

A Study on Validity of Commercial Grade Item Dedication Using Certification Based on Safety Integrity Level

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1. Introduction

Nuclear power plants have upgraded the analog-based systems for safety functions with commercial digital equipment due to the difficulties in procuring replacement parts and increased maintenance costs. To apply the commercial grade equipment to safety-related systems in a nuclear power plant, dedication, defined as the acceptance process to provide reasonable assurance that a commercial grade item will perform its intended safety functions, is required under 10 CFR Part 21 and Appendix B to 10 CFR 50 in U.S. nuclear regulatory. U.S. Nuclear Regulatory Commission (NRC) has developed useful guidance on commercial grade dedication (CGD) for items and services used in nuclear power plants in Regulatory Guide 1.164 where the technical report of the Electric Power Research Institute (EPRI) 3002002982 is in part endorsed [1]. In addition, EPRI 3002002982 has been based on both EPRI NP-5652 and EPRI TR-102260 for providing the general process and evaluation methods of CGD, as well as both EPRI TR-106439 and EPRI TR-107330 guiding CGD for digital equipment [2]-[5].

NRC has built the integrated action plan (IAP) to modernize the digital instrumentation and controls (I&C) regulatory infrastructures, where one of the topics is the improvement of CGD for digital equipment [6]. In [6], The proposed CGD process employs the certification of the digital equipment based on the International Electrotechnical Commission Standard (IEC Std.) 61508 to substitute for evaluating the dependability critical characteristic (CC) of commercial digital equipment [7]. In addition, Nuclear Energy Institute (NEI) has published the technical report of NEI 17-06, which specifically explains the overall framework, the dependability CC, the IEC Std. 61508 certification (SIL-certification), and the accreditation for the proposed CGD process [8].

In this paper, we introduce the modified CGD process to understand the proposed CGD deeply and then evaluates the applicability of the proposed CGD as the alternative to a conventional CGD process

2. Introduction of CGD for Digital Equipment

In this section, we explain the generic dedicating process for commercial equipment that is accepted in nuclear regulatory. We then introduce the improved CGD process for digital equipment by utilizing the certification based on the IEC Std. 61508.

2.1 Traditional CGD Process

The generic process for acceptance of commercial-grade items is presented in Fig. 1, where the overall process composed of 7 steps is divided into the technical evaluation and the acceptance process. First, the safety classification as a basic component and CGD information such as safety function and critical characteristics are mainly identified in the technical evaluation. Next, the acceptability for the commercial equipment is accessed by using the evaluation method suitable to the investigated critical characteristics in the acceptance process. Finally, the results of the technical evaluation and the acceptance process are documented. The explanation of each step is as follows:

- Step 1: Identify the item being procured
- Step 2: Determine if the item performs a safety function
- Step 3: Determine if the item will be procured as a commercial-grade item
- Step 4: Identify the item being procured
- Step 5: Determine if the item performs a safety function
- Step 6: Determine if the item will be procured as a commercial-grade item
- Step 7: Conduct acceptance activities, and document the results

2.2 CGD Process Proposed in IAP

Among four acceptance methods presented in Fig. 1, commercial grade survey (method 2) is employed to verify “dependability” critical characteristic of commercial digital equipment. However, commercial grade surveys have been not favorable to licensees because the original equipment manufacturers (OEMs) have been reluctant to be surveyed. To be more, the commercial grade surveys require the dedicating specialist for target digital equipment. To remedy these problems, NEI have proposed the improved CGD process employing the IEC Std. 61508 certification to substitute for the evaluation of the dependability critical characteristic [8]. The proposed CGD process in Fig. 2, where the left side shows types of critical characteristics

