

Safety Integrity Level (SIL) and Commercial Grade Dedication (CGD) perspectives

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1. Background

In the limited market of nuclear power plants, an increasing number of equipment suppliers having been giving up Nuclear Quality Assurance (NQA) based on 10CFR50 Appendix B due to economic reasons such as stagnation in new power plant construction and prolonged demand-supply cycles of parts. From the 1980s, this atmosphere was detected, and the guidelines for quality evaluation for use of commercial grade item (CGI) began to be developed. Another reason is that the realistic atmosphere of convergence of products not designed under NQA, namely artificial intelligence (AI) and Internet of Thing (IoT)-based products, with nuclear power plant technology emphasizes the need for “dedication¹”.

Therefore, dedication assurance metrics are suggested to review the safety of commercial grade item (commercial off the shelves: COTS) that have not been designed, developed, manufactured, assembled, tested, or delivered under Nuclear Quality Assurance (NQA) envelope.

Ultimately, how long will the huge barriers to enter nuclear by non-nuclear (IoT) last? Also, what are going to be the measures to assure safety if the barrier is broken down?

Licensee Commercial-Grade Procurement and Dedication Programs (Generic Letter 91-05) is saying;

“This generic letter notifies the industry of the staff's pause in conducting certain procurement inspection and enforcement activities and identifies a number of failures in licensees' commercial-grade dedication programs identified during recent team inspections performed by the U.S. Nuclear Regulatory Commission (NRC)”

Apart from the products developed under NQA, it is necessary to review CGI that is defined as below;

Commercial Grade Item (10CFR21.3):

- (1) When applied to nuclear power plants licensed pursuant to 10 CFR part 50, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a “*basic component*”. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (*i.e.*, one or more critical characteristics of the item cannot be verified).

¹ terms such as *dedication, selection and use, justification, suitability, qualification and reasonable assurance* for nuclear application of general technologies and products not under NQA are interchangeably used in nuclear fields such as IAEA, IEC, IEEE and EPRI,

- (2) When applied to facilities and activities licensed pursuant to 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, commercial grade item means an item that is:
- (i) Not subject to design or specification requirements that are unique to those facilities or activities;
 - (ii) Used in applications other than those facilities or activities; and
 - (iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

2. Activities in organizations (IAEA, IEC, IEC/IEEE, EPRI)

Along with IAEA, the standard organization such as IEC, IEEE and EPRI have kept trying to develop the technical evaluation and acceptance methods to ensure reasonable assurance of commercial products to be applied into safety-related in nuclear power plants.

2.1 IAEA

IAEA has issued for safety report dealing with “challenges and approaches for selecting, assessing and qualifying commercial industrial digital instrumentation and control equipment” to apply in nuclear power plants [1]. The focus of this publication is on the activities required to demonstrate the suitability of commercial off the shelf (COTS) digital instrumentation and control equipment for use in nuclear power plant safety applications.

2.2 IEC TC 45 SC 45A

IEC typically has issued 62671[2], the way of “selection and use of industrial digital devices of limited functionality” for application of nuclear power plants. It provides requirements for the selection and evaluation of such devices where they have dedicated, limited, and specific functionality and limited configurability.

IEC 62988:2018[3] establishes requirements relevant to the selection and use of wireless devices in instrumentation and control (I&C) systems important to safety used in nuclear power plants (NPPs). Both fixed and mobile devices and all data types (voice, process data, etc.) are included within the scope if they provide a safety classified function. IEC 62566-2:2020[4] Nuclear power plants - Instrumentation and control systems important to safety - Development of HDL-programmed integrated circuits - Part 2: HDL-programmed integrated circuits for systems performing category B or C functions, which gives a guidance to HDL-programmed devices for Category B or C system according to IEC classification.

IEC TR 63084:2017 Nuclear power plants - Instrumentation and control important to safety - Platform qualification for systems important to safety [5]. It is to enable parties implementing plant specific I&C systems to concentrate on application functions, while for basic system functions to rely on platform qualification. Basic means of equipment qualification, as prescribed by the IEC/IEEE 60780-323, are through analysis, type testing and documented operational experience. This TR is in NWIP phase for international standardization. Other documents applicable for qualification for nuclear use include IEC 61513, IEC 60880, IEC 62138, IEC 62566, IEC 62671 and IEC 61226.

