

Office of Nuclear Reactor Regulation			
Minimal Revisions Review Topical Report Final Safety Evaluation for GE Hitachi Nuclear Energy Topical Report NEDO-11209A, "Quality Assurance Program Description (QAPD)"			
Topical Report Information		Review Information	
<b>Report Number:</b> Topical Report NEDO-11209A <b>Title:</b> Proposed Revision 15 to GE Hitachi Nuclear Energy (GEH) Topical Report NEDO-11209A, "Quality Assurance Program Description (QAPD)" <b>EPID:</b> L-2020-TOP-0023 <b>Docket No.:</b> 99902024		<b>Division/ Branch:</b> DRO/IQVB <b>Project Manager:</b> Ngola Otto  <b>Reviewers:</b> Carla Roque-Cruz	
Determination of Minimal Revisions			
Is this the review of very limited scope?	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>
Does the TR change maintain the original SE conclusions?	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>
Do the staff methods for establishing the original conclusions remain unaffected?	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>
If any of the above questions are answered no, a simplified safety evaluation cannot be used.			
<b>1. Introduction</b>  <p>By letter dated April 29, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20120A553), GE Hitachi Nuclear Energy (GEH), requested approval of a proposed change to its quality assurance (QA) program description (QAPD). In response to the United States Nuclear Regulatory Commission (NRC) staff's request for additional information (ADAMS Accession No. ML20125A033) to clarify the proposed changes, GEH provided a supplemental submittal (ADAMS Accession No. ML20134J088) to include additional information to its QAPD. The proposed change was considered a change to an NRC-accepted QAPD from nonlicensees (i.e., architect/engineers, nuclear steam system suppliers (NSSS)), in accordance with Title 10 of <i>the Code of Federal Regulations</i> (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," 50.4(b)(7)(ii). GEH is also a 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," licensee holder and utilizes the same QAPD to meet the requirements of 10 CFR Part 71. The proposed change extends the supplier audit frequency from once every three years (i.e., triennial) for 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. The change is applicable to supplier audits performed 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, as described in GEH's QAPD.</p> <p>Currently, GEH's QAPD Chapter 18, "Audits," requires supplier QA programs to be audited on a triennial basis starting with the year that the first audit occurs, and if the procurement scope significantly changes from the originally audited scope. In addition to triennial audits, annual evaluations of suppliers are conducted as described in Section 7 of the QAPD.</p> <p>GEH proposed change to its QAPD is a new section to Chapter 18, Section 18.5.2, to incorporate Exigent Condition requirements. This section includes an overall 25 percent extension of the triennial audit period for audits or surveys of domestic and international suppliers that may be exercised during periods of exigent conditions affecting GEH facilities or</p>			

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<p>its suppliers, and where performance of such activities is not feasible. Subsection 18.5.2, "Exigent Conditions" to this QAPD states that:</p> <p style="padding-left: 40px;">During periods of exigent conditions affecting GEH facilities or its suppliers, and where performance of audit or survey activities for domestic and international suppliers is not feasible, a 25 percent extension of the triennial audit period may be exercised. The total allowable extension for exigent conditions is 275 days.</p> <p>Exigent conditions, such as the state of emergency caused by COVID-19, impacts GEH's ability to complete external supplier audits and surveys within the frequency specified in their NRC-approved QA program. Exigent conditions have restricted both domestic and international travel and restricted access to supplier facilities. The proposed change to GEH's QAPD would provide an extension to the external supplier audit and survey frequency that need to be completed during exigent conditions.</p> <p>The NRC staff has reviewed the proposed change to GEH's QAPD that would be implemented in the event of exigent conditions for QA programs submitted under 10 CFR 50.4(b)(7)(ii).</p> <p>Details of the NRC staff's evaluation are summarized below.</p> <p><b>2. Regulatory Basis</b></p> <p>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, 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.</p> <p>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</p>	

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<p>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 shall be carried out to verify compliance with all aspects of the QA program and to determine the effectiveness of the program.</p> <p>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.</p> <p><b>3. Technical Evaluation</b></p> <p>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.</p> <p>The extension of the audit frequency during exigent conditions as proposed by GEH 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 GEH 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.</p> <p>During the exigent conditions, GEH 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,</p>	

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<p>"Exigent Conditions," within the GEH QAPD, Revision 15. The NRC staff found that the descriptions provided in Subsection 18.5.2 are consistent with the following NRC staff's considerations for allowing extensions to the periodicity of audits and surveys for suppliers during exigent conditions:</p> <ul style="list-style-type: none"> <li>a. GEH 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.</li> <li>b. There is verification that the supplier is still implementing a quality assurance program that meets Appendix B to 10 CFR Part 50. <ul style="list-style-type: none"> <li>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.</li> </ul> </li> <li>c. The alternative method of the 25 percent extension discussed above is applicable to domestic and international suppliers.</li> <li>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.</li> <li>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: <ul style="list-style-type: none"> <li>i. Review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions.</li> <li>ii. Results of previous source verifications, audits, survey and receiving inspection activities.</li> <li>iii. Operating experience of identical or similar products furnished by the same supplier.</li> <li>iv. Results of audits from other sources (e.g., customer, American Society of Mechanical Engineers (ASME), or NRC inspection).</li> </ul> </li> </ul>	

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<p>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.</p> <p>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 GEH's prudent judgement.</p> <p>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.</p> <p>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 GEH attempts to maintain the current triennial audit or survey period. Unlike the existing alternative on the use of a grace period, GEH 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.</p> <p>The NRC considered the maturity of the GEH 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 also considered the potential risk significance of extending the audit and survey frequency by 25 percent. Based on the reliability of GEH's QA program, the expected short duration that GEH will be under an exigent condition, and GEH'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.</p>	

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<b>4. Conclusion</b>  <p>The NRC staff has reviewed GEH's QAPD, Revision 15 submittal. As stated above, the NRC staff concluded that there is reasonable assurance that GEH's QA program 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 GEH's proposed changes to its QAPD, Revision 15 to be an acceptable method for extending audit frequencies during exigent conditions.</p> <p>Principal Contributor: Carla P. Roque-Cruz</p> <p>Date: May 21, 2020</p>			
<b>ADAMS Accession Nos: Package: ML20141K704; Transmittal Email: ML20140A332</b> <b>SE: ML20140A322</b>			
<b>Approval</b>	<b>Printed Name</b>	<b>Signature</b>	<b>Date</b>
<b>Technical Branch Chief</b>	Kerri Kavanagh	/RA/	5/20/2020
<b>Projects Branch Chief</b>	Dennis Morey	/RA/	5/20/2020