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Suitability Evaluation of Commercial Grade Products for Use in Nuclear Power Plant Safety Systems

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International Atomic Energy Agency

SUITABILITY EVALUATION OF COMMERCIAL GRADE PRODUCTS FOR USE IN NUCLEAR POWER PLANT SAFETY SYSTEMS

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The Agency's Statute was approved on 23 October 1956 by the Conference on the Statute of the IAEA held at United Nations Headquarters, New York; it entered into force on 29 July 1957. The Headquarters of the Agency are situated in Vienna. Its principal objective is "to accelerate and enlarge the contribution of atomic energy to peace, health and prosperity throughout the world''.

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FOREWORD

Quality management of systems, structures and components important to safety is one of the most central themes in the construction and operation of nuclear power plants. Selecting and preserving a qualified supplier base capable of manufacturing products conforming to stringent specifications is vital. During the life cycle of an installation, technology may become obsolete, some suppliers may leave the market, mergers and acquisitions may take place, and new suppliers may join the marketplace. All this may cause serious bottlenecks in the supply of safety related items. One solution proposed to ensure that enough suppliers and products are available for safety related items has been to use components not designed or manufactured according to nuclear quality standards which undergo a suitability evaluation process. These are often called commercial or industrial grade items.

The IAEA has developed this publication to provide information on approaches to evaluating the suitability of commercial grade items for use in nuclear power plant safety systems. This includes both the fitness of their design and quality of their manufacturing. An often used concept related to the latter is commercial grade dedication.

This publication is to be used in conjunction with the IAEA Safety Standards Series, IAEA Nuclear Energy Series and other IAEA publications dealing with management systems, project management, procurement and quality. The expected audience ranges from senior management to quality experts managing products and services important to safety. Individuals developing their skills in supply chain and quality management may also benefit as the presented concepts may be novel.

Near term deployment of advanced reactor designs, including small and medium sized or modular reactors, would benefit from the large scale use of commercial grade products. The Nuclear Harmonization and Standardization Initiative includes common approaches on codes and standards as it presents considerations for various acceptance processes and suitability evaluation techniques for utilizing commercial grade products.

This publication would not have been possible without contributions by many experts from different Member States. The IAEA wishes to especially acknowledge the contribution of J. Kickhofel (Switzerland) for his role. The IAEA officer responsible for this publication was P. Pyy from the Division of Nuclear Power.

CONTENTS

1. INTRODUCTION 1

1.1. Background 1
1.2. Objective 2
1.3. Scope 2
1.4. Structure 3

2. COMMERCIAL GRADE PRODUCTS 4

2.1. Global supply chain and its actors 4
2.2. Supply chain management and procurement 5
2.3. Commercial grade versus nuclear grade 6
2.4. Commercial codes and standards 9
2.5. Guidance related to commercial grade products 9

3. SUITABILITY EVALUATION PROCESS 15

3.1. Suitability of design 16

3.1.1. Review of design 16
3.1.2. Design verification 19

3.2. Quality of manufactured items 20

3.2.1. Manufacturer readiness 20
3.2.2. Quality control 25

3.3. Risk considerations 28

3.3.1. Design related risks 28
3.3.2. Procurement related risks 29
3.3.3. Quality related risks 30

4. SUITABILITY EVALUATION STRATEGIES 32

4.1. Commercial grade dedication 32
4.2. Graded or risk-informed approach 33
4.3. Justification process for COTS digital I&C equipment 34

5. SPECIAL TOPICS 36

5.1. Services and their suitability 36
5.2. Outsourcing suitability evaluation 37
5.3. Nuclear power plant lifecycle considerations 37

5.3.1. Project development phase 37
5.3.2. Construction and commissioning 38
5.3.3. Commissioning and operation 38

5.4. Advanced manufacturing 38
5.5. Commercial grade products in advanced power reactors 39

APPENDIX I. EXAMPLES OF COMMERCIAL CODES, STANDARDS AND OTHER NON-NUCLEAR RULES 41

APPENDIX II. EQUIPMENT QUALIFICATION 43

APPENDIX III. QUALITATIVE AND QUANTITATIVE RISK ANALYSIS METHODS 47

APPENDIX IV. QUALITY ASSURANCE GUIDELINE FOR PROCURING HIGH-QUALITY INDUSTRIAL GRADE ITEMS AIMED AT SUPPORTING SAFETY FUNCTIONS IN NUCLEAR FACILITIES (NUCLEAREUROPE CGD GUIDELINE) 51

APPENDIX V. COMMERCIAL GRADE DEDICATION AT KRŠKO NPP 53

APPENDIX VI. GLOBAL SCHEME FOR THE PROCUREMENT OF ITEMS IMPORTANT TO SAFETY AT ENGIE ELECTRABEL 57

APPENDIX VII. COMMERCIAL GRADE ITEM DEDICATION AT KOREA HYDRO & NUCLEAR POWER CO., LTD (KHNP) 61

APPENDIX VIII. GRADED APPROACH PRINCIPLE IN KELPO COOPERATION 65

APPENDIX IX. EXAMPLES OF SUITABILITY EVALUATION (KINETRICS) 69

REFERENCES 75

ABBREVIATIONS 81

CONTRIBUTORS TO DRAFTING AND REVIEW 83

1. INTRODUCTION

1.1. BACKGROUND

Nuclear power plants (NPP) rely on products (systems, structures and components), which need to comply with international, national, local and license-specific requirements. These often include detailed nuclear specific management system, design, quality, qualification, licensing, testing and inspection related requirements, and the products are thus designed and manufactured under a very accurate oversight one at a time. Obsolescence issues have been exacerbated by nuclear specific conformity requirements, which can make potential suppliers of nuclear products reluctant to offer their products to the nuclear sector. In some cases, operators and reactor technology vendors are thus unable to find suppliers whose organization and/or product comply with the requirements, except at an excessive cost, or even willing to engage in business.

The continuing expansion of nuclear energy around the world will also be expedited by the existence of an international supply chain offering high quality products at competitive prices and manufactured to widely accepted and equivalent standards. Moreover, the energy transition from reliance upon fossil fuels to nuclear and other forms of low-carbon energy will be eased if suppliers who are currently tied into high carbon emitting sectors can readily switch to these expanding markets. Thus, methodologies that permit customers and regulators to understand the merits of commercial grade products and services conforming with all the requirements need to be recognized internationally if they are to assist in the wider transition to a clean energy system.

This situation has led to the need for suitability evaluation processes for commercial grade products to be used in NPP safety systems performing safety functions. The IAEA Fundamental Safety Principles [1] describes the need to assess and demonstrate that the safety functions of engineered safety features are fulfilled. In addition, the IAEA Safety Guide, No. GS-G-3.5 [2] states that “when a commercial grade product is proposed for any safety function, a process should be used to determine the product’s suitability…”. Despite this, there is currently little IAEA practical guidance describing potential suitability evaluation processes, challenges, good practices and lessons learned from the nuclear industry.

Engineering, quality, procurement, and operational staff at NPPs may all have a role to play in the suitability evaluation process to use commercial grade items. The general process obviously also hinges on the function expected of the product, and the product needs to be qualified for its use. Some Member States (MSs), such as Canada, South Korea, Spain, Slovenia, and the United States follow established guidelines for the justification of commercial grade products (referred to as dedication), while others rely on methodologies individual to the owner operator organizations and their regulatory body. In some MSs and regions, projects are underway to explore ways in which nuclear operators can assess and demonstrate the suitability of commercial grade products for use in safety systems.

It is important to collect lessons learned, good practices, approaches and processes used in different jurisdictions in assessing, selecting, and approving commercial grade products for use in nuclear power plant safety systems.

IAEA 63rd General Conference (GC) (63)/RES/DEC(2019) resolution number 8 in Section 5:

> “[encourages the] Secretariat to identify best practices and lessons learned with respect to procurement, supply chain, engineering, and related issues in the delivery of large, capital-intensive nuclear

> engineering projects and to promote and disseminate them through publications and web-based tools with respect to supply chain management" [3].

Furthermore, a recommendation of the 2019 Second Meeting of the Technical Working Group on Nuclear Power Plant Operations (TWG-NPPOPS) states: "IAEA is recommended to continue to work on general principles for use of commercial grade items taking into account risk-informed approach".

A Peaceful Uses Initiative (PUI) project entitled 'Quality and Management System Aspects of Nuclear Procurement Engineering and Supply Chains', has been running since 2018 to produce the necessary practical guidance. This publication is one of the deliverables conforming with its ideas.

1.2. OBJECTIVE

The objective of this Technical Document (TECDOC) is to provide approaches, strategies, lessons learned and good practices for procuring and accepting commercial grade products and services for safety related uses in nuclear power plants; to provide practical examples of these activities from Member States; and to elucidate all stakeholders and their roles in the suitability evaluation process.

This information is intended to:

- Emphasize that given appropriate measures, commercial grade products can be and already are utilized in nuclear safety systems;
- Help ensure the sustainability of nuclear facilities by well-specified requirements and acceptance criteria and their application in all activities, deliverables and services;
- Provide a reference for plant operators, conformity assessment bodies, suppliers, governmental bodies and regulators when they discuss quality assurance and quality control of commercial grade products and services;
- Identify principles for the suitability evaluation (i.e., dedication, acceptance, identification of appropriate measures) of commercial grade items for use in nuclear safety systems.

The main focus of this publication is nuclear power plants, but the concepts are applicable to all nuclear facilities and activities and their safety related uses.

1.3. SCOPE

This publication provides basic concepts and good practices with regards to the suitability evaluation and use of commercial grade products and services within nuclear facilities in safety-related applications. It focusses on electro-mechanical components, as the digital ones are covered by IAEA Nuclear Energy Series No NR-T-3.31 [4]. Organizational, technical, and regulatory aspects related to the use of commercial grade products in safety systems belong to the scope as well as risk considerations.

The publication also discusses the elements of a management system relevant for the acceptance of commercial grade products, such as the processes, procedures and records related to the evaluation of these products and their suppliers. Interface to the related topic of equipment qualification (EQ) is also covered.

The publication does not suggest one approach that would fit all applications. Rather, its aim is to present a spectrum of tools and approaches.

1.4. STRUCTURE

This publication consists of five (5) sections and nine (9) appendices.

Section 1 is an introduction to purpose and contents of this publication. Section 2 provides background and context about commercial grade products, such as how they differ from nuclear-grade products and why they might be considered for applications requiring the performance of safety functions. Section 3 is an overview of the suitability evaluation process and its typical elements including establishing suitability of design, suitability of manufactured items and risk considerations when planning to utilize commercial grade products. Section 4 describes specific approaches for the suitability evaluation of commercial grade products. Finally, Section 5 discusses special topics including services and their suitability, commercial grade products in advanced power reactors and advanced manufacturing.

2. COMMERCIAL GRADE PRODUCTS

This section gives background and context about commercial grade products, such as how they differ from nuclear grade products and why they might be considered for applications requiring the performance of safety functions.

2.1. GLOBAL SUPPLY CHAIN AND ITS ACTORS

Manufacturing activity has become more fragmented. Goods are created through several stages that may be located in different countries and/or supply chain facilities. This restructuring and relocation of supply chains has been underway since the end of the last century and is reflected in an increasing volume of trade in intermediate goods [5]. The tendency is also visible in the nuclear sector [6].

Sometimes referred to as the extended enterprise, the supply chains of NPPs are comprised of different organizations, of different sizes often spread across continents. Supply chains are not static and evolve with time for many different reasons; reasons which may or may not be within the control of the end-user, the nuclear power plant. For example, equipment manufacturers may be serving a range of other industries which encourage their supply chain to relocate production or outsource activities to gain competitive advantage.

In the process of constructing a large reactor, huge volumes of structures, systems, and components (SSCs) are procured, manufactured, assembled, transported, received, installed, and commissioned. During this lifecycle phase the supply chain is assembled. If the reactor being constructed is first-of-a-kind (FOAK), the supply chain is often a unique combination of partner organizations comprising a newly created conglomeration of technology vendors, system integrators, original equipment manufacturers (OEMs), sub-component suppliers, fabricators, and raw material suppliers[1] [7]. Construction companies and contractors present in the supply chain during the construction phase do not necessarily play a significant role in the operational reactor supply chain [8].

Localization efforts related to an individual NPP [9] or the construction of a reactor many decades after the last, when suppliers and their legacy products are no longer active on the market may mean FOAK supply chains are used. In such cases, new actors enter the supply chain even if the reactor technology itself is proven and functioning elsewhere. Supply chain localization efforts identify what equipment is to be procured locally according to various project value criteria. Frequently, the selection of suppliers initially focuses on commercial grade products which are already manufactured for other industries locally.

Once operational, the role of the supply chain of an NPP changes dramatically. While some suppliers will leave the supply chain after commercial production of electricity begins, OEMs can remain a part of the supply chain for the remainder of a reactor's operational life. Spare parts, consumables and services related to refuelling and maintenance of the plant come to dominate the operating organization's procurement agenda. Major safety upgrades or refurbishments bring new and established actors temporarily into the supply chain once again.

The long lifetime of NPPs means that it may at some point be necessary to change suppliers. This may be because continual improvement, innovations or economic benefits can be realized or necessary because of obsolescence or quality issues. The transition from analogue to digital

[1] It should be noted that while one nuclear steam supply system (NSSS) of a nuclear reactor is unique from another, the auxiliary systems, site structures and non-safety-related infrastructure may essentially remain the same.

instrumentation and control that is prevalent in other industries serves as an example of modernization resulting from obsolescence in certain analogue hardware. Also, suppliers may cease to exist, discontinue their nuclear quality assurance programme, or otherwise compel the NPP to reconsider where to access corresponding products. Shocks to the supply chain like that caused by the coronavirus disease 2019 (COVID-19) pandemic can also prompt operating organizations and their top tier supplier to seek out alternate suppliers and sub-suppliers or otherwise optimize their procurement strategy to become more agile and resilient.

Many products used in nuclear power plants become obsolete over time as manufacturers develop new products to replace old technology; this is true whether the products are commercial or nuclear grade. Furthermore, the product lifecycle is tending to shorten due to the rapidity of technical advance and planned obsolescence policies by OEMs [5] [6]. However, commercial grade products are especially prone to obsolescence due to faster development cycles and market dynamics. An alternative component that is deemed equivalent to the original can be selected as a replacement to an obsolete product, however this option is not always possible as the alternative products may not be the same in form, fit or function. The most common example is analogue technology replaced with digital technology. Where it is not possible to replace the obsolete product with an equivalent replacement, the option of reverse engineering may be suitable. Reverse engineering involves redesigning the obsolete component to meet the same form, fit, and function as the original.

Beyond the nuclear industry, supply chains are sometimes constrained and influenced by a similar set of competitive pressures. Changing consumer preferences and corporate strategies mean that suppliers need to be able to vary their production runs more frequently, in terms of the volume of products manufactured and product attributes. Automated production lines therefore need to be more flexible and computer-controlled, which represents a significant capital investment by the supplier [5]. However, product and production flexibility are tightly bounded to a set of standardized requirements issued by the customers. If another customer requests a product to be manufactured to a set of requirements that as far as the supplier is concerned is non-standard, then it becomes more costly for the supplier to comply and may even lead the supplier to turn down the business.

2.2. SUPPLY CHAIN MANAGEMENT AND PROCUREMENT

An operating organization will need to identify when and how commercial grade products can be utilized. This analysis can be performed based on factors like safety significance, risk, and technological complexity. Supply chain factors are also important to consider, knowing that commercial grade products tend to have a larger installed basis and, correspondingly, be manufactured at larger scales. This can mean that commercial grade products may have advantages or disadvantages over nuclear-grade products from the perspective of an operating organization’s supply chain management function. Furthermore, logistical matters such as lead times, commercial conditions such as guarantees or warranties and technical issues such as access to reliability data can vary greatly between commercial grade product offerings on the market.

Establishing the suitability of commercial grade products for use in NPP safety systems is an activity which requires strategic planning. For example, the degree to which the suitability evaluation process is insourced or outsourced may vary, with the licensee always maintaining ultimate responsibility for safety.

When it comes to strategic commodity positioning, the procurement of commercial grade products for use as items important to safety may make more sense in certain categories (routine, leverage, strategic, bottleneck) than in others [10]. This applies not only to the mechanical and electromechanical equipment on which this publication is focused, but also to the procurement of services related to these items (see Section 5.1).

2.3. COMMERCIAL GRADE VERSUS NUCLEAR GRADE

Components and equipment that adhere to nuclear design codes, referred to as ‘nuclear grade’, are distinguishable from those following non-nuclear industry specific standards, known as ‘commercial grade’, in the way they document applied manufacturing techniques and undergo quality assurance/quality control procedures, inspections during production, performance testing, and other life cycle development steps. These differences may also extend to the assembling of the items [11].

Quality assurance and quality control play a major role in ensuring items and services procured for nuclear facilities and activities are fulfilling the requirements expected of them [9]. This is especially valid for items relied upon to perform safety functions and services which can impact those items.

Nuclear grade products are designed, manufactured, tested, or inspected specifically for nuclear facilities. Commercial grade products are those which were not designed, manufactured, tested, or inspected according to regulation, codes, or standards specific to the nuclear industry. The ability of a product to fulfil its nuclear safety function(s) is intrinsic to the nuclear codes and standards from which its engineered design, manufacture and qualification is based. On the other hand, commercial grade products are generally furnished by suppliers without specific awareness of the product’s intended nuclear safety function(s). Products (which includes whole pieces of equipment, parts thereof or materials) procured as commercial grade ultimately, after a suitability evaluation process, can be used as safety class structures, systems, and components.

The IAEA Fundamental Safety Principles make no distinction between nuclear-grade or commercial grade products when requiring that “engineered safety features are assessed to demonstrate that they fulfil the safety functions required of them” [1]. Products which have not been designed specifically with nuclear safety functions for nuclear facilities and activities in mind cannot be automatically assumed to be suitable for use without careful assessment. IAEA SSR-2/1 (Rev. 1) addresses the requirements for items important to safety [12].

Organizations in the nuclear supply chain comply with international and national laws, regulations, standards, or customer specific expectations related to quality assurance and quality control which are often unique to the nuclear industry. This means that international trade and transport bodies, national governments, local governments, nuclear regulatory bodies, conformity assessment bodies and standards development organizations (SDOs) need to be considered. The rules and regulations related to the supply of products and services by these actors play a major role in setting the requirement framework for a nuclear supply chain.

Commercial grade products, including commercial-off-the-shelf (COTS) items, have been utilized in nuclear safety systems for a variety of reasons, these include:

- To take advantage of a commercial product with exceptional quality, reliability and performance;
- As an alternative to a nuclear-grade product which has become obsolete;
- No suitable nuclear-grade product exists on the market;

- A historically nuclear-grade product which can no longer be classified as such due to changes within the supplier's Quality of management (QM) system or nuclear certifications;
- To procure state-of-the-art or innovative products relative to those currently in place.

Figure 1 outlines the general scenarios of the suitability evaluation process, which are influenced by factors external and internal to the licensee's organization.

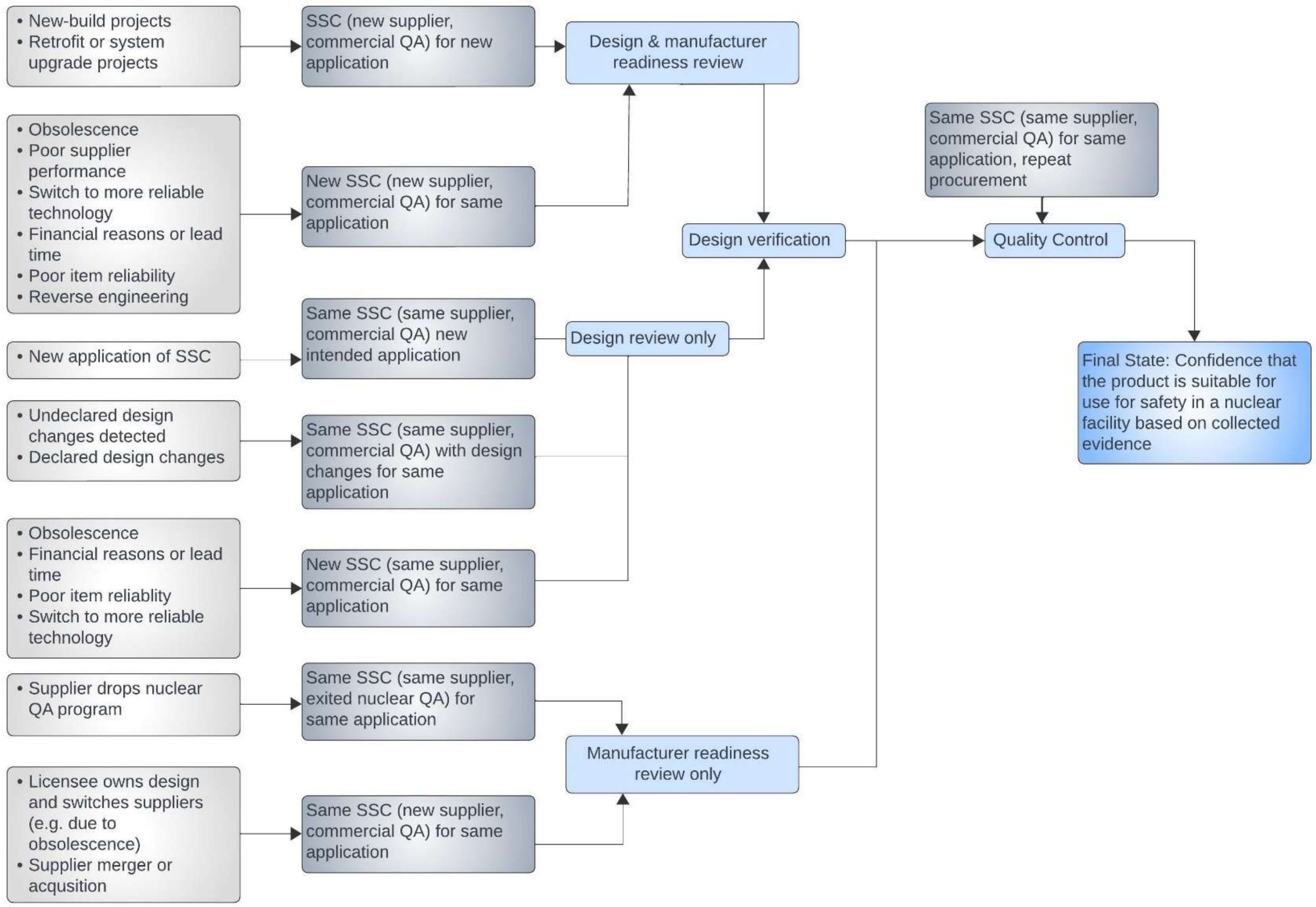

FIG. 1. Various categorized commercial grade product procurement scenarios (grey boxes) and the suitability evaluation process elements (blue boxes) necessary to reach the final state of confidence in the item's suitability for use.