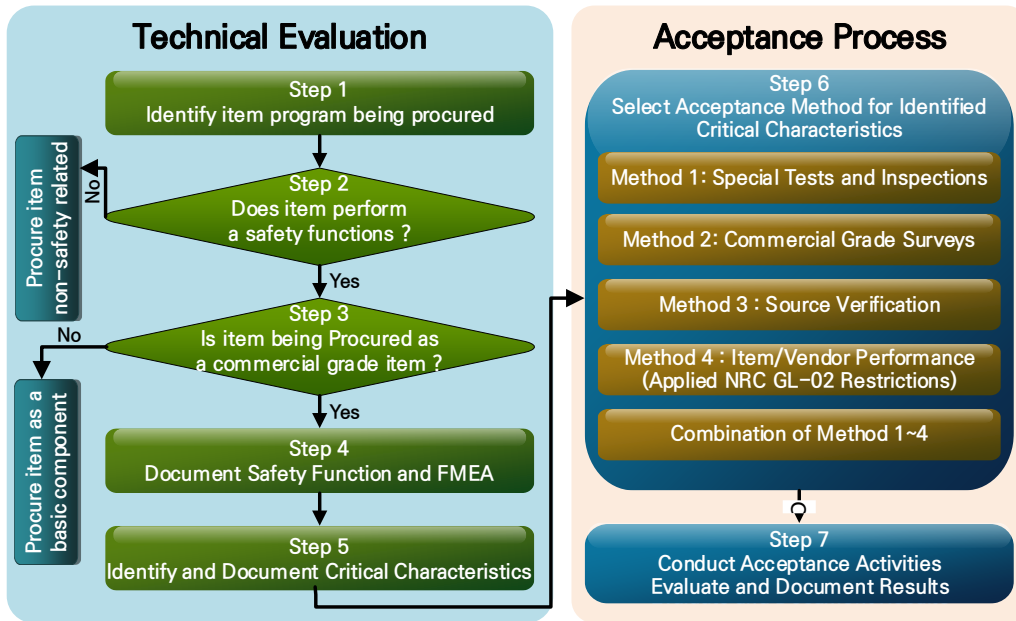


Fig. 1 Generic process for acceptance of commercial grade items.

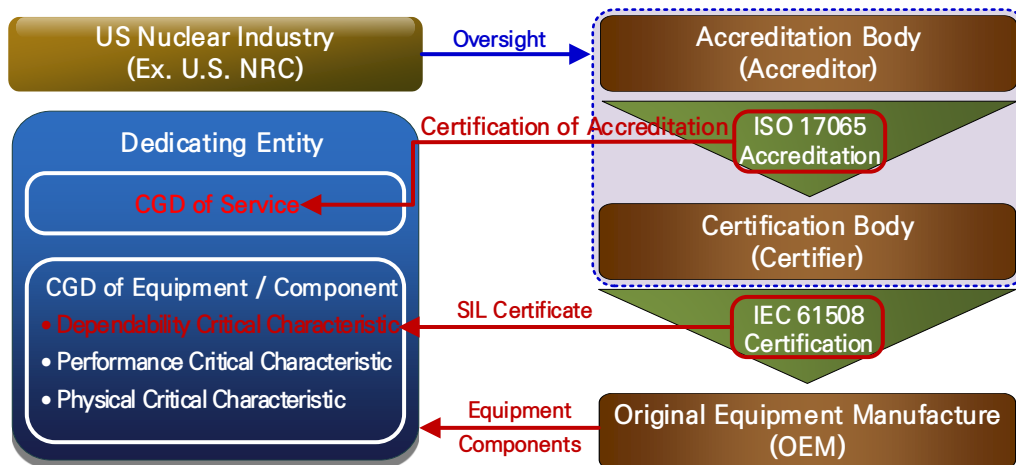


Fig. 2 Process of proposed commercial grade deification

considered by the dedicating entities, as well as the right side represents the IEC Std. 61508 certifying process.

On the right side of Fig. 2, the certifying body (CB) evaluates the documentation, manufacturer, and product to determine whether the requirements of IEC Std. 61508 are met for the desired safety integrity level (SIL) or not [7]. The roles of the CB include visiting and auditing the manufacturer's design and manufacturing facilities, reviewing design documentation, and so on. To maintain the role of the certifier, the CB is accredited by the national accreditation body (AB) in accordance with ISO Std. 17065. The AB performs auditing and monitoring the CB's activities in order to confirm that their processes, procedures, and implementation meets based on ISO Std. 17065. On the left side of Fig. 2, the dedicating

entity complying with Appendix B to 10 CFR 50 follows the traditional CGD process exempt for the evaluation of the dependability critical characteristic. In place of evaluating the dependability critical characteristic, the dedicating entity reviews the SIL certificate. The improved CGD precedes as follows:

- Step 1: Identify the requirements of the end user's application
- Step 2: Identify SIL certified equipment, and review the SIL certification and the manufacturer's safety manual
- Step 3: Perform a technical evaluation of the equipment to identify physical, performance, and dependability CC

- Step 4: Perform a technical evaluation of the CB's service (evaluating of manufacturer's equipment and issuing the appropriate SIL certificate)
- Step 5: Review the CB's certificate of accreditation to confirm that IEC 61508 certifications are within the CB's scope.
- Step 6: Use the CB's certificate of accreditation and the supplemental U.S. nuclear industry to complete the CGD of the service similarly to how accreditations to ISO Std. 17025.
- Step 7: Use the SIL-certification to complete the determination of acceptability of the dependability CCs of the item CGD
- Step 8: Use traditional methods to determine the acceptability of the physical and performance CCs.

3. Availability of CGD for Digital Equipment Using SIL-Certification

3.1 Coverage of SIL-Certification for Dependability Critical Characteristic

To validate the proposed CGD process, It is confirmed that whether the CB's certification covers the evaluation of dependability CC considered in the EPRI TR-106439. The EPRI has compared the contents of the safety justification methodology based on IEC Std. 61508 to the attribute of the dependability CC based on EPRI TR-106439. The EPRI has concluded that the safety justification methodology covers the attribute of dependability CC except for the quality assurance requirement. However, the EPRI has described that this deviation can be overcome by OEM's maintaining the quality assurance program in compliance with ISO Std. 17065, which mostly covers to quality assurance requirement of Append B to 10 CFR 10. In addition, it has been revealed that the difference between the requirements of ISO Std. 9001 and Appendix B to 10 CFR 50 is only the independence of the inspectors and design verification. Moreover, this difference in independence can be also resolved by the independence of the CB.

3.2 Acceptability of Accreditation based on ISO Std. 17065

National AB accredits the CB if the evaluation of the certification capability (ex, technical competence, certifying activities) of CB completely meets the requirements of IEC Std. 61508. Especially, the accreditation activity has to be similar to the commercial grade survey of CB in order for the SIL certification to apply to the evaluation of dependability CC. In this perspective, the NEI has compared the checklist for the commercial grade survey based on Appendix B to 10 CFR 50 with that for the accreditation based on ISO Std. 17065. The deviation has been

founded from the design control requirement in ISO Std. 17065, as follows.

- ISO Std. 17065 Section 7.1.1: "The certification body shall operate one or more certification scheme(s) covering its certification activities."
- ISO Std. 17065 Section 7.1.2: "Evaluation requirements of products shall be contained in specified standards."

Although the ISO Std. 17065 requires the CB's certification scheme for the certification activities, it does not specifically provide how to evaluate the requirement of products on specified standards (herein IEC Std. 61508). Through the participation in the accreditation process, both NEI and NRC confirmed that AB's checklist for accreditation reflects the dependability CC of commercial digital equipment. The observation of both NEI and NRC reveals that it needs to implement a compensating measure to confirm that a CB's scheme meets the requirements of IEC 61508. As a compensating measure, NEI suggests the two compensating measures: one is to encourage AB to improve the assessment of Section 7.1.2 of ISO 17065 and the other is to develop a supplemental accreditation checklist to be applied to each CB that would assess their scheme's compliance with IEC 61508. These compensating measures would contribute to accessing the dependability CC of CB.

4. Conclusions

We analyzed the improved dedication process for commercial digital equipment that is proposed to modernize the digital instrumentation and controls (I&C) regulatory infrastructures. First, we explain the generic dedicating process for commercial equipment that is accepted in nuclear regulatory. Then we introduce the improved CGD process for digital equipment by utilizing the certification based on the IEC Std. 61508. Finally, we evaluated the availability of the proposed CGD process in that the proposed CGD can be applied to assessment of the dependability critical characteristic. Although several concerns for the proposed CGD to extract dependability critical characteristic is founded, we concluded that the proposed CGD may be available thanks to compensating measures to resolve the concerns

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