

MP3 : NEI 17-06

Review

QA Aspects of SIL
Certification

April 01, 2020



Quick Review of NEI 17-06 Process

CBs & ABs

- Certification Bodies (CBs) have a standardized, rigorous, and reliable evaluation process



- Accreditation Bodies (ABs) ensure CBs are consistent and trustworthy



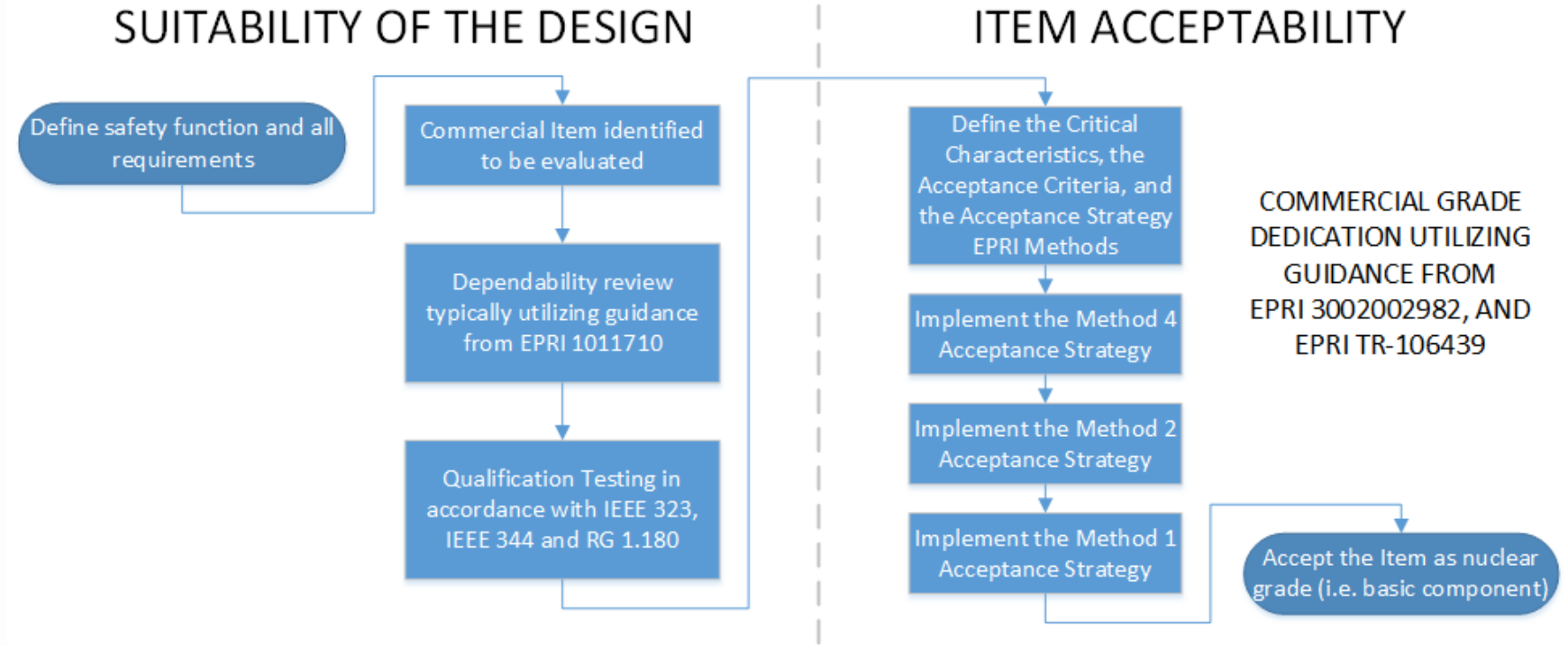
The EPRI Report- Section 3 of NEI 17-06



- SIL Certification Aligns Well With EPRI TR-106439

EPRI TR-106439	SIL Certification- Safety Case
Development Personnel Qualifications/ Experience	
HW/SW Design, Development, Verification & Validation Processes	
Availability/Reliability Requirements	
Failure Modes Analysis/ Testing/ Management	
Design Documentation	
Configuration Management	
Quality Assurance	
SW Requirements Definition & Requirements Traceability	
Vendor Testing (Performance, Environmental, SW V&V, Fault Insertion)	
Product Operating History	
Error Tracking/ Problem Reporting	