2.4. COMMERCIAL CODES AND STANDARDS

The role of safety and quality in commercial industrial facilities and activities has steadily grown throughout the last centuries. Assuring the quality of goods and services is an important element in gaining competitive advantage in a global economy and in protecting human health. Demonstrating that a product conforms to standard communicates important information to customers and regulators and facilitates trade across borders [13]. Today, commercial codes and standards exist for every important step in the supply of engineered equipment and services. Risk-informed approaches [14], defence-in-depth [15], prevention of common cause failures [4], safety classification [16], graded approach [17] and safety culture [18] exist not only in the nuclear industry but also elsewhere in the energy, medical, pharmaceutical and transportation industries [19].

Starting with a single standard in 1951, the International Standards Organization (ISO) today maintains more than 20,000 standards on subjects like quality management, occupational health and safety and IT security. Likewise, the International Electrotechnical Commission (IEC) and International Telecommunication Union (ITU) have developed countless standards thanks to the experience, input, and agreement of the world’s foremost subject matter experts.

In addition to international bodies, regional SDOs like the European Committee for Standardization (responsible for European Standard EN standards) or Euro-Asian Council for Standardization, Metrology and Certification (responsible for GOST standards) also maintain standards on all major industrial process and a wealth of industry-specific standards.

In its infancy in the 1950’s and early 1960’s, the civil nuclear industry relied on commercial codes and standards like the ASME (American Society of Mechanical Engineers) Boiling and Pressure Vessel Code Section I and VIII. The nuclear specific Section III was published in 1963. While primarily used in America, the French nuclear fleet relied on American rules for the design of their first three and four loop NPPs until a native code, RCC-M was finalized in 1979, followed shortly by the creation of the French Society for Codified Rules for Design, Construction and In-service Inspection of Nuclear Island Components (AFCEN) [20].

Equipment designed according to commercial codes and standards have been utilized in NPPs for many decades. Pressure vessels according to the European EN 13445, digital instrumentation and control (I&C) with functional safety according to IEC 61508 or valves qualified to (American Petroleum Institute User Acceptance of Refinery Valves) (API 591) all may be found in NPPs, for example. Such equipment is produced in significantly larger quantities when compared to nuclear-grade products and commercial codes and standards cover large geographical areas if not the whole globe.

Appendix I presents references to some commercial codes and standards and other useful literature.

2.5. GUIDANCE RELATED TO COMMERCIAL GRADE PRODUCTS

The existing guidance published by the IAEA and other sources is provided to the reader for reference (see Table 1). The material shown here is not comprehensive, and new and superseding guidance may become available any time. Nuclear power plant personnel responsible for commercial grade item suitability evaluation processes should ensure compatibility with regulatory expectations when following any guidance document.

TABLE 1. EXISTING IAEA GUIDANCE AND INFORMATION ON COMMERCIAL GRADE PRODUCTS AND THEIR SUITABILITY EVALUATION

Document	Paragraph	Relevant text
Safety Fundamentals No. SF-1 [1]	3.15	“Safety assessments cover the safety measures necessary to control the hazard, and the design and engineered safety features are assessed to demonstrate that they fulfil the safety functions required of them.”
Leadership and Management for Safety GSR Part 2 [21]	4.34	“The organization shall have a clear understanding and knowledge of the product or service being supplied. The organization shall itself retain the competence to specify the scope and standard of a required product or service, and subsequently to assess whether the product or service supplied meets the applicable safety requirements.”
Safety of Nuclear Power Plants: Commissioning and Operation SSR 2/2 (Rev 1) [22]	Requirement 13	“The operating organization shall ensure that a systematic assessment is carried out to provide reliable confirmation that safety related items are capable of the required performance for all operational states and for accident conditions”
Application of the Management System for Facilities and Activities (GS-G-3.1) [23]	III.2.	“Inspection and testing requirements: When inspection or testing of products is necessary, this should be specified. Acceptance criteria for the requirements should also be specified.”
The Management System for Nuclear Installations (GS-G-3.5) [24]	5.35	“Certain products with a proven record may be available from commercial stock. Procurement documents should provide sufficient information from catalogues and suppliers’ specifications to enable the correct product to be supplied.”
	5.36	“Relevant technical data and trial information regarding the product should be requested from the manufacturer as necessary. Where appropriate, a commercial grade product may need to undergo confirmatory analysis or testing to demonstrate the adequacy of the product to perform its intended function”.
	5.37	“When a commercial grade product is proposed for any safety function, a process should be used to determine the product’s suitability; this is sometimes referred to as a ‘dedication’ process in some States. This process should identify whether the following activities are required: (a) A thorough technical evaluation of critical characteristics such as reliability and failure modes. (b) Verification of compliance of the product with requirements that are safety significant. I Determination of specific tests, inspections and verification activities to ensure the capability of the product to meet requirements for any critical characteristics.

TABLE 1. EXISTING IAEA GUIDANCE AND INFORMATION ON COMMERCIAL GRADE PRODUCTS AND THEIR SUITABILITY EVALUATION

Document	Paragraph	Relevant text
		(d) Performance of tests and acceptance of results on the basis of criteria. The critical characteristics required for any safety function should be included as acceptance criteria in the procurement documentI(e) The need to conduct verification or inspection of the product at the supplier's facility prior to authorization for delivery. (f) Evaluation of the capability of, and the controls applied by, the suppliers of the product. (g) Retention of records and documents that substantiate the product's conformity and history".
Procurement Engineering and Supply Chain Guidelines in Support of Operation and Maintenance of Nuclear Facilities (NP-T-3.21) [25]	5.1.4	— Commercial grade dedication [Page 99 – 106 on the subject of Commercial grade dedication]
Challenges and Approaches for Selecting, Assessing and Qualifying Commercial Industrial Digital Instrumentation and Control Equipment for Use in Nuclear Power Plant Applications (NR-T-3.31) [4]	All	"The primary intent of this publication is to provide a starting point for Member States to develop or improve their processes for the digital COTS justification. While high level expectations are identified in IAEA SSG-39 [2], the practical methods to justify digital COTS devices in nuclear safety applications often vary among Member States. In this context, this publication helps identifying good practices, based on the combined experience of Member States involved in related discussions. The key objectives of the publication are to: ▪ Identify the key challenges associated with the use of digital COTS devices in nuclear safety applications. ▪ Provide guidance on the requirements for what would constitute an adequate justification process".
Core Knowledge on Instrumentation and Control Systems in Nuclear Power Plants (NP-T-3.12) [26]	2.5.3	— Qualification of I&C equipment "Qualification is the acceptance process of assessing and determining the suitability of a pre-developed or pre-existing equipment (i.e. product or component) or a final realized I&C system design for a specific nuclear application or use".
	3.2.4.1.1	— Commercial-off-the-shelf (COTS) products

TABLE 1. EXISTING IAEA GUIDANCE AND INFORMATION ON COMMERCIAL GRADE PRODUCTS AND THEIR SUITABILITY EVALUATION

Document	Paragraph	Relevant text
		"There may be significant cost and availability advantages to using commercial products in NPP I&C systems, instead of products specially developed for nuclear applications. The development cost of commercial products may be amortized over tens-of-thousands of users rather than tens of units. This may reduce cost or allow more effort to be applied to product development, verification, and testing. Commercial products and the companies that make them have known track records that indicate the confidence that may be placed in the quality of both the product and the developer. Often there is extensive field experience that has driven design improvement. All other things being equal, the functional quality of a mature commercial product is often better than that of a one-of-a-kind system; even one built under the strictest quality assurance (QA) procedures. Functional qualification of commercial products may, however, be more difficult because commercial development processes may be less well controlled or less transparent than those described in Section 2.5.3. If so, functional qualification of a COTS item must address these shortcomings. In some Member States, functional qualification of COTS items is a significant element of the process known as commercial dedication'. Normally, this term also encompasses the concept that the organization that qualified an item must also notify regulatory authorities of any defects or non-compliances identified after that item is in nuclear safety service".

Strategies for evaluating the suitability of commercial grade products and their acceptance have been developed within the context of national regulation in some Member States. The commercial grade dedication methodology, which has been established for a number of decades in various Member States, is described in various guidance publications. Aside from guidance documents, some national standards have been published on the commercial grade dedication acceptance process. In Europe, a guideline on the use of commercial grade products in nuclear facilities which is generalized for use across jurisdictions was recently published [27].

In 1989, the U.S. Nuclear Regulatory Commission (NRC0 issued Generic Letter 89-02 that conditionally endorsed the Electric Power Research Institute (EPRI) guideline NP-5652 for the utilization of commercial grade items [28]. NP-5652 was revised in 2014. Furthermore, NRC issued in 2017 Regulatory Guide 1.164 [29] that conditionally endorsed this first revision of the EPRI guideline.

In addition to the United States, this guideline was later adopted by Canada, Spain, Slovenia, South Korea and many other IAEA Member States. In some cases, the rules for the acceptance of commercial grade items evolved domestically within these countries. In others, completely new methodologies appeared, or regulatory bodies made case-by-case determinations on the matter.

The guidance documents and standards in the table below are sometimes endorsed by national regulatory bodies as acceptable practice to meet expectations of regulation in procurement control or quality assurance. The information listed in the Table 2 should not be understood as comprehensive list but instead an overview of some selected examples.

TABLE 2. OTHER GUIDANCE AND INFORMATION ON COMMERCIAL GRADE PRODUCTS AND THEIR SUITABILITY EVALUATION

Code, Standard or Rule	Title	Type
EPRI 3002002982 [30]	Plant Engineering: Guideline for the Acceptance of Commercial grade Items in Nuclear Safety-Related Applications Revision 1 to EPRI NP-5652 and TR-102260	Guidance
EPRI TR-106439 [31]	Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications	Guidance
EPRI TR-017218-R1 [32]	Guideline for Sampling in the Commercial grade Item Acceptance Process	Guidance
10 CFR Part 21 [33]	Reporting of Defects and Noncompliance	Regulation
US DOE-HDBK-1230-2019 [34]	Functional safety of electrical/electronic/programmable electronic safety-related systems	Guidance
ASME NQA-1 [35]	Quality Assurance Requirements for Nuclear Facility Applications	Standard
FORATOM European Guideline [27]	Quality Assurance Guideline for Procuring High-Quality Industrial Grade Items Aimed at Supporting Safety Functions in Nuclear Facilities	Guidance

TABLE 2. OTHER GUIDANCE AND INFORMATION ON COMMERCIAL GRADE PRODUCTS AND THEIR SUITABILITY EVALUATION

Code, Standard or Rule	Title	Type
CSN Guía de Seguridad 10.8 Rev. 1	Quality assurance for the management of elements and services for nuclear installations (Garantía de calidad para la gestion de elementos y servicios para las instalaciones nucleares)	Regulation
UNE 73401:1995 [36]	Nuclear Facilities Quality Assurance	Standard
UNE 73403:1988 [37]	Use of Commercial Grade Items in Safety Related Applications of Nuclear Facilities	Standard
UNE-73104:1994 [38]	Guidelines for Dedication of Commercial grade Components in Nuclear Power Plants	Standard
ISO 19443:2018 [39]	Quality management systems – Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)	Standard
ISO/TR 4450:2020 [40]	Quality management systems – Guidance for the application of ISO 19443:2018	Guidance

3. SUITABILITY EVALUATION PROCESS

As part of the procurement process, when a potential product is identified a suitability evaluation process is typically undertaken to establish confidence on its' suitability to perform the intended functions. A suitability evaluation process is undertaken to establish confidence that a product is suitable for use in support of safety in a nuclear facility. This process is sometimes called a 'justification' process [4]. This Section presents the typical activities and considerations relevant to the suitability evaluation process in the context of commercial grade products. The strategic approach to the suitability evaluation process will vary from procurement to procurement.

This Section divides the suitability evaluation process into four segments, namely, design review, design verification, manufacturer readiness and quality control. The order in which these activities are presented is connected to their typical chronology. Special attention is given to quality assurance, quality control and risk elements throughout the process (see Fig. 2).

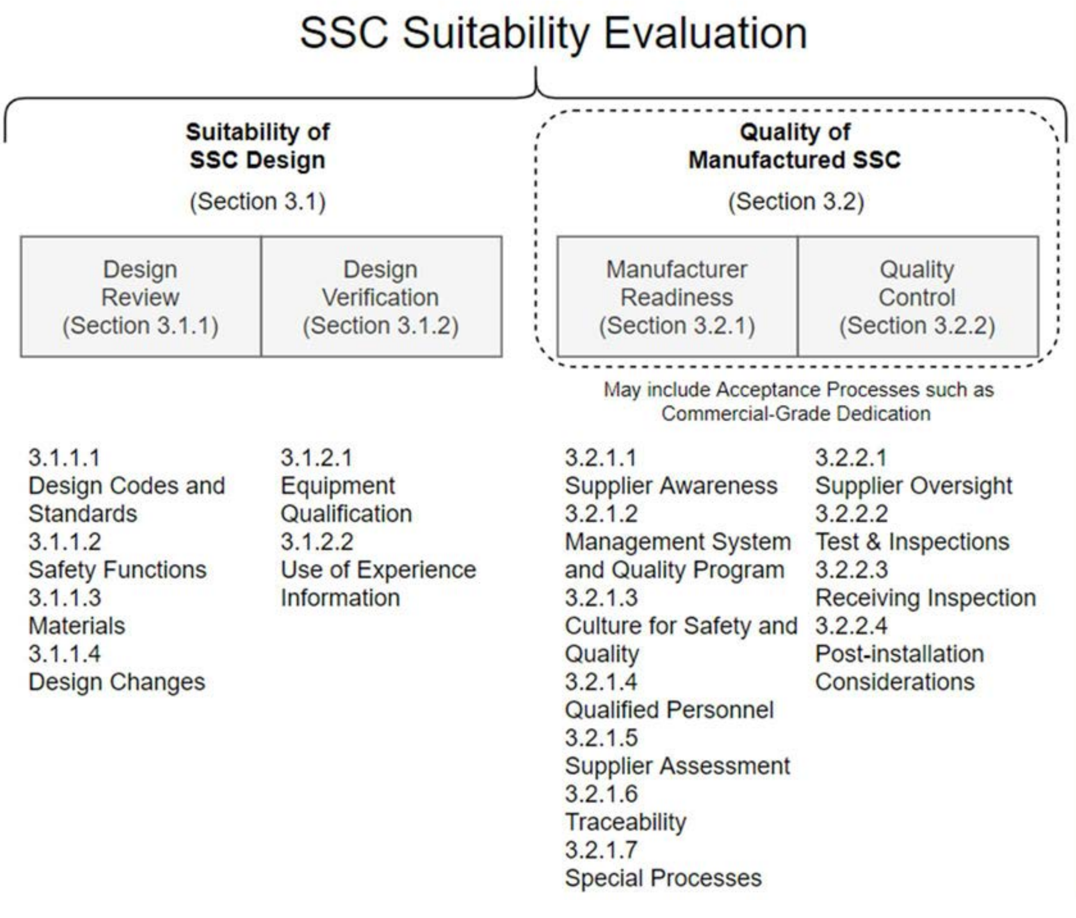

FIG. 2. Main elements of the suitability evaluation process for commercial grade items.

Once demand for an SSC or part thereof has been established by the developer and/or licensee, it becomes necessary to identify potentially appropriate products on the market. The process of finding potentially suitable suppliers and products is outside of the scope of this TECDOC. In this Section, it is assumed that potential suppliers and products of interest have already been discovered by the buyer. The suitability evaluation process begins when those suppliers and products start to be reviewed and assessed with respect to relevant requirements. An example of one NPP operator's suitability evaluation process is found in Appendix IV and examples of equipment suitability evaluation are provided in Appendices VIII - IX.

3.1. SUITABILITY OF DESIGN

Suitability of design consists of review of the design and its verification, as discussed in the following.

3.1.1. Review of design

Once identified, products need to be screened for their applicability against the design basis requirements of the intended application(s). This design review process[2] often involves engineering evaluation to ensure compliance with applicable requirements such as those related to design codes, materials, safety functions, reliability and/or performance of the product in the nuclear safety system. When commercial grade products are being considered, this part of the suitability evaluation process might require additional efforts when compared to nuclear grade procurement, such as clearly defining the items' safety function(s) and performance requirements.

Commercial grade products are designed for industries other than the nuclear industry, therefore their suppliers are likely to utilize codes or standards which may be unfamiliar to a buyer at an NPP. When evaluating the suitability of the potential product against the requirements of the NPP, care is taken to identify and, if necessary, justify any gaps between the requirements of the application and the design of the product. Ideally, the supplier provides support to the buyer during this process by submitting data sheets, technical drawings, operating experience, reliability data and other documentation describing the design features and associated product data, as necessary.

This section does not address testing or inspection of the physical product to establish design suitability (see Section 3.1.2) but rather only the review of documentation and data.

3.1.1.1. Design codes and standards

The suitability evaluation process can include an analysis of commercial design codes and standards as they relate to the expectations of the intended item use and installed location in the nuclear power plant.

Over the past three to four decades, standards in non-nuclear industries, such as ISO and EN, have undergone significant development. This includes the ISO 9000 family of quality management standards, which serve as the foundation for quality assurance in a wide range of industries. Since their introduction in 1987, these standards have become the most widely adopted globally and are used to ensure that items both meet customers' requirements and continually improve in quality. Also, national nuclear safety regulations often reference the ISO 9000 family of standards [11].

According to a recent study conducted by the Finnish utility Teollisuuden Voima Oy (TVO) [17], the quality assurance requirements for safety related components (such as valves) in Finnish nuclear facilities are similar to those of the oil and gas industry for the same components. This suggests that high quality, high reliability components and equipment can be produced using established non-nuclear industry standards, such as the American Petroleum Institute (API) and IEC. From a technical standpoint (including design, manufacturing, and assembly), the use of commercial grade items for safety classified components in nuclear facilities is therefore feasible [11]. Differences between nuclear-grade items and commercial

[2] Sometimes also referred to as a 'preliminary suitability assessment.'

grade items originate in additional tests to meet seismic and environmental requirements of the component and equipment in scope when used in a nuclear facility and more stringent QA requirements and documentation needs.

Commercial grade items are usually designed and manufactured according to industrial codes and standards specific to the technology type (e.g., solenoid valves) which describe main design, quality and/or qualification aspects. Examples of some commercial codes and other non-nuclear rules can be found in Appendix I.

3.1.1.2. Safety functions

Safety function is defined by the IAEA Safety Glossary as a

> "specific purpose that must be accomplished for safety for a facility or activity to prevent or to mitigate radiological consequences of normal operation, anticipated operational occurrences and accident conditions" [41].

For the purposes of this publication, the safety functions of interest are those functions of items important to safety. These safety functions, at the level of individual plant equipment, support the fundamental safety functions of the NPP, such as the control of reactivity.

Safety functions to be performed by items are defined during the process of designing an NPP and are an important factor in classifying the safety significance of items important to safety [12].

A clear understanding of items' safety functions facilitates the suitability evaluation and is useful during a commercial grade dedication process, for example. A lack of information regarding safety functions for a given plant application (where a commercial grade item is to be introduced) greatly challenges the suitability evaluation and demands added conservatism. This may be the case when a third party is accepting a commercial grade item or when the item being procured is to be installed in many plant locations with varying functional expectations.

