2024 TECHNICAL REPORT

Commercial-Grade Item Dedication (CGD) Experience and Efficacy

Commercial-Grade Item Dedication (CGD) Experience and Efficacy

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ABSTRACT

The purpose of this study is to explore experience with, and the efficacy of, commercial-grade dedication (CGD). EPRI and its members developed CGD in 1988, and the methodology has been successfully used to accept commercial-grade items for use in nuclear safety-related applications for over 35 years. During this time, EPRI has updated the methodology, and practitioners have adjusted implementation accordingly to reflect lessons learned and U.S. regulatory changes.

Factors such as suppliers discontinuing nuclear quality management and assurance programs, aging equipment, obsolescence, and the need to assure the quality of items used in safety-related applications have prompted jurisdictions worldwide to successfully adopt and institutionalize CGD methodology. The methodology has also been incorporated in quality standards such as ASME NQA-1, CSA N299.1, 2, and 3, and ISO-19443.

A review of available data indicates that while the use of CGD by nuclear licensees and suppliers has increased, the performance of plant safety systems in the United States has improved. The review did not identify any systematic issues or significant safety concerns resulting from use of the methodology. Surveys and interviews conducted pursuant to this research indicate that worldwide use of CGD is also increasing and that successfully dedicated items exhibit performance comparable to that of items accepted for use using traditional quality management and assurance program techniques.

It is reasonable to conclude that use of CGD will expand to more jurisdictions and that it is an effective tool for addressing obsolescence, managing long-term operation, and assuring the quality of commercial- or industrial-grade items. It could also be an effective method for enabling the use of high-quality serially manufactured industrial-grade items in the construction of advanced and small modular reactors.

Keywords

Acceptance
Commercial-grade dedication (CGD)
Industrial grade
Procurement
Serially manufactured
Supply chain

EXECUTIVE SUMMARY

Deliverable Number: 3002029261

Product Type: Technical Report

Product Title: Commercial-Grade Item Dedication (CGD) Experience and Efficacy

Primary Audience: Nuclear regulators, nuclear licensees involved in procurement and acceptance of safety-related items, and nuclear suppliers that provide safety-related items

Secondary Audience: Nuclear design and nuclear new-build organizations interested in expanding the supply chain and use of high-quality serially manufactured industrial-grade items

KEY RESEARCH QUESTION

This study was performed in response to increasing international interest in the potential use of commercial-grade dedication (CGD) from nuclear power plant (NPP) licensees and regulatory agencies in jurisdictions that have not yet implemented or are evaluating expanding the use of CGD and similar methodologies.

The objectives of the study are to:

- Provide quantitative data related to CGD and commercial-grade items from different jurisdictions
- Provide information on how CGD is applied by entities in different jurisdictions
- Provide information on the degree to which commercial-grade items are dedicated and utilized globally in NPPs as safety-related structures, systems, and components
- Provide newcomers with an understanding of the historical use and efficacy of CGD as an acceptance process for commercial-grade items in the nuclear industry

RESEARCH OVERVIEW

This study included:

- Collection and review of operating experience
- Surveys of and interviews with international suppliers that provide CGD services
- Surveys of and interviews with international NPP licensees with CGD experience
- Review and analysis of publicly available data on defects and noncompliance of NPP safety-related equipment, including dedicated items

This multi-faceted approach included discussions with regulators, licensees, and nuclear industry entities familiar with use of the CGD process and commercial/industrial-grade products in Europe, North America, and Asia. Available historical data was reviewed to ascertain the efficacy of CGD and the reliability of products accepted using the CGD process. Available databases related to operating experience and nonconformance reporting were queried for relevant information. The project also included visits to NPP and third-party facilities performing CGD for in-depth discussion about historical efficacy and experience with the CGD methodology. In addition, the project engaged other suppliers. such as reactor vendors, to learn about their experiences with CGD.

KEY FINDINGS

- Approximately 40% of nuclear power reactors worldwide currently utilize dedicated items on a regular basis. About another 40% have piloted or performed a small number of procurements using CGD. CGD accounts for a significant percentage of procurements involving safety-related items in many of the jurisdictions surveyed.
- Most jurisdictions implement CGD in accordance with EPRI guidance documents and, in some cases, local or regional derivatives.
- The CGD process is used or has been trialed in at least 11 jurisdictions to effectively procure commercial-grade items and establish that they meet specified safety requirements, perform as intended, and contribute to the overall safety and functionality of NPPs. Use of CGD is expanding into new jurisdictions, notably in Europe and Asia.
- The CGD acceptance method developed by EPRI members in 1988 has been used successfully for over 35 years in the United States. During this time, the overall performance of plant safety systems has improved. Sixty-four percent of the licensees surveyed (hailing from eight jurisdictions) reported that use of CGD remains relatively constant, while another 31% reported that it is increasing. Fifty percent of these licensees report more than 20 years of experience using the methodology, and an additional 34% report 10 to 20 years of experience.
- Licensees and suppliers surveyed recognize items accepted using CGD as equal in quality to items accepted via traditional nuclear quality management and assurance methods and therefore do not distinguish between the two methods with respect to monitoring the reliability and failures of safety-related items.

WHY THIS MATTERS

The study presented in this report can support regulatory consideration of the CGD methodology. CGD offers a reliable method to handle the increasingly complex procurement of safety-related items in the nuclear industry. As the first published report discussing the long-term successful application of CGD and the experience of licensee users of dedicated products, it increases awareness that this methodology has been in use for over three decades with successful results.

Furthermore, the findings support global decarbonization efforts by enabling the use of serially manufactured industrial-grade items for certain applications, which in turn can support the design and construction of advanced and small modular reactors. This research demonstrates that the nuclear industry can confidently rely on suppliers of serially manufactured industrial-grade items without introducing traditional, complex, and onerous nuclear contractual requirements.

HOW TO APPLY RESULTS

The information in this report can be used by various stakeholders involved in the regulation, planning, implementation, production, and development of alternatives to traditional procurement of safety-related items. Regulators can use the findings to assess the viability of CGD and develop guidelines for its implementation. For example, they may adapt existing regulations to accommodate CGD or establish a framework for evaluating the acceptability of serially manufactured industrial-grade items.

NPP licensees can apply the results to streamline their procurement processes and expand their supplier base. They can work with regulators to develop plant-specific procedures for implementing CGD, considering factors such as the relative importance of the items and the available quality assurance measures. Suppliers of industrial-grade items can use the findings to understand their role in the CGD methodology in different jurisdictions.

To facilitate the adoption of CGD or similar processes in jurisdictions exploring alternative acceptance methodologies, it is recommended to:

- Engage with stakeholders to identify potential challenges and develop solutions tailored to the specific regulatory and organizational context
- Organize workshops, training sessions, or stakeholder meetings to disseminate the findings and share best practices among organizations with CGD experience
- Encourage collaboration and knowledge sharing through the establishment of working groups or online platforms where practitioners can exchange insights and lessons learned

LEARNING AND ENGAGEMENT OPPORTUNITIES

- EPRI Nuclear Utility Procurement Course, instructor led, 3002015153.
- EPRI Commercial-Grade item Dedication Computer-Based Training, 3002015921.
- EPRI Procurement Engineering and Related Topics Symposium (P^EARTS), which discusses lessons learned about CGD and similar topics.
- Smart Procurement Engineering Evaluation Data (SPEED), an online tool that permits collaborative development and approval of CGD templates. EPRI members currently have access to this tool. They can use approved templates to create partially completed CGD technical evaluations for specific item types and applications.
- The WNA's Supply Chain Working Group meetings, which share lessons and seek to develop good practices in acceptance of industrial/commercial-grade items and related topics. The World Nuclear Association (WNA) played an important supporting role in this project.
- The International Atomic Energy Agency's Nuclear Harmonization and Standardization Initiative Industrial Track Working Group 2 discusses similar topics.

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DEFINITIONS AND ACRONYMS

Definitions

Assessment	For the purposes of this report, assessments typically include 1) audits to verify the adequacy of the quality management programs of suppliers of safety-related items and 2) commercial-grade surveys to verify identified critical characteristics are controlled by suppliers providing commercial-grade items that will be dedicated by entities relying upon the assessment to accept the identified critical characteristics.
Commercial-grade dedication	The process of evaluating and accepting a commercial-grade item (an item not controlled under a nuclear quality management or quality assurance program) for use in a nuclear safety-related application.
Commercial-grade item	An item that is not a safety-related item, that is, has not been controlled under a nuclear quality management or quality assurance program.
Critical characteristics	Those important design, material, and performance characteristics of a commercial-grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function [17].
Licensee	For the purposes of this report, a company, organization, institution, or other entity licensed in its jurisdiction to operate a commercial nuclear power generation facility.
Method 1	A quality activity involving the use of special tests and inspections to verify critical characteristics of commercial-grade items.
Method 2	A quality activity involving the use of a commercial-grade survey (assessment of the supplier's controls) to verify critical characteristics of commercial-grade items.
Method 3	A quality activity involving the use of source verification to verify critical characteristics of commercial-grade items.
Method 4	A quality activity involving the use of documented historical performance of an item or supplier to verify critical characteristics of commercial-grade items.
Nuclear supplier	An organization in the supply chain that has developed a nuclear quality management or quality assurance program and is capable of furnishing safety-related items.
Original equipment manufacturer	A supplier that is responsible for the manufacture of a specific brand of equipment. (Note: The term also applies to organizations that have acquired the rights to a specific brand of equipment.) [22]

Performance-based assessment	An assessment using a methodology that evaluates processes or activities on the basis of their performance and allows subsequent conclusions about the products of the process or activity and the quality assurance program of the supplier audited [51].
Supplier	An entity that provides an item or service. Sometimes referred to as a vendor.
Technical support organization	Any organization that provides technical support for a nuclear power plant project from planning and construction through operations and decommissioning. This may include technical support in various areas, such as engineering, technology advances, or research and development.
Vendor	An entity that provides an item or service. Sometimes referred to as a supplier.

Acronyms:

ANAV	Asociación Nuclear Ascó-Vandellós II, A.I.E.
ANSI	American National Standards Institute
API	American Petroleum Institute
ASME	American Society of Mechanical Engineers
ASN	Autorité de Sûreté Nucléaire (French Nuclear Safety Authority)
ASQ	American Society for Quality
ASTM	ASTM International, formerly American Society for Testing and Materials
BWR	Boiling water reactor
CANDU	CANada Deuterium Uranium
CC	Critical characteristic
CFR	Code of Federal Regulations (U.S.)
CFSI	Counterfeit, fraudulent, and suspect items
CG	Commercial-grade
CGD	Commercial-grade dedication
CGI	Commercial-grade item
CGID	Commercial-grade item dedication
CGS	Commercial-grade survey
CNAAA	Central Nuclear Almirante Alvaro Alberto
CNAT	Centrales Nucleares Alamaraz-Trillo, A.I.E.