COTS Justification Process Overview



Justification Process- Section 4 of NEI 17-06

SUITABILITY OF THE DESIGN

ITEM ACCEPTABILITY

Define safety function and all requirements

Commercial Item identified to be evaluated

Review of SIL Certification

Qualification Testing in accordance with IEEE 323, IEEE 344 and RG 1.180

Define the Critical Characteristics, the Acceptance Criteria, and the Acceptance Strategy EPRI Methods

Review of SIL Certification

Implement the Method 1 Acceptance Strategy

COMMERCIAL GRADE DEDICATION UTILIZING GUIDANCE FROM EPRI 3002002982, AND EPRI TR-106439

Accept the Item as nuclear grade (i.e. basic component)

Not replacing CGD

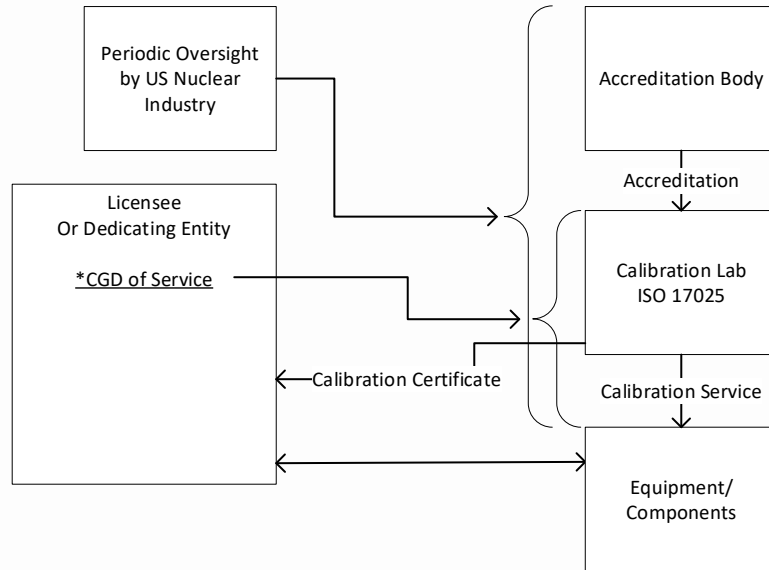
How to Address QA Aspects of NEI 17-06 Process

Accreditation Replaces Commercial Grade Survey of SIL Certifier Service

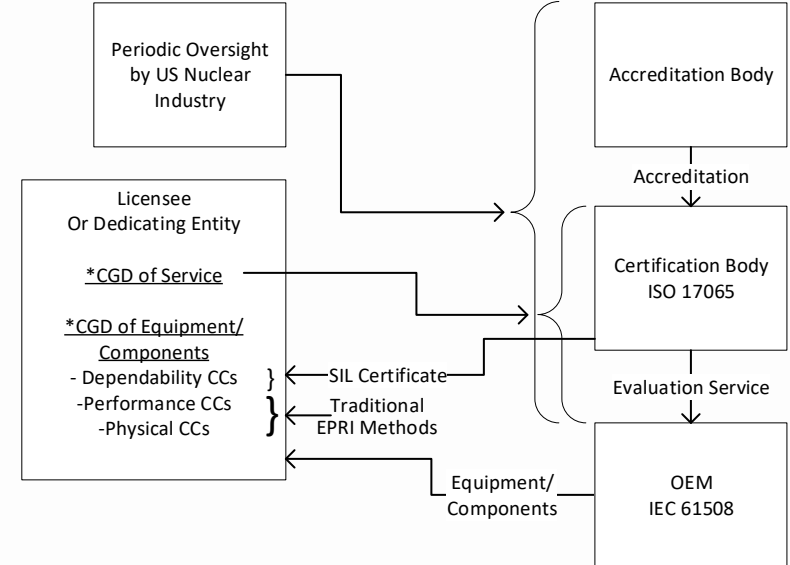
- Accreditation of SIL Certifier to ISO 17065 should be comparable to the NRC accepted practice for commercial grade surveys as a method of CGD of a service
- NEI 17-06 will describe how ISO/IEC-17065 requirements address the quality activities included in a commercial grade survey addressing the CC associated with the service provided by the certifier
 - Any identified gaps will be justified, or compensating measures defined
- SIL Certifier accredited by AB to ISO/IEC-17065
 - Similar to Calibration Service accredited by AB to ISO/IEC-17025
 - NRC, in ML14322A535, “finds that the ILAC accreditation process [based on ISO/IEC-17025] continues to satisfy the requirements of Appendix B to 10 CFR Part 50 and, therefore, is acceptable.”