Critical characteristics[3] are a subset of those properties of the item which are necessary to provide confidence it can perform its safety function(s). Critical characteristics can include design, performance and/or dependability characteristics of the item. Maintaining equipment qualification may demand that attributes related to environmental or seismic resistance also need to be considered when developing a set of critical characteristics. Critical characteristics are selected by suitably qualified personnel who are familiar with the commercial grade product technology. Examples of critical characteristics include dimensions, materials, tensile strength, hardness, or configuration, among many others depending on the product and engineering judgement.

In some Member States, the suitability evaluation process for commercial grade items is focused on verifying the conformance of critical characteristics with respect to defined acceptance criteria, thereby providing confidence in the ability of the item to perform the necessary safety function(s). In the context of commercial grade item procurement and acceptance, acceptance criteria are specified bounds on the value of physical, performance or dependability attributes used to assess the ability of an SSC to perform its intended function.

[3] Sometimes referred to as 'critical characteristics for acceptance'

3.1.1.3. Materials

Nuclear design codes set stringent requirements on materials to be used for components important to safety. These requirements concern material composition (including melting process), manufacturing & possible heat treatment, mechanical properties and their validation (i.e., sampling and mechanical tests) and, for example, maximum cobalt content. To meet these requirements specific standard or custom steels and alloys have evolved for safety-classified components and reactor internals, which are commonly used in today's operating LWRs (e.g., stainless steels 304L and 316L). Compliance with all these requirements needs to be demonstrated. Material composition and cobalt content of safety-classified components and reactor internals need to be validated via ladle and product analyses in most cases. Mechanical properties need to be validated via well-defined standardized material characterization tests on samples extracted either from ingots or additional material batches produced with the component.

For pressure bearing components in non-nuclear industries (e.g., oil & gas industry, chemical industry), i.e., commercial grade items with high requirements on their integrity, similar requirements exist concerning material composition, manufacturing, heat treatment, mechanical properties, etc. These are defined in associated codes & standards (e.g., ISO, API, etc.) and need to be adequately validated. However, the requirements for such commercial grade items may not be as stringent as for safety-classified components in nuclear facilities.

The cobalt content of the commercial grade item is crucial when the item is to be installed inside the containment of a nuclear power plant. Nuclear design codes define stringent upper limits for the cobalt content of safety-classified components and reactor internals (see e.g., Sections B 2400, C 2400, D 2400, G 2400 of AFCEN's RCC-M Design and Construction Rules for Mechanical Components of PWR Nuclear Islands) [20]. The allowed cobalt content depends on the level of exposure to the primary coolant and neutron irradiation. Reactor internals that are exposed to the primary coolant all the time and face heavy neutron irradiation may only contain maximum 0.06% cobalt according to RCC-M, whereas for SC3 mechanical components, which are usually not directly exposed to the primary coolant, higher cobalt contents are allowed up to a certain limit.[4] Such limits on cobalt content of components do not necessarily exist in other industries. A too high cobalt content of a commercial grade item most likely prevents its use for safety classified components in nuclear facilities.

In certain Member States, such as the United States materials used in certain pressure retaining applications are required by regulation to meet material standards such as ASME Section II. For this reason, such items need to be furnished by an approved nuclear supplier with ASME accreditation and cannot be dedicated for use.

3.1.1.4. Design changes and their management

Changes to SSC design in NPPs can impact safety and the licensing basis of the facility itself. It cannot be assumed that commercial manufactures have the same understanding as the licensee of what constitutes a meaningful design change to their product. The suitability evaluation process, especially that part which seeks to establish the suitability of the manufactured product, needs to address the potential for undeclared design changes during the course of procurements.

[4] According to RCC-M the cobalt content of SC3 components may not exceed 0.20% if it has a pressure resisting function or if its surface area in contact with the coolant is at least 1 m2.

If a commercial grade item is intended for installation in a seismically or environmentally qualified application or component, the licensee accepting the item should be confident that, once installed, the item will not adversely affect the original qualification of the system or component. Justification is provided during the reassessment of equipment qualification whenever changes occur that could alter the initial equipment qualification.

Commercial grade item suppliers, including original equipment manufacturers have no obligation to divulge design or manufacturing history; it is important to recognize this as part of the acceptance process (specifically for items requiring qualification such as environmental or seismic). Design changes may be identified through review of the manufacturer's literature such as drawings, inspection of configuration (model number, etc.), or detailed inspection and testing.

If the manufacturer follows a typical commercial quality management program such as ISO 9001, then they may have some form of configuration management program whereby they identify any changes that have been made throughout the product lifecycle. If such program is being followed, is appropriately robust and can be relied upon would need to be evaluated by the buyer. The concept of configuration management is well defined in IAEA NR-T-3.31 Section 5.5, as it relates to configuration management of hardware and software [4]. Furthermore, an upcoming IAEA TECDOC on Design Basis Reconstitution for Long Term Operation of Nuclear Power Plants also addresses major aspects of the design modification process [42].

3.1.2. Design verification

This sub-section addresses the physical testing, analysis or review of operating experience performed in order to verify that the commercial grade item is suitable for the intended application in support of nuclear safety. The activities described in this sub-section do not always require a physical sample of the product in question, some, such as an analysis of qualitative reliability and risk analysis are generally paper based. Type testing, on the other hand, does require a test specimen. This part of the suitability evaluation process is not fixed chronologically, it might take place before or after the procurement of the commercial grade products intended for use or even after their delivery, but it always is completed prior to an authorization to use the product in service.

The suitability evaluation process includes consideration for the equipment qualification program requirements of the licensee as dictated by IAEA SSR-2/1 (Rev. 1) Requirement 30 for nuclear power plants [12]. Commercial grade items need to undergo equipment qualification if their specified intended application in the nuclear facility requires it, which it typically would if the application is categorized in a safety class.

3.1.2.1. Equipment qualification

The qualification of a commercial product for its application in nuclear power plant systems important to safety could be more difficult because its development process may be less controlled than what is required for a nuclear-grade product. Often, equipment qualification is almost impossible without cooperation from the original equipment manufacturer.

Equipment qualification demonstrates that products will be capable of performing its intended safety function(s) in service conditions specified for the nuclear installation in operating modes and in accidents. Service conditions may begin with an initiating event, e.g., seismic events and electromagnetic phenomena, and other relevant conditions like humidity, temperature and radiation need also to be considered on the same occasion. Equipment qualification includes an evaluation of the ability of the item to perform in normal operation, postulated accidents and during external events not excluded by the design of the nuclear installation. Equipment qualification aims at preventing simultaneous unavailability of safety equipment in specified service conditions.

The IAEA Specific Safety Guide 69 [81] presents a structured approach to equipment qualification and its preservation in nuclear installations in accordance with IAEA SSR-2/1 (Rev. 1) [12], IAEA SSR-2/2 (Rev. 1) [22], IAEA SSR3 [43] and IAEA SSR-4 [44].

Qualification methods described in the IAEA Safety Guide applies to both nuclear grade products as well as commercial grade products that needs to be assessed/qualified to confirm their suitability of meeting the functional and performance requirements while operating within specified service conditions. See Appendix II for further information on this subject.

3.1.2.2. Use of experience information

Suppliers of serially manufactured commercial grade items often collect operating experience and reliability data of their products. The suppliers may not always wish to release this kind of valuable information to consumers as potentially the competitors might use it, too. In any case, it is recommended to request operating experience (OPEX) and reliability data from the supplier latest as a part of the procurement process.

OPEX information normally comes in many forms of experienced problems and disturbances. It is called reliability data when it includes indicators such as failure rate, mean time between failures or mean time to failure. Often such values are the only available failure data for a component. Appendix III contains further discussion of OPEX and reliability data.

3.2. QUALITY OF MANUFACTURED ITEMS

Manufacturer readiness and the quality control play important roles in the quality of the manufactured items. The different factors belonging to them are discussed in the following.

3.2.1. Manufacturer readiness

Not only the product itself, but also the potential supplier or manufacturer of the product from whom the buyer is considering procuring is addressed in the suitability evaluation process. When procuring commercial grade items, the supplier is likely not familiar with nuclear industry requirements. However, by evaluating the supplier’s organization the licensee might discover that the commercial grade quality management system already in place are similar to those expected of nuclear-grade suppliers.

The supplier organization can be evaluated, before or after a contract for the supply of products has been established, to achieve confidence in their ability to provide a high quality product. Evaluations of the supplier’s organization in the form of questionnaires, assessments or visits to the supplier’s facilities can be useful in collecting evidence of the supplier’s ability to deliver a compliant product.

The management system of the supplier, their ability to trace the parts and raw materials which comprise a final product, the training of their personnel and the organization culture in terms of safety and quality can all be important factors to consider. An important ability of the supplier is the ability to identify, track and resolve non-conformances during fabrication and assembly. If a defect were to be discovered the supplier after delivery of a product to the customer, the supplier is ideally prepared to inform all affected users and recall products, as necessary.

3.2.1.1. *Applicable requirements*

When procuring commercial grade items for the use as an item important to safety, it is necessary to pass on all applicable requirements to the supplier to ensure the commercial grade acceptance process can be fulfilled to the extent required. Applicable requirements may include commercial terms and conditions, quality, and technical requirements. Support from the supplier throughout this process is important to satisfy the acceptance process.

Below is a list of example requirements which may be imposed on the supplier when procuring a commercial grade item (as applicable):

- Material test report (MTR): For items where materials of construction are important, the MTR may be used to provide the materials of construction, mechanical properties, chemical analysis, etc.;
- Evidence of processes, procedures or other work instructions to prevent counterfeit, fraudulent or suspect items (CFSI);
- Special Processes Requirements: This requires the supplier to submit specific information if special processes such as welding are applicable;
- Lot/Batch Requirements: This requires the supplier to provide items from the same manufactured batch, lot, or date-code wherever possible;
- Shelf Life: This requires the supplier to supply an item with a minimum specified shelf life based on the expiration date, or manufacturing date;
- Design Configuration Changes: This requires the supplier to identify if any design changes have been made since the product manufactured on DD/MM/YYYY (add any design version codes, etc.). This is used to assess any design changes for subsequent purchases of items that were previously successfully evaluated for suitability.

3.2.1.2. *Management system and quality program*

A commercial grade item is furnished by a manufacturer or supplier whose management system does not explicitly conform with national nuclear regulation or licensee expectations relating to items important to safety and their supply. The ability of a supplier to deliver a product conforming to the procurement requirements often relies upon the soundness of their management system. Like at nuclear facilities, management systems at supporting organizations like manufacturers ideally integrate all elements of management such that all requirements are adhered to. In the context of the commercial grade item suitability evaluation process, the quality management aspects of the supplier’s management system are especially relevant.

Manufacturers of commercial grade products often adhere to general, sector-specific and/or customer-specific quality management rules and standards. In this regard, the manufacturer might be certified by third parties or other industry groups. An evaluation of the supplier’s management system by means of an audit, for example, can be a means to gain evidence.

Where practicable, the management system of a commercial supplier could be credited where its processes, procedures, work instructions or other quality controls are deemed sufficient by the licensee.

3.2.1.3. *Culture for safety and quality*

International Nuclear Safety Advisory Group INSAG 4 gave a definition of safety culture in 1991 [45]. This definition has been later deepened, for instance, in the IAEA safety standards GSR Part 2 [21], introducing the term ‘culture for safety’ and thus emphasizing that safety is one facet of a culture and GS-G-3.5 [24]. As a wider discussion about the nature of culture for safety falls outside this publication, we discuss manufacturer in the following.

In this respect, it is important to note the following from INSAG4 [45]:

> "Supporting organizations, which include those responsible for design, manufacture, construction and research, influence greatly the safety of nuclear plants. Their primary responsibility is for quality of the product, whether this is a design or a manufactured component, installed equipment, a safety report or software development, or any other output important to safety. The basis for Safety Culture in such an organization is the directive establishing policy and practices to achieve quality, and thereby to meet the safety objectives of the future operator."

Clearly, it is important to abide to the principles to culture for safety tightly at the construction and operating nuclear site in all activities. This needs to be achieved independently of the management structures, and it is the operator that is finally responsible for this. When it comes to lower tier suppliers in the supply chain, the contribution to nuclear safety comes via the conformance to the requirements i.e., quality. In many cases manufacturing and related services take place off-site – sometimes even on another continent. In such cases suppliers may not fully understand of the safety significance or required functions of their products [46]. Independent of the specifics of the procurement scenario, it is crucial that the whole supply chain conforms to the principles of good quality management. This also includes cultural aspects, as all contribute to quality.

ISO 19443:2018 presents certain principles of culture for safety applicable to organizations aiming to achieve customer satisfaction when supplying items important to nuclear safety [39]. They have to do with senior management, communication, documentation, reporting and operational experience. This applies to both manufacturers and service providers.

Other quality management or quality assurance standards such as ISO 9001 present principles to ensure the products and services conform with the requirements including some important aspects that may be seen to belong to culture [47]. The ISO 10010 standard provides guidance to understand, evaluate and improve organizational quality culture [48].

3.2.1.4. Qualified personnel

The acceptance of commercial grade products is a cross-functional activity at any nuclear power plant, personnel from design engineering, purchasing, supply chain and quality management are all likely to play a role in the selection of a commercial supplier and the acceptance of that supplier's product for use as an item important to safety in the plant. IAEA General Safety Requirements Part 2 clearly states that "the organization shall have a clear understanding and knowledge of the product or service being supplied" [21]. To be an informed customer at the level of equipment's constituent parts can be challenging, with or without the support of one's supplier. For this reason, the backing of a methodology for the acceptance of commercial grade products from senior management is necessary.

The successful implementation of a commercial grade product acceptance process relies on testing an inspection capabilities, qualified personnel, and engineering judgement. For this reason, a systematic approach to the recruitment, qualification and training of personnel, as laid out in IAEA Safety Guide NS-G-2.8, along with a methodology to evaluate the effectiveness of training is essential [49] [50].

Power plants in some Member States have opted to create a new function which has the ability to manage activities such as the acceptance of commercial grade products or equipment qualification. This function, referred to as procurement engineering integrates relevant aspects of design engineering and purchasing [25].

Commercial suppliers, following commercial codes and standards, are often familiar with the close connection between qualified personnel and the quality of their final products. Modern quality management system standards demand competent workers. ISO 9001:2015, for example, requires that organizations determine and ensure the necessary worker competencies as they relate to the performance and effectiveness of the quality management system [47].

The manufacturing of equipment presents certain occupational hazards. Commercial suppliers with occupational health and safety management systems (e.g., ISO 45001:2018) may have special requirements related to the qualification of personnel involved in key fabrication steps, such as welding.

When performing a performance-based audit as a part of the commercial grade product justification process, it can be worthwhile to review the qualifications of supplier personnel involved in designing, manufacturing, assembling, inspection and testing the products.

3.2.1.5. Supplier assessment

Assessments of the commercial grade item manufacturer can support the justification of the use of those items in NPP safety systems.[5] Assessing or auditing of the commercial manufacturer in a performance-based manner is useful as a means of verifying the suppliers' ability to control the design and quality of the items they are furnishing.

Supplier assessments are a fundamental part of quality assurance and quality control activities in nuclear facilities and activities [19]. Supplier assessments performed by the customer (sometimes referred to as second party audits, see TECDOC 1910 [19]) might focus on the supplier's management system or specific implementation of procurement requirements, such as those related to detecting Counterfeit, Fraudulent and Suspect Items (CFSIs). Supplier assessments sometimes are performed face-to-face, during which time the customer (e.g., an NPP) can support a supplier who may be new to the industry or the fundamentals of nuclear safety.

Third party assessments for the purpose of certification to a standard are examples of compliance-based audits. Beyond ensuring compliance with a code or standard, supplier assessments can also be used to observe specific activities related to the design, manufacture, assembly or testing of purchased products.

In collecting evidence of the suitability of commercial grade products as a part of the evaluation process, performance-based audits are sometimes used. Table 3 compares key features of performance-based versus compliance-based audits. This is because a manufacturer's compliance with a non-nuclear standard is not necessarily useful evidence of an item's suitability. It might be more valuable to gather an understanding of how the manufacturer is performing their work with respect to what is important to the NPP procuring the item, regardless of the standards they (the manufacturer) may claim to be adhering to.

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[5] When such audits are carried out as a part of the commercial-grade dedication process they are called a commercial-grade survey.

Performing a performance-based audit is one of the methods for verifying critical characteristics of an item within the commercial grade dedication (CGD) methodology (see Section 4). In that methodology a performance-based audit is called a commercial grade survey.

TABLE 3. COMPARISON BETWEEN PERFORMANCE-BASED AUDITS AND COMPLIANCE-BASED AUDITS

Performance-based	Compliance-based
• Emphasis on processes and activities related to items or services of interest • Emphasis on in-process activities • Flexible schedule during the audit/survey, expect to focus on areas of concern recognized only during the survey • Sparse pre-planned sequence	• Emphasis on codes, standards and laws • Fixed schedule revolves around each and every requirement • Addresses documented QA program for compliance/non-compliance with respect to norm(s) or standard(s) • Highly standardized • More about reading than observing

EPRI has published guidelines for performance-based supplier audits and conducting audits of supplier Commercial grade Dedication programs [51]. Discussion on Method 2, Commercial Grade Survey in EPRI 3002002982 discusses assessment of commercial supplier's controls that are directly related to the quality of the items the commercial supplier is providing [30].

3.2.1.6. Traceability

Traceability in production and manufacturing is a familiar concept to nuclear suppliers and nuclear operators. Sometimes defined as the "ability to verify the history, location, or application of an item by means of recorded identification" [23], traceability is important in that it enables the end-user to have confidence that the product is the one they ordered. Furthermore, traceability can give the buyer confidence that the manufactured lot is homogeneous, which leads to the justified use of sampling during the acceptance process. Sampling plans have long been used in quality control and are integral parts of Member State's existing guidelines for the acceptance of CG products [24]. If traceability is only partially able to demonstrate that a manufactured lot of products were of the same configuration, made from the same materials, according to the same methods, then it becomes necessary to sample at higher and higher rates which may become cost prohibitive.

Although commercial suppliers are no doubt familiar with the concept of traceability, their management systems control the traceability of their products to varying degrees. Special processes like welding are especially sensitive in the nuclear industry and require high degrees of traceability when it comes to welding materials and gas (if present). Commercial suppliers of mass-produced goods frequently embrace lean enterprise principles which includes establishing 'just in time' manufacturing, often including a scheduling system for material flows [52]. In these scenarios, traceability between a particular customer's ordered lot and quality records related to constituent parts may not be demonstrable.

The concept of traceability is important when it comes to quality records which furnish evidence of compliance with defined specifications and acceptance criteria. Without such records, the buyer needs to invest their own resources to control the quality of products, often by means of destructive testing. Having a clear record of what raw materials, individual parts and sub-assemblies went into a safety-related product, how they were configured and how those items performed during inspections or tests can add meaningful evidence to the justification case.

Additionally, the traceability of 'sign-off' and 'pass' at particular manufacturing stages by the manufacturing staff and management are of particular importance to assure the appropriate quality control arrangements have been in place.

3.2.1.7. Special processes

Special processes or critical manufacturing processes are production processes that directly impact product quality, but which cannot be verified by subsequent monitoring or measurement. Such processes need therefore to be validated by ensuring that the performance of the process is being undertaken correctly and consistently. In the case of welding, for example, the organization should monitor the temperature, pressure and cycle-time of the welding operation and ensure that the welder is competent to undertake the process. Non-destructive examination and testing tools are available, such as visual inspection, use of a liquid/dye penetrant, or through magnetic particle, ultra-sonic and radiographic inspection, but the strength of the weld can only be tested through a destructive test whereby the joint is pulled or bent to separate the two materials that had been welded together. The IAEA Glossary states: "a process where the conformity of the resulting product cannot be readily or economically verified is frequently referred to as a special process" [41].

For these reasons, special processes are often defined in production plans along with verification methods and acceptance criteria. Verification methods can include a qualification procedure for the operator and equipment, controls on the physical and environmental pre-requisites for the operation, usage of defined work procedures, and regular re-validation. Together these methods seek to demonstrate that the production process is able to fulfil the requirements of creating a product that is suitable for its intended safety-related application.

Several critical manufacturing processes are deemed to be special in industries where safety is a priority. These include casting, machining, welding, forming, adhesive bonding, cladding, heat treating, and non-destructive testing. By their nature, special processes are often viewed as activities that the original equipment manufacturer controls directly, but some, like non-destructive testing, for example, may be outsourced. Many of the lower tier original equipment manufacturers in the nuclear supply chain are also suppliers to other industries where special processes are defined and controlled in-house to common industry-defined criteria. They might therefore already possess quality management systems that would in principle satisfy the requirements of the nuclear industry in terms of special processes.

3.2.2. Quality control

Monitoring of supplier activities during a supply contract is a common way to gain confidence in the quality of procured products, it may also be a regulatory requirement. Typically, supplier oversight takes the form of quality control actions such as hold[6] or witness[7] points along the chain of manufacturing activities during which the customer, a designated third party or an independent organization observe tests, inspections, or special processes at the supplier's facility. Commercial grade product suppliers may or may not be familiar with the concept of supplier oversight depending on the market segment in which their products are typically sold. The direct observation of the conformance of a product with its requirements could build significant confidence in the product's quality. Resources expended on supplier oversight

[6] A manufacturing activity may not proceed beyond a hold point without the approval of the customer or customer's representative.
[7] A witness point means that the manufacturer needs to notify the customer or customer's representative before proceeding. The activity may continue after the agreed notice period if the purchaser does not attend.

activities and the rigor with which such activities are undertaken is a function of the safety significance of the application for which the product is intended with due consideration for credible risk elements.