CNCAN	Comisia Nationala pentru Controlul Activitatilor Nucleare (Romanian National Commission of Nuclear Activities Control)
CNRA	Committee on Nuclear Regulatory Activities
CNSC	Canadian Nuclear Safety Commission
CPE	Central Procurement Engineering (KHNP)
CRDF	Central Receiving and Dedication Facility (Duke Energy)
CRI	Central Research Institute (KHNP)
CSA	Canadian Standards Association
CSN	Consejo de Seguridad Nuclear (Spanish Nuclear Safety Council)
DI&C	Digital instrumentation and control
DIN	Deutsches Institut für Normung
ENISS	European Nuclear Installations Safety Standards Initiative
ENSREG	European Nuclear Safety Regulators Group
EU	European Union
GSR	General safety requirements (IAEA)
IAEA	International Atomic Energy Agency
IEC	International Electrotechnical Commission
IRSN	Institute for Radiation Protection and Nuclear Safety (France)
ISO	International Organization for Standardization
ITNS	Important to nuclear safety
ITP	inspection and test plan
JEMA	Japan Electrical Manufacturers' Association
JUTG	EPRI Joint Utility Task Group (now EPRI Procurement Engineering and Related Topics Symposium)
KHNP	Korea Hydro & Nuclear Power
KINS	Korea Institute of Nuclear Safety
KNA	Korea Nuclear Association
MCC	Motor control center
NCR	Nonconformance report
NEA	Nuclear Energy Agency
NEI	Nuclear Energy Institute
NEK	Nuclearna elektrarna Krško
NNEC	National Nuclear Energy Commission (Brazil)
NNSA	National Nuclear Safety Administration (China)

NPP	Nuclear power plant
NRC	Nuclear Regulatory Commission (U.S.)
NRSC	North China Nuclear and Radiation Safety Centre
NSC	Nuclear Safety Commission (Taiwan)
NSSS	Nuclear steam supply system
NUMARC	Nuclear Utility Management and Review Committee (now Nuclear Energy Institute)
NUPIC	Nuclear Procurement Issues Corporation
OECD	Organisation of Economic Cooperation and Development
OEM	Original equipment manufacturer
P^{E}ARTS	EPRI Procurement Engineering and Related Topics Symposium (formerly EPRI Joint Utility Task Group)
QA	Quality assurance
RB	Regulatory body
RG	Regulatory Guide
SIL	Safety integrity level
SNSA	Slovenian Nuclear Safety Administration
SPEED	Smart Procurement Engineering Evaluation Data (EPRI)
SSCs	Systems, structures, and components
STUK	Säteilyturvakeskus (Finnish Radiation and Nuclear Safety Authority)
SÚJB	State Office for Nuclear Safety (Czech Republic)
SÚRO, v.v.i.	National Radiation Protection Institute (Czech Republic)
TSO	Technical support organization
TVO	Teollisuuden Voima Oyj
UCI	United Controls International
U.S.	United States
WENRA	Western European Nuclear Regulators Association
WNA	World Nuclear Association

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1 INTRODUCTION AND RESEARCH SUMMARY

1.1 Introduction

In the early 1980s, there were plans to construct over 160 commercial nuclear power generating units in the United States. In the wake of the Three Mile Island accident that occurred in 1982, construction plans for many of these units were curtailed, and demand for nuclear products decreased to the point where many suppliers decided to discontinue support for the nuclear power generation industry. Due to the loss of nuclear suppliers, it became increasingly difficult for operating nuclear plants to procure needed spare and replacement items. This identified the need for licensees to be able to accept items from a supplier that had discontinued its nuclear quality assurance (QA) program (commercial supplier) to avoid design changes and replacement of all the equipment initially supplied when the supplier did have a nuclear QA program (nuclear supplier). This led to regulatory and industry actions to develop what is known as the commercial-grade item dedication (CGID) or commercial-grade dedication (CGD) process. CGD is an acceptance process undertaken to provide reasonable assurance that a commercial-grade item (CGI) to be used in a nuclear safety-related application will perform its intended safety function(s). It is an alternative to procuring an item from a supplier with a nuclear quality management or QA program.

In 1988, EPRI published the Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety Related Applications (NCIG-07) (NP-5652) [1] for use by nuclear licensees. Subsequently, CGD methodology was widely adopted by licensees as well as nuclear suppliers to accept an abundance of products from commercial/industrial inventories by establishing reasonable assurance that the items are capable of performing their safety-related design functions. Recently, a European guideline for accepting CGIs for use was published by Nucleareurope [2, 3]. Methodology and terminology similar to those of the CGD process are included in the International Organization for Standardization (ISO) nuclear-grade supplier quality management system standard, ISO 19443:2018 [4], and were recently included in Canadian Standards Association (CSA) N299.1, 2, and 3 [5, 6, 7].

A basic premise of CGD is that the item being procured is an established, reliable product from an experienced manufacturer that meets applicable design requirements. CGD methodology encompasses four basic methods of acceptance:

1. Inspection, testing, or analysis performed after receipt of the item (hereafter “tests and inspections”)
2. Assessment of the supplier’s quality controls pertaining to the item (hereafter “commercial-grade survey”)
3. Inspections or surveillance at the manufacturing facility or supplier source (hereafter “source verification”)
4. Analysis of historical performance of the supplier and/or item (hereafter “historical performance”)

Table 1-1 includes references to existing nuclear quality management and assurance documents that also describe these methods. The primary difference between traditional acceptance methods for safety-related items and CGD is that CGD affords more flexibility to the purchaser in accepting items from suppliers.

Table 1-1. Standards that describe acceptance methods

<table>
<tr><th>Jurisdiction</th><th>Standard/Regulation</th><th>Section</th><th>Method 1</th><th>Method 2</th><th>Method 3</th><th>Method 4</th></tr>
<tr><td>United States</td><td>10 CFR 50 Appendix B [8]</td><td>Criterion VII</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>International</td><td>IAEA GSR Part 2 [9]</td><td>Requirement 11</td><td colspan="4">“The organization shall put in place arrangements with vendors, contractors and suppliers for specifying, monitoring and managing the supply to it of items, products and services that may influence safety.”
“The organization shall itself retain the competence to … assess whether the product or service supplied meets the applicable safety requirements.”</td></tr>
<tr><td>International</td><td>ASME NQA-1 [10]</td><td>Requirement 7/700, Part II, Subpart 2.14</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>International</td><td>ISO 9001:2015 [11]</td><td>8.4 Control of externally provided processes, products and services/8.1 General</td><td colspan="4">“The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.”</td></tr>
<tr><td>International</td><td>ISO 19443:2018 [4]</td><td>8.4 Control of externally provided processes, products and services/8.4.2
Type and extent of control</td><td colspan="4">“The organization shall: d) determine the verification or other activities, necessary to ensure that the externally provided processes, products and services, meet requirements.”

“For d), the verification shall consider the critical characteristics of commercial grade items or activities.”</td></tr>
</table>

As the concept and implementation of CGD are relatively new in some jurisdictions, nuclear facility licensees (and their regulators) that are seeking to utilize the CGD acceptance process are interested in information on its implementation in different jurisdictions, as well as data on the use of CGIs in nuclear power plants (NPPs). The object of this report is to review available information to collect data related to the global nuclear fleet’s experience with CGD and its efficacy as an acceptance method to ensure procured items have suitable quality and reliability.

Regulators, licensees, and nuclear industry entities familiar with use of the CGD process and commercial-grade products in Europe, North America, and Asia were engaged as a part of this research. Available historical data, sourced globally, has been reviewed to determine the efficacy of CGD and reliability of products accepted using the CGD process. Available databases related to operating experience and nonconformance reporting have been queried for relevant information. Facilities performing CGD have been investigated to learn about historical activities and experience. In addition, the project has interacted with reactor suppliers, equipment suppliers, and third parties (e.g., CGD service providers with testing and inspection capabilities) to source data on CGD experience.

1.2 Objectives

The purpose of this report is to provide information to regulatory bodies, licensees, nuclear suppliers, and other industry actors regarding experience with and efficacy of the CGD methodology, and specifically to:

- Provide quantitative data related to CGD and CGIs from different jurisdictions
- Provide information on how CGD is applied by entities in different jurisdictions
- Provide information on the degree to which CGIs are dedicated and utilized globally in NPPs as safety-related structures, systems, and components (SSCs)
- Provide newcomers with an understanding of the historical use and efficacy of CGD as an acceptance process for CGIs in the nuclear industry

1.3 Research Summary

This research investigated the effectiveness and practical application of CGD in nuclear safety-related contexts. The research was initiated in response to increased global interest in CGD, particularly from NPP licensees and regulatory bodies in regions where CGD implementation is being considered or expanded. A diverse set of methods was employed to conduct this research, including an examination of operational data, engagement with CGD service providers and NPP licensees through surveys and interviews, and a thorough analysis of publicly accessible information on safety-related equipment issues in NPPs. Licensees and suppliers surveyed recognize items accepted using CGD as equal in quality to items accepted via traditional nuclear quality management and assurance methods and therefore do not treat safety-related items accepted using CGD any differently with respect to monitoring their reliability and failures. The scope of the study extends across multiple continents, incorporating insights from industry professionals, regulatory authorities, and site visits to facilities actively employing CGD to accept CGIs for safety-related applications in NPPs.

The findings of this research paint a positive picture of CGD's robust, long-term success as an acceptance method. Furthermore, the research indicates that CGD is capable of assuring quality in CGIs prior to their use in nuclear safety-related applications. The research reveals that the

CGD methodology, which has been in use for several decades, demonstrates effectiveness comparable to that of traditional nuclear QA approaches in ensuring the safety and reliability of components, according to surveyed NPP license holders.

This research has addressed questions for which answers did not previously exist, such as the volume of CGD taking place globally and trends in these practices. The volume of procurements utilizing the CGD methodology was found to be particularly high, representing a significant fraction of all safety-related procurements across different jurisdictions. The research provides a solid foundation for regulatory bodies to consider CGD as a valid methodology potentially leading to more flexible and efficient procurement processes for NPPs. For NPP licensees, the study offers evidence to support the expansion of their supplier base without compromising on quality or safety. Overall, this study represents a contribution to the body of knowledge on CGD, offering data-driven support for its wider adoption and implementation in the nuclear industry.

2 RATIONALE FOR CGD AND HISTORICAL CONTEXT

The concept of using commercial off-the-shelf parts during new reactor construction is not new. When construction of commercial nuclear power facilities began, the intent was to use proven, high-quality products in critical applications. Even the oldest operating plants contain a large number of commercial off-the-shelf components, as their design requirements were met by existing commercial products prior to the advent of nuclear QA programs, codes, and standards. Commercial components can be found in both safety-related and non-safety related applications. In some cases, individual commercial components were assembled into larger components; then, as required, supplemental testing of the components was performed to establish suitability of design, including compliance with nuclear-specific requirements, such as the ability to withstand seismic events or harsh environmental conditions.

