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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.

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