Once a product has been delivered, its quality can be reviewed in a variety of ways as part of the suitability evaluation process. Receipt inspection is a fundamental part of verifying the basics of a delivery, such as the confirming the correct order number, product quantity, configuration or size and documentation certifying the products meet their requirements. In addition, a customer who is now in possession of the final product might decide to perform additional acceptance activities as a part of establishing confidence in the product's suitability for use in support of safety. Delivery verification activities can prove to be especially useful for commercial grade products since it represents an opportunity for the customer to investigate the product and validate its conformance under its own management system.

Some equipment can complete the suitability evaluation process only after passing post-installation tests or inspections, which sometimes are also part of the design validation of the product.

3.2.2.1. Supplier oversight

Supplier oversight activities[8] include the witnessing of manufacturing, assembly, inspection and/or testing by the supplier or sub-suppliers for the purpose of ensuring safety functions of a commercial grade product. In some Member States, in the context of commercial grade item acceptance, these activities are referred to as source verification. Hold points and witness points are typically used to organize oversight during fabrication [53]. These concepts appear in inspection and test plans, but, in the case of commercial grade items, may instead be written directly into the supply contract. The benefits of verifying critical characteristics or other attributes of a commercial grade item by means of witnessing versus the associated risks arising from disrupting a supplier's operations need to be considered.

The observation of an activity during the production of a commercial grade item is a means to verify a critical characteristic or other attribute of that product or the fabrication process conforms with defined acceptance criteria. Oversight activities, when allowed by the commercial supplier, can save time and effort spent on post-delivery tests and inspections. The verification of an item's conformance with requirements by witnessing during fabrication has the potential to offset the need for destructive testing and inspections at a later point.

For mechanical or electro-mechanical equipment, oversight activities may be well suited for verifying the conformance of parts or sub-assemblies not easily accessible once the product's manufacturing and assembly is complete. Special processes such as welding, heat treatment or surface treatment are good candidates for verification by witnessing because it can otherwise be difficult to verify conformance.

The ability of the buyer to enter the facilities of a commercial supplier for the purpose witnessing of a particular step in product fabrication is not always possible. Commercial suppliers involved in large volume serial production manufacturing may be unable or unwilling to accommodate this type of intervention from individual customers. In such cases, the buyer cannot rely on supplier oversight activities to provide evidence in support of the suitability evaluation process for the product. In lieu of supplier oversight, evidence will need to be gained via alternative elements of the suitability evaluation process.

[8] Sometimes referred to as source verification or source surveillance.

Remote source verification techniques may be applied to accomplish oversight activities when appropriate to minimize disruption at the commercial supplier's facility. Remote source verification would not be appropriate for initial qualification of a commercial supplier. However, remote techniques might be appropriate when the licensee has experience with the supplier, is familiar with the supplier's facilities and processes, and the supplier has a successful performance record with the licensee. Use of remote verification techniques should be discussed with the supplier in advance to ensure the necessary equipment is available and personnel are proficient in use of the equipment. Additional information on use of remote techniques is available in *Remote Source Verification During a Pandemic or Similar State of Emergency: Screening Criteria and Process Guidance, 3002019436-A* [54].

3.2.2.2. Tests & inspections

Quality control activities, when performed on items such as mechanical or electro-mechanical equipment, often comprise the execution of tests or inspections undertaken to verify conformance with stated requirements. The subject of quality control is not unique to the nuclear industry; manufacturers of commercial grade items are likely to be carrying out quality control activities on their own products as a means of ensuring conformance with customer requirements and thereby customer satisfaction. Commercial suppliers following lean enterprise principles might be leveraging quality control to a high degree in order to stabilize manufacturing processes and reduce scrap rates.

As a part of ensuring the suitability of commercial grade items, the licensee might consider taking credit for quality control measures incorporating tests or inspections established by the manufacturer. These measures could be within the scope of a supplier audit (see Section 3.2.1.3) or the buyer might witness the supplier performing the tests and inspections (see Section 3.2.2.2). Alternatively, or additionally, the licensee can perform tests or inspections themselves using in-house resources under their quality assurance program or by outsourcing to a qualified supplier.

Capability of the entity purchasing commercial grade equipment to test and inspect it during the acceptance process is essential. In addition to initial purchase of measuring and test equipment, it is important to recognize other start-up costs such as establishment of procedures and processes for use of the measurement and test equipment, as well as training and qualification of personnel who will perform tests and inspections and document the results. Ongoing costs and activities include periodic, calibration, maintenance, and in some cases subscriptions to software and data library updates. Associated risks include failure to follow applicable processes, lapses in qualifications of inspectors, and use of equipment that is out of calibration.

3.2.2.3. Receiving inspection

IAEA GS-G-3.1 states that "products and associated documents should be inspected immediately upon receipt in order to verify that they meet specified requirements" [24]. Commercial grade products typically undergo the same receipt inspection process as nuclear-grade products intended for use in a given safety and quality class arriving at a nuclear power plant. A thorough receipt inspection is an especially important preventive action against substandard, counterfeit, and fraudulent items [55]. In the case of off-the-shelf item procurement, receipt inspection represents the first interaction the buyer has with the items and any associated documentation.

The buyer may choose to perform more or less rigorous receipt inspection based on a graded approach. In addition to confirming the basics of an order's conformance with its requirements upon receipt such as, for example, quantity or configuration of the product, receipt inspection activities can also seek to control the quality of the delivery according to established acceptance criteria. Additionally, receipt inspection is one way in which NPPs have the opportunity to detect counterfeit or fraudulent items before they enter service [55]. When quality control activities being undertaken to establish the suitability of the delivered commercial grade item cannot be reasonably performed at receipt inspection, the item is sometimes sent to a separate physical area at the nuclear power plant or within its warehouse for additional investigation prior to releasing the item for installation and use.

3.2.2.4. Post-installation considerations

In some cases, the justification of the suitability of a manufactured commercial grade product is supported by quality control actions taken once the item has been installed in its final intended position in the nuclear power plant. Post-installation tests or inspections represents the last opportunity to collect evidence related to the suitability of a commercial grade item prior to which the item goes into service. The management system of the nuclear power plant ensures that, although the item is installed, the item is not relied upon to perform its safety function until its suitability has been established and all acceptance criteria have been met. Items important to safety often undergo some sort of commissioning procedure in an NPP, in the same manner commissioning of a commercial grade product could include steps as a part of its suitability evaluation in case the evaluation was not already completed at an earlier stage.

3.3. RISK CONSIDERATIONS

Risk analysis has traditionally been used in nuclear power industry for evaluation and development of nuclear (a.k.a. radiological) risk. Besides nuclear safety applications, risk analysis methods may be useful in performance assessment, maintenance optimization, configuration management and risk informed decision making, for example. This Section presents typical risks related to design of the products, the procurement process and supplier quality management. In addition, some qualitative and quantitative risk analysis methods, potentially applicable to the procurement of commercial grade products intended for use in safety systems at NPPs are presented in Appendix III.

3.3.1. Design related risks

Design risks refers to potential problems or issues that may arise due to the physical properties of the commercial grade structure, system or component being procured.

3.3.1.1. Common cause failures

Common cause failures (CCF) are failures that cause inoperability due to the same cause in several structures, systems, or components. They may lead to complicated accident scenarios and need to be avoided. The best general management strategy against CCF is functional diversity. The highest degree of diversity is assured through different functional principles and different personnel actions at NPPs. Sourcing products from different manufacturers with different design and manufacturing practices may also decrease CCF-related risks.

The presence of diversity in a design does not impact the safety classification of equipment that perform a safety related function or preclude the need to perform commercial grade dedication.

3.3.1.2. Different regulatory and environmental requirements

Regulatory requirements differ across the IAEA Member States. Changes in regulation arising, e.g., from operating experience and recent studies also often takes place. A national regulator has the power to set conditions under which a decision to use commercial grade items in safety systems is acceptable. Early engagement of prospective suppliers with the requirements of the national legislation and regulation is important for them to understand what exactly will be necessary for successful suitability evaluation. Generally, acceptance to use of commercial grade items has increased during the past few decades in the IAEA Member States.

Furthermore, environmental conditions may differ between sites. This may lead to a situation where standard commercially available products that are used at one site may not always be environmentally qualifiable to be used at another site even if the units would represent the same family of plant design. An example this is seismicity.

3.3.2. Procurement related risks

Procurement related risks refers to potential problems or issues that may arise as a result of the procurement process or intention to procure commercial grade products.

3.3.2.1. Supply chain

IAEA safety standards such as GSR Part 2 [25] define requirements for managing the supply chain and procurement. IAEA Nuclear Energy Series No. NP-T-3.21 [25] covers procurement and supply chain issues in a detailed manner, and it includes a section on typical risks and risk management. Changes in the role of supply chains and a licensee's QA/QC activities when moving from construction phase to operation phase are described in both NP-T-3.21 and TECDOC 1910 [19] [25]. An IAEA Nuclear Energy Series publication on "Integrated Life Cycle Risk Management for New Nuclear Power Plants" discusses risks related to suppliers and supply chains in new build NPP projects [56]. To some extent this discussion can be applied also to suppliers and supply chains of commercial grade products.

Counterfeit and fraudulent items (CFIs) need to be managed in the nuclear industry [55]. Commercial grade replacement items are recognized as one potential avenue for the introduction of CFIs into nuclear power plants. Engineering involvement in the suitability evaluation process for commercial grade products is important to combating CFIs. It is beneficial for the buyer's organization to have a clear understanding of what constitutes an at-risk procurement, such as the first-time procurement of a commercial grade product through an unknown distributor.

3.3.2.2. Localization and globalization

IAEA Nuclear Energy Series No. NG-T-3.4 and NP-T-3.21 [25] discuss procurement localization issues in detail. Global supply chains operating according to the just-in-time principle normally function well if no disturbances occur within the logistics chain. Recent pandemics and supply chain bottlenecks have led to a need to reconsider supply chain strategies. Having manufacturers located nearby can be beneficial and could be a part of procurement and stakeholder involvement strategy. In all cases, a commercial grade product suitability evaluation process is developed to be country- and organization-specific, only in this way can it be easily implemented and accepted both by the nuclear and non-nuclear stakeholders.

Localization of equipment or services supply may sometimes be required due to political or commercial reasons. It is usually an important component of any new nuclear program planning and execution. Expanding localization plans with consideration of ability to use commercial grade items for safety application under an established process may help both the country and the vendor in meeting the localization objectives in an efficient manner.

Risks and mitigating actions related to supply globalization and localization need to be assessed as a part of strategic procurement decisions. Measures may include introducing only proven technology, a gradual introduction of local products, or establishing a joint-venture company to ensure knowledge transfer. Potential disturbance situations need to be taken into account in the analysis.

3.3.2.3. Import restrictions and export control

Export control seeks to prevent nuclear proliferation. Nuclear vendor countries control technology, materials and equipment that might be used for nuclear weapons. Export control also applies to so-called dual-use equipment and information material, e.g., detailed design documents. Some countries may not have the ability to import some types of commercial grade products or services e.g., based on the used materials (not fulfilling directives), the country of origin — or due to other factors e.g., potential sanctions.

In the planning phase of the procurement of commercial grade products, control restrictions need to be analysed closely as any infringement may seriously affect the process. Political crises, military conflicts and regional instability may lead to e.g., sanctions. It is essential to maintain a good overview of the situation and update the risk analyses accordingly.

3.3.2.4. Potential for unevaluated changes

Establishing suitability of design of a commercial grade item is a prerequisite to using a commercial grade item in a safety-related application. Establishing suitability of design typically involves review of specification sheets, drawings, and other manufacturer documentation and design analysis to determine if the product as specified will be capable of performing its design functions, including successfully interfacing with connected equipment. Qualification testing may also be required to establish suitability of design for some items that need to function in harsh environmental conditions or during and after seismic events.

A risk associated with use of commercial grade items is that the manufacturer’s baseline design (bounding conditions) for commercial grade products may allow for changes in materials, dimensions, manufacturing processes, and addition of digital content without changes in part number or other indications that the design has changed.

Therefore, when a commercial grade item is acquired for use in a safety-related item, the procurement and acceptance processes (dedication activities) should assure that when the item is received, it indeed possesses the characteristics upon which suitability of design was based.

3.3.3. Quality related risks

Quality related risks are less frequently a topic in traditional risk assessment, and therefore it deserves special attention in this TECDOC.

3.3.3.1. Omitting the monitoring of supplier activities

Oversight of supplier activities as part of the suitability evaluation process is sometimes omitted when, for example, the supplier does not allow the customer to witness fabrication activities or if the product being procured is of a simple design. Also, the supplier may not want customer staff in its manufacturing facility because of confidentiality reasons (e.g., to protect intellectual property). The direct observation of the conformance of a product with its requirements can build significant confidence in a product's quality. Resources expended on supplier oversight activities and the rigor with which such activities are undertaken is a function of the safety significance of the application for which the product is intended with due consideration for credible risk elements. When omitting the monitory of supplier activities during the fabrication of a commercial grade product, evidence needs to be collected in other ways by utilizing other elements of the suitability evaluation process.

3.3.3.2. Cost of destructive tests

Destructive testing as means to verify the conformance of a commercial grade product with the intended application's design basis may be applied alone or in combination with analysis and use of operating experience. Destructive test programs require careful planning, especially when the cost per test is high due to high cost of test arrangements or if items to be tested are expensive or complex. It is also important to include the quantity of items required for destructive testing in the purchased quantity.

3.3.3.3. Buy cheaper risk

If a supplier can offer to furnish a commercial grade version of a product and he promises to validate it so that the product is cheaper than the original supplier's nuclear grade component, there is a temptation to buy the cheaper one. Risks associated with this scenario should be considered carefully. Firstly, the licensee procuring the product risks that the suitability evaluation process fails to be successfully completed and secondly, risks that the product does not fulfil all system requirements, although being validated as a standalone component. For example, a valve likely meets the performance capabilities specified by the supplier, but its capabilities also need to meet all system level requirements for this component in service.

4. SUITABILITY EVALUATION STRATEGIES

This section presents specific approaches for the suitability evaluation of commercial grade products. Commercial grade dedication graded and risk-informed approach and approaches to justify digital commercial off-the-shelf products are presented as examples of such approaches.

4.1. COMMERCIAL GRADE DEDICATION

For an NPP operating in accordance with U.S. regulation, codes and standards, Commercial Grade Dedication (CGD) is an acceptance process whereby items are procured without imposing normal nuclear quality assurance requirements on the supplier. Instead, parts are '*dedicated*' for use in safety-related applications [33].

The CGD consists of 1) an engineering evaluation to identify critical characteristics of the item based upon the required safety function (technical evaluation), and specification of acceptance methods and criteria (acceptance plan); and 2) acceptance activities to ensure the item(s) supplied meets the acceptance criteria specified. The CGD process does not include establishing suitability of design which is a matter of design control in U.S. regulation (Criterion III of 10CFR50 Appendix B), but rather focuses on suitability of manufactured items. Suitability of design is typically completed before the CGD process is started.

In the late 1980's and early 1990's, it was observed that suppliers of safety-related items were discontinuing their nuclear quality assurance programs and/or product lines (obsolescence). As one of the viable solutions, members requested EPRI to develop guidance for the use of commercial grade items in safety related applications. The method and practice were later endorsed by the Nuclear Regulatory Commission (NRC).

10 CFR, Part 21 defines dedication (in part) as follows [33]:

> "Dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, Appendix B, quality assurance program.
> The need to dedicate an item is typically identified during the initiation of the procurement process (request for procurement). The item is purchased as a non-safety related item from a commercial supplier (a supplier that does not have an approved nuclear quality assurance program). When the item(s) is received, the acceptance activities specified in the acceptance plant are conducted. If acceptance activities are successful, the item is accepted for use and place into warehouse stock".

As part of the dedication evaluation process, the following is typically generated:

- CGD technical evaluation that typically includes:
  - Safety classification based upon the item's applications (installation locations) and functions;
  - Identification of critical characteristics that provide reasonable assurance the item is capable of performing its intended safety-related function;

- CGD Acceptance Plan the typically includes:
  - Critical characteristics to be verified;
  - Acceptance criteria (range of acceptable values) for each critical characteristic;
  - Acceptance method applicable to each critical characteristic;
  - Sampling plans for applicable characteristics, along with rational for use of sampling and sample plan selected;
  - When necessary, documents such as drawings and other supplier information that include information referenced in the acceptance criteria;

- CGD Acceptance Results: a set of documents created for every purchase which include the actual results of acceptance activities, along with other pertinent information such as equipment calibration information, personnel qualification, etc.

For activities like safety classification, equivalency evaluation, sampling, the existing and established methods and processes (mostly based upon EPRI guidelines) are applied. The dedication acceptance process identifies the acceptance methods described in Table 4. These four different ways to verify critical characteristic as developed by EPRI and endorsed by NRC Regulatory Guide 1.164 [29].

TABLE 4. DEDICATION ACCEPTANCE METHODS

Acceptance Method	Activity associated with the method
Method 1	Special tests and inspections
Method 2	Commercial grade survey
Method 3	Source verification
Method 4	Supplier/item performance record
Combination of two or more of the four methods	

In the U.S., restrictions apply to the use of Methods 2 and 4 as indicated in NRC Generic Letter 89-02 [57]. Examples about commercial grade dedication are shown in Appendix IX.

4.2. GRADED OR RISK-INFORMED APPROACH

SSCs are normally classified according to the safety function they fulfil or support (i.e., reactivity control, residual heat removal, radiation material containment, other functions preventing the occurrence of events or reducing the consequences of events) and severity of consequences if their safety function is not performed [17].

Virtually all countries with operating NPPs classify SSCs accordingly and larger differences between countries may only exist among safety class 2 and 3. The requirements for design, manufacturing, QA/QC for safety classified SSCs are laid down in nuclear codes and standards and normally vary with safety class, in the sense that safety class 1 SSCs have the most stringent reliability targets and, respectively, QA/QC requirements. However, depending upon the SSC it may be subject to more stringent QA/QC requirements compared to other SSC of the same safety class (see TECDOC-1740) [17].

According to IAEA Specific Safety Guide no. SSG-30, Point 3.23, the safety classes shown in Table 5 can be defined based on severity of consequences of SSC failure [16].

TABLE 5. SSC SAFETY CLASSES BASED ON SEVERITY OF CONSEQUENCE OF FAILURES

Safety class	Description
"Safety class 1"	"Any SSC whose failure would lead to consequences of high severity"
"Safety class 2"	"Any SSC whose failure would lead to consequences of medium severity"
"Safety class 3"	"Any SSC whose failure would lead to consequences of low severity"

Commercial grade products can be classified and approved for use in different safety classes and be used in systems of different levels of safety significance. Consequently, a graded approach should be applied also for the suitability evaluation of commercial grade products considering different safety related targets of the applications and considering various safety classes in question.

A commercial grade supplier's products are typically based on uniform product families, where single products (items) are scaled in size and performance for different categories of use. The suitability evaluation of commercial grade products for safety related use can be performed respectively in two phases. The first step can be performed generally for the product family in question, while the second step needs to address the individual product within the family considering the specified operating conditions.

The classification of SSCs according to a risk-based approach, rather than a deterministic approach, is possible in some Member States [58]. In this model, components may be categorized into high- or low-safety significance based on a risk analysis. The categorization is based on an engineering evaluation which considers factors such as experience, observations, and data. When SSCs are categorized as low-safety significant, the suitability evaluation may be less stringent, based on a graded approach.

An example of a graded/risk-informed approach in a Finnish joint utility project can be found in Appendix VIII.

4.3. JUSTIFICATION PROCESS FOR COMMERCIAL OFF THE SHELFDIGITAL INSTRUMENTATION AND CONTROL SYSTEM EQUIPMENT

IAEA Nuclear Energy Series No. NR-T-3.31 describes a justification process for COTS digital I&C items intended for use in NPP applications [4]. These types of items are frequently procured as commercial grade by NPPs since there exists a limited amount of digital equipment designed specifically for the nuclear industry. The suitability evaluation process for the COTS devices is based on a three-pronged strategy which comprises a vulnerability assessment, a property-based verification approach and a standards compliance exercise. Once justified and in-use, the justification of the COTS item is maintained.

In IAEA NR-T-3.31, justification is defined as the "process by which COTS digital device is proved to be suitable for application in a nuclear power plant. In other contexts, justification is also referred to as qualification or dedication". On the other hand, qualification is most often used for environmental certifications (e.g., seismic, temperature, electromagnetic interference/radiofrequency interference, EMI/RFI) [4]. The justification process shown in Fig. 3 could be applied to elements of electromechanical SSCs in certain circumstances.