A good example of this might be the motor control centers (MCCs) that were originally provided by nuclear steam supply system (NSSS) suppliers such as Westinghouse. NSSS suppliers established adequacy of design using methods such as design reviews, calculations, and testing programs. The manufacture of these MCCs included known high-quality commercially manufactured components such as circuit breakers, contactors, fuses, indicator lights, switches, sheet metal, wiring, and other hardware. These components were usually sourced from either subsidiary companies or other commercial suppliers. The NSSS suppliers subsequently controlled manufacture of the MCCs in accordance with quality requirements and used techniques such as audits, source verification, inspection, and testing (as necessary) to ensure the commercial parts and components used during manufacturing and the finished MCCs met applicable design requirements. The NSSS suppliers controlled these design and manufacturing activities under the auspices of their nuclear QA programs. After successful assembly, manufacture, and completion of acceptance activities such as testing, the MCCs were certified as safety-related components and sold to licensees.

In addition to the use of commercial products during new construction, as early as 1976, American National Standards Institute (ANSI) Standard N18.7-1976 [12] recognized the need to address commercial “off-the-shelf” parts that were being purchased by licensees as spare and replacement parts. The ANSI standard stated that “spare and replacement parts found to be commercial ‘off-the-shelf’ may be similarly procured as the original item or part, but care must be exercised to ensure at least equivalent performance.” Industry guidance on how to meet the intent of that statement was not developed until the 1980s, when commercial nuclear facilities began to purchase spare and replacement items from original equipment manufacturers (OEMs) to support operations and maintenance.

Development of CGD methodology was driven primarily by licensees’ needs to procure safety-related spare and replacement items from suppliers that no longer were maintaining their nuclear QA programs and therefore could not meet the applicable regulatory QA requirements imposed on nuclear suppliers by NPP customers. In addition to CGD guidance, EPRI outlined a procurement process in Guidelines for the Procurement and Receipt of Items for Nuclear Power Plants (EPRI NP-6629) [13] and Guidelines for the Technical Evaluation of Replacement Items in

Nuclear Power Plants (EPRI 1008256) [14] in 1990. These reports provided insights on safety classification, evaluating equivalency of alternative replacement items, and engineering involvement in the procurement process.

Today, CGD is considered an effective tool for reducing the impact of obsolescence, supporting long-term operations, reducing lead time for spare and replacement items, and in some cases reducing the cost of those items.

At the supplier/manufacturing level, most safety-related items that are manufactured today under nuclear-grade QA programs also contain commercial piece parts and materials. Items such as bearings, plastics and other chemical compounds, discrete electrical items (resistors, transistors, integrated circuits, diodes, etc.), uninsulated copper wire and cable, etc., are all typically sourced from commercial suppliers or distributors. A similar situation exists for the chips, programmable logic controllers, and other devices used to manufacture digital control systems. The level of control placed on these items is left up to the discretion of the higher-tier nuclear supplier, using a graded approach, as detailed by its nuclear QA program. In some cases, these suppliers have used the concept of CGD to help define appropriate controls for items procured commercially that go into their safety-related components.

In summary, all NPPs operating today contain a broad range of commercially manufactured components or sub-components, many of which are used in safety-related applications. This is most prevalent in the electrical/electronic area, with the discrete parts used to manufacture such components typically sourced primarily from commercial suppliers (including authorized distributors). In the mechanical area, the use of commercial parts in safety-related applications is usually limited to non-pressure boundary parts that do not require certification by the American Society of Mechanical Engineers (ASME) or similar organizations.

2.1 What Is a Commercial-Grade Item?

Perhaps the clearest definition of a CGI was the definition proposed in the approved Final Regulatory Basis to Clarify 10 CFR Part 21, “Reporting of Defects and Noncompliance” [15]:

> “Commercial grade item means an item that is not a basic component.”

In U.S. terminology, this means a CGI is an item that has not been accepted for use in a nuclear safety-related application. For NPPs licensed in the United States under 10 CFR Part 50 [16], a CGI is defined in 10 CFR Part 21 [17] as:

> “A structure, system, component, or part thereof that affects its safety function, but was not designed and manufactured as a basic component. This definition excludes items where the design and manufacturing process necessitate in-process inspections and verifications to identify and correct defects or compliance failures, meaning one or more critical characteristics of the item cannot be verified.”

"Commercial-grade item" is not always explicitly defined in the regulatory infrastructure of a country. In some cases, however, it is. In Taiwan, for example, the Regulations on the Dedication of Commercial Grade Items and Certification of Dedication Agency define a CGI as an item not designed or fabricated in accordance with the nuclear-grade item's unique specifications [18]. In Japan, the Regulations of the Nuclear Regulation Authority No. 2 of 2020, Ordinance on Standards for the System Necessary for Quality Control Related to Operations for the Safety of Nuclear Facilities [19], use the term "general industrial products." These are defined as equipment, structures, and systems related to the safety functions of nuclear facilities, as well as their components, that are industrial products other than those specifically designed, developed, and manufactured exclusively for use in nuclear facilities.

In Europe, CGD guidance published by Nucleareurope [2, 3] uses the term "high-quality industrial-grade item" to emphasize the pedigree of items that undergo CGD to be installed in nuclear facilities. That is, such items are not sourced from a local hardware store, but tend to be those that are widely used in safety- or operationally relevant applications in non-nuclear industrial facilities. In Finland, the KELPO methodology is focused on "serially manufactured equipment," defined as equipment that is not designed or manufactured for the location of use specifically according to the licensee's requirements. Typically, the equipment is manufactured in large batches and is also suited to other applications. The structure, dimensions, and materials of the equipment and the methods and quality of manufacture do not essentially differ within or across manufacturing batches [20].

The original definition of a CGI in the United States clearly indicated the CGD methodology was intended for use in accepting serially manufactured commercial/industrial-grade items. The criteria in this definition required that a CGI be:

- Not subject to design or specification requirements that are unique to nuclear facilities,
- Used in applications other than nuclear facilities, and
- Able to be ordered from the manufacturer or supplier based on specifications included in the manufacturer's published product description.

The definition was later changed to expand applicability of the methodology. In practice, CGIs can be everything from raw materials or discrete small electrical components to emergency diesel generators or Boron analyzers.

2.2 Why Commercial-Grade Items Are Procured

The historical rationale for using CGD within the nuclear industry is anchored in the necessity to ensure the safety and reliability of NPPs while addressing the challenges of dwindling availability of parts specifically designed and certified for nuclear safety-related applications. Over time, the number of suppliers maintaining nuclear QA programs has decreased, leading to a scarcity of readily available parts from suppliers with approved nuclear QA programs. Licensees contacted for this study reported overwhelmingly that nuclear-grade item availability was the most influential factor in deciding whether to accept an item using the CGD process.

Other reasons behind the use of CGIs and the CGD methodology are:

- Ability to access a larger, more competitive supply chain
- Quality issues with unique nuclear-grade equipment
- Need for shorter delivery lead times
- Need to verify quality in warehoused or off-the-shelf items such as surplus inventory from other jurisdictions
- Lower costs

Licensees reported that quality and lead time could be decisive in choosing to accept an item using CGD, while cost was the least influential factor.

3 THE CGD PROCESS

The CGD acceptance process in the nuclear industry is a systematic approach for achieving reasonable assurance that a procured commercial-grade item (or service) will perform its safety function(s) in service. This process is integral to ensuring that CGIs to be used in support of safety at nuclear facilities have a high degree of quality, despite not being originally designed or manufactured for nuclear use. The CGD process encompasses several interrelated steps and elements, each critical to the overall integrity and safety assurance of the nuclear facility.

The CGD process typically begins with a technical evaluation conducted to ensure that the item is eligible for dedication, that its safety function(s) are known, and that its design and performance capabilities align with the requirements of the intended safety-related application. This evaluation typically involves a thorough review of the manufacturer's published data and the licensee's own data related to the application.

As a part of the technical evaluation, critical characteristics of the CGI are determined and defined, along with their acceptance criteria, by suitably experienced engineering staff. The identification and verification of critical characteristics is necessary for the safe and reliable operation of the CGI within its intended nuclear application. These characteristics relate to physical, performance, or dependability properties that are essential for the item's performance under specified conditions.

Following the identification of critical characteristics, acceptance methods are chosen and executed. The acceptance methods are common QA and quality control activities. They are:

- Method 1 (tests and inspections): examination of products upon delivery
- Method 2 (commercial-grade survey): source evaluation and selection
- Method 3 (source verification): inspection at the contractor or subcontractor source
- Method 4 (historical performance): objective evidence of quality furnished by the manufacturer

Typically, each critical characteristic is verified by at least one acceptance method.

Upon successful verification of all of an item's critical characteristics, the item is formally dedicated for use, accompanied by a dedication package that encapsulates all relevant documentation, affirming the item's compliance with the CGD plan and its suitability for use in a nuclear safety-related context. Detailed records are maintained to provide traceability of the decision-making process, evaluations, testing results, and any corrective actions undertaken. This comprehensive documentation confirms the item's suitability for use in safety-related applications within the nuclear facility.

It is important to note that the process of CGD is a safety-related activity and requires the dedicating entity to have an approved nuclear QA program.

Details about the CGD process in different jurisdictions can be found in the industry guidance documents included in Section 3.1 of this report.

3.1 Industry Guidance Documents

Since the first EPRI guideline on the utilization of CGIs in nuclear safety-related applications was published in 1988, additional guidance documents, reports, and standards related to the acceptance process have been published, both in the United States and abroad. Table 3-1 lists worldwide industry guidance documents on CGD.

Table 3-1. CGD guidance documents and standards

Country or Region	Title	Reference Number	Publisher, Year
USA	Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications, revision 1 to EPRI NP-5652 and TR-102260 [21]	3002002982	EPRI, 2014
USA	Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07) [1] (superseded by EPRI 3002002982 [21])	NP-5652	EPRI, 1988
USA	Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items [22] (superseded by EPRI 3002002982 21])	TR-102260	EPRI, 1994
Europe	Quality Assurance Guideline for Procuring High-Quality Industrial Grade Items Aimed at Supporting Safety Functions in Nuclear Facilities [2, 3]	Nucleareurope European CGD Guideline	Nucleareurope, 2022
Spain	Guía para la dedicación de componentes de grado comercial en centrales nucleares (Guide for the dedication of commercial-grade components in nuclear power plants) [23]	UNE 73-104-94	UNE, 1994
Spain	Utilización de elementos de calidad comercial en aplicaciones relacionadas con la seguridad de instalaciones nucleares (Use of commercial quality elements in applications related to the safety of nuclear facilities) [24]	UNE 73-403-95	UNE, 1995
Japan	Draft guidelines for the adoption of industrial products for general industries Reiwa 3 edition [25]	ME-OG-0003 Rev. 0	2020
South Korea	Commercial Grade Item Dedication (CGID) Process Guideline for Nuclear Supplier [26]	Korea Nuclear Association (KNA)22-03-1	KNA, 2022

3.2 Topical Reports on CGD

The CGD methodology is applicable to many different procurement scenarios and item types. In order to address many of these cases in more detail, EPRI has published a wealth of guidance on specific topics. Table 3-2 lists EPRI reports on specific CGD topics.