2.3 IECQ

Under IEC organization, IECQ WG11 “Nuclear Technologies” is established for quality assessment system for electronic components in nuclear world. It is world-wide approval and certification system covering the supply of electronic components and associated materials and assemblies and processes, which could be considered to ensuring the reasonable assurance of commercial products.

2.4 EPRI

US, already detected this atmosphere in nuclear power plants as mentioned in §1, has systematic development of methods for commercial products spanning from mechanical, electrical and the digital products as indicated in Figure 1 (EPRI 3002002982, §14).

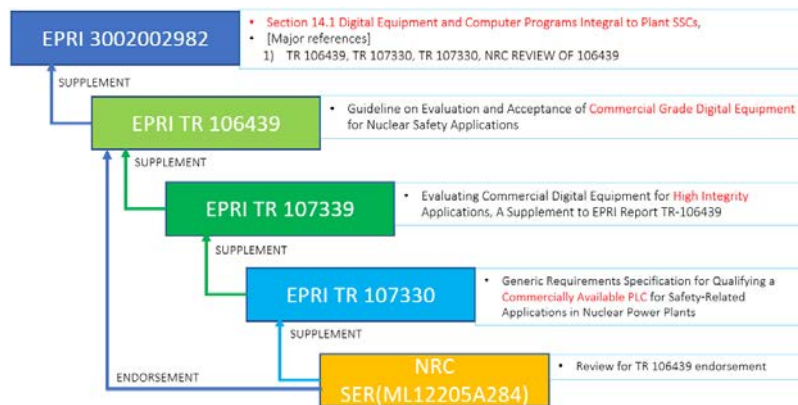


Figure 1 Interface for EPRI 3002002982 and relevant

Through EPRI 3002002982, licensee is able to recognize the suppliers and utility position for the CGD as indicated in Table 1.

Table 1 Factors of supplier and commercial dedication

Items	Supplier’s position	EPRI 3002002982 for supplier
Built-in quality	Internal QA (Quality Assurance)	Not NQA (ISO 9000 equivalent), Hold and witness point, Survey
Confidence building	Product excellence via SIL	PIT (Post-Installation Test) for plant level safety
	Function, interface, performance and code compliant)	DC (design characteristics) and CC (critical characteristics) for reasonable assurance
	EQ (Equipment Qualification) in general	EQ, FMEA (Failure Mode and Effect Analysis), Hazard and SPV (Single Point Vulnerability) analysis for traceability
	Quality assessment through internal verification activities	Acceptability through dedication methods
	Quality assessment through operating references	Acceptability through based on operating history

2.5 CSA (Canadian Standard Association)

CSA N290.14:15, Qualification of digital hardware and software for use in instrumentation and control applications for nuclear power plants. The CSA N299 series of Standards defines quality assurance program requirements for the provision of items and services for nuclear power plants when specified in the contract between the customer and the supplier [6].

There are qualification activities specified in CSA N290.14-15 that are dependent on pre-developed software (and digital items) or custom software (and digital items) to cover a wider range of software qualification applications, and also covers hardware qualification of digital systems.

2.6 IEC/IEEE Joint Working Group²

IEC TC45 SC45A WG7 and IEEE WG6.6 is collaborated to organize the Joint project team proposed by IEEE, which is expected primarily to deal with dedication in various way.

2.7 Republic of Korea (KINS)

Korea also maintains the dedication guidelines and criteria [7] by Korea Institute of Nuclear Safety (KINS) for sharing the consensus of technological stand points.

Summarizing activities and standard documents above, it is obviously clear that there are two separate factors to make sure of quality assurance of products and engineering services regardless of the type of them, which is very similar to Table 1 & 2. The two areas are divided into a *quality management* and a *technical management*, and although it is difficult to separate the detail actions and results between them, they are roughly summarized as follows.