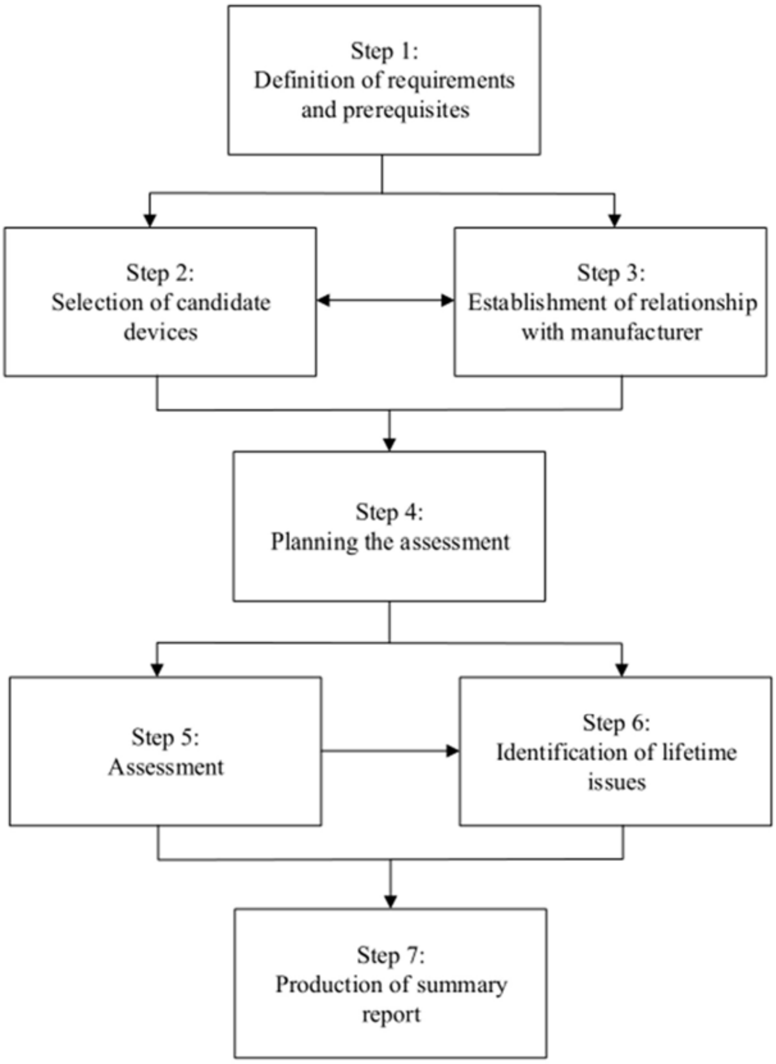

FIG. 3. The COTS device suitability evaluation process according to IAEA NR-T-3.31.

When electromechanical products contain digital devices and software, the suitability evaluation process needs to consider computer security vulnerabilities. Commercial grade products may not be designed and developed with cyber security measures needed to appropriately protect instrumentation and control systems at nuclear power plants. Security management of commercial grade products containing digital devices is a good practice in order to avoid the introduction of vulnerabilities before, during or after manufacturing and repeat procurements [59].

5. SPECIAL TOPICS

This section discusses special topics related to suitability of commercial grade items. This includes services and their suitability, outsourcing suitability evaluation, nuclear facility life-cycle considerations, advanced manufacturing and commercial grade products in advanced power reactors.

5.1. SERVICES AND THEIR SUITABILITY

Services, rather than physical products, are typically the first and last thing procured by nuclear powerplants through their lifecycle. The classification of services as nuclear grade or commercial grade is an important distinction affecting procurement requirements and the overall suitability evaluation process, similar to equipment. Management of the supply chain includes services that may influence safety [21].

Labour services such as those that involve the installation, maintenance, repair, or dismantlement of equipment at the nuclear facility are generally controlled by site-specific rules according to the management system of the licensee. Service supplier personnel are often supervised by the licensed operator's own personnel while on site.

The suitability evaluation process of commercial grade services generally takes place in two stages, just as it does for equipment (see Section 3). Rather than suitability of design, it is the suitability of the service description or service plan which may be reviewed to establish confidence that, prior to execution of the service, the activities meet all requirements. The work plan and/or specification of the labour services to be undertaken on site by a contractor's operatives would be reviewed and authorized by the licensed operator's own personnel before work is started. The review would take account of any industrial safety issues pertaining to the work and its timing in relation to preceding, parallel and subsequent tasks being undertaken in the vicinity.

In the second stage of the suitability evaluation process, the licensee will wish to check the readiness of service provider to undertake the work specified prior to contracting. Checks may include the following:

- Legal eligibility to perform the work requested;
- Commercial information to establish the capability of the provider;
- Confirmation of the contractual basis for undertaking the work requested including warranties and acceptance of liability for rectifying unsatisfactory work discovered on and after completion;
- Proof that the provider has the capacity and expertise to carry out the work requested, including references from past clients and certification of proposed operatives who will undertake the work requested;
- Information on any proposed sub-contracting to be undertaken;
- Work plan proposed and commentary, if any, on the feasibility of undertaking the work requested, including any proposed deviations from the specification.

Given the importance of documenting the suitability evaluation processes relating to the design, manufacture, installation, testing and commissioning of items important to safety, the nuclear facility will wish to have adequate traceability as to the way the work requested was performed. This implies that the operatives involved in performing tasks are suitable, are ready to certify their own work has been completed in accordance with the requisite standards and specifications and can be contacted if issues regarding workmanship have to be clarified later.

It is important to note that the suitability evaluation process for commercial grade services is dependent on the type of service and how it can influence items important to safety and the safety functions of the nuclear power plant. With these considerations guiding the suitability evaluation, the general principles of Section 3 can guide the process.

5.2. OUTSOURCING SUITABILITY EVALUATION

There may be services specifically designed to support the suitability evaluation process for commercial grade products and services. Services which are intended to perform the suitability evaluation process can have an impact on nuclear safety and therefore are typically expected to be performed by nuclear-qualified organizations or under the quality management system of the procurer. The use of third parties during the suitability evaluation process is typical. For example, the verification of design by means of shake table tests or harsh environment chambers are activities often outsourced to equipment qualification service providers.

When third parties are contracted to support the suitability evaluation process it is crucial that open and frequent communication between the parties is prioritized. A common pitfall when outsourcing the suitability evaluation process occurs when the service provider does not receive all necessary information from the end-user regarding the commercial grade product being evaluated. For example, when knowledge of intended safety functions or acceptance criteria is lacking it can be difficult or impossible to appropriately assure the suitability of a commercial grade product.

5.3. NUCLEAR POWER PLANT LIFECYCLE CONSIDERATIONS

Prior to the development of a new nuclear facility, and throughout its lifecycle, the procurement of equipment and services are influenced by a number of policies, technical and programme requirements. The following is a summary of specific milestones [60] and situations where the suitability evaluation of commercial grade products and services are likely to be considered.

5.3.1. Project development phase

Consideration of supply chain localization may be a target stated at the outset of the agreement for a new build project within government policies and national commitments. Thus, the potential for commercial grade products as an enabler for a local supply chain, who may not be familiar with nuclear quality assurance requirements, as in the case of newcomer countries, to participate in the project delivery would need to be considered. Local manufacturing capabilities may be available for a major part of the supply. Similarly, accredited laboratories may be available to performing testing activities for dedication [61].

Experienced workers from other high reliability industries may also transition to a nuclear supplier. Examples of such industries are oil & gas, aerospace and even to some extent car manufacturing. Programmes to begin early training and activities to support commercial grade suppliers enter the nuclear market are necessary. The ‘Fit4Nuclear’ (F4N) programme in the UK is one example of such an approach [62]. Companies may compare their standards with what is required in the nuclear industry in F4N in order to understand which kind of development will be necessary to conform.

Designers of new NPPs would consider the potential supply chain landscape of SSCs over the lifetime of the plant. Reasonable efforts are to be taken to enable ease in potential replacement of nuclear grade items with commercial grade items where applicable. In many cases, this will not be possible, but in some areas system which have a nuclear safety function could be optimized to enable greater ease for an SSC to be replaced by a commercial dedicated item at a future instance.

5.3.2. Construction and commissioning

During construction there is an opportunity for bulk materials to be procured in large volumes, such as metal sections, welding electrodes, bolts, screws, nuts, washers, bearings, fuses, capacitors, gases, lubricants, sealants, paints, oils, greases, chemicals (used for leak detection, cleaning, markings) consumables, standard pipes, fittings and supports, conduits, junction boxes, non-destructive examination materials, concrete anchors, terminals, etc. In some cases, items may be required to support products with safety functions, in such cases there may be the need for a graded approach to dedication to be applied to the commercial supplier.

Consideration of commissioning activities needs to be factored in the suitability evaluation of the item. For example, activities such as flushing, electrical checks, system functional tests etc. may not be fully understood by a commercial supplier. Consideration of any special system commissioning and testing activities needs to be given when for consideration of procurement of dedicated items.

5.3.3. Commissioning and operation

During the operational phase of the plant the suitability evaluation process may become an important factor in the procurement strategy of items and services during the following:

- Normal Operations – inventory management (spares, consumables, resilience strategies);
- Obsolescence management strategies;
- Replacement, retrofit and reverse engineering programmes;
- Plant performance optimisations;
- Refurbishment programmes [63];
- Capacity increases/power uprates;
- Modernisation programmes;
- Lifetime extension works/Licence renewals [64].

5.4. ADVANCED MANUFACTURING

Advanced manufacturing is the synonym for a number of still relatively novel manufacturing methods for components. These include additive manufacturing (often referred to as 3D printing), powder metallurgy – hot isostatic pressing, advanced cladding techniques (e.g., diode laser cladding) and advanced welding and joining techniques (e.g., electron beam welding).

Of the above advanced manufacturing methods additive manufacturing currently receives significant attention in the nuclear industry with regards to producing parts. Additive manufacturing are processes of joining materials (e.g., in the form of a metallic powder) to make parts from 3D model data, usually layer upon layer [65]. Additive manufacturing technology have advanced significantly in recent years and have found their way in a number of industries (e.g., aerospace industry). A large variety of different additive manufacturing processes exist. Their determining factor is the technique used for adding material, which itself is determined by the way of fusion or adhesion of the material.

Additive manufacturing has a comparative advantage to conventional manufacturing methods when parts have complex geometries and especially when those parts need to be produced in limited numbers. This makes additive manufacturing interesting for the nuclear sector where quantities for spare parts, replacement components are normally limited. Among all existing additive manufacturing processes laser power bed fusion (LPBF) has received most attention in the nuclear sector and many other industries producing engineered metallic parts. For LPBF a laser selectively melts and consolidates a fine metallic powder layer-by-layer. LPBP allows processing a wide range of different metallic materials including stainless steels, Ni-based alloys, aluminium-based alloys, and titanium alloys.

In the nuclear sector additive manufacturing has been used for a limited number of non-safety classified components (e.g., an impeller in the Krško NPP) and recently in a safety-classified application namely fuel assembly channel fasteners at Browns Ferry NPP. The potential for the application of additive manufacturing in the nuclear industry is seen as high. Possible applications in NPPs are components of complex geometries, e.g., fuel assembly debris filters, the reproduction of obsolete components as part of reverse engineering strategies.

Technical challenges in the additive manufacturing processes and the fact that they are not included in nuclear design codes yet (this applies to the other advanced manufacturing methods as well) limits their use for nuclear applications. In 2019 the Nuclear Energy Institute (NEI) published a roadmap for regulatory acceptance of advanced manufacturing methods in the nuclear industry. It also includes approaches to enable a more rapid adoption of advanced manufacturing methods in the nuclear sector [66].

There are a number of initiatives and projects underway with the aim of adoption of advanced manufacturing including additive manufacturing in the nuclear sector. ASME is currently developing a code case for producing parts made of stainless steel 316L using LPBF. EPRI together with Westinghouse, the Nuclear Advanced Manufacturing Research Centre in Sheffield, UK and other organisations are currently running a large R&D project involving all the above advanced manufacturing methods. TVO and Rosatom also are investigating additive manufacturing. At European level the Euratom-funded project NUCOBAM was launched in October 2020. The project has a duration of 4 years, involves 13 European nuclear organisations and has aim to develop a qualification process for components and materials produced via additive manufacturing for their usage in nuclear facilities and thus provide the way for including additive manufacturing in nuclear design codes.

5.5. COMMERCIAL GRADE PRODUCTS IN ADVANCED POWER REACTORS

Currently a significant number of advanced reactors, mainly in the form of (but not limited to) small modular reactors (SMRs) using different types of coolants (water, gas, liquid metal, or molten salt), are at various stages of design maturity and with some of them even in the licensing process in a number of countries [67]. Most of the SMR designs are water-cooled reactors (pressurized water reactor (PWR), Boiling Water Reactor (BWR) and very few pressurized heavy water reactor (PHWR)) and it is expected that these will be designed, manufactured and constructed according to the common nuclear codes and standards for large power Gen III/III+ reactor designs, meaning ASME Boiler & Pressure Vessel Code, AFCEN RCC-M [20], etc.

Non-water cooled SMRs or Gen IV reactor systems in general require to a large extent different codes and standards, because they operate at significantly higher temperature ranges than water-cooled Gen III/III+ designs and because of the intrinsic chemical and physical behaviour and characteristics of their coolants, in particular for liquid metal cooled designs and molten salt designs). A number of nuclear design codes for mechanical components of non-water-cooled reactors have been published and are under continuous development. These codes account for degradation mechanisms that are related to the higher temperature ranges in which non-water-cooled reactors operate, like creep or creep fatigue, and the handling of specific materials that are immanent for the functioning of reactor, e.g., graphite for high-temperature gas-cooled reactors in ASME BPVC Section III Division 5 or sodium for sodium-cooled fast reactors (SFRs) in RCC-MRx [68].

RCC-MRx makes significant reference to EN 13445 [69], the European standard for unfired pressure vessels, EN 13480 [70], the European standard for metallic industrial piping, and Eurocode 3 (EN 1993-1 for steel structures), which all originally were not intended for nuclear applications. RCC-MRx [68] allows in principle the use of pressure vessels and pipes designed and manufactured according to these standards (so commercial grade items) for so-called Level 3 components of advanced reactors in scope of RCC-MRx. These are components that are not subject to irradiation nor to creep. For components that are subject to irradiation or creep additional and stringent requirements according to RCC-MRx apply. The general trend in the further development of RCC-MRx (and other AFCEN codes) is to increasingly make reference to common non-nuclear industry standards like ISO/EN (e.g., for welding and materials) and define additional requirements, arising from the safety significance of the SSC in scope or potentially significant material degradation like irradiation or creep, as 'add-ons'.

Ultimately, the suitability evaluation process for commercial grade items intended for safety-related use in advanced reactors need not deviate largely from the same process when applied to items important to safety of NPPs. The success of SMR market with its supply chain using extensively serially manufactured items represents an avenue to reduce the obsolescence of items, bottlenecks in supplies, and enable to use modern and proven equipment.

APPENDIX I.
EXAMPLES OF COMMERCIAL CODES, STANDARDS AND OTHER NON-NUCLEAR RULES

Codes and standards exist today for a huge range of technologies and industries. When evaluating the suitability of commercial grade products, the licensee may wish to familiarize themselves with the contents of these publications, so as to better understand how they compare to typical expectations for items important to safety. Virtually all industries have quality management systems in place, often based on the ISO 9000 standards family, including the nuclear sector while some other industries have sector specific quality management system requirements, like ISO 29001 in the oil & gas industry or EN 9100 standards family for the aerospace industry.

Table 6 contains a selection of some common codes, standards and other non-nuclear rules which can be found in the manufacturer specifications of some commercial grade products used in NPP safety systems. In Table 7 valves are taken as a specific example for which a few examples of commercial standards are presented.

TABLE 6. SELECTED EXAMPLES OF COMMERCIAL CODES AND STANDARDS

Commercial Codes, Standards or Rules	Title	Type
CE Marking	Conformité Européenne (European Conformity)	Design, Testing & Quality
ISO 9001:2015 [71]	Quality management systems — Requirements	Quality
API Spec Q1 [72]	API Specification Q1, Quality Management System Requirements for Manufacturing Organizations for the Petroleum and Natural Gas Industries	Quality
AS9100D:2016 [73]	Quality Management Systems – Requirements for Aviation, Space and Defense Organizations	Quality
ISO 29001:2020 [47]	Petroleum, petrochemical and natural gas industries — Sector-specific quality management systems — Requirements for product and service supply organizations	Quality
ISO 13485:2016 [74]	Quality Management for Medical Devices	Quality
EN 13445-x [69]	Unfired Pressure Vessels	Design & Testing
Directive 2011/65/EU [75]	Restriction of Hazardous Substances (RoHS) Directive	Design

TABLE 7. EXAMPLE OF COMMERCIAL STANDARDS RELATED TO VALVES (NON-EXHAUSTIVE LIST FOR INFORMATION ONLY)

Commercial Standards related to Valves (Non-exhaustive list of examples)	Title	Type
ISO 5208:2015 [76]	Industrial valves - Pressure testing of metallic valves	Testing
EN 12266-1:2012 [77]	Industrial valves. Testing of metallic valves. Pressure tests, test procedures and acceptance criteria. Mandatory requirements	Testing
ANSI/FCI 70-2-2006 [78]	Control valve seat leakage	Testing
IEC 60534-x	Industrial-process control valves	Design & Testing
API 591 [79]	API Recommended Practice 591 Process Valve Qualification Procedure	Testing
API 598 [80]	Valve Inspection and Testing	Testing

APPENDIX II.
EQUIPMENT QUALIFICATION

II.1. INTRODUCTION

With rapidly advanced technologies, the use of commercial products is found in more and more applications for both operating and new nuclear power plants. There is a larger market for commercial products. Developing products only for nuclear market poses risks that could lead to marketing dead-end. Certainly, there are exceptions when nuclear specific functions and equipment has to be used.

Commercial products are developed according to non-nuclear industry standards. Some of these products are certified by non-nuclear authorities using those non-nuclear standards for the use in industrial safety applications (e.g., oil industry, railways, aircrafts). The qualification of an industrial or commercial product for its application in nuclear power plant systems important to safety could be more difficult because its development process may be less controlled than that of a nuclear-grade product. Often, the qualification is almost impossible without cooperation from the supplier. The difficulty associated with acceptance of these products may often lie with the unavailability of the information to demonstrate quality and reliability.

II.2. EQUIPMENT QUALIFICATION BASIS

Paragraph 2.5 of SSG-69 states:

> "...equipment qualification is required to demonstrate that the equipment will be capable of performing its safety function(s) in the range of service conditions specified for the nuclear installation in operational states and in accident conditions. This includes an evaluation of the ability of systems or components to perform these safety functions under the effects caused by specified service conditions during plant states and during external events not excluded by the design of the nuclear installation (e.g., seismic events, electromagnetic phenomena such as arcing, lightning). In contrast, internal fires, explosions, internal flooding, tornadoes, and hurricanes are not normally considered in equipment qualification because the design generally protects the equipment from the effects of these events" [81].

Furthermore, one of the objectives of equipment qualification is the prevention of common cause failures arising from the exposure of equipment to the specified service conditions [81].

Equipment qualification includes seismic, environmental qualification (e.g., mild and harsh environments) and electromagnetic qualification (e.g., effects of EMI/RFI). While seismic qualification generally applies to structures, systems and components, the environmental qualification applies primarily to electrical, instrumentation and controls, active mechanical equipment, and components associated with this equipment (e.g., seals, gaskets, lubricants, cables, connections, mounting/anchoring structures). The qualification process for passive mechanical components (e.g., piping and vessels), for which the safety performance is assured by design is performed in accordance with applicable codes. Another form of equipment qualification is verification and validations that applies to digital systems important to safety performing safety functions (e.g., SW of computer-based systems, devices with limited functionality, smart devices).

II.3. THE EQUIPMENT QUALIFICATION CONCEPT AND PROCESS

Paragraph 4.48 of IAEA SSR-2/2 (Rev. 1) states that

> "Appropriate concepts and the scope and process of equipment qualification shall be established, and effective and practicable methods shall be used to upgrade and preserve equipment qualification" [22].

The equipment qualification process comprises three phases:

- Establishment of appropriate design inputs (e.g., safety functions, service conditions);
- Establishment of equipment qualification process steps (e.g., type testing, analysis, operating experience, combined methods);
- Preservation of the status of qualified equipment.

A number of international standards related to the subject of equipment qualification, these include IEC/IEEE 60980-344:2020 (Nuclear Facilities — Equipment Important to Safety — Seismic Qualification), IEC/IEEE 60780-323:2016 (Nuclear Facilities — Electrical Equipment Important to Safety — Qualification) and ASME QME-1-2017 (Qualification of Active Mechanical Equipment Used in Nuclear Facilities). Additional standards relating to equipment qualification can be found in IAEA SSG-69, Annex I [81].

II.4. EQUIPMENT QUALIFICATION PROGRAMME

Paragraph 4.48 of SSR-2/2 (Rev. 1) further states that

> "A programme to establish, to confirm and to maintain required equipment qualification shall be launched from the initial phases of design, supply and installation of the equipment. The effectiveness of equipment qualification programmes shall be periodically reviewed" [22].

Equipment qualification need to be considered as an essential programme throughout the whole lifetime of a nuclear installation. The equipment qualification programme objective is to provide confidence that equipment is designed, manufactured, installed, commissioned, operated, and maintained such that it is capable of performing its intended safety functions, when needed, under the specified service conditions and throughout its qualified life, with due account taken of conditions during maintenance and testing.

