation will be performed and will include a verification of the following:*
     - *The calibration laboratory holds a domestic (United States) accreditation by an NRC approved domestic (United States) accrediting bodies, recognized by the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement.*
     - *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.*

  f) *The review of calibration records (e.g., as part of receipt inspection) to verify that the critical characteristics had been met.*

The staff determined that the provisions of this exception are consistent with the regulatory guidance provided in Section 17.5, Paragraph II.L.8, for the procurement of commercial-grade calibration services for safety-related applications and as documented in a previous staff SE (ADAMS Accession No. ML052710224). The staff expects full conformance to the guidance in Section 17.5, Paragraph II.L.8, and subparagraph h, that the alternative method is limited to domestic calibration service suppliers.

- *Holders of ASME Nuclear Certificates of Accreditation/Authorization shall be considered qualified as suppliers to perform or have performed, under their control, ASME III code work. The ASME certificate is considered sufficient evidence of an acceptable QA program and of the Supplier's capability to perform work within the scope of the Certificate. Post award QA implementation audits of the Certificate Holder are required.*

The staff addressed this issue in Information Notice (IN) 86-21, "Recognition of American Society of Mechanical Engineers Accreditation Program for N Stamp Holders," dated March 31, 1986. IN 86-21 and it's supplements document the staff's recognition of the ASME Accreditation Program and Certificate Program as providing evidence of an acceptable documented QA program that meets the requirements of Appendix B to 10 CFR Part 50. However, Westinghouse is still responsible for ensuring that the ASME supplier is effectively implementing the approved QA program. Westinghouse will perform post award QA implementation audits to verify effective implementation of the QA program. Therefore, the staff finds this clarification acceptable.

- *For Section 600, Westinghouse clarifies the term approval when a deviation from technical procurement requirements is identified by a supplier.*

The staff finds this clarification acceptable since it provides additional detail and is consistent with NQA-1.

3.1.8 Identification and Control of Materials, Parts, and Components

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.H, for establishing necessary measures for identification and control of items such as materials, including consumables, and items with limited shelf life, parts, components, and partially fabricated subassemblies. Identification of items is maintained throughout fabrication, erection, installation, and use so that the item is traceable to its documentation. The staff's review finds that in establishing its program Westinghouse commits to implement the quality standards described in NQA-1, Requirement 8, and is consistent with guidance in Section 17.5 without further clarifications or exceptions, and is therefore acceptable.

3.1.9 Control of Special Processes

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.I, for establishing and implementing programs, procedures, and processes to ensure that special processes requiring interim process controls to ensure quality, such as welding, heat treating, chemical cleaning, and NDEs, are controlled in accordance with applicable codes, specifications, and standards for the specific application.

The staff's review finds that in establishing its program Westinghouse commits to implement the quality standards described in NQA-1, Requirement 9, and is consistent with the guidance in Section 17.5 without further clarifications or exceptions, and is therefore acceptable.

3.1.10 Inspection

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.J, for establishing necessary measures to implement inspections that ensure items, services, and activities affecting safety meet established requirements and conform to documented specifications, instructions, procedures, and design documents. The inspection program establishes requirements for planning inspections, determining applicable acceptance criteria, setting the frequency of inspection, and identifying special tools needed to perform the inspection. Qualified personnel perform the inspections and are independent of those who performed or directly supervised the work.

The staff's review finds that in establishing its program Westinghouse commits to implement the quality standards described in NQA-1, Requirement 10, and is consistent with the guidance in Section 17.5 without further clarifications or exceptions, and is therefore acceptable.

3.1.11 Test Control

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.K, for establishing necessary measures and governing provisions to demonstrate that items within the scope of the QAPD will perform satisfactorily in service. Testing is accomplished by qualified personnel in accordance with written controlled test procedures. Westinghouse's test control program includes, as appropriate, proof tests before installation, preoperational tests, post maintenance tests, and operational tests. Tests are performed according to applicable procedures.

Westinghouse QMS establishes and implements provisions to assure that computer software used in applications affecting safety is prepared, documented, verified and tested, and used such that the expected output is obtained and configuration control maintained. To this end, Westinghouse commits to compliance with the requirements of NQA-1, Requirement 11 and

Subpart 2.7 to establish the appropriate provisions in addition to the commitment to NQA-1, Requirement 3.

The staff's review finds that in establishing its program Westinghouse commits to implement the quality standards described in NQA-1, Requirement 11, without further clarifications or exceptions and is consistent with the guidance in Section 17.5, and is therefore acceptable.

3.1.12 Control of Measuring and Test Equipment

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.L, for establishing necessary measures to control the calibration, maintenance, and use of M&TE that provides information important to safe plant operation. In establishing provisions for control of M&TE, Westinghouse commits to the quality standards described in NQA-1, Requirement 12.

The staff's review finds that in establishing its program Westinghouse commits to implement the quality standards described in NQA-1, Requirement 12, without further clarifications or exceptions and is consistent with the guidance in Section 17.5, and is therefore acceptable.