3. Issues and suggestion

For reasonable assurance of commercial products for safety application in nuclear power plants, it is necessary to ensure the products are compliant with codes and standards in a sense that there is various spectrum of dedication to share technical position of stakeholders. It could be accomplished through training of supplier and dedicating entity, and reasonable maintenance of dedication.

Unfortunately, dedication until now has been done in purely qualitative ways, which could cause the gaps and misunderstanding of dedication results between suppliers and utilities (dedicating entity). What is worse, due to the upsurge of edge technologies in IoT technologies and relevant products such as artificial intelligence (AI), exploratory data analysis (EDA), deep learning (DL) from conventional mechanic devices and limited electronical devices, dedication would be the main stream of regulatory criteria and guideline for application of commercial technologies in nuclear power plants.

At this point, it is meaningful to consider the framework of dedication assurance metric model for qualitatively quantitative dedication (QQD) for acceptance of commercial products in nuclear safety application.

² This working group is convened by Mr. Andrew Nack (IEEE) and Mr. Nicholas Chevaux (IEC), and it is expected to deploy meaningful standardization activities.

Additionally, it might be reasonable to identify the differences of “certification of product” and “reasonable assurance of product” with aspects of dedication. This paper is going to suggest a conceptual framework for dedication assurance metrics along with referring to differences between product certification and plant level safety when applying those commercial products in safety of nuclear power plants.

3.1 Perspectives of SIL and CGD [8]

This includes the hardware and software to build product. SIL and CGI product are assumed to have system design life cycle outcomes like equipment qualification and verification reports in common. The main differences between certification and dedication is dictated in Figure 2 and Table 2, highlighting the plant level safety in application and operation phase of products.



Figure 2 Elements ensuring the overall quality of plant equipment [10]

Some paper [9] addresses the need for application of SIL to consider the supplier’s reluctance on “*commercial grade survey*”, which is conceptually equivalent to Method-2 for acceptance.

Table 2 Perspectives from SIL and dedication

Item	SIL	Dedication
Focus	Products	<i>Plant level safety</i>
Identity	Certification Organization	Qualified engineer
Life-cycle	Sell and delivery	Plant operation
Test	Functionality	Field adaptation

As mentioned earlier, certificates such as SIL are certifications for products, but dedication pursues dependability of the entire power plant level safety considering product application, operation, and maintenance (See Table 2). Therefore, although DC, CC selection and TE are important technical information, the activities of 5(post acceptance/installation control) in Figure 2 should be additionally considered.

3.2 QQD (Qualitatively Quantitative Dedication) model

QQD is absolutely not a new method for technical evaluation and acceptance process of commercial products to be deployed in nuclear safety application. Main target of QQD is systematic way of qualitatively quantitative dedication by harmonize the technical evaluation and acceptance methods provided in many standards and reports indicated in § 2.1 through § 2.7.

Table 3 and 5 typically shows a qualitatively quantitative dedication by grading the base score and weight of each built-in quality and confidence building of dedication products. Furthermore, QQD is not criteria for judging PASS or FAIL of dedication, but for reference for quantitative measure for communication among stakeholder as a way of deterministic alternatives for ensuring the reasonable assurance for products and technologies.

Table 3 Conceptual model for QQD (typical)

classification ³	Quantification category	Quantification Subcategory	Base score	Weight ⁴
Built-in quality	Quality system based on 10CFR50 Appendix B	NQA, or Operation of other quality systems (1) Personnel, (2) Process and system, (3) Resources	1-5	0.0-0.25
	SDLC (Software Development Life Cycle) Design document Traceability	Design Activity traceability	1-5	0.0-0.25
	Quality assurance activities (1) Verification and validation (2) FMEA, Reliability analysis (3) Equipment Qualification (irradiation, seismic, environment, EMC etc.	Various activities for other quality checks	1-5	0.0-0.25
	Product certificate	Related certification	1-5	0.0-0.25
	Other quality support activities	In-house unique quality system	1-5	0.0-0.25
Confidence building	EPRI 3002002982-based (1) Method-2 Commercial grade survey (2) Method-3 Source verification	Technology evaluation and acceptance process (1) TE (Technical Evaluation) suitability (2) AP (Acceptance Plan) suitability	1-5	0.0-0.25
	(3) Method-1 Special testing and inspection	Suitability of test and inspection (1) witness & inspection (2) Test procedure, Report	1-5	0.0-0.25
	(4) Method-4 Item/Supplier performance record	Operating reference information (1) Reference site, Duration, (2) Non-conformance report history (3) Reference data quality etc.	1-5	0.0-0.25
	(5) Other measures for quality assurance	Any	1-5	0.0-0.25