Table 3-2. EPRI guidance documents providing more detail on the application of CGD

Title	Reference	Year
Guideline for Sampling in the Commercial-Grade Item Acceptance Process [27]	TR-017218-R1	1999
Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI) [28]	TR-112579	2000
Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (Revision 1) [14]	1008256	2006
Plant Support Engineering: Information for Use in Conducting Audits of Supplier Commercial Grade Item Dedication Programs [29]	1016157	2008
Plant Engineering: Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications: Revision 1 of 1025243 [30]	3002002289	2013
Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications [31]	TR-106439	1996
Commercial-Grade Digital Equipment for High-Integrity Applications: Oversight and Review of Evaluation and Acceptance Activities [32]	1025283	2013
Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants [33]	107330	1996

3.3 Evolution of Nuclear Quality Assurance and Acceptance of Commercial-Grade Items in the United States

Over the last 50 years, the practice of CGI in the United States has evolved through the convergence of two separate but related regulatory paths. The first path pertains to the standards and guidance developed to meet the QA regulations associated with the design, construction, maintenance, and operation of nuclear reactors. These regulations originated with Criterion 1 of the Atomic Energy Commission (later renamed the Nuclear Regulatory Commission [NRC]) General Design Criteria contained in Appendix A to 10 CFR Part 50 [34], which in general terms specifies that:

> "Structures, systems, and components important to safety shall be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions to be performed" [34].

The regulations associated with QA were further refined in 1971 with the issuance of Appendix B to 10 CFR Part 50 [8], which contains the 18 principal criteria associated with nuclear QA, including Criterion VII, “Control of Purchased Material, Equipment, and Services.”

To provide guidance on how to meet the requirements of Appendix B, the nuclear industry developed multiple industry standards, including the general requirements and guidelines for establishing and executing a QA program during the design and construction phases. This guidance is provided in ANSI N45.2 1971, Quality Assurance Program Requirements for Nuclear Power Plants [35]. The standard was subsequently endorsed by the Atomic Energy Commission (later renamed the NRC) via Safety Guide 28 [36]. A subsequent standard, ANSI N18.7-1976 [12], also endorsed by the NRC, was focused more on the operational phase of the NPP lifecycle. This standard recognized the need to address commercial “off-the-shelf” parts that were being purchased as spare and replacement items. The ANSI standard stated that:

> “spare and replacement parts found to be commercial ‘off-the-shelf’ may be similarly procured as the original item or part, but care must be exercised to ensure at least equivalent performance” [12].

In the 1980s, ANSI N45.2 [35] and N18.7 [12] were combined in, and superseded by, ASME NQA-1 [37]. As construction of new nuclear facilities decreased in the early 1980s, the number of suppliers with nuclear QA programs also decreased. This resulted in the need to develop a methodology for licensees to accept items from suppliers that had discontinued their nuclear QA programs but could still manufacture spare and replacement items for the equipment installed in nuclear facilities. In 1988, nuclear licensees collaborated through EPRI to develop Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07) (NP-5652) [1].

The 1989 revision to ASME NQA-1 [37], Supplement 7S-1, required that for CGIs:

> “Inspection and/or testing is accomplished, as required by the Purchaser, to assure conformance with the manufacturer’s published requirements.”

The 2009 revision to ASME NQA-1 [38] expanded upon the previous guidance and included new requirements in Part I, Requirement 7, and Part II, Subpart 2.14, associated with the procurement of commercial-grade items and services. In the 2017 edition [39], important clarifications were made to the language added in 2009. Part 1, Requirement 7, was updated to clarify that CGD is not mandatory; it is an alternative to meeting the other requirements in sections 200 through 600 in Part 1 of Requirement 7. The language in Subpart 2.14 was also clarified to address specific questions and misinterpretations.

3.4 Evolution and Regulatory Acceptance of CGD Methodology

In parallel with the evolution of nuclear QA requirements, regulatory consideration of CGD methodology began in June 1977, when the NRC issued 10 CFR Part 21 [17] as a new regulation pertaining to the reporting of defects discovered in safety-related components. In 1979, 10 CFR Part 21 was revised to clarify the reporting requirements for manufacturers. In this revision, the term “dedication” was introduced as a “point in time” as follows:

> “Dedication of a commercial grade item occurs after receipt when that item is designated for use as a basic component” [17].

In 1988, EPRI issued NP-5652, Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications [1]. The guidance was developed to address licensees’ need for a documented methodology that would ensure that CGIs used in nuclear safety-related applications were properly accepted or “dedicated” for use in safety-related applications in accordance with the terminology in the definitions section of 10 CFR 21 [17]. In 1989, this guidance was conditionally endorsed by the NRC via Generic Letter (GL) 89-02 [40].

In 1991, the NRC issued GL 91-05, Licensee Commercial-Grade Procurement and Dedication Programs [41], which highlighted specific weaknesses that had been identified during NRC inspections. The letter also sought to provide enhanced guidance on use of the term “critical characteristics.” EPRI followed this in 1994 with Supplemental Guideline for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items, TR-102260 [22], which provided additional clarification in certain areas, captured lessons learned, and addressed industry and regulatory developments subsequent to the issue of NP-5652.

A 1996 revision to 10 CFR Part 21 [17] revised the regulatory definition of “dedication” for commercial nuclear power facilities:

> (1) . . . 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. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at hardpoints at the manufacturer’s facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted In accordance with the applicable provisions of 10 CFR Part 50, appendix B. The process is considered complete when the item is designated for use as a basic component.
>
> (2) . . . dedication occurs after receipt when that Item Is designated for use as a basic component. [17]

The new definition incudes a description of the dedication process consistent with EPRI NP-5652 [1] and emphasizes that

> "the objective of dedication is 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."

This equivalency from a quality perspective is consistent with the overall concept of CGD as it is defined and practiced today.

Lastly, in 2014, EPRI issued Plant Engineering Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications, Revision 1 to NP-5652 and TR-102260 (3002002982) [21], which provides the detailed guidance for CGD currently utilized by most practitioners in the United States. In 2017, the NRC conditionally accepted this EPRI guidance in Regulatory Guide (RG) 1.164 [42] as being an acceptable way of meeting the applicable regulatory requirements for the dedication of commercial-grade items and services used in NPPs.

In a 2019 survey of 12 countries performed by the Organisation of Economic Cooperation and Development Nuclear Energy Agency, Committee on Nuclear Regulatory Activities (OECD/NEA CNRA), which focused on digital instrumentation and control (DI&C) [43], it was noted that the nuclear industry employs a systematic approach for qualifying commercial off-the-shelf products, which might include a formal CGD process. Among other important findings, the survey found that the integration of embedded digital devices is a common international practice among commercial suppliers, primarily to replace analog components that are dated or becoming obsolete.

In 2020, the FORATOM Supply Chain Optimisation Working Group published a working paper [44] that called for the global nuclear industry to develop a European guideline that includes a common methodology for the acceptance of high-quality industrial-grade items in certain safety-classified applications. To achieve this goal, cross-stakeholder collaboration between entities such as European Nuclear Installations Safety Standards Initiative (ENISS), Western European Nuclear Regulators Association (WENRA), and the European Nuclear Safety Regulators Group (ENSREG) was encouraged. During the following two years this project was realized, and in 2022 the FORATOM (now Nucleareurope) European guideline on high-quality industrial-grade dedication was published [2, 3]. The project was a first-of-its-kind effort as it assembled and was directed by a broad base of stakeholders, primarily European nuclear facility license holders. The European nuclear industry is continuing to pursue objectives laid out in the original working group paper [44], namely, that EU member states and other European countries should develop national guidance for the use of high-quality industrial-grade items based on the common European guideline.

The two-volume FORATOM (now Nucleareurope) European Guideline is entitled Quality Assurance Guideline for Procuring High-quality Industrial Grade Items Aimed at Supporting Safety Functions in Nuclear Facilities [2, 3]. It is a publicly available report largely compatible with the previously referenced EPRI guidance. It expands upon the EPRI guidance in some areas, and it is aligned to accommodate the varied regulatory requirements in Europe and the needs of the European nuclear community.

CGD has also become integral to modern nuclear quality management systems and QA programs, including ASME NQA-1 [10], ISO 19443 [4], and CSA N299.1, 2, and 3 [5, 6, 7]. The use of CGIs and a means to control their suitability for use as items important to safety in nuclear facilities is categorized within the procurement process and relates to the control of procured items and services. For example, in ASME NQA-1 [10], the detailed requirements for CGD currently included in Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services, are referenced in Requirement 7, Control of Purchased Items and Services, while in ISO 19443:2018 [4], the verification of critical characteristics of CGIs is part of Requirement 8.4 on control of externally provided processes, products, and services. In CSA N299.1 [5], N299.2 [6], and N299.3 [7], dedication requirements are discussed in Section 8, Dedication Requirements.

3.5 U.S. Experience with CGD

As described previously in this report, the CGD process has been used extensively in the United States to accept commercial-grade components, parts, and services for use in safety-related applications. Its use began in the mid-1980s and has expanded significantly over the past 36 years. Currently, CGD is broadly used by licensees and suppliers in the United States and is accepted by the regulator (NRC) as a means of procuring replacement parts and services. Some licensees use the process for substantial portions of safety-related procurements.

Users of the CGD process identify and carefully evaluate an item's intended safety-related functions and determine and verify characteristics of the item that are critical to its ability to perform those functions. Thus, successful completion of the CGD process provides reasonable assurance that the item will be capable of performing its safety functions.

Throughout this 36-year period, the NRC has devoted significant resources to the oversight of the nuclear industry supply chain, including the practice of CGD. This oversight includes inspections at licensees and suppliers, monitoring and assessment of 10 CFR Part 21 [17] reports associated with the failure of safety-related items, participation in related standards development and industry guidance committees, and development of related regulatory guidance. This continued oversight has provided extensive information on the effectiveness of the industry's implementation of CGD throughout the supply chain, with the goal of providing reasonable assurance that items accepted for use in safety-related applications using CGD are capable of performing their safety-related functions. Additional information concerning the review of recent Part 21 reports associated with the failure of safety-related items is contained in Section 3.17 of this report.

3.6 Users of CGD

CGD is used by various organizations in and around the commercial nuclear power industry. Since its initial development by and for NPP licensees, CGD has become a regular practice throughout the supply chain. Users include both power-generating and fuel cycle nuclear facility licensees. Users include licensees, nuclear suppliers, and third-party CGD service providers. CGD service providers generally serve the licensees that request the dedication of one or more specific CGIs.

The distinction between a "nuclear-grade" item (that is, a "basic component" or "safety-related" item) and a CGI depends upon the type of quality management or assurance system that accepted the item. A CGI becomes a nuclear-grade item when an entity with a nuclear quality management or assurance program accepts it for use in a nuclear safety-related application. In reality, all items start out as commercial grade. Since the nuclear industry is characterized by a small but specialized supply chain, many of the necessary materials, piece parts, and other sub-components present in an NPP started their journey at industrial suppliers with non-nuclear quality management programs, such as those defined by quality standards (e.g., ISO 9001 [11]) or industry-specific standards (e.g., ASTM, DIN, or API). According to survey responses received during development of this report, reactor technology vendors like Westinghouse perform large volumes of CGD.