3.1.13 Handling, Storage, and Shipping

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.M, for establishing necessary measures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss and to minimize deterioration.

In establishing provisions for handling, storage, and shipping, the Westinghouse commits to the quality standards described in NQA-1, Requirement 13. Westinghouse also commits to compliance with the requirements of NQA-1, Subpart 2.1, Subpart 2.2, Subpart 2.3, Subpart 2.15, and Subpart 3.2, Appendix 2.1.

The staff's review finds that in establishing its program Westinghouse commits to implement the quality standards described in NQA-1, Requirement 13, without further clarifications or exceptions is consistent with the guidance in Section 17.5, and is therefore acceptable.

3.1.14 Inspection, Test, and Operating Status

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.N, for establishing necessary measures to identify the inspection, test, and operating status of items and components within the scope of the QAPD to maintain personnel and reactor safety and avert inadvertent operation of equipment.

The staff's review finds that in establishing its program Westinghouse commits to implement the quality standards described in NQA-1, Requirement 14, without further clarifications or exceptions is consistent with the guidance in Section 17.5, and is therefore acceptable.

3.1.15 Nonconforming Materials, Parts, or Components

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.O, for establishing the necessary measures and governing procedures to control items, including services that do not conform to specified requirements, in order to prevent inadvertent use. Controls provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming items, and notification to affected organizations.

Nonconformances are corrected or resolved before relying on the item to perform its intended safety function. Nonconformances are evaluated for impact on the operability of quality SSCs to ensure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements which are dispositioned "repair" or "use-as-is" are subject to design control measures commensurate with those applied to the original design. Nonconformance dispositions are reviewed for adequacy, analysis of quality trends, and reports provided to the designated management. Significant trends are reported to management in accordance with Westinghouse procedures, regulatory requirements, and industry standards.

In addition, the Westinghouse QMS provides for establishing the appropriate interfaces between the QA program for identification and control of nonconforming materials, parts, or components, and the non-QA reporting program in order to satisfy the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance."

The staff's review finds that in establishing its program Westinghouse commits to implement the quality standards described in NQA-1, Requirement 15, without further clarifications or exceptions and is consistent with the guidance in Section 17.5, and is therefore acceptable.

3.1.15 Corrective Action

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.P, for establishing the necessary measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. The QAPD provides for procedures to ensure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards.

The Westinghouse QMS also requires personnel to identify known conditions adverse to quality. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined, and actions to preclude recurrence are taken. In the case of suppliers working on safety-related activities, or other similar situations, Westinghouse may delegate specific responsibilities for corrective actions, but Westinghouse maintains overall responsibility for the effectiveness of corrective action measures.

The staff's review finds that in establishing its program Westinghouse commits to implement the quality standards described in NQA-1, Requirement 16, and the guidance in Section 17.5 without further clarifications or exceptions, and is therefore acceptable.

3.1.16 Quality Assurance Records

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.Q, for establishing the necessary measures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The provisions of such procedures establish the scope of the records retention program for Westinghouse and include requirements for records administration including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

The Westinghouse QMS establishes measures to ensure that sufficient records of completed items and activities affecting quality are appropriately stored. The records and retention times are based on Regulatory Position C.1 of RG 1.28, Revision 4. In all cases where state, local, or other agencies have more restrictive requirements for record retention, the Westinghouse QMS provides that those requirements will be met.

When using electronic records storage and retrieval systems, the Westinghouse QMS provides

for compliance with the NRC guidance contained in NRC Generic Letter 88-18, “Plant Record Storage on Optical Disks,” Regulatory Issue Summary (RIS) 2000-18, “Guidance on Managing Quality Assurance Records in Electronic Media (Reference 7),” and the associated Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guidelines (TG), including TG 11-1998, “Authentication of Records and Media,” TG 15-1998, “Management of Electronic Records,” TG 16-1998, “Software Configuration Management and Quality Assurance,” and TG 21-1998, “Electronic Records Protection and Restoration.”

The staff’s review finds that in establishing its program Westinghouse commits to implement the quality standards described in NQA-1, Requirement 17, the guidance in Section 17.5, and regulatory positions stated in RG 1.28, Revision 4, without further clarifications or exceptions, and is therefore acceptable.

3.1.17 Audits

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.R, for establishing necessary measures to implement audits to verify that activities covered by the QAPD are performed in conformance with the established requirements. The effectiveness of the audit program is reviewed as part of the overall audit process. The QAPD provides measures to conduct periodic internal and external audits. Internal audits are conducted to determine the adequacy of the program and its procedures and to determine if they are meaningful and comply with the QAPD requirements. Internal audits are performed with a frequency commensurate with safety significance and in such a manner as to ensure that an audit of all applicable QA program elements are completed for each functional area within a period of 2 years after the initial determination that the audit program has been soundly established. External audits determine the adequacy of a supplier’s or contractor’s QA program. Responsible management reviews audit results; these reviews are documented.

Management responds to all audit findings and initiates corrective action where indicated. Where corrective actions are indicated, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means is conducted to verify that corrective actions have been adequately implemented.