3.3 Quantitative vs. Qualitative

According to the quantitative and qualitative research in scientific domain, quantitative modeling has pros and cons in application. Quantitative modeling enables to perform a direct comparison of evaluation results and analysis using reliable constant procedure through quantitative data analysis.

In the other hands, it has challenges such as superficiality and narrow focus of analysis. Also, despite standardized procedures, structural framework can still affect quantitative modeling. Missing data, imprecise analysis or inappropriate evaluation and acceptance methods are biases that can lead to the misleading conclusions. Quantitative modeling often uses unnatural settings like laboratories or fails to consider historical and cultural contexts that may affect modeling.

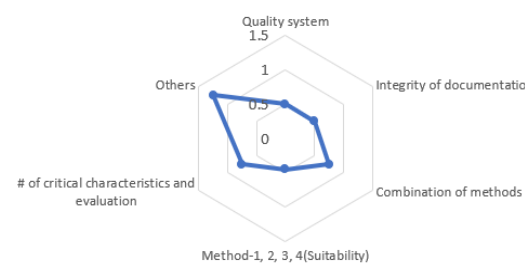
Nonetheless this paper suggests the qualitatively quantitative dedication model as a first step to survey and bridge these gaps between qualitative and quantitative dedication as in Table

³ Varies based on the specific applications

⁴ Adjustable according to the priority of project issues

5. Ultimately the goal of this attempt is to provide the deterministic alternative for measuring the reasonable assurance of technologies, products and services from research and development.

Table 4 QQD evaluation and visualization of index(typical)

Evaluation item(typical)		Adjustable weight(A)	Score(B)	Score based on weight (A) x (B)	Radar chart (typical visualization)
Built-in quality	Quality system	0.10	1~5	0.5	
	Integrity of documentation	0.10	1~5	0.5	
Confidence building	Combination of methods	0.15	1~5	0.75	
	Method-1, 2, 3, (Suitability)	0.15	1~5	0.45	
	# of critical characteristics and evaluation	0.25	1~5	0.75	
	Others (operating history, setpoint compliance)	0.25	1~5	1.25	
		0.25	1~5	1.25	
Total		1.00	5.00	4.2	Visualization of quantification of CGD

3.4 Issues to be considered in future

Based on idea of QQD for deterministic decision assisting reasonable assurance of I&C parts to be applied in nuclear power plants, the following issues should be considered and elaborated;

- 1) Harmonize worldwide dedication methodologies and practices
- 2) Elaborate and specify the sub-criteria of each classification and criteria,
- 3) Way of grading the combination of dedication methods
- 4) Way of addition and deduction of score and weight (statistically and mathematically)
- 5) Simulation of existing dedication results
- 6) Continuous enhancement of QQD model and its implementation

4. Conclusion

Simple mechanical products, various IoT-based smart devices, platform-level systems, and highly complex software models are currently showing convergence in nuclear power plant domain. It is necessary to ensure *reasonable assurance* through technical review and acceptance process of these commercial products, and to develop improved regulatory technologies and guidelines. Because the regulation based on deterministic is going to be case-by-case in random and alternative ways.

To support this, it is one of the options to develop a model for *qualitatively quantitative dedication (QQD)* for qualification and technical verification. In the future, concrete implementation methods for these efforts could be developed, and it will be able to play a positive role in supplying commercial products for nuclear power plants safety application.

References

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