

Enclosure 2

MFN 16-026

Markups to NEDO-11209-A, Rev. 12

Non-Proprietary Information – Class I (Public)



GEH Quality Assurance Program Description

7.8 Commercial Grade Items and Services - Dedication

1. Utilization of commercial grade items or services is permitted if controls are in place to provide reasonable assurance that the item or service will perform its intended safety function.
2. Such controls include, but are not limited to the following:
 - (a) A determination that the item or service performs a safety function
 - (b) Confirmation that the item or service meets the applicable commercial grade item definitions
 - (c) Identification and documentation of the critical characteristics, including acceptance criteria
 - (d) Selection, performance (inspection/test/survey/surveillance), acceptance, and documentation of the dedication methods for determining compliance with the critical characteristic acceptance criteria
3. The commercial grade item or service dedication process will be controlled via documented procedures and retention of objective evidence.

7.9 Records

Records are maintained to indicate the performance of the following functions:

- (a) Supplier evaluation and selection
- (b) Acceptance of the items or services procured
- (c) Supplier nonconformances to procurement document requirements, including a description of their evaluation and disposition

7.10 Commitment

1. In establishing a program for the control of items and services, GEH commits to compliance with 10 CFR Part 50 Appendix B, Criteria VII and NQA-1-2008 Edition with the NQA-1a-2009 Addenda, Requirement 7 with the following exceptions:
 - GEH considers 10 CFR Part 50 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies, which may provide items or services to GEH, as not requiring evaluation or audit.
 - When purchasing commercial grade calibration or testing services from a laboratory holding accreditation by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement, commercial grade surveys and source verifications need not be performed provided each of the following conditions are met:
 - A documented review of the supplier's accreditation will be performed and will include a verification of each of the following:
 - The calibration or test laboratory is accredited to ISO/IEC 17025:2005 “General Requirements for the Competence of Testing and Calibration Laboratories” by an accreditation body that is a signatory to the ILAC Mutual Recognition Arrangement per NEI 14-05A as endorsed by the US NRC.
 - For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, ranges, and uncertainties.



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- For procurement of testing services, the published scope of accreditation for the test laboratory covers the necessary testing services including test methodology and tolerances/uncertainty.
 - The purchase documents require the following:
 - The service must be provided in accordance with the supplier's accredited ISO/IEC-17025:2005 program and scope of accreditation.
 - The reporting of as-found calibration data in the certificate of calibration when calibrated items are found to be out-of-tolerance.
 - The certificate of calibration includes identification of the laboratory equipment and standards used to perform the calibration.
 - The supplier is to notify GEH of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
 - Impose any additional technical and administrative requirements, as necessary, to comply with the GEH QA program and technical provisions, which may include but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.
 - At receipt inspection, GEH shall validate the following:
 - The contracted calibration or testing service has been performed in accordance with the supplier's ISO/IEC-17025:2005 program, and has been performed within the laboratory's scope of accreditation, and
 - The purchase order's requirements are met.
2. The GEH program for dedication of commercial-grade items commits to be consistent with NQA-1a-2009, Subpart 2.14.