Within the context of equipment qualification, the equipment needs to be considered as an integrated assembly of one or more interconnected components or subassemblies, each with dedicated functionality and specified interfaces to perform or contribute to one or more safety functions. The equipment to be qualified has to be an accurate representation of the type or series type of the equipment to be installed.

The qualified configuration of the equipment should include the equipment itself and the equipment it interfaces with. The qualified configuration should include the final versions of software, firmware, hardware description language, and process, electrical and mechanical interfaces, mounting and equipment orientation [22].

II.5. PRELIMINARY SUITABILITY ASSESSMENT

A selection process of a commercial product to be used in nuclear safety applications typically includes a preliminary suitability assessment[9]. T

his demonstrates the potential of the chosen product to meet necessary functional and performance standards under defined operating conditions. According to IAEA SSG-69, the following information are needed to perform the assessment [81]:

- A description of the equipment used to perform safety functions;
- The design requirements, service conditions and the performance requirements for the equipment, derived from the safety design of the nuclear installation;
- Criteria for assessing equipment suitability;
- Criteria for installation, for electrical and mechanical interfaces, and for maintenance.

The preliminary suitability assessment necessitates an evaluation of the equipment's functional attributes, projected performance under the designated operating conditions, and additional factors. These include electrical safety standards, adherence to product norms, as well as testing and maintenance guidelines. Should the preliminary assessment uncover any shortcomings in satisfying design prerequisites for specified service conditions, additional qualification measures become requisite.

II.6. QUALIFICATION METHODS

Internationally recognized methods for equipment qualification are type testing, analysis, use of operating experience, and a combination of these methods. [81] These methods are applicable to both, nuclear grade product as well as commercial product, provided it will be used in nuclear safety application.

The method of qualification through type testing involves conducting a test or sequence of tests on a representative example of the equipment (inclusive of its interfaces), which mimic the impacts of significant aging processes during regular operation, as well as the environmental and/or dynamic circumstances linked with accidents. Equipment qualification via type testing is carried out with the equipment (along with any software) operating in a manner indicative of its intended use during actual operation.

The distinct blend of methodologies chosen is contingent upon the equipment assembly or component under scrutiny. For instance, when qualifying commercial products, greater weight may be given to previous operational experience. For components not expected to function during accident conditions or subsequent to an earthquake, a stronger emphasis could be placed on analysis.

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[9] A ‘preliminary suitability assessment’ is another term for ‘design review’ used in Section 3.

II.7. PRESERVATION OF EQUIPMENT QUALIFICATION

Maintaining equipment qualification necessitates the regular replacement of component parts, such as seals, gaskets, lubricants, and filters, that are prone to faster degradation. These components may require replacement during specific maintenance activities designed for the purpose of equipment qualification and should not be reused [81]. Configuration management (change control) provides a systematic process to ensure that the implications of equipment qualification are appropriately considered whenever changes occur to the installation, to equipment, or to operating, maintenance or replacement activities.

Among factors that can adversely impact the established equipment qualification include "unavailability of qualified spare parts, storage conditions of the qualified equipment and spare parts, obsolescence of the equipment or spare parts" [81]. In order to provide replacement for an original qualified part, a commercial product is often used. In this case, the commercial products have to be assessed by means of preliminary suitability assessment whether it is capable of meeting the functional and performance requirements while operating within specified service and accident conditions. If this cannot be demonstrated, supplemental qualification steps as described above are needed. Justification needs be provided during the reassessment of equipment qualification whenever changes occur that could alter the initial equipment qualification.

II.8. IAEA FRAMEWORK FOR EQUIPMENT QUALIFICATION

IAEA Specific Safety Guide No. 69 [81] provides recommendations on a structured approach to the establishment and preservation of equipment qualification in nuclear installations to meet the relevant requirements established in SSR-2/1 (Rev. 1) [12], SSR-2/2 (Rev. 1) [22], SSR3 [43] and SSR-4 [44]. Specifically, this safety Guide provides recommendations on the establishment and preservation of equipment qualification in nuclear installations, confirmation of the reliable performance of safety functions by such equipment during operational states and accident conditions, in order to avoid vulnerability due to common cause failure of the equipment. Qualification methods described in this Safety Guide applies to both nuclear-grade products as well as commercial grade products that needs to be assessed/qualified to confirm their suitability of meeting the functional and performance requirements while operating within specified service conditions.

APPENDIX III.
QUALITATIVE AND QUANTITATIVE RISK ANALYSIS METHODS

IAEA TECDOC-1910 [19] Appendix VII presents a classified collection of techniques and tools that are usually used in quality management. They may be divided into three groups.

Structured qualitative analysis (identification, questioning and problem solving) approaches include, e.g.: failure mode and effects (and criticality) analysis, failure mode and effects analysis (FMEA)/failure mode effects and criticality analysis (FMECA), hazard and operability study (HAZOP), root cause analysis of five whys (5WHYs), management oversight and risk tree (MORT), action error analysis (AEA) and cause-consequence diagram (CCD) [82]. Logic modelling approaches include, e.g., fault tree (FT), event tree (ET) and influence diagrams. Quantitative -or semi-quantitative - quality tools include, e.g.: Pareto analysis and control charts.

FMEA is a tool used for reliability analysis, particularly in the nuclear industry. It involves identifying potential failure modes, examining their causes and consequences, and determining the appropriate course of action to address them. This can be done using a tabular format and may involve evaluating the criticality of the faults (FMECA) [19]. The basic version of FMEA/FMECA is standardized [83]. These techniques are also commonly used in process improvement, quality development, reliability engineering, safety and availability analysis, and root cause analysis, and can be advanced using statistical and probabilistic methods [84].

III.1. PROBABILISTIC SAFETY ANALYSIS

Probabilistic safety analysis (PSA) is a comprehensive methodology, which is used to estimate the frequency of accidents and to evaluate the importance of systems, components, and operator errors in this context. PSA applies a number of different qualitative and quantitative methods e.g., for estimation of failure data, analysis of initiating events, analysis of human actions and modelling of common cause failures. Most often used methods include: 1) event trees to present failure logic on a plant level; 2) fault trees to present the logic on a system level; and 3) FMEA to document component failure modes with causes and consequences. Applications of PSA is described in [85] and [86].

In case a nuclear-grade item is changed to a commercial grade one, the following analyses with PSA may be useful:

- First, if no changes in the system are done, and if reliability data, test data and repair data of the new component type remain the same as for the old one, the importance of the new component will also remain unchanged;
- Second, if the reliability data of the new component differs from the old one, but the system remains unchanged, the new data is applied in the model. There are techniques based on importance measures for evaluation of the impact of change of component reliability without complete calculation of the model [87];
- If the replacement of a nuclear grade component with a commercial grade one requires design modifications (at least in case of system modifications like new voltage supplies, changes in cooling or lubrication, etc.), the PSA has to be modified accordingly, and complete calculation of the model will be necessary.

PSA can be used in allocating component reliability requirements to systems and components for prevention, management, and mitigation accidents. Reliability and performance requirements of a component are based on the reliability and performance requirements of the system of which the component is a part. Requirements of the system are based on the functions – including the safety functions - of the system, and they are allocated from the unit or plant level requirements. This is the situation independently if the component is manufactured as commercial grade or nuclear grade, although components (or products when manufactured) may have their own requirements and specifications.

Commercial grade products with substantial operating experience, large production series and long development history may have as good or even better reliability than the corresponding nuclear grade ones that have been manufactured only in small quantities. In practice, it may however be difficult to prove this completely [88].

The following general text may be used to help understanding what factors mostly affect reliability and availability of safety functions independently of the design and manufacturing pedigree of the components.

Availability of safety functions at NPPs is based on:

- Systems with redundant components and redundant trains or subsystems;
- Diverse systems performing the same function by different physical principle;
- Separation of the trains against fire, flooding, seismic events, and many other external and internal natural and man-made hazards; and
- Preventive maintenance to improve the reliability of safety functions and to decrease unplanned repair outages.

Reliability and performance requirements depend on the possibility of corrective maintenance or replacement of the component during operation. Some examples of reliability and performance requirements depending on the consequences of failure and the repair:

- High reliability by means of low failure rate is important, if recovery from failure requires shut down of the plant, or if outage of the component is not allowed otherwise;
- Short test interval, easy and reliable testing and good coverage of tests is important in stand-by components, which are of high importance on safety functions;
- Short recovery time and often easy replacement is important in safety systems or their auxiliaries, where the duration of recovery without shutting down the unit is limited in NPP technical specifications - special attention is required in systems required during power reduction or in shut down states;
- In case of standby components, testability and good coverage of testing is important, because the probability of failure is directly proportional to the test interval;
- High reliability is possible to achieve with good system design, even though the failure rate of the available components is high. However, high degree of component redundancy and continuous condition monitoring is necessary. Short recovery times are necessary leading to increased maintenance costs/staff.

These principles are used, e.g., for a balanced maintenance classification as will discussed in the following text. The management of requirements is included in systems engineering. [89] [90] PSA and Performance assessment methodology (PAM) can be used in setting reliability and performance requirements.

Common cause failures normally dominate in PSA results. The probability of a CCF is normally low, but it is significantly higher than the probability of simultaneous independent failures of the same components. Design qualification normally cannot be used to ensure absence of CCFs.

The Organization for Economic Cooperation and Development (OECD) Nuclear Energy Agency (NEA) International Common Cause Data Exchange (ICDE) project has revealed that deficiencies in design are the most important root cause of CCFs. Moreover, operational and maintenance activities at the NPPs lead to complete CCFs, i.e., where all the similar redundant components have completely failed at the same time [91]. Modifications to the safety systems of NPPs have thus the potential to cause complete CCFs [92]. Manufacturing and ageing related aspects may lead to parallel degradations of redundant components, but not necessarily to a full loss of safety function.

The consequences of a CCF might be high if one component type, like pneumatic pilot valve, valve actuator or auxiliary relay is used in many places, for example, in redundant trains of one system. Another possibility is the use in several operational systems, safety related systems and auxiliary systems. Plant-specific PSA models usually cover CCF of identical components within a system but modelling CCFs of identical components between different systems is a huge effort, and therefore often omitted.

The best general strategy against CCF is functional diversity. The highest degree of diversity results in safety is assured through different functional principles and different personnel actions at NPPs. Separate item manufacturers with independent design and manufacturing practices decreases the probability of CCF. System design may be supported by the use of PSA. The requirement for low CCF probability may lead to the need to use several products or the same product from independent suppliers with separate supply chains. In practice, this may not always be possible.

Use of different commercial grade products in redundant trains, instead of one nuclear grade product, requires planning and documentation. Savings in the cost of spare parts by replacing several diverse spare part types with one single “multipurpose” type of commercial grade product may be tempting but can introduce unwanted risk if the same potential failure possibilities exist both in operational systems and in systems important to safety. Care has to be taken if, for example, electromechanical components are changed to smart components (i.e., components including digital technology like time relays), which can be tailored to different applications.

III.2. PERFORMANCE ASSESSMENT METHODOLOGY

PAM is presented in the European Utility Requirements (EUR) [38]. Probabilistic performance assessment (PPA) predicts the electricity production availability of an NPP. The model is mainly based on systems that directly or indirectly affect the production of electricity, and their operating experience from similar plants, systems, and components. Preventive and corrective maintenance practices of the components in safety systems also have impact on the availability performance of the analysed NPP. Other factors are the NPP technical specifications, regulatory requirements and environmental conditions affecting the maintenance strategies.

Besides estimating the load factor and production duration curve, PPA methodology can be used for many purposes like planning of maintenance, planning of design modifications, mapping out availability risk significant systems and components. PPA produces also valuable input for maintenance classification of systems and components.

III.3. MAINTENANCE CLASSIFICATION

Maintenance classification (or graded approach to maintenance) is based on several qualitative and quantitative parameters such as:

- Safety class of a component;
- Allowed outage time (AOT) in NPP technical specifications;
- Importance measures (risk increase, risk decrease, etc.) of the component in PSA, and
- Importance measures (impact on loss of production) of the component in PAM.

These classification parameters are not mutually independent. The safety class of a component or its AOT may be based on risk informed decision. This may be based on the PSA results as the maintenance class parameter obtained, e.g., by use of importance measures from the same PSA.

Maintenance classification may be an aid in evaluating and setting maintainability requirements for components to be procured (both nuclear and commercial grade).

III.4. RELIABILITY DATA

Failure rates of components are often collected as reliability data, but alone they do not give much information on the reliability. Being useful and applicable in reliability evaluations, the failure rate needs to include different failure modes with their corresponding failure rates. As an example, for a pump the failure rates could be: 1) pump fails to start, 2) fails to stop, 3) starts inadvertently or 4) leaks. Reliability evaluation also needs information on testing, maintenance, and maintainability. Examples of this information are repair times, repair delays, testability, test intervals, preventive maintenance program, recommended spare parts, tools, manuals, etc.

Best reliability data is obtained from components that are identical and operating in equal load in equal environment. Such ideal data may be collected from NPPs. Typical problems in data collection include:

- The population is not homogenous, because the supplier modifies his products based on operating experience, available materials and parts, subcontractors, and economical reasons;
- The operational environment of the product is assumed to be within the defined limits, but there may be different types of components for e.g., different temperature ranges; or
- The loading of the component may be different, e.g., stand-by with short test runs, whole time running on nominal load or intermittent use with large number of starts.

Same needs and problems apply to both nuclear grade and commercial grade components.

A reliability data collection system may also be a part of the supplier’s after-delivery-follow-up system, maintenance records or guarantee follow-up system. Such systems normally cover a few years at the beginning of the lifetime of each component with varying reporting coverage.

APPENDIX IV. QUALITY ASSURANCE GUIDELINE FOR PROCURING HIGH-QUALITY INDUSTRIAL GRADE ITEMS AIMED AT SUPPORTING SAFETY FUNCTIONS IN NUCLEAR FACILITIES (NUCLEAREUROPE COMMERCIAL GRADE DEDICATION GUIDELINE)

The European Atomic Forum (nucleareurope) is the Brussels-based trade association for the nuclear energy industry in Europe. The nucleareurope European guideline aims to be the foundation from which nuclear licensees and third parties would to be able to develop their own processes and procedures related to the acceptance of commercial grade items. The guideline supports the safety of the industry by clearly prescribing the proven ways in which commercial grade items and their suppliers should be verified. It supports the sustainability of the nuclear industry by creating a harmonized procurement approach for existing and future licensed operating organizations.

Across the world, a number of safety authorities recognize one or more EPRI guidelines or local standards on the use of dedicated items as acceptable ways in which to meet regulatory requirements related to items important to nuclear safety. Nations who have introduced dedication were typically those whose regulatory regime is built on an American-style system in which the quality assurance requirements found in U.S. regulations apply not only to licensees but also suppliers of safety-related items. Recently, however, some European countries with a different style of requirements have been starting the process of implementing the dedication approach. The guideline is of benefit to the nuclear industry by promoting and providing:

- A dedication methodology which can be applied across the continent and is not tied to US requirements and guidelines which stem originally from a US defect reporting regulation (10 CFR Part 21);
- A robust and stable acceptance process in lieu of no process, many different processes or case-by-case decision-making;
- A basis for regulatory stability on the subject of high-quality industrial grade item acceptance;
- Clear instructions for how to demonstrate that a high-quality industrial grade item is suitable and of sufficient quality such that it will perform its safety functions in nuclear facilities;
- The ability to combat obsolescence issues and leverage proven processes for the manufacture of high-quality commercial items from other high-reliability industries;
- The procurement of items which have already been manufactured. This may include unused inventory from shut down nuclear power plants which other licensees could utilize.

The guideline is structured in two Volumes. Volume 1 is the Methodology with a description of dedication, primarily from the point of view of a nuclear facility licensee. Volume 2 is a User's Guide with advice on implementing the guideline, graded- and risk-informed approaches to dedication, examples, templates as well as information on many specific topics such as purchasing documentation, choosing acceptance methods, product families, advanced manufacturing and more. Figures 4 and 5 show figures from the guideline which provide additional context [93].

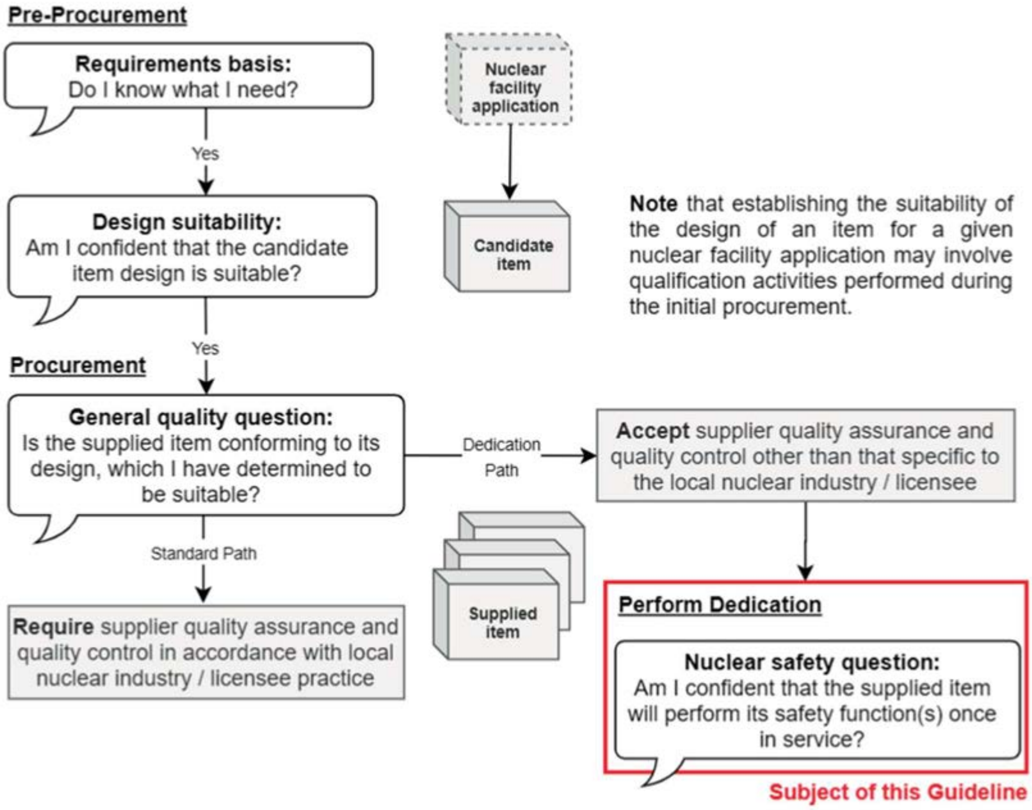

FIG. 4. Depiction of the focus of the Guideline within a typical pre-procurement and procurement workflow (Reproduced with permission courtesy of nucleareurope).

Qualification	Dedication
Qualification is a **one-time** effort intended to establish the suitability of an SSC	Dedication is performed **each time** an item is procured in order to gain confidence in the ability of the supplied item to perform its safety function(s)
Qualification has to do with **design**, process, or credentials verification	Dedication has to do with **quality assurance and quality control** of procured items or services important to safety
Qualification cannot replace supplier quality assurance or quality control during procurement	Dedication cannot replace environmental and seismic qualification of items important to safety
Qualification is typically performed **prior to procurement** of an SSC or service important to safety	Dedication is performed as a **part of the procurement process**
Environmental and seismic qualification **demonstrates** that an SSC, typically in the form of a test specimen, is capable of performing its safety function(s) throughout its qualified life and after an accident	Dedication **provides confidence** (in the form of documented evidence) that an item which is to be installed in a nuclear facility will perform its safety function(s) by verifying its critical characteristics are identical to those in the qualification test specimen
Qualification is typically carried out on an **SSC**	Dedication may be carried out on an **SSC or part thereof, material or software**

FIG. 5. Differences between (equipment) qualification and dedication according to the Guideline. The Guideline is focused on dedication (Reproduced with permission courtesy of nucleareurope).

APPENDIX V.
COMMERCIAL GRADE DEDICATION AT KRŠKO NPP

As part of a reorganization and redefinition of the procurement process in accordance with the EPRI guidelines, CGD was introduced at Krško NPP (NEK) in 1995.

V.1. POLICY

The key to implementation of an effective program at NEK were the lessons learned in the USA.

The following definitions are respected:

- Commercial Grade Item as defined in 10CFR21:

> "A structure, system or component, or part thereof that affects its safety function, that was not designed and manufactured as the 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)" [33].

As defined in the NEK plant programs and procedures, it is an item satisfying three criteria as follows: 1) the item is not subject to design or specification requirements that are unique to nuclear facilities; 2) the item is used in applications other than nuclear facilities; and 3) the item may be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example in a published catalogue).

Precondition for the CGD procurement initiation is an existing safety classification, capability to define critical characteristic for design and critical characteristics for acceptance including the method and criteria for acceptance. Available resources (manpower, test equipment) are to be considered as well.

