

**Enclosure 1**

**Comments on Draft Safety Evaluation for Westinghouse Quality Management System (QMS) Revision 8.0  
(Non-Proprietary)**

**May 2020**

**OFFICIAL USE ONLY — PROPRIETARY INFORMATION****U. S. NUCLEAR REGULATORY COMMISSION****DRAFT 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. **ML20118C993ML20118C994**), 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 **7.07.1**, 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:

**45 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.

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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.

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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 the 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.

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1 The NRC staff has reviewed the modification of Westinghouse's QMS TR that would be  
2 implemented in the event of exigent conditions for QA programs submitted under  
3 10 CFR 50.4(b)(7)(ii).  
4

5 Details of the NRC staff's evaluation are summarized below.  
6

## 7 2.0 REGULATORY BASIS 8

9 The regulations at 10 CFR 50.4(b)(7)(ii), set forth the NRC's regulatory requirements regarding  
10 changes to an NRC-accepted QA TR from non-licensees (i.e., architect/engineers, NSSS  
11 suppliers, fuel suppliers, constructors, etc.) that must be submitted to the NRC's Document  
12 Control Desk. Similarly, 10 CFR 71.106 sets forth the NRC's regulatory requirements regarding  
13 changes to NRC-approved QA programs that will reduce commitments in the program  
14 description as approved by the NRC.  
15

16 The regulatory requirements for QA program audits of suppliers is set forth in Criterion VII,  
17 "Control of Purchased Material, Equipment, and Services," and Criterion XVIII, "Audits," of  
18 Appendix B to 10 CFR Part 50, and in 10 CFR Part 71.115, "Control of Purchase Material,  
19 Equipment, and Services and 10 CFR 71.137, "Audits." Licensees contractually impose these  
20 requirements upon their suppliers. Criterion VII of Appendix B to 10 CFR Part 50 and 10 CFR  
21 71.115 require establishing measures for assuring that purchased material, equipment, and  
22 services, whether purchased directly or through contractors and subcontractors, conform to the  
23 procurement documents. These measures shall include provisions, as appropriate, for source  
24 evaluation and selection, objective evidence of quality furnished by the contractor or  
25 subcontractor, inspection at the contractor or subcontractor source, and examination of products  
26 upon delivery. Documentary evidence that material and equipment conform to the procurement  
27 requirements shall be available at the nuclear power plant or fuel reprocessing plant site prior to  
28 installation or use of such material and equipment. Criterion XVIII of Appendix B to 10 CFR Part  
29 50 and 10 CFR 71.137 require a comprehensive system of planned and periodic audits to be  
30 carried out to verify compliance with all aspects of the QA program and to determine the  
31 effectiveness of the program.  
32

33 Regulatory Guide (RG) 1.28, "Quality Assurance Program Criteria (Design and Construction),"  
34 Revision 4 (ADAMS Accession No. ML100160003) and RG 7.10, "Establishing Quality  
35 Assurance Programs for Packaging Used in Transport of Radioactive Material," Revision 3  
36 (ADAMS Accession No. ML14064A505), identify the ASME's Standard, NQA-1, "Quality  
37 Assurance Requirements for Nuclear Facility Applications," as an adequate basis for complying  
38 with the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 71 Subpart H.  
39 RG 1.28 identifies some exceptions which are discussed in the Regulatory Position section of  
40 RG 1.28, Revision 4. Both RGs state that the audits and surveys are to be conducted on a  
41 triennial basis. The NRC staff has approved, through a SE (ADAMS Accession No.  
42 ML101820108), that a general grace period may be taken for a supplier audit that must be  
43 performed on a triennial basis. Further, the grace period does not allow the supplier audit  
44 "clock" to be reset forward. However, the "clock" can be reset backwards by the supplier audit  
45 activity being performed early.  
46

## 47 3.0 TECHNICAL EVALUATION 48

49 In evaluating the adequacy of the proposed change, the NRC staff considered the guidance of  
50 NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear

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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 ~~length-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.