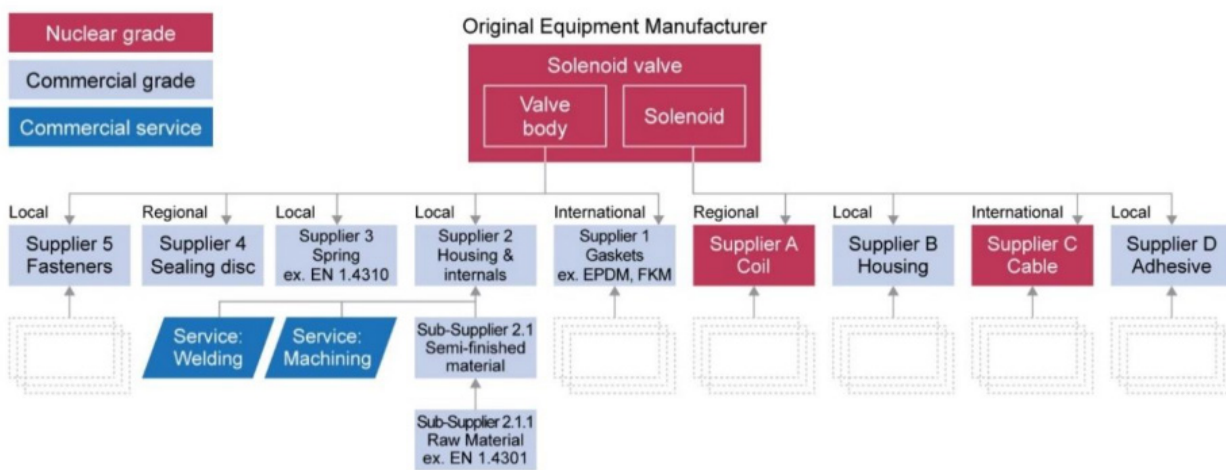

Figure 3-1. Example of a supply chain of a safety-class solenoid valve manufacturer, demonstrating widespread use of commercial-grade items and services in the fabrication and assembly of the final safety-class item (courtesy of World Nuclear Association) [45]

Figure 3-1, from The World Nuclear Supply Chain 2023 [45], represents the supply chain of a nuclear OEM that supplies solenoid valves for safety-related use. Manufacture of these solenoid valves by a nuclear supplier involves CGIs (represented by light blue shapes) and commercial-grade services represented by dark blue shapes). Nuclear suppliers may accept these commercial-grade raw materials, parts, and services by using CGD, by verifying that applicable design requirements are met without CGD, or a combination of both methods. Dedicated products are controlled under the nuclear supplier's nuclear quality management program and supplied as safety-related items to its licensee customers.

3.7 CGD Performed by Licensees

Licensees have been performing CGD in accordance with EPRI guidelines since 1988. Results of research conducted for this report indicate that around 40% of nuclear power reactors worldwide currently utilize dedicated items on a regular basis. Another approximately 40% of the global reactor fleet have piloted CGD or performed a small number of CGD procurements, while around 20% have never utilized any form of CGD. Licensees around the world are performing CGD in highly similar ways, thanks to guidance and standards documents that are well harmonized. Small differences do exist, but they tend to pertain to restrictions imposed on the methodology or jurisdiction-specific rules related to circumstances in which CGD can be utilized. Section 4 of this report describes differences in the application of CGD by licensees due to local regulatory realities.

Key Benchmarking Point

CGD is practiced globally and regularly as part of the licensees' procurement process to support approximately 40% of all reactors worldwide.

Some of the licensees surveyed reported that a high percentage of all safety-related procurements involve CGD, whether performed internally by the licensee or outsourced to a CGD service provider. One licensee reported that CGD is involved in more than half of all safety-related procurements. As illustrated in Figure 3-2, licensees surveyed indicate that for more than 20 reactors, between 25% and 50% of all safety-related items procured involve CGD (performed internally or outsourced). As indicated in Figure 3-3, these CGIs comprise hundreds of unique item types (for example, stock codes or part/model numbers) and demonstrate the fundamental role of the CGD acceptance process in supporting plant operations and maintenance.

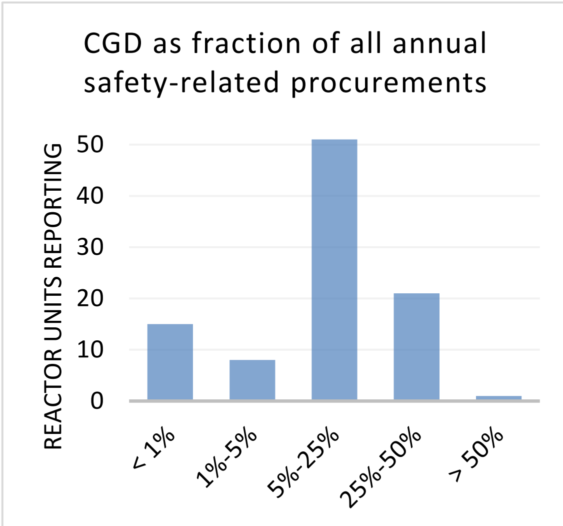

Figure 3-2. Estimated percentage of total safety-related procurements by licensees involving CGD based on survey results

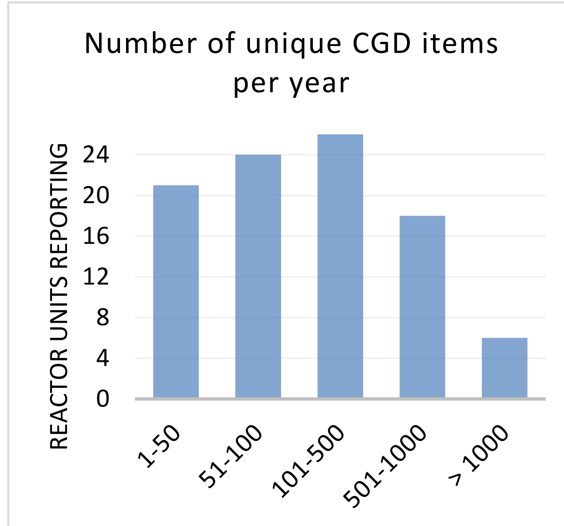

Figure 3-3. Estimated quantity of unique item types accepted by licensees using CGD per year

CGD is increasingly common globally among both new and experienced licensee users. The process is being applied for procurements supporting construction of NPPs and other nuclear facilities and to support long-term operation of existing reactors. As shown in Figure 3-4, 31% of the licensee survey respondents reported an increasing trend in the volumes of CGD items being accepted. According to interviews and survey responses, the increasing trend can be attributed to the decreasing number of qualified nuclear suppliers as well as the factors discussed in Section 2.2 of this report. Figure 3-5 shows that licensees surveyed at 84% of reactors report more than 10 years of experience performing CGD.

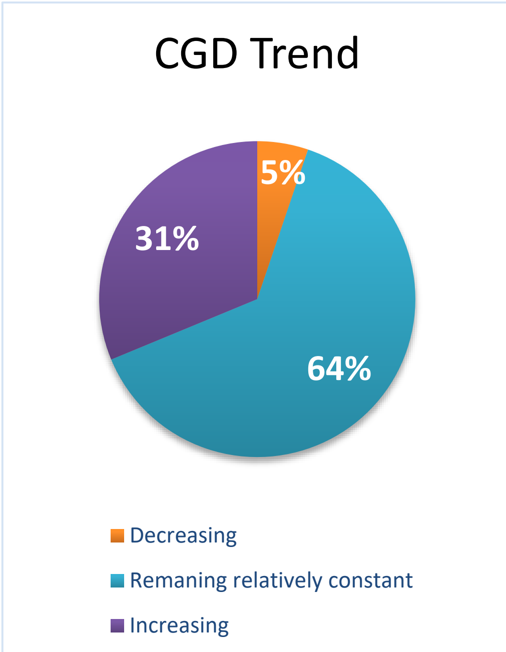

Figure 3-4. Percentage of surveyed operating units reporting increasing, decreasing, or stable application of CGD

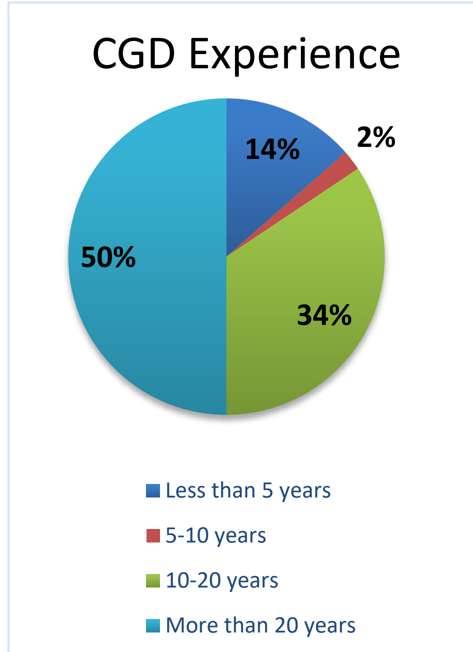

Figure 3-5. Percentage of surveyed operating units reporting various levels of CGD experience

Licensees surveyed reported that identification and verification of critical characteristics are the most challenging aspects of performing CGD. They frequently report having dedicated staff or teams whose primary responsibility relates to CGD activities such as determining critical characteristics of CGIs, selecting acceptance methods, and documenting the CGD process. Secondary challenges include obtaining supplier CGD plans as well as identifying suppliers of the CGIs. Infrequent orders in low quantities can in some cases make it difficult to find industrial suppliers, which might have high minimum order quantities.

Notable Survey Response

KHNP has performed CGD internally on approximately 185 unique items each year over the last four years (with a remaining 515 dedications outsourced to CGD service providers), using just over 100 pieces of measurement and test equipment in a laboratory space of approximately 200 m^2 (2150 square feet).

Fleet owners or licensees typically centralize CGD testing and inspection infrastructure or leverage infrastructure on site at different plants within the fleet in a coordinated manner. Some fleet owners or licensees, like Korea Hydro & Nuclear Power Company (KHNP) in South Korea, perform large volumes of CGD at a central CGD laboratory that is not co-sited with one of their nuclear facilities.

In-house CGD laboratories operated by licensees or fleet owner/operators for performing CGD Acceptance Method 1 (tests and inspections) rely on calibrated measurement and test equipment pieces ranging from simple calipers to bespoke equipment specifically designed and built for functional testing and verification of performance of the CGIs. This equipment is operated by qualified individuals and is controlled as measuring and test equipment under the licensee's nuclear quality management or assurance program.

When licensees do not have the necessary calibration, testing, or inspection infrastructure, they sometimes outsource individual testing and inspection activities to capable local industrial laboratories. In many cases, the laboratories hold ISO 17025 [46] certification. In the United States, these calibration and testing services are considered "commercial grade" and must be dedicated. The Nuclear Energy Institute (NEI) published NEI 14-05A, Revision 1, Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services [47], which provides guidance on how to dedicate certain calibration and testing services provided by laboratories with ISO 17025 [46] certification.