Comparison of Methodologies

Dedication of Testing/Calibration Service with Accreditation (NEI 14-05)



Dedication of a Programmable Digital Device with Accreditation and Certification (NEI 17-06)



*Note that CGD activities include a technical evaluation

NEI 17-06 Methodology

- The service provided by the SIL certifier will be dedicated
 - Each time a programmable digital device (PDD) SIL certification is used to support a CGD, a CGD package is prepared to dedicate the service provided by the SIL certifier.
 - The CGD package credits the SIL certifier's AB accreditation to conclude the certifying service is equivalent to nuclear grade.
 - The specific SIL certification becomes acceptable for use (from a QA perspective).
 - The accepted SIL certification is then used to confirm acceptability of the dependability CCs in the CGD of the PDD.

NEI/Licensee Responsibilities

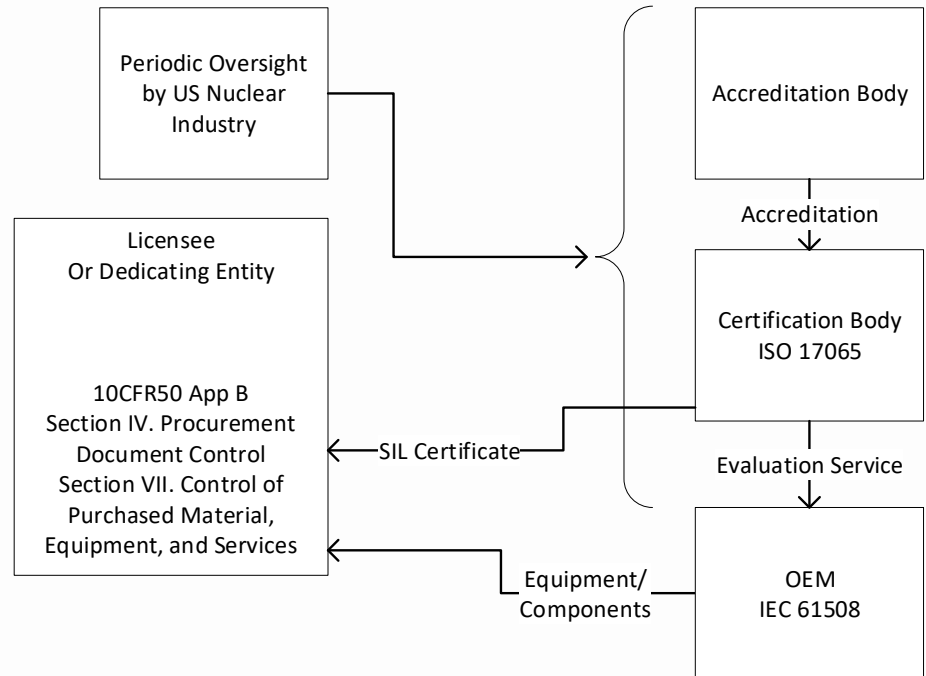


- NEI 17-06 will evaluate for any gaps between ISO/IEC-17065 quality activities and the commercial grade survey quality activities (in respect to CCs of the certifier's service), and will either justify the gaps or identify licensee compensating measures for the gaps
- When ISO/IEC 17065 is revised, NEI will evaluate the changes for impact to NEI 17-06 evaluation
- The licensee, on a periodic basis, will observe the ANSI or DAkkS accreditation of CBs to ISO/IEC-17065
 - Similar to ILAC process of licensee observing AB accreditation of calibration services to ISO/IEC-17025
 - Observations will include documentation review of previous certifications performed by the certifier

Future Work, After NEI 17-06

- 10CFR50 App B procurement requirements (Section IV & VII) satisfied by ISO 17065 accredited certification to IEC 61508
- 10CFR50 App B does not require that suppliers have a 10CFR50 App B QA program. That is just how the industry has implemented it.

Acceptance of a Programmable Digital Device with an ISO 17065 Accredited IEC 61508 Certification





MP3 Schedule

Task	Resource	Due Date
Public Meeting on MP3 - NEI 17-06	NRC/NEI	4/01/2020
NEI submits NEI 17-06, rev. C for NRC Review	NEI	5/29/2020
Public Meeting on MP3 - NEI 17-06	NRC/NEI	June 2020
Comments issued on NEI 17-06, rev. C	NRC	TBD
NEI submits NEI 17-06, rev. 0 for NRC Review	NEI	TBD
Issue RAIs for NEI 17-06, rev. 0	NRC	TBD
Respond to NRC RAIs and re-submit revised NEI 17-06, rev. 0	NEI	TBD
Issue SER on NEI 17-06, rev. 0	NRC	TBD
Publish NEI 17-06, rev. 0 including NRC SER	NEI	TBD