

Enclosure 1

MFN 16-026

**GEH Response to Request for Additional Information Regarding
Review of NEDO-11209-A Revision 12**

Non-Proprietary Information – Class I (Public)

Question

General Electric Hitachi Nuclear Energy QAPD, draft changes to Revision 12, Part II, "QAPD Details," Section 7.10, "Commitment," provides a brief description of the requirements to be followed when procuring commercial-grade calibration services from a calibration laboratory.

Section 4 of NEI 14-05, "Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1, states, in part, "Purchasers that rely on the accreditation by ILAC signatories in lieu of commercial-grade surveys are required by 10 CFR Part 50, Appendix B to document this alternative method in their QA Program.... A Template for describing the use of the ILAC process in lieu of a commercial-grade survey in a Purchaser's QA Program is provided in Appendix A. Although a Purchaser is not required to use the Template in Appendix A, all of the actions and steps described in Appendix A need to be included in the Purchaser's QA Program." The staff's evaluation and endorsement of NEI 14-05, is documented in the "Final Safety Evaluation for Technical Report NEI 14-05, 'Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services,' Revision 1," (ADAMS No. ML14322A535), dated February 9, 2015. Additionally, the staff recently issued Regulatory Issue Summary (RIS) 2016-01, "Nuclear Energy Institute Guidance for The Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," (ADAMS No. ML15323A346), dated March 16, 2016. The RIS also reiterated the requirement to include all of the actions and steps in the QA Program.

The proposed change to NEDO-11209-A, Revision 12, does not address the requirements of Appendix A of NEI 14-05 as approved by the staff. Provide clarification on how General Electric Hitachi Nuclear Energy incorporates these requirements of Appendix A in its QAPD.

GEH Response

GEH will revise its QAPD, NEDO-11209-A, to add all requirements in Appendix A of NEI 14-05A as applicable to procurement of commercial-grade calibration and testing services from a laboratory. These changes can specifically be seen in the attached markup (Enclosure 2) of Section 7.10 of the QAPD and will be incorporated into the final, approved Revision 13 of the QAPD.

Effect on QAPD Topical Report

The QAPD is modified as described in the GEH response. Enclosure 2 provides a revised Section 7.10 that will be incorporated into the final, approved Revision 13 of the QAPD. Because of the extensive changes, a revision bar version of Section 7.10 is provided in lieu of a redline-strikethrough version. Other administrative changes to the QAPD from the draft version submitted via GEH letter MFN 15-091, dated October 14, 2015, are associated with organizational changes within General Electric and GEH. Namely, "GE Power and Water" will be changed to "GE Power" throughout, and Jay Wileman has replaced Caroline Reda as President and CEO of GE Hitachi Nuclear Energy. Finally, the copyright year on the cover page will be changed from 2015 to 2016. These administrative changes are not shown in this response, but will be incorporated in the final, approved Revision 13 of the QAPD.