NEI 17-06 Review

Modernization Plan #3-Commercial Grade Dedication

November 6, 2019





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	

The EPRI Report- Section 3 of NEI 17-06



 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



- Failure Data Indicates Reliable Operation of SIL Certified Equipment.
- SIL Certifications is an Accurate Indicator of Reliability







COTS Justification Process Overview



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Since SIL Certification Aligns Well With EPRI TR-106439, It Can Be Used By Dedicating Entities In Place Of:

- Commercial Grade Surveys- CGD Method 2
- Operating History- CGD Method 4
- Dependability Reviews- Suitability of Design

Nuclear Grade **Commercial Grade SIL Certified** Adequate level of Acceptance/Installation Testing Acceptance/Installation Testing, Acceptance/Installation Testing, assurance the item QC QC OC Dedicating Entity Evaluation and Utility Evaluation will perform Utility and/or Third Party Dedicator Acceptance Review of: satisfactorily in its Evaluation and Acceptance • design and its documentation Review of Design and its Utility Utility intended design/development process documentation, Design/development Efforts and/or_ Review of: QA and configuration control Dedicator process, QA and configuration control, application design and its documentation vendor testing Vendor testing, Product operating Efforts product operating experience Utility design/development process experience QA and configuration control and/or Failure analysis Failure analysis, Supplemental vendor testing Level of Assurance Problem reporting per 10 CFR 21 Dedicator activities. Preparation of dedication product operating experience Efforts Product Operating Experience package, Problem reporting 10 CFR 21 Failure analysis Supplemental activities: Product Operating Experience product inspection . testina • analyses/verifications Vendor Activities Working To documentation Preparation of dedication package IEC 61508 Nuclear Vendor Activities Problem reporting per 10 CFR 21 Design/development process Note: Product Operating Experience Consideration of failure modes/ACEs Relative heights shown for Vendor Design/development process Design verifications/ reviews the items that make up the Efforts Consideration of failures modes/ACEs Vendor Additional Activities for Nuclear ISO 9000 QA Program bars are for illustration Design verifications/reviews Efforts purposes only -- not to Sales Testing 10 CFR 50 Appendix B QA program scale! See the Qualification s/experience of personn el Testing Commercial Vendor Activities accompanying text Defect reporting per IEC 61508 Qualifications/experience of personnel Problem reporting per 10 CFR 21 Vendor Design/development process Efforts Consideration of failure modes/ACEs Design verifications/reviews Commercial standards/practices used Testina Qualifications/experience of personnel

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- No Specific SIL Prescribed, Any SIL Potentially Valid to Meet EPRI TR-106439 Dependability Critical Characteristics
- Graded Approach (NRC Safety Evaluation Report of EPRI TR-1064339)
 - Safety Significance
 - Complexity
- Documented Engineering Judgement for Achieving Reasonable Assurance

NEI 17-06 Document Clarifications

- Previously Dedicated Items are Not Impacted by the Expiration of a SIL Certificate, Just Like the Impact of the Expiration of a Previously Utilized Commercial Grade Survey
- The word "supplier" will be updated to be "dedicating entity" in several places throughout Section 5.

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NRC Comments on NEI 17-06 Rev B

Comment #1:

[content omitted] I don't think that the "are adequately controlled" is accurate because CBs certify the equipment for more applications than nuclear power plants, and nuclear power plants have requirements such as radiation resistance which may not be examined by CBs. [content omitted]

Response- Will be reworded for clarity, as follows: to provide reasonable assurance that critical characteristics, and in particular dependability critical characteristics described in EPRI Technical Report 106439, "[content omitted]" are adequately controlled.

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Comment #2:

The last sentence of Section 1.2 states "[content omitted]" Again, the staff believes that [content omitted] one cannot declare adequately controlled.

Response- Will be reworded for clarity, as follows:

This supplemental guidance document describes a method for using the accredited SIL certification process in lieu of a commercial grade survey as a dedication acceptance method to provide reasonable assurance that critical characteristics of digital devices, and in particular dependability characteristics, are adequately controlled.

Comment #3:

The error in the last paragraph of Section 2 on page 12 should be fixed.

Response- More information is needed to identify the error.

Comment #4:

In the first sentence of the second paragraph, "EPRI explained that the motivation of this work comes from the desire of the nuclear industry to utilize the existing ecosystem of SIL certified electrical, electronic, and programmable electronic (E/E/PE) equipment." The highlighted "this" should be "its" as "this work" means NEI 17-06.

Response- Comment Incorporated

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Comment #5:

The last sentence of the second bullet on Page 19 claims "in no cases did they result from software faults (i.e., no instances of software CCF)." NRC/RES staff indicated to the NEI staff that this claim is not firmly supported from EPRI's report (again a searchable e-document may be helpful).

Response- This content is not on page 19. It is believed that this comment concerns the 2nd bullet on Page 20. A searchable version of the EPRI report is available from EPRI. Chapter 6 and Appendix F of the EPRI report address the failure data.

Comment #6:

Figure 4.2 may be misleading. The two blocks "Review of SIL Certification" may not be equivalent to the corresponding blocks on the left because CBs certification may not consider nuclear specific requirements such as radiation resistance.

Response- The remaining blocks on the left labeled as "Qualification Testing..." and "Implement the Method 1..." are where the nuclear specific requirements such as radiation resistance are addresses.

Comment #7:

Section 4.2, which documents the technical evaluation and acceptance method, includes statements such as the following regarding "reliability" under the "SIL Certification Process Method of Verification": "See p3-7 through p3-13 of Reference 8 for details", where reference 8 is the EPRI research report. If such information is needed to complete the technical evaluation then, it should be included in NEI 17-06 in order to make it a standalone document.

Response - These pointers are only added for convenience.

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Comment #8:

[content omitted] Section 3 should be scrubbed to ensure that it focuses on providing the necessary information from the EPRI report to complete the technical evaluation in Section 4 of NEI 17-06.

Response- Section 3 will be scrubbed accordingly

MP3 Schedule

NEI 17-06 Schedule for Completion

Task **Due Date** 12. NEI submits NEI 17-06 for NRC Review 12.a NEI submits NEI 17-06 Rev B for NRC Review (Rev B will include draft of Sections 3 and 4) 9/30/2019 - complete 12.b MP3 Public Meeting to discuss Sections 3 and 4 of NEI 17-06 Rev B 11/06/2019 12.c NEI submits NEI 17-06 Rev 0 for NRC Review (*assuming all comments received by 11/15) 12/13/2019* 12.d NEI submits NUPIC Observation Procedure Rev 0 for NRC Review (*assuming all comments received by 11/15) 12/13/2019* 13. NRC makes decision on technical adequacy of NEI 17-06 TBD 14. NUPIC Observation of SIL Accrediting Body with NRC staff participation 10/29-30/2019 - complete 15. NRC formally enters NEI 17-06 into the Regulatory Guide development process (if decision is made to endorse) TBD

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