Under the policy, commercial grade items are procured in lieu of a basic component under one of the following circumstances:

- The supplier of the item cannot furnish the item under a nuclear quality assurance program meeting the full intent of 10CFR50, Appendix B;
- The original supplier can no longer furnish the item and a suitable alternate replacement can only be furnished as a commercial grade item (obsolescence);
- Delegating the acceptance of a finished commercial grade item either to an original equipment supplier, a third-party organization, or the nuclear steam system supplier is more costly than NEK dedicating the item under the NEK 10CFR50 Appendix B program.

V.2. PROCUREMENT PROCESS

NEK procurement process is a cross-functional process involving various internal organizations (Engineering, Maintenance, QA, QC and Purchasing) and external parties (Suppliers, Manufacturers, Agencies, Regulatory bodies etc.). To ensure *proper item is provided each time* and to prevent degradation of designed safety and reliability of the NEK plant, this process is subjected to strict compliance with 10CFR50 Appendix B and NEK Quality Assurance Program (Criterion III, IV and VII).

In order to comply with the plant design bases requirements and maintain the configuration control of the NEK plant, based upon the plant application, two basic elements necessary for effective procurement were established:

- Accurate technical and quality requirements specified in order to assure properties or attributes of importance are imparted to the item;
- Acceptance criteria determined in order to provide reasonable assurance that the technical and quality requirements have been met.

Two more items were identified that enhanced the procurement process quality:

- Training of personnel on items such as applicable NRC Regulatory Guides, Generic Letters, Information Notices and Bulletins; NUMARC (Nuclear Management and Resources Council - now Nuclear Energy Institute) Comprehensive Procurement Initiative; plant-specific licensing commitments, plant design bases, configuration management; and EPRI guidance;
- Communication within the plant (e.g., communication between design engineering procurement engineering, quality assurance and control, maintenance, purchasing); with the various suppliers; and with industry organizations. Sharing information is essential for success.

V.3. COMMERCIAL GRADE ITEM DEDICATION

NEK original plant classification of structures, systems and components was based upon codes applicable at the time of construction (ASME, American National Standards Institute (ANSI), Institute of Electrical and Electronics Engineers (IEEE), etc.) and that was transferred into plant documentation and licensing commitments. At that time part classification issues were not specifically addressed. NEK procurement process was primarily 'Like for Like' from turn-key contractor or Original Equipment Manufacturer and conservative in imposing technical and quality requirements.

Recognizing the need to classify parts not only in accordance with manufacturing codes (e.g., ASME) but also based upon the components actual function within the plant and specially to prevent that substandard, fraudulent, and counterfeit items are installed in nuclear power plants, NRC issued Generic Letters 89-02 "Actions to improve the detection of counterfeit and fraudulently marketed products" and Generic Letter 91-05 "Licensee Commercial Grade Procurement and Dedication Programs". Guidance for the USA utilities to make the required enhancements to their procurement processes was provided by NUMARC's 'Comprehensive Procurement Initiative'.

Because of lack, inconsistency and accountability of historical data Method 4 is not allowed as an acceptance process at NEK but it can be used in combination with other methods and for sampling plan optimization when commodity items are purchased as CGI and are subject to a statistically based dedication acceptance process.

V.4. REMARKS

Several reasons initiated and later supported the utilization of commercial grade item procurement and then upon dedication. These are:

- Nuclear supplier drops qualification;
- Original parts not available - replacement parts are offered non-qualified;
- Discrepancies between Manufacturing and Operations codes/standards;
- Reduced cost and lead time;
- Falsified/Fraudulent items and documents;

The trend of suppliers leaving the nuclear industry, stopping product lines (obsolescence) is obvious. Development of tools (procedures, methodologies, and computer applications) and personnel training programs present plants investments into the future when the CGI procurement will have no alternative because qualified parts and suppliers will not be available.

The process increases the knowledge and competences of plant personnel, and confidence in test/inspection records because they are performed by the plant self. The exchange of information/experience with other utilities/plants is very important.

When applying the Commercial Grade Dedication process, the following need to be considered:

- Simple items initially, with raising complexity as competences increase;
- Qualified product not available;
- Not above but all NEK requirements can be met:

    - Identified critical characteristic (including seismic) can be verified against known acceptance criteria;
    - Test/inspection equipment and qualified personal is available;
    - Significant cost reduction;

- Purchasing to specific application;
- Available resources.

For new complex items to be used in nuclear safety related applications, third party qualifiers with references and a nuclear program are contracted. In addition to providing the necessary expertise, they are often the more economical solution.

APPENDIX VI.
GLOBAL SCHEME FOR THE PROCUREMENT OF ITEMS IMPORTANT TO SAFETY AT ENGIE ELECTRABEL

At ENGIE Electrabel in Belgium a global scheme for the procurement of items important to safety has been developed. The Tihange NPP and Doel NPP comprise the ENGIE Electrabel fleet. The global scheme is divided into 4 separate areas related to:

- Supply Chain Management (included supplier qualification);
- Equipment Qualification Management;
- Obsolescence Management;
- Configuration Management.

Figure 6 presented at the end of this Appendix shows the entire scheme. There are several triggers which initiate request for procurement (lower left corner of the diagram):

- Specific demand (e.g., Triggered by a corrective action from a component health report, a project related procurement, etc.); or
- Pro-active obsolescence management (through a last time buy); or
- Safety stock demand.

Once there is a requisition to purchase items important to safety, the first step is to check if the design is the same as qualified one. This is checked by supply chain management.

The next step consists of a verification of the supplier status; whether the supplier is qualified or not. If yes, the standard acceptance process is to be applied. If not, CGD process should be followed according to the supply change process. If the design is not the same, but known, design changes are validated through a type test.

If the item is obsolete, obsolescence management takes over according to the obsolescence mitigation process to choose the most appropriate strategy regarding the situation. Considerations include effort, cost, feasibility, and applicability. Note that the preferred mitigation strategy is always licensee-specific and highly dependent on the remaining lifetime of the plant. Licensees with a higher expected lifetime would consider an equivalent replacement as a more sustainable solution compared to a licensee close to its end of life, which will rather prefer a rebuild/repair strategy as a more cost-effective solution.

Strategies considered to address obsolete items are as follows (from lowest effort to highest effort) and the related processes are:

- Reuse & rebuild/repair (process);
- Surplus (process);
- Extend qualified life (process);
- Equivalent replacement (process);
- Reverse engineering (process);
- Declassify/design change(process).

It is also possible to enter the obsolescence mitigation process through the proactive obsolescence process. Depending on the chosen strategy the obsolescence mitigation process is closely linked to equipment qualification.

Alternatively, configuration management approaches such as of item equivalency evaluation process or modification process (MP) may be used.

If the equivalency of an item cannot be validated by the item equivalency evaluation process, the modification process is usually performed.

As shown in the global scheme in Fig. 6, all mitigation obsolescence solutions are linked with the equipment qualification process. For each of these mitigation strategies it is verified whether the original qualification of the item is respected, or whether a new qualification is required. Generally, equipment qualification can be performed by analysis, tests, or a combination of both. When qualification can be performed solely by analysis, the item can be ordered according to the normal procurement process by checking the supplier's qualification status.

If qualification tests need to be performed, there are two possible scenarios:

- The most sustainable solution is to audit the supplier prior to ordering the test samples (via supply chain) and performing the qualification tests;
- When the quality program of the supplier is insufficient, or when the supplier does not want to obtain a nuclear supplier qualification, a batch can be procured and qualified. This scenario consists of ordering a batch to cover the plant demand for a certain period, taking into account additional specimens needed for testing via the Batch Procurement & Sampling Process (Supply Chain) and making the type test qualification.

If additional pieces are needed, they can be ordered by following the normal procurement process.

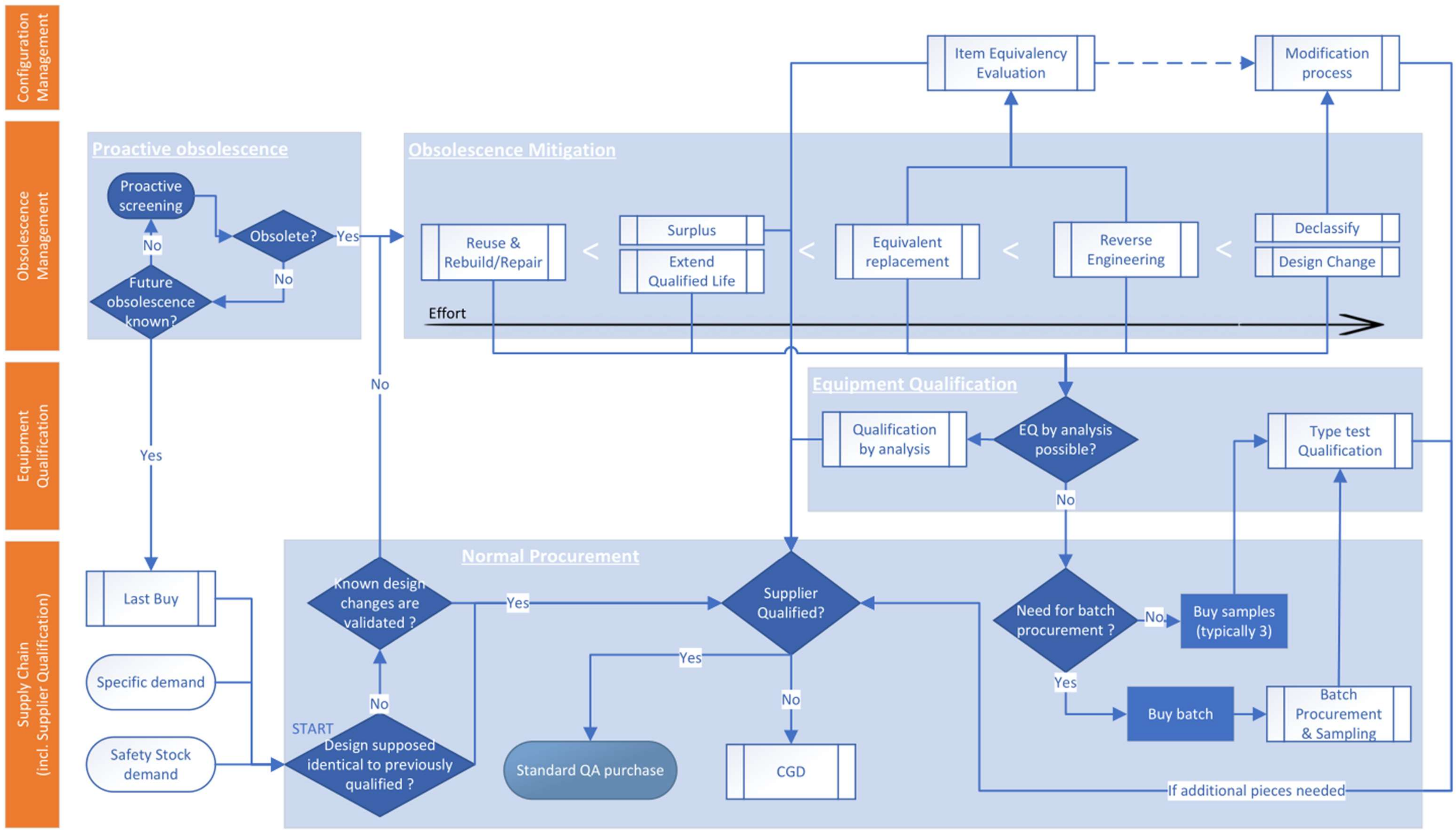

FIG. 6. ENGIE Electrabel global scheme for procurement of QA items (Reproduced with permission courtesy of ENGIE Electrabel).

APPENDIX VII.
COMMERCIAL GRADE ITEM DEDICATION AT KOREA HYDRO & NUCLEAR POWER CO., LTD (KHNP)

Commercial Grade Dedication in South Korea was first partially introduced in the 1990s by USA supplier of construction nuclear power plants for safety-grade electrical and instrumentation and control equipment or parts. Regulatory body in South Korea reviewed the acceptance requirement for commercial grade item used in safety-related installations and requested KHNP to establish the acceptance process for CGD in the early 2000s. After that, in 2012, an incident of counterfeit of quality documents of CGD parts by supplier in South Korea occurred, which had a great impact on the nuclear industries. For this reason, regulatory body and KHNP completed the improvement of the procurement engineering system and process including CGD.

VII.1. REGULATION OF COMMERCIAL GRADE DEDICATION REGULATION OF CGDS INCLUDES LEGISLATION, CRITERIA AND REGULATORY GUIDES.

VII.1.1. Safety-related installations in Nuclear Safety Act

In Korea, the Nuclear Safety and Security Commission rules define the applicable standards. See Figure 7 for an overview of the standards for nuclear power plants and the commercial grade equipment.

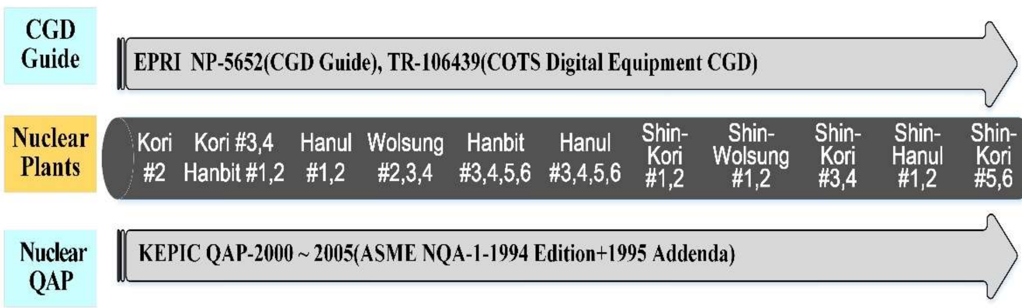

FIG. 7. Nuclear power plants and relevant codes, standards and guidelines for the use of commercial grade items in South Korea. Note Shin-Hanul 1,2 unit and Shin-Kori 5,6 unit are under construction (Courtesy of KHNP).

VII.1.2. Commercial Grade Item in Regulations on Reporting of Defects and Noncompliance (Notice 2018-2)

Commercial grade item was not designed and manufactured according to safety class and standards applied to a safety-related installation.

VII.1.3. Quality Assurance Program

The notice No. 2016-13 in Nuclear Safety and Security Commission (NSSC) approved KEPIC QAP-2000~2011(ASME NQA-1-1994~2009) [35] as quality assurance criteria of power plants in operation and construction for detailed requirements. A commercial grade items that perform safety function in safety-related installations have to be accepted by CGD process.

VII.1.4. Commercial Grade Dedication Guide

The regulatory guide N17.12 (Dedication for commercial grade item in Safety-related installations) in NSSC endorsed NP-5652(CGD Guide) and TR-106439(COTS Digital Equipment CGD) [31] in 2011.

VII.2. PROCESS AND PERFORMANCE FOR COMMERCIAL GRADE DEDICATION

CGD process may be applied both to power plants in operation and in construction.

VII.2.1. Power plants in operation

KHNP has a supplier and in-house CGD process for procuring commercial grade item that perform safety function in safety-related installations. The CGD of suppliers, a nuclear manufacturer and dedicating entity, follows the following procedures, as depicted in Fig. 8:

- The technical evaluation includes safety function analysis (for parent equipment and parts), critical characteristics, acceptance criteria, acceptance method, and sampling of commercial grade item;
- The supplier submits the CGD plan to KHNP and engineers in KHNP's central CGD organization review it with a check sheet and approves it;
- If CGI is an alternative item, the central CGD organization collaborates with site procurement and design engineering organization to verify a design requirement such as an equipment qualification;
- The supplier verified the acceptance of each critical characteristic by the following one or more of acceptance methods with the approved CGD Plan:

  - Method 1: Special Tests and Inspections;
  - Method 2: Commercial grade Survey;
  - Method 3: Source Verification;
  - Method 4: Item/Supplier Performance Record.

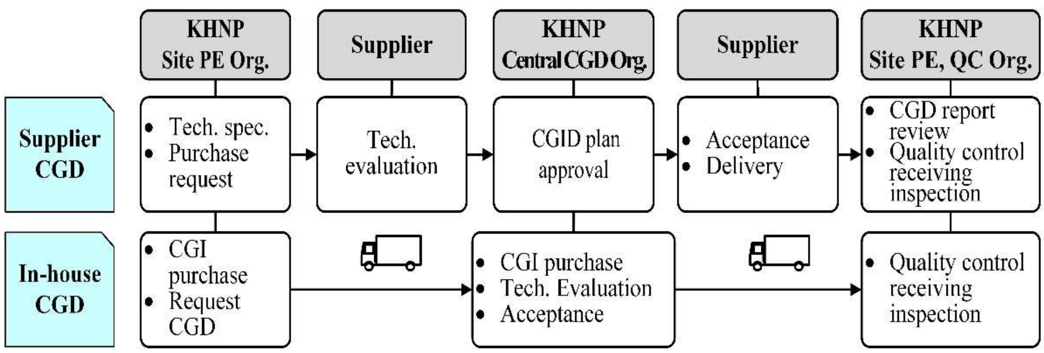

FIG. 8. CGD process steps for performance at supplier or in-house (Courtesy of KHNP).

In-house CGD is carried out by KHNP's CGD engineers and is a process of accepting commercial items that perform safety functions in safety-related installation and procurement engineering as basic items:

- The technical evaluation includes safety function analysis (for parent equipment and parts), FMEA, operating experience (OE), critical characteristics, acceptance criteria, acceptance method, and sampling of CGI;
- Acceptance of CGI is carried out in-house test facility, and most of the acceptance method is the tests and inspections.

There are a variety of commercial grade items such as a ball bearing, fuse, and capacitor that perform safety function in safety-related installations, and these are CGD for periodic preventive maintenance and/or trouble shooting through supplier and/or in-house CGD process. The main CGIs supplied to power plants using CGD process over the past 10 years are shown in Fig. 9.

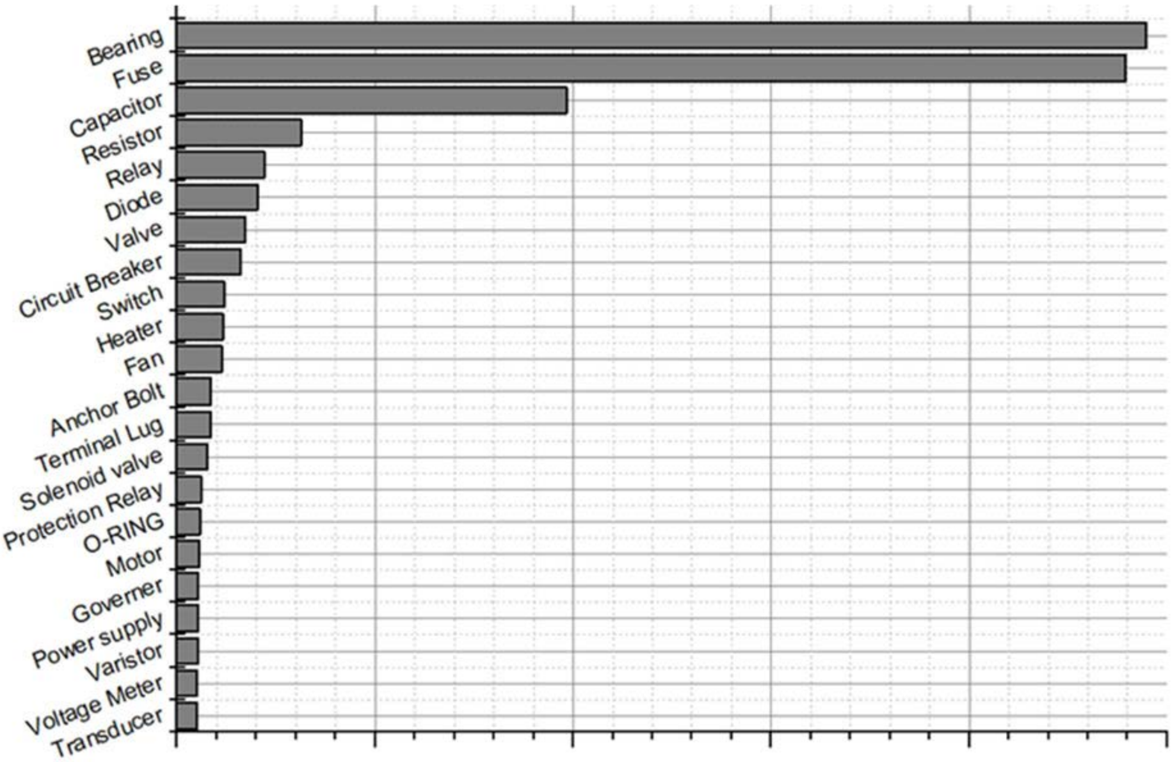

FIG. 9. Relative volume of various commercial grade items supplied to South Korea nuclear power plants over the past decade (Courtesy of KHNP).

VII.2.2. Power plants in construction

KHNP is under construction of APR 1400 nuclear power plants, Shin-Hanul units 1&2, Shin-Kori units 5&6. Nuclear suppliers design and manufacture safety-related equipment with commercial raw materials and parts and accept them by CGD requirement according to the process steps shown in Fig. 10. At this time, supplier submits the CGD plan to KEPCO E&C Co., Inc. (Nuclear engineering company in South Korea) for approval. And after CGD is completed, KEPCO E&C Co., Inc. reviews a supplier's CGD reports to prevent the possibility of CFSI.