Collaborative joint-utility efforts to facilitate CGD in the United States have existed for decades. After publication of EPRI NP-5652 in 1988, EPRI's Procurement Engineering and Related Topics Symposium (P^{E}ARTS, previously the Joint Utility Task Group [JUTG]) developed a set of technical evaluations for 139 types of items [48]. These evaluations helped promote understanding and consistency of approach during initial application of CGD methodology. EPRI's Smart Procurement Engineering Evaluation Data (SPEED) application is currently being used for collaborative development and approval of CGD templates that EPRI members can use to generate partially completed CGD technical evaluations. The SPEED application includes provisions to assure compliance with changes to 10 CFR Part 21 that were made after development of the initial 139 technical evaluations [48]. These changes are helpful to EPRI members from all jurisdictions as they involve establishing a clear relationship between safety function and the critical characteristics selected for verification.

In 1990, the U.S. nuclear industry developed and published NUMARC 90-13, Nuclear Procurement Program Improvements [49]. As part of this initiative, the Nuclear Procurement Issues Corporation (NUPIC, originally Nuclear Procurement Issues Committee) was formed to facilitate collaborative assessments of suppliers. NUPIC's membership includes all U.S. and many international commercial nuclear power licensees. NUMARC 90-13 included a Comprehensive Procurement Initiative [50] that called for other improvements, including implementation of procurement engineering processes, such as CGD; engineering involvement in procurement and supplier assessment processes; and "performance-based" supplier assessments in lieu of "administrative" assessments.

The scope of performance-based supplier assessments is based on establishing that the supplier's processes ensure the items it provides will perform their intended safety functions. Performance-based assessments focus on the supplier's in-process activities in addition to programmatic review of compliance with a QA or management standard. In June 1990, EPRI issued Guidelines for Performance-Based Supplier Audits (NCIG-16) [51]. NUPIC plans and schedules supplier assessments, which are conducted by teams comprising assessors from several licensee organizations in accordance with the assessment team leader organization's procedures. Standard NUPIC audit and commercial-grade survey planning tools and checklists are used to ensure engineering involvement in the assessment and conduct of a performance-based assessment.

The NUPIC commercial-grade survey checklist focuses on evaluations (surveys) of commercial suppliers pursuant to CGD Acceptance Method 2 (commercial-grade survey). Through this program, NUPIC members conduct standardized supplier surveys, employing specific checklists to assess the ability of the supplier's commercial-quality activities to control specific critical characteristics identified in CGD technical evaluations for the items the supplier provides. The results of these commercial-grade surveys are shared among NUPIC members, facilitating a collaborative and efficient approach to Method 2. A supplier must be audited and approved by at least five commercial nuclear plant licensees to be eligible for assessment by a NUPIC audit team. Eight commercial suppliers underwent NUPIC's commercial-grade survey activities in 2024.

NUPIC's commercial-grade surveys occasionally take place at entities outside North America. NUPIC does not share measurement and testing infrastructure for the purpose of CGD Acceptance Method 1 (tests and inspections) and does not perform CGD Acceptance Method 3 (source verification).

Jurisdictions outside the United States have initiated efforts to develop common CGD plans for specific item types or critical characteristics for specific CGIs.

3.8 CGD Performed by Nuclear Suppliers

It is difficult to quantify the amount of CGD taking place in the supply chain as most nuclear-grade items comprise many individual industrial materials or parts that are purchased by the nuclear OEM as CGIs. This is especially true of electrical and mechanical piece parts. In other words, there are few if any safety-related components controlled by a nuclear quality management system from the raw materials to the final product installed in the NPP.

In the United States, 10 CFR 50 Appendix B [8] does not explicitly mention CGIs or CGD, while ASME NQA-1 [10] and some other standards written subsequent to 10 CFR 50 Appendix B do so. Nuclear suppliers in the United States are at liberty to choose whether they will accept CGIs using CGD or control those items under the auspices of their nuclear quality management program. In the latter case, the supplier is relying on its knowledge of the important physical, performance, or other characteristics of the product and the original design requirements and acceptance criteria and ensures appropriate QA and/or quality control during manufacturing activities. Typically, the actions taken by nuclear suppliers to ensure the adequacy of commercially purchased parts and materials are very similar, whether controlled under their nuclear QA programs (compliant with 10 CFR 50 Appendix B) with or without CGD.

The ASME NQA-1 standard [10], for example, is accepted by the NRC as being compliant with 10 CFR 50 Appendix B and is widely followed by safety-related equipment suppliers. Suppliers with quality management or assurance systems meeting the requirements of ASME NQA-1 are familiar with CGIs and CGD and possess processes, procedures, or other documented instructions for performing technical evaluations and acceptance activities. Used primarily by the suppliers outside of the United States, the ISO 19443:2018 standard [4] also includes considerations for the verification of critical characteristics of CGIs.

In most jurisdictions where CGD is a widespread practice, suppliers of safety-related components do not need to inform customers (e.g., licensees) if their products include dedicated CGIs. The same holds true if dedicated commercial-grade services were utilized during the order. The CGD procedures of a safety-related supplier would likely be included in the QA or management system audit that a licensee would conduct to qualify or re-qualify a supplier of safety-related items.

3.9 CGD by Third-Party Dedicating Entities

It is estimated that more than 30 companies worldwide offer some form of CGD services under a nuclear QA program or management system. The largest market for CGD services is the United States, but local service providers exist in Belgium, Canada, South Korea, Spain, Ukraine, and elsewhere.

Survey data collected during preparation of this report indicates that most suppliers that provide CGD services have significant CGD experience. Figure 3-6 shows that seven of the eight suppliers surveyed have more than 10 years of CGD experience, with five of those reporting more than 20 years' experience. As illustrated in Figure 3-7, the largest individual CGD service providers are performing dedication on more than 500 unique items on an annual basis, with dedicated products being sold to a wide range of nuclear facility licensees, both domestic and international. The greatest challenge reported by these suppliers is obtaining customer approval for CGD plans, along with identifying safety functions and finding suitable suppliers of commercial parts.

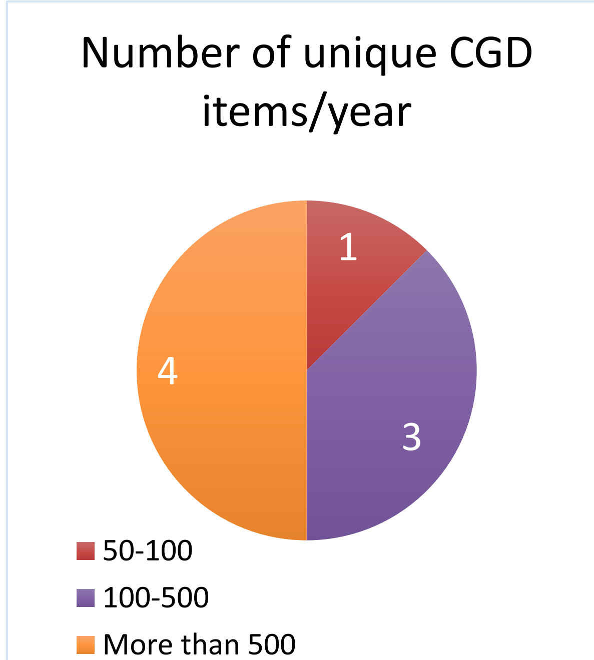

Figure 3-6. The number of suppliers surveyed reporting years of CGD experience	Figure 3-7. The number of suppliers surveyed reporting quantities of unique items dedicated annually

CGD service providers maintain libraries of CGD plans stemming from historical experience with particular CGIs. The CGD plans are sometimes considered intellectual property and not shared readily with the licensee customers. In other cases, the licensee specifically approves the CGD plan before the supplier performs the dedication service. More rarely, the licensee issues the dedication plan for the CGI to the CGD service provider.

Licensees qualify nuclear suppliers that provide CGD services in the same manner as they qualify other nuclear suppliers that perform services or supply products that are safety-related. In jurisdictions where the regulatory body is involved in the qualification or licensing of safety-related suppliers, CGD service providers need to obtain the same authorizations. In addition to specialized third-party CGD service providers, survey results indicate North American NSSS suppliers are performing large volumes of CGD both to support their own supply chain and as a service to licensees.

Half of the suppliers surveyed reported electrical items as the most commonly dedicated for their customers. Others perform dedication on a mixture of electrical, mechanical, and electro-mechanical items as well as lubricants and chemicals.

3.10 Use of Acceptance Methods

The CGD methodology is flexible in terms of the methods available to verify critical characteristics when accepting a CGI. The dedicating entity is free to use sound engineering judgment to select the acceptance method most suitable for verifying each critical characteristic of the item being dedicated. A single CGD may involve use of one or more acceptance methods to verify critical characteristics.

3.10.1 Method 1 (Tests and Inspections)

Method 1 in CGD focuses on special tests, inspections, and analyses after acceptance of commercial items to verify their critical characteristics, emphasizing that basic receipt inspections, while necessary, are not sufficient on their own for CGD. Acceptance criteria for these tests and inspections are typically included in CGD technical evaluations. Since acceptance criteria often originate from engineering documents and are specified by engineers, collaboration and coordination between engineering and the organizations performing the acceptance tests and inspections are necessary. As for all methods, all test or inspection results must fall within the defined tolerances or data input ranges specified in the CGD technical evaluation. If an item fails to meet any acceptance criterion, it is rejected as unacceptable and nonconforming. In some cases, the item may be returned to the supplier or disposed. In others, engineering evaluation may be conducted to determine if the item can still perform its safety function and meet design requirements. When necessary, the CGD technical evaluation is revised.

Survey results indicate Method 1 is by far the most widely used by entities performing CGD. Method 1 is often the least intrusive for the supplier and is typically an effective way of verifying performance-related critical characteristics.

3.10.2 Method 2 (Commercial-Grade Survey)

Method 2 is conducted at the supplier's facility by the dedicating entity before procurement of the item begins. Method 2 involves direct observation of the supplier's processes and commercial quality controls to verify that the supplier successfully controls critical characteristics. The critical characteristics are identified in a CGD technical evaluation before the survey is conducted and are based on the items, product lines, or services provided by the supplier. The characteristics selected are those necessary for the item to perform its safety function(s). The survey is performance based, focusing on observation of the supplier's activities to verify the supplier effectively implements its processes and quality program controls, and that the controls are effective. In accordance with NRC GL 89-02, use of Method 2 in the United States is restricted to suppliers with documented quality controls and may not be used to accept items from distributors unless the survey confirms adequate controls by both the distributor and the manufacturer [40].

Method 2 is well suited for joint-utility approaches to CGD when many licensees procure the same product or product family from a commercial supplier. In Finland, the KELPO methodology discussed in Section 5.1 of this report is based entirely on a supplier assessment and is in many ways similar to a Method 2 survey.