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

4  
5 The above frequency extension for supplier audits or surveys during exigent conditions is a  
6 different alternative to the 90-day grace period previously approved by the NRC (ADAMS  
7 Accession No. ~~ML101830108~~ML101820108). The general 90-day grace period alternative will  
remain

8 unchanged for conditions of a minor nature. Examples of conditions of a minor nature would  
9 include, but not limited to: 1) staffing limitations preventing a timely audit to be completed and  
10 2) scheduling conflicts by either the vendor, supplier, or sub-tier supplier.

11  
12 As previously stated, the expectation for the use of the 25 percent frequency extension would  
13 be limited to implementation for exigent conditions. The expectation would be that  
14 Westinghouse attempts to maintain the current triennial audit or survey period. Unlike the  
15 existing alternative on the use of a grace period, Westinghouse would not have to reset the  
16 "clock" backwards when the audit or survey is finally performed to the original date the audit or  
17 survey should have been performed. The date that the audit or survey is finally performed  
18 would be the start of the new triennial audit or survey frequency. The NRC staff considered that  
19 should events of a severe nature occur closely together, the requirement for not allowing the  
20 "clock" to be reset forward would result in an additional potential scheduling constraint on  
21 completing audits or surveys in a timely manner.

22  
23 The NRC staff considered the maturity of Westinghouse's QA program and its supply chain  
24 oversight in determining this allowance of a 25 percent extension for audits and surveys to be  
25 completed from the date of the expiration of the triennial audit or survey frequency. The NRC  
26 staff also considered the potential risk significance of extending the audit and survey frequency  
27 by 25 percent. Based on the maturity of Westinghouse's QA program, the expected short  
28 duration that Westinghouse will be under an exigent condition, and Westinghouse's continuous  
29 monitoring of ongoing and previous supplier performance, the NRC staff determined that there  
30 is minimal risk associated with implementing the extended audit and survey frequencies during  
31 exigent conditions. Therefore, the NRC concluded that the conditions stated above ensure that  
32 reasonable assurance of the quality of items and services will continue to be maintained during  
33 this extension period.

34  
35 **4.0 CONCLUSION**

36  
37 The NRC staff reviewed Westinghouse's QMS TR, Revision 8.0, submittal. As stated above,  
38 the NRC staff concluded that there is reasonable assurance that Westinghouse's QMS TR will  
39 continue to meet the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 71  
40 Subpart H while implementing the 25 percent extension of audit and survey frequencies during  
41 exigent conditions. Therefore, the NRC staff found Westinghouse's proposed changes in the  
42 QMS TR, Revision 8.0, to be an acceptable method for extending audit frequencies during  
43 exigent conditions.

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45 Principal Contributor: Deanna Zhang

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47 Date: May 5, 2020

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Table of Comments on Draft SE for Westinghouse Quality Management System 8.0

| Comment Number | Comment Location | Comment Type | Comment   | NRC Response |
|----------------|------------------|--------------|---|--------------|
| 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.  |              |
| 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)  |              |
| 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"'.<br><br>The quoted QMS text is missing the following paragraphs:<br>"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:"<br><br>"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              | Page 1/Line 46   | Editorial    |   |              |



| Comment Number | Comment Location  | Comment Type  | Comment  | NRC Response |
|----------------|-------------------|---------------|--|--------------|
| 5              | Page 2/Line 27    | Editorial     | "type" should be changed to "types"  |              |
| 6              | Page 2/Line 42    | Editorial     | "the" should be deleted  |              |
| 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.   |              |
| 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. |              |
| 9              | Page 4/Line 10    | Editorial     | "length" should be changed to "duration"   |              |
| 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. |              |
| 11             | Page 5/ Line 7    | Editorial     | "ML101830108" should be changed to "ML101820108"   |              |