The staff’s review finds that in establishing its program Westinghouse commits to implement the quality standards described in NQA-1, Requirement 18, the guidance in Section 17.5, and regulatory positions stated in RG 1.28, Revision 4, without further clarifications or exceptions, and is therefore acceptable.

3.2 Regulatory Commitments

The Westinghouse QMS follows the guidance of Section 17.5, Paragraph II.U, for establishing QA program commitments. Furthermore, Westinghouse commits to comply with the following NRC RGs and other QA standards to supplement and support the QA program:

- RG 1.26, Revision 4, "Quality Group Classification and Standards for Water, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants,” dated March 2007. Regulatory Guide 1.26 defines classification of systems and components.

- RG 1.28, Revision 4, "Quality Assurance Program Requirements (Design and Construction)," dated June 2010. Regulatory Guide 1.28 describes a method acceptable to the NRC for complying with the provisions of Appendix B with regard to establishing and implementing the requisite QA program for the design of nuclear power plants.

- RG 1.29, Revision 4, "Seismic Design Classification," dated March 2007. RG 1.29 defines systems required to withstand a safe shutdown earthquake (SSE).

- ASME NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II, as described above in Sections 3.1.1 through 3.1.18 of this SE.

- NIRMA Technical Guides, as described in Section 3.1.17 of this SE.

- RG 1.54, Revision 2, “Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants,” dated October 2010. RG 1.54 discusses an acceptable method for the selection, application, qualification, inspection, and maintenance of protective coatings applied to nuclear power plant structures, systems, and components.

For projects which specify earlier versions of NQA-1 or ANSI N45.2 or earlier versions of regulatory guides, by contract, Westinghouse commits to the appropriate versions that are required by the contract or individual customers’ safety analysis reports (SARs).

4.0 CONCLUSION

The Westinghouse QMS follows the NRC guidance contained within, and conforms to the format of, Section 17.5. The NRC staff used the acceptance criteria of Section 17.5 as the basis for evaluating the acceptability of the Westinghouse QA program in conformance with the provisions of 10 CFR 50.4 and Appendix B to 10 CFR Part 50. On the basis of its review of the Westinghouse QMS, the NRC staff concludes that:

- The Westinghouse QMS adequately describes the authority and responsibility of management and supervisory personnel, performance and verification personnel, and self-assessment personnel, in relation to activities to which the Westinghouse QMS is applicable.

- The Westinghouse QMS adequately provides for organizations and personnel to perform verification and self-assessment functions related to Westinghouse activities that affect the quality of safety-related nuclear plant SSCs, as well as select nonsafety-related SSCs, with these organizations and personnel having the authority and independence to conduct activities without undue influence from those directly responsible for costs and schedules.

- The Westinghouse QMS adequately applies to activities and items that are important to safety.

- The Westinghouse QMS adequately establishes controls that, when properly implemented, comply with the requirements of Appendix B to 10 CFR Part 50, and 10 CFR Part 21, and 10 CFR 50.55(3), consistent with the criteria contained in Section 17.5, as well as the relevant regulatory guidance.

On the basis of its review, the NRC staff determined that the Westinghouse QMS adequately describes the Westinghouse QA program. Accordingly, the NRC staff concludes that the Westinghouse QA program complies with the applicable NRC regulations and industry standards and can be used by Westinghouse for engineering, procurement, and construction activities affecting the quality and performance of safety-related SSCs.

5.0 REFERENCES

1. NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Section 17.5, “Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants," dated March 2007 (ADAMS Accession No. ML063190019)

2. Westinghouse submittal of topical report “Quality Management System”, Revision 7, in letter dated August 28, 2013 (ADAMS Accession No. ML13246A105)

3. Westinghouse request for information response in letter dated June 12, 2014 (ADAMS Accession No. ML14230A680)

4. ASME NQA-1-2008, “Quality Assurance Program Requirements for Nuclear Facilities” (with a 2009 Addenda), New York, NY, dated March 14, 2008

5. RG 1.28, Revision 4, “Quality Assurance Program Criteria (Design and Construction), dated June 2010 (ADAMS Accession No. ML100160003)

6. NRC Generic Letter 1988-18, “Plant Record Storage on Optical Disks,” dated October 20, 1988

7. RIS 2000-18, “Guidance on Managing Quality Assurance Records in Electronic Media,” dated October 23, 2000 (ADAMS Accession No. ML003739359)

8. RG 1.189, Revision 2, "Fire Protection for Operating Nuclear Power Plants," dated October 2009 (ADAMS Accession No. ML092580550)

9. NRC Generic Letter 1985-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety-Related," dated January 16, 1985

10. RG 1.155, "Station Blackout,” dated August 1988

11. RG 1.26, Revision 4, "Quality Group Classification and Standards for Water, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants,” dated March 2007 (ADAMS Accession No. ML070290283)

12. RG 1.29, Revision 4, "Seismic Design Classification," dated March 2007 (ADAMS Accession No. ML070310052)

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