3.10.3 Method 3 (Source Verification)

Method 3 is conducted at the supplier's facility or other applicable locations to verify that critical characteristics meet acceptance criteria during fabrication or development. This method includes witnessing specific fabrication and assembly processes, quality control processes, non-destructive examinations, performance tests, or final inspections. Source verification is applicable only to the actual item or service verified at the supplier's facility and is used when in-process verification of critical characteristics is needed. Source verification may also be appropriate when nonconformances have been detected during prior receipt inspections, or when there are questions regarding the adequacy of the supplier's QA program/procedures. Method 3 is not frequently used by dedicating entities but is leveraged from time to time when other methods are impractical, expensive, or more time-consuming.

3.10.4 Method 4 (Historical Performance)

Method 4 involves the use of an item's or a supplier's historical performance record to verify the critical characteristics of an item. The documented performance history is reviewed to provide reasonable assurance that a critical characteristic is acceptable. However, some jurisdictions, including the Czech Republic, South Korea, Spain, and the United States, limit the use of Method 4. According to the regulatory bodies, Method 4 may not be used alone to verify critical characteristics.

Limitations relating to use of Method 4 date back to 1989. NRC GL 89-02 [40] discussed restrictions on its use, as described in EPRI NP-5652, for dedicating CGIs for safety-related applications in NPPs.

Specifically, GL 89-02 stated [40]:

> "Acceptance Method 4, 'Acceptable Supplier/Item Performance Record,' should not be employed alone unless:
>
> a. The established historical record is based on industrywide performance data that is directly applicable to the item's critical characteristics and the intended safety-related application; and
>
> b. The manufacturer's measures for the control of design, process, and material changes have been adequately implemented as verified by audit (multi-licensee team audits are acceptable)."

For this reason, Method 4 is not commonly used by dedicating entities. However, historical performance may be considered when selecting sampling plans for verification of critical characteristics using Method 1 (tests and inspections).

3.11 CGD of Digital Items

The dedication of digital items is a developing area of activity that includes research, guidance development, regulatory development, pilot projects, and real-world CGD procurements. EPRI TR-106439, Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications [31], notes that digital item failures are typically attributed to lack of dependable results. Therefore, verifying critical characteristics related to the dependability of the item should be considered as a part of the dedication process. More recent EPRI research documented in Safety Integrity Level (SIL) Certification Efficacy for Nuclear Power (3002011817) [52] describes how the IEC 61508 [53] SIL certification process can be used to provide assurance of dependability critical characteristics.

Safety Integrity Level (SIL) Certification Efficacy for Nuclear Power [52], which discussed efficacy of the SIL process, was published in 2019. Subsequently, NEI issued NEI 17-06, Guidance on Using IEC 61508 SIL Certification to Support the Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Related Applications, Revision 1 [54]. This report provides methodology for use of the SIL process as an acceptable part of the dedication process for digital equipment. A CGD technical evaluation is still required, as are verification of other (non-dependability) critical characteristics and a separate dedication of the services involved in the SIL certification process. NRC RG 1.250, Dedication of Commercial-Grade Digital Instrumentation and Control Items for Use in Nuclear Power Plants [56], accepts the methodology in NEI 17-06 [54] as an acceptable way of meeting regulatory requirements. This is an important evolution as the dependability of the embedded software is highly dependent on the adequacy of the software development process and typically cannot be assessed after the fact.

Additional discussion about dependability characteristics and use of digital items is included in IAEA NR-T-3.31, Challenges and Approaches for Selecting, Assessing and Qualifying Commercial Industrial Digital Instrumentation and Control Equipment for Use in Nuclear Power Plant Applications [55].

3.11.1 Dedication of Digital Devices in South Korea

Industry associations and researchers have been investigating how industrial digital equipment designed and certified to international consensus standards can be dedicated. Research led by Inha University in South Korea with the support of a CGD service provider and authorized inspection organization is developing a conformity verification methodology for commercial digital devices based on the SIL IEC 61508 [53] verification system. Here the focus is specifically on dependability verification. The research has identified some key elements of adopting SIL certification:

- Selecting target items (or categories)
- How to determine SIL level
- How to cover (evaluate) additional hardware/software design review to IEEE 7-4.3.2 [57]
- Approval of SIL certificates (oversight of the authentication process)

Table 3-3 provides examples of the types of digital items considered suitable for CGD in the Republic of South Korea. These include digital items with complex functions, items with simple control functions, simple indicators, and individual digital components.

Table 3-3. Examples of digital items considered for CGD by KHNP

Category	Items	Manufacturer
Complex function	Digital relay	GE Grid Solutions Universal Relay
	Programmable logic controller	Schneider M340
	Heat trace controller	Thermon TC 202
	Turbine controller	Woodward 505
Simple control function	Level transmitter, temperature detector, controller, switch	
Simple indicator	AC voltage meter, DC voltage meter, input/output module, indicator, timer	
Component	Touch screen, central processing unit, memory	

CGD has been used to accept digital devices at KHNP since 2014. The quantity of item types being accepted has increased since 2018, as indicated in Figure 3-8.

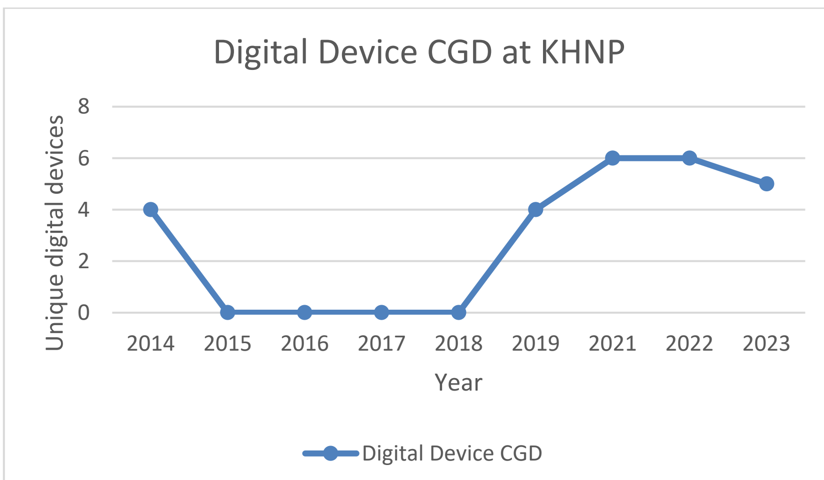

Figure 3-8. Quantity of unique item types (not total quantities) dedicated for the KHNP fleet

3.12 CGD of Software/Computer Programs

Licensees generally report limited experience with CGD of software; this is especially true of organizations that have started CGD within the last 5–10 years. Dedicated commercial-grade code and software programs falls into one of three areas: commercial design analysis software (non-process/not installed in the plant); custom embedded software/code that is integral to the operation of a discrete digital commercially manufactured device (installed in the plant); and software/code that is integral to installed plant safety systems (such as reactor protection systems).

Commercial design analysis software (structural analysis software, software for performing electrical load studies, piping analysis software, etc.) is often used to design and/or validate the acceptability of the design of safety-related components or systems. Such commercial software is typically widely used throughout multiple high-risk industries. In 2013, EPRI published Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications: Revision 1 of 1025243 [30], which was accepted for use by the NRC in RG 1.231 [58] and provides guidance on the dedication of such software. The dedication process is dependent on determination of how the software will be used within the design process, the capability to perform audits or surveys of the software supplier during the software development process, and the extent to which other methods are in place for verifying the adequacy of the design of the safety-related item. Oftentimes, such software is dedicated by performing alternate calculations using other methods on sample problems that are then used to verify the adequacy of the software and to bound the use of the software application.

With respect to commercial software that is embedded in or integral to a discrete commercially manufactured item (e.g., digital overcurrent trip devices for safety-related circuit breakers), Section 14.1 of EPRI 3002002982 [21] lists EPRI guidance documents developed to address different types of digital equipment.

For complete systems that contain commercial software or code, the process of dedication can be more complicated. In the United States, the NRC has issued RG 1.152, Criteria for Programmable Digital Devices in Safety-Related Systems of Nuclear Power Plants, Revision 4 [59], which endorses, with some exceptions, the 2016 edition of IEEE Std. 7-4.3.2 [57]. Clause 5.17 of IEEE Std 7-4.3.2-2016 presents the fundamental criteria for demonstrating that a commercial computer will perform its intended safety functions and provides criteria that the NRC staff has found acceptable for addressing the use of commercial digital equipment in safety-related systems of nuclear power generations [57].

3.13 Regulations and Regulatory Guides Addressing CGD

The CGD methodology does not necessarily need to appear in regulations or regulatory guides for the practice to be approved by the regulator and utilized by license holders. Different jurisdictions have taken different approaches when it comes to the oversight and regulation of CGD. Globally, three typical scenarios are encountered in the nuclear industry:

- National regulation or regulatory guidance specifically addresses CGD (examples: United States, South Korea, Spain).
- National regulation or regulatory guidance does not specifically address CGD, but CGD is an acceptable practice of licensees based on approval mechanisms such as review of licensee CGD processes (examples: Finland, Romania, Slovenia).

- National regulation or regulatory guidance does not specifically address CGD, and CGD is not an acceptable practice of licensees (examples: Switzerland, Bulgaria, Russia).

Table 3-4 lists some of the regulations and regulatory guidance found in different jurisdictions that are related to CGD or mention the CGD methodology or related concepts like CGIs, critical characteristics, and acceptance methods.

Table 3-4. Sampling of regulations and regulatory guidance related to CGD

Country or Region	Title	Reference	Publisher, Year (Latest Revision)
USA	Reporting of Defects and Noncompliance	10 CFR Part 21 [17]	NRC, 2019
USA	Dedication of Commercial-Grade Items for Use in Nuclear Power Plants	RG 1.164 [42]	NRC, 2024
Japan	Regulations on the Standards for Quality Control Systems Necessary for Work Related to the Security of Nuclear Facilities	Nuclear Regulation Authority Rule No. 2, Reiwa 2nd year [19]	NRA, 2020
Spain	Garantía de calidad para la gestion de elementos y servicios para las instalaciones nucleares	Guía de Seguridad 10.8 (Rev. 1) [60]	CSN, 2001
South Korea	Quality Verification for Alternating of CGIs in Nuclear Safety-Related Applications	KINS/RG-N17.12 [61]	KINS, 2015
Taiwan	Regulations on the Dedication of Commercial Grade Items and Certification of Dedication Agency	Decree Her-An-Tze No. 11200178691 [18]	NSC, 2023

3.14 Regulatory Oversight of CGD Process

National regulatory bodies have different approaches to the oversight of nuclear safety and security that extend to the procurement processes of the license holders. The most typical, widely used approach is to include CGD processes of the licensees within the scope of regularly performed audits or inspections. In the United States, the NRC also performs inspections of suppliers and third-party dedicators. It is not common for other regulatory bodies to be involved in the review or approval of individual CGD plans, except in jurisdictions new to the methodology or performing it in low volumes. However, in certain jurisdictions, in some cases where the licensee and regulatory body are new to the methodology, close cooperation on the first pilot projects and real CGD activities does take place.