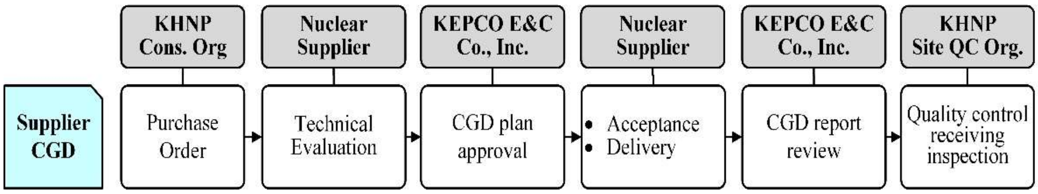

FIG. 10. CGD process steps for performance at suppliers providing products to nuclear power plants under construction (Courtesy of KHNP).

VII.3. LESSONS LEARNED ON COMMERCIAL GRADE DEDICATION

Lessons learned including guidance and management actions.

VII.3.1. Commercial Grade Dedication Guide

Korea regulatory body endorsed the EPRI CGD guides, EPRI NP-5652 and TR-106439 [31] in 2011 and did not approve EPRI TR-102260 (Supplemental Guidance for the Application of EPRI NP-5652), TR-017218-R1 (Guideline for Sampling in the Commercial grade Item Acceptance Process). Therefore, regulatory body, KHNP and nuclear suppliers in South Korea are working on a project for EPRI 3002002982 (CGD Guide, NP-5652+TR-102260, Rev.1) technical evaluation, based on South Korea's nuclear law and regulatory guide [30].

VII.3.2. Commercial Grade Dedicationof Commercial Off-the-shelf digital equipment

According to EPRI TR-106439, COTS digital equipment need to be dedicated by commercial survey method to identify dependability critical characteristics in a digital equipment's manufacture [31]. Just because their products would be for nuclear power plants, some suppliers did not cooperate with commercial survey to review quality assurance programs, software verification & validation reports, and operation history data etc. The introduction of CGD guide for COTS digital equipment using IEC 61508 safety integrity level (SIL) Certification in US NRC and NEI is considered a reasonable alternative. Recently, Korea regulatory body has launched the project to review IEC 61508 safety integrity level (SIL) Certification to support the acceptance of COTS digital equipment in the Safety-related installations.

VII.3.3. Procurement and inventory management of a maintenance material

KHNP operates 24 nuclear power plants and 2 nuclear power plants under construction are scheduled for the commercial operation in 2022. Timely procurement and inventory management of maintenance materials are important for stable operation and to support preventive maintenance of power plants. KHNP is trying to supply parts necessary on the requested date and control inventory materials with upgraded procurement systems such as Supply Chain Management, Integrated Purchase and Material Information System, and Procurement Procedures.

APPENDIX VIII.
GRADED APPROACH PRINCIPLE IN KELPO COOPERATION

The Finnish nuclear power companies (TVO and Fortum) have implemented a cooperation framework called KELPO, which aims to promote the use of high-quality serially manufactured industrial standard equipment (i.e., commercial grade products), standardize equipment requirements, and harmonize procedures towards equipment suppliers and the Finnish Radiation and Nuclear Safety Authority (STUK).

VIII.1. KELPO COOPERATION IN EQUIPMENT QUALIFICATION IN FINLAND

The KELPO cooperation model has been developed by the Finnish nuclear power companies with STUK participating as an observer. Graded approach is one of the main elements of the KELPO cooperation.

These development measures are important, as they help to ensure the availability of high-quality equipment, which promotes positive safety development in the evolving operational environment. Furthermore, the measures advance to allocate resources to relevant targets by minimizing overlapping work and thus affect also cost efficiency.

KELPO operating method refers to the licensee's joint approval procedures for serially manufactured high quality industrial standard equipment. KELPO cooperation also includes the harmonization of the technical requirements and documentation related to the procurement and approval of equipment. In addition, it enables the licensees to exchange lessons learned within the limitations set by competition legislation.

Both licensees have their own equipment procurement processes. The KELPO procedures provide an alternative procedure for a defined part of the procurement process used by licensees for necessary approvals in their equipment procurement procedure. The KELPO part of the process, which is shared by the licensees, may include joint approvals related to general equipment requirement specifications, suppliers, and product families offered by suppliers. The joint approvals are completed and documented on the shared KELPO digital platform.

VIII.2. UTILISATION OF HIGH-QUALITY SERIALLY MANUFACTURED INDUSTRIAL STANDARD EQUIPMENT

KELPO methodology implements graded approach principles and enables utilization of high-quality serially manufactured industrial standard equipment operated in safety classified places. Procedures results into licensees jointly approved General Equipment Requirement Specification (GERS) that is also reviewed and approved by STUK as needed.

The KELPO scope extends to SC3 and significant amount of SC2 equipment. In the KELPO cooperation model the graded approach is implemented e.g., through the following principles:

- The regulatory authority's (STUK) role is focused to the higher safety class items and license holder may take bigger role in approval of the lower safety class equipment;
- In safety class 3 and partly safety class 2 high quality industrial standard equipment can be used by applying graded approach:

- Industrial standard equipment can be used as such when nuclear specific requirements (e.g., seismic, radiation resistance, etc.) are not relevant and the suppliers' capability to supply the equipment with required quality is assessed;
- Industrial standard equipment can be used as such even in the case where nuclear specific requirements are relevant. In such cases the license holder assures that any necessary additional qualification actions are carried out according to the relevant requirements;
- Industrial standard equipment can be also tailored in small extent to meet nuclear specific requirements, as long as this is feasible for the equipment supplier considering their standard design, manufacturing and testing processes;

• In the higher safety classes (meaning safety class 1 and part of safety class 2 equipment) or in the cases of specific nuclear requirements which cannot be met by serially produced industrial standard equipment, the equipment is purchased from the supplier capable to meet nuclear specific standards or other relevant nuclear specific requirement;

• When industrial standard equipment is used for safety classified applications, a graded approach is used for the preparation of the requirement specifications and approvals in the following way:

  - General equipment requirements are prepared, and capable suppliers are mutually approved by all three Finnish nuclear utilities; and
  - Requirements that are specific for the operating location or intended application(s) of the equipment are handled solely by relevant license holder;
  - The regulatory authority's (STUK) processing and approvals are related to the safety significance of the equipment.

VIII.3. UTILIZATION OF MANUFACTURERS' PRODUCT FAMILIES

The KELPO equipment approval procedure can be applied provided that serially manufactured industrial standard equipment is able to meet the safety classification of the equipment and the safety functions set to the service place of the item. The manufacturers' product families of the are in essential role in the KELPO approval process. The process starts by preparation of a general equipment requirement specification for the equipment group or family, including template for the specific requirements relevant for the service place of the item. After completion the approval of the authority is applied for the general equipment requirement specification.

Potential equipment manufacturers offering product families that meet the equipment requirement specification are sought on the market. Selected suppliers and respective product families are assessed and when compliancy with requirements is established a joint approval of the supplier and product family in question can be given covering all three licensees (see Fig. 11).

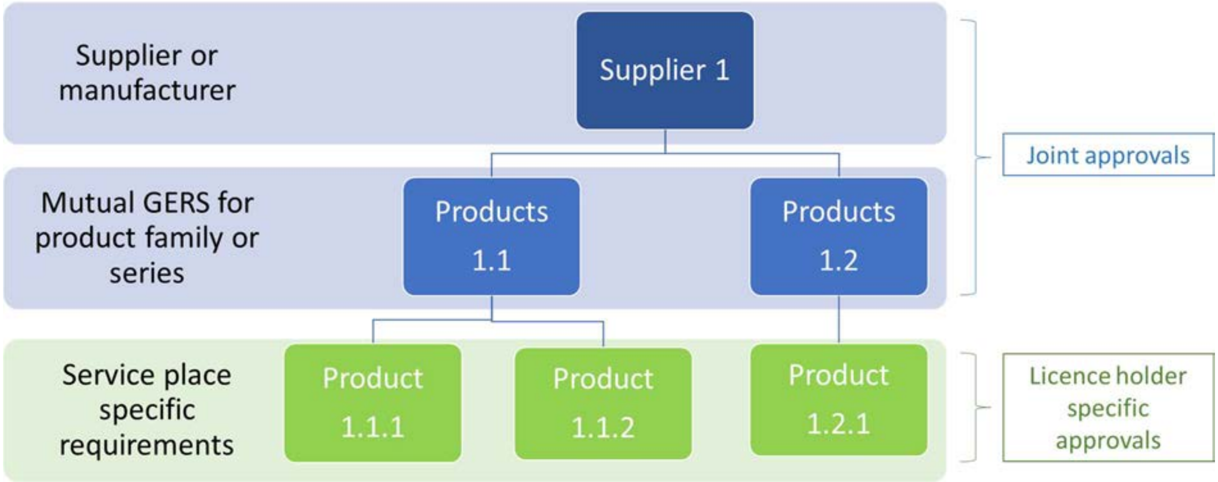

FIG. 11. Utilization of mutual approvals in KELPO equipment approval process.

The procuring licensee completes the general equipment requirements with specific requirements of the item service place by using template in the GERS. After delivery of the item, equipment receiving inspection is made by the relevant licensee when the item will get to the site. Authority or authorized inspection organization participate the receiving inspection when needed.

Finally, before installing the item to the service location, relevant licensee will make an installation plan for the item, and a final check that the equipment in question meets the relevant requirements. This is made in similar way for all equipment regardless of whether the item is procured and approved by KELPO procedures or traditional equipment procedures.

APPENDIX IX.
EXAMPLES OF SUITABILITY EVALUATION (KINETRICS)

This Appendix presents examples of commercial grade dedication obtained from Kinetrics, Canada.

IX.1. COMMERCIAL GRADE DEDICATION OF BALL BEARINGS

The following is an example of the suitability evaluation process of safety-related ball bearings (see Fig. 12) using commercial grade dedication.

FIG. 12. Photo of commercial grade single-row double-shielded ball bearings (Courtesy of Kinectrics).

IX.1.1. Project objective

The client required commercial grade dedication and of single-row double-shielded ball bearings. The grease used in the ball bearings was previously environmentally qualified by the client.

IX.1.2. Commercial Grade Dedication method application

A test program was developed that included the following:

- Test plan development in accordance with relevant technical and QA requirements;
- Execution of testing and analysis of data, in accordance with customer supplied specifications, test plan, and Canadian Nuclear Standard CSA Z299.3;
- CGD results and certificate of conformance were supplied to the customer along with the ball bearings.

IX.1.3. Commercial Grade Dedication program schedule

The execution of the CGD program included preparation of the CGD test plan in parallel with the delivery of the bearings from the OEM. Customer acceptance of the CGD test plan was carried out in parallel to incoming inspection. The items were successfully tested and shipped to the customer once the test plans had been accepted by the customer. Overall project schedule was six (6) weeks as shown in Fig. 13.

Note: On subsequent orders, the CGD plan preparation and customer review steps were not required, reducing the overall project schedule by one (1) week.

Activity	Duration					
1. Preparation of CGD Plan	1 Week					
2. Customer Approval of CGD Plan		2 Weeks				
3. Purchase of Bearings & OEM Delivery Timeline	1 Week					
4. Incoming Inspection		1 Week				
5. CGD Testing				2 Weeks		
6. Final QA Review & Shipment to Client						1 Week
Total Project Duration	6 Weeks					

FIG. 13. CGD schedule for dedication of single-row double-shielded ball bearings(Courtesy of Kinectrics).

IX.1.4. Scope of testing

Testing of the ball bearings included a verification of configuration and dimensions on a destructive sample (as the bearing needed to be disassembled to verify these parameters. Dimensions were recorded using a ring gauge to an accuracy of ± 0.010mm. The lubricant within the bearing was analyzed using Fourier Transform Infrared spectroscopy (FTIR) to confirm the lubricant was the Environmentally Qualified material.

IX.2. COMMERCIAL GRADE DEDICATION OF ENRICHED BORIC ACID

The following is an example of the suitability evaluation process of safety-related boric acid (see photo in Fig. 14) using commercial grade dedication.

FIG. 14. Photo of commercial grade Enriched Boric Acid (Courtesy of Kinectrics).

IX.2.1. Project objective

The client presented an urgent requirement to have 100 L of Enriched Boric Acid (EBA) to be tested and dedicated as quickly as possible to support an ongoing outage. The test requirements for the EBA were provided by the customer which acted as the basis for the CGD test plan.

IX.2.2. Commercial Grade Dedication method application

A test program was developed that included the following:

- Execution of testing and analysis of data, in accordance with customer supplied specifications, test plan, and Canadian Nuclear Standard CSA Z299.3;
- CGD results and certificate of conformance were supplied to the customer along with the EBA.

IX.2.3. Scope of testing

Testing of the EBA included an incoming inspection which verified lot and batch code, manufacturing location as well as a fraudulent part inspection. A chemical analysis was carried out which determined the percent concentration (by weight) of Boric Acid within the lot. Sampling was used based on lot homogeneity determined during incoming inspection in order to reduce costs and reduce testing time required while also maintaining surety that the entire lot had been tested.

IX.2.4. Commercial Grade Dedication program schedule

The execution the CGD program included preparation and customer acceptance of the CGD test plan in parallel with OEM delivery of the EBA. Testing was carried out immediately following incoming inspection of the material and preparation of final shipping docs were generated in anticipation of acceptable test results. Once test results were available, they were verified to be within acceptance parameters and the EBA was shipped to the customer. Overall project schedule was less than a week as shown in Fig. 15.

Activity	Duration				
1. Purchase of EBA & OEM Delivery Timeline	3 Days				
2. Development of CGD Plan	1 Day				
3. Customer Acceptance of Test Plan		1 Day			
4. Incoming Inspection				2 Hours	
5. CGD Testing				24 Hours	
6. Final QA Review & Shipment to Client					4 Hours
Total Project Duration	<5 Days				

FIG. 15. CGD schedule for dedication of enriched boric acid (Courtesy of Kinectrics).

IX.3. COMMERCIAL GRADE DEDICATION OF DUPLEX STRAINER

The following is an example of the suitability evaluation process of a safety-related duplex strainer (see Fig. 16) using commercial grade dedication.

FIG. 16. Photo of duplex strainer (Courtesy of Kinectrics).

IX.3.1. Project objective

The client required commercial grade dedication and seismic qualification of a duplex strainer with attached differential pressure gauge. The strainer would be used to filter zebra mussels from the shutdown cooling (SDC) water system before the water enters the SDC system.

IX.3.2. Commercial Grade Dedication method application

A test program was developed including:

- Test plan development in accordance with all technical and QA requirements;
- In-house design and fabrication of a test flow loop for flow testing;
- Execution of testing and analysis of data, in accordance with customer supplied specifications, test plan, and Canadian Nuclear Standard CSA Z299.3;
- Test report providing assurance of qualification to Design Basis Event (DBE) Category B, which requires that a device maintain its pressure boundary integrity and functions during and following an applicable seismic event.

IX.3.3. Scope of testing

The seismic qualification program for this project was completed to meet Design Basis Event (DBE) Category 'B', which requires that a device maintain its pressure boundary integrity and functions during and following an applicable seismic event.

The scope of testing included a visual inspection, functional baseline test, tri-axial Random Multi-Frequency (RMF) Seismic Test, and final functional test. Testing was completed under Kinectrics' QA program, which meets the requirements of Canadian nuclear standards.

The commercial grade dedication testing included verifying pressure boundary integrity, dimensions, configuration, and a one-time functional test to verify the flow capabilities of the strainer (see Fig. 17).

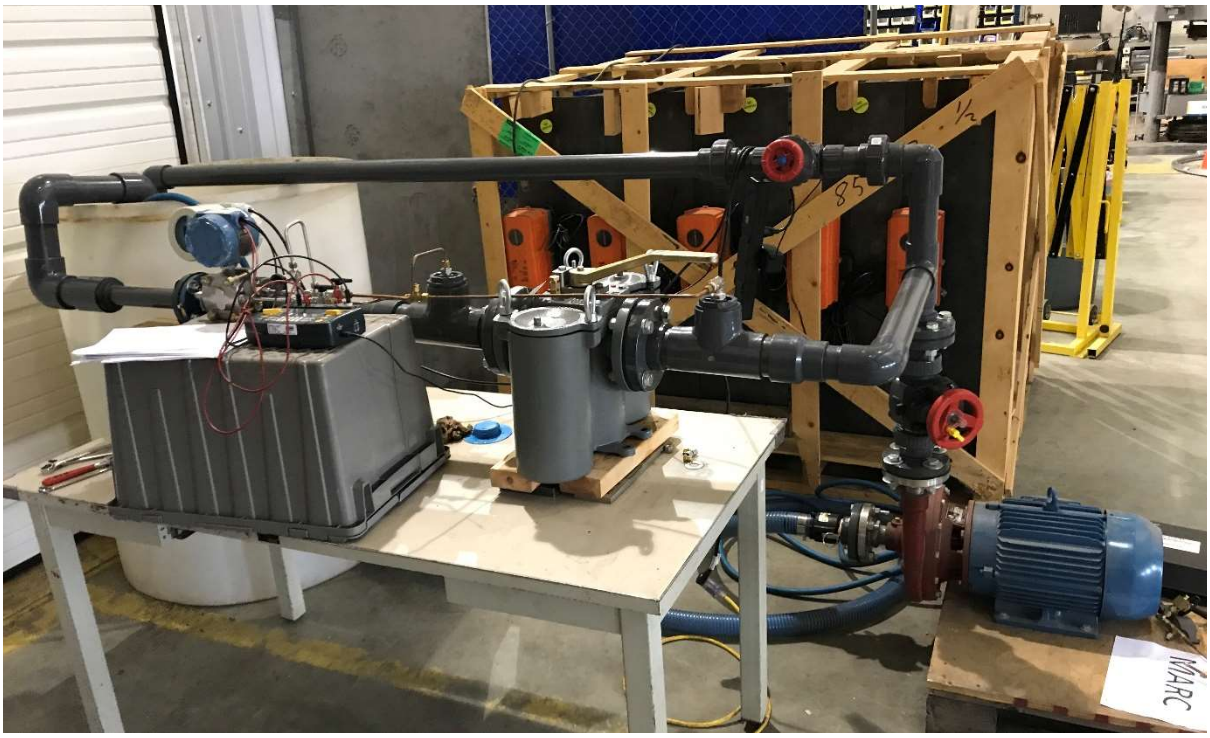

FIG. 17. Photo of duplex strainer dedication testing setup (Courtesy of Kinectrics).

IX.3.4. Commercial Grade Dedication program schedule

The execution of the CGD program included preparation of the CGD plan and Seismic Qualification plan in parallel. Following customer acceptance of the test plans and receipt of the items from the OEM, testing was carried out to the approved procedures, a report was generated and accepted by the client and the dedicated item was supplied to the customer. The seismically tested sample was marked as a destructive sample, was not supplied to the customer, and was stored at the test facility to use to compare for future orders. Overall project schedule was eleven (11) weeks as shown in Fig. 18. On subsequent orders, the activities related to seismic testing were not repeated and the overall project schedule was shortened to seven (7) weeks.

Activity	Duration
1. Preparation of CGD Plan	1 Week
2. Customer Approval of CGD Plan	2 Weeks
5. Purchase of Bearings & OEM Delivery Timeline	5 Weeks
6. Incoming Inspection	1 Week
7. Seismic Qualification Testing	3 Days
8. CGD Testing	3 Days
9. Seismic Qualification Report	1 Week
10. Customer Acceptance of Seismic Report	2 Weeks
11. Final QA Review & Shipment to Client	1 Week
Total Project Duration	11 Weeks

FIG. 18. CGD and qualification testing schedule (Courtesy of Kinectrics).

IX.3.5. Commercial Grade Dedication test program benefits

The seismic qualification and one-time verification of the flow capacity of the strainer provided a baseline for future purchases of the strainer. Subsequent orders only needed the following characteristics to be verified:

- Configuration;
- Dimensions;
- Weight;
- Pressure boundary integrity.

This reduced scope on subsequent orders led to significantly shorted delivery times and cost to the client.

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ABBREVIATIONS

AFCEN	French Society for Codified Rules for Design, Construction and In-Service Inspection of Nuclear Island Components
API	American Petroleum Institute
ASME	American Society of Mechanical Engineers
CCF	common-cause failure
CFSI	counterfeit, fraudulent and suspect items
CGD	commercial grade dedication
COTS	commercial off-the-shelf
EPRI	Electric Power Research Institute
FMEA	failure mode and effects analysis
FMECA	failure mode effects and criticality analysis
GSR	General Safety Requirements
I&C	instrumentation and control
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
ISO	International Standards Organization
LPBF	liquid powderbed fusion
MS	Member State
NEK	Nuklearna elektrarna Krško
NPP	nuclear power plant
NRC	Nuclear Regulatory Commission
OEM	original equipment manufacturers
PAM	performance assessment methodology
PPA	probabilistic performance assessment
PSA	probabilistic safety assessment
QA	quality assurance
QC	quality control
SMR	small modular reactor
SSC	structure, system or component
STUK	Finnish Radiation and Nuclear Safety Authority (Säteilyturvakeskus)
TVO	Teollisuuden Voima Oy, a Finnish utility

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