Incorporating commercial off-the-shelf items for nuclear facility upgrades has been increasingly considered due to their accessibility and the inclusion of embedded software or firmware. The OECD/NEA CNRA has concluded that it is incumbent upon regulatory bodies to ensure that licensees possess the requisite competence and processes to assess these products effectively. Moreover, regulatory bodies are urged to develop policies for the review of these products, especially when existing certifications fall short of nuclear standards [43]. Table 3-5 summarizes responses from 10 OECD/NEA member states.

Table 3-5. Sample of responses to OECD/NEA CNRA questionnaire from the 2019 Special International Nuclear Regulatory Inspection Workshop on Digital Instrumentation & Control [43]

Country	Answer to OECD/NEA CNRA survey question: How does your Regulatory Body (RB) authorize/approve and inspect the CGD process for DI&C?
Canada	CNSC staff request the relevant documents produced during the dedication process and review and approve the documents for use. For example, they review the Shutdown System Platform Qualification against CSA N290.14 [62].
China	The RB uses HAD 003/03 [63] and HAD 102/16 [64] to review, approve, and inspect the use of commercial-grade DI&C components. With specific CGD processes and in its inspection and review, the RB may refer to EPRI NP-5652 [1], TR-102260 [22], and TR-106439 [31].
Finland	The RB does not have to authorize the CGD process, but licensees may ask for the RB's informal comments on the process before applying it.
France	ASN doesn't inspect the CGD process for DI&C. ASN makes sure that the criteria are met by the licensee's solution. In the case of digital devices with limited functionalities, IRSN requires the certification reports and may ask for supplementary justifications.
India	The RB reviews the process of the assessment of commercial DI&C items. However, RB does not inspect the commercial item assessment process during its execution. The RB reviews the assessment report and supporting evidence. The RB may witness specific tests at the NPP site after a dedicated item is integrated in the design.
South Korea	For CGIs that are based on digital technology, KINS has used the guidance in EPRI 106439 [31], IEEE 7-4.3.2 [57], etc. KINS performs vendor inspections on selected CGIs.
Slovenia	Authorization of the CGD process for DI&C is a part of the SNSA licensing process. Currently the SNSA does not perform regular inspections of the CGD process for DI&C.
Spain	For authorization, compliance with RG 1.152 [59] and its reference rules is verified. This in the end means endorsing EPRI's TR-106439 [31], at least regarding commercial, off-the-shelf equipment. Inspections fall under the Reactor Oversight Program design modifications inspections.
United Kingdom	As a non-prescriptive regulator, ONR does not authorize or approve the CGD process for licensees. Each application of the CGD process is assessed on its own merits. The inspection typically involves a review of the licensee safety case and a sample of the documentation provided by the system/component manufacturer.
United States	The NRC has the ability to inspect the CGD of DI&C systems. The NRC has developed procedures for the inspection of both licensee and vendor CGD processes.

3.15 U.S. NRC Inspections

In 2022, the U.S. NRC announced its intent to inspect CGD activities at every commercial nuclear power facility in the United States between 2023 and 2027. To support this effort, the NRC published inspection procedure (IP) 71111 21N.03, Commercial Grade Dedication [65].

At the time this report was prepared, the NRC had completed 30 inspections. Although the inspections have identified minor issues with implementation of CGD, the results suggest overall effective implementation of CGD by licensees.

3.16 CGD Risk Assessment and Mitigation Strategies

As with any procurement method, choosing to utilize the CGD process to procure an item that is intended for use in a safety-related application comes with its own set of perceived risks. However, these risks can be largely mitigated through effective implementation of the CGD process and other existing nuclear quality management and assurance activities.

As with items procured from suppliers with nuclear QA programs, some limited number of failures of installed CGD items do occur. Most often such failures are associated with commercial quality issues such as faulty workmanship during manufacture, undeclared material substitutions by suppliers and sub-suppliers, or unverified design changes. However, it is important to recognize that such quality issues are not limited to items procured from suppliers of commercial products but also occur with items procured from suppliers with nuclear QA programs.

In the United States, 10 CFR Part 21 [17] requires that failures of safety-related items be reported to the NRC. A review of all such failures reported to the NRC in 2022 and 2023 (discussed in Section 4.2.4 of this report) indicates that the majority of the reports associated with commercial-grade dedicated items involved latent failures. Latent failures involve items that performed acceptably when first tested and installed but later failed due to defects that were not readily detectable through the CGD process. Latent failures often involve issues with the implementation of the commercial manufacturer's quality program. In such cases, after identifying the root cause or causes of the failure, licensee and supplier quality programs require that corrective actions be taken. Corrective action may include changing suppliers or revising the dedication process to conduct additional testing or inspections, as appropriate.

Overall, the reported failures were few in comparison to the large number of dedicated items currently installed throughout the U.S. nuclear fleet. Additionally, the reported failures were all documented via licensee or supplier corrective action programs and were fully evaluated, reported, and corrected before the issues became a significant safety concern. Even where multiple identical dedicated items had been installed (in some cases hundreds), no instances were identified of concurrent failures. Where multiple items were affected by the reported defect, the typical random nature of the failure was such that the defect did not result in the failure of redundant components at the same time. These results are what might be expected, as the quality issues that might lead to the failure of a dedicated item would likely be identified through surveillance programs common to operating nuclear facilities, which limit the risk exposure associated with such failures, should they occur.

A review of safety system performance indicators included in NEI 20-04, The Nexus Between Safety and Operational Performance in the U.S. Nuclear Industry [66], for three key safety systems shows stable safety system performance from 2004 through 2018, during which time the use of the CGD process broadened. Review of overall U.S. nuclear plant performance indicator data also supports the conclusion that items procured using the CGD process and installed in safety-related applications are performing at acceptable levels. Improving or stable trends are apparent when looking at overall nuclear plant performance indicators, such as plant availability and safety system performance over the last 30 years [66], while the number of CGD items installed has increased dramatically during this period. While these stable or improving performance metrics can be attributed to a number of factors, it is reasonable to assume that if there were a significant issue with the performance of CGD items, these metrics would be negatively impacted.

The analysis described above indicates the increasing use of the CGD process has not resulted in a discernible impact on overall plant performance or an increase in safety-related equipment failures. However, there are actions that can be taken to further reduce the risk, particularly the risk associated with latent failures. One such action is to try to source items from commercial suppliers with proven, effective quality programs. When comparing commercial quality standards such as ISO/9001 [11] against nuclear quality standards such as Appendix B to 10 CFR Part 50 [8], the large majority of the requirements overlap [67, 68]. While commercial programs may not always explicitly address all the criteria required for nuclear-grade programs, the added assurances achieved through explicit assessment, identification, and verification of critical characteristics as part of the CGD process can provide additional confidence in the long-term performance of the dedicated items. Furthermore, the large industrial base of a typical commercial item serves to increase the likelihood that any latent quality defects not detected through the CGD process would likely be identified and reported back to the commercial manufacturer for evaluation and correction, both by those inside and by those outside the nuclear industry.

In conclusion, based upon the analysis performed above, the risk associated with use of CGD does not appear to be significantly greater than that of procuring items from suppliers with nuclear QA programs. Furthermore, these risks can be mitigated to some degree by ensuring items to be dedicated are sourced from reliable suppliers with proven commercial quality programs; effectively implementing corrective action programs to identify, evaluate, and correct component failures should they occur; and implementing effective surveillance programs that can detect latent failures and ensure the continued operability of important safety systems.

4 USE OF CGD AND CGD ITEMS IN DIFFERENT JURISDICTIONS

This section provides detailed information about CGD implementation, history, applicable regulations, standards, and regulatory positions and summaries of CGD experience, in various jurisdictions. Many, but not all, jurisdictions in which CGD is performed are represented in this section. Section 6 of this report includes an illustration (Figure 6-1) representing all the jurisdictions in the world that use or have trialed CGD based on research conducted pursuant to this study.

4.1 United States

The United States produces the most nuclear energy of any country and has the most operating history. In 2024, there are 94 nuclear reactors in the United States, supplying around 20% of the country's electricity.

4.1.1 Current State of CGD Implementation and History

The concept of CGD began in the United States in the late 70s and early 80s as a way of meeting both QA and noncompliance reporting requirements. Throughout the 80s, CGD became more widespread, with a few utilities making focused efforts to develop more advanced capabilities in the CGD area. As the use of CGD increased, so also did the development of new industry standards and regulatory guidance. During the last four and a half decades, much operating experience related to CGD has been gathered and captured. Today, CGD is widely practiced in the United States and is accepted by both the industry and the regulator (the NRC) as an alternate means for procuring safety-related replacement parts, components, and services.

4.1.2 Applicable Regulations, Standards, and Regulatory Positions

The NRC has been engaged throughout the development and expansion of CGD in the nuclear industry. While the NRC does not directly approve specific CGD plans or activities, NRC staff have participated in the development of industry standards, developed extensive regulatory guidance, and performed numerous inspections at both utilities and third-party suppliers in the CGD area. Most recently, the NRC made CGD a "focus area" inspection and is performing CGD team inspections at every operating NPP in the United States. To date, these inspections have not identified any significant safety issues related to CGD. None of the CGD inspection findings have been characterized as having greater than very low safety significance (green findings).

As discussed in Section 3.4, a process for CGD was first developed and documented in EPRI NP-5652 [1] in 1988 and was accepted for use by the NRC in GL-89-02 [40]. EPRI published TR-1066260 [22] as a supplement to NP-5652 in 1994. EPRI published 3002002982 [21] in 2014 as a revision that superseded NP-5652 and TR-102260.

The NRC participated in the development of 3002002982 [21], and in 2016, the NRC accepted 3002002982 for use in RG 1.164 [42]. The methodology has also been incorporated and updated in versions of ASME NQA-1 [10].

4.1.3 Experience Summary

All NPPs in the United States utilize dedicated CGIs. Currently, several utilities maintain centralized CGD laboratories where CGD items are tested and CGD plans are developed and implemented. There are also multiple third parties that specialize in CGD and that supply dedicated parts and components to the nuclear industry. These dedicated parts and components in some cases represent a large portion (and in some cases a majority) of a utility's safety-related procurements. Recent industry initiatives to minimize operating costs have also resulted in some utilities expanding their use of CGD.

EPRI's Procurement and Related Topics Symposium (P^EARTS, formerly known as the Joint Utility Task Group, or JUTG) has been the industry's procurement engineering community of practice since NP-5652 was initially developed. Shortly after issue of NP-5652, procurement engineers began meeting on a triannual basis to develop a set of 139 CGD technical evaluations for different types of items [48]. These evaluations helped promote consistent application of CGD methodology in the United States.

EPRI members currently have access to an online tool called Smart Procurement Engineering Evaluation Data (SPEED) that permits collaborative development and approval of CGD templates. Members can use approved templates to create partially completed CGD technical evaluations for specific item types and applications.

4.2 U.S. Case Studies

4.2.1 Duke Energy

4.2.1.1 Company Overview

The American electric utility Duke Energy operates a total of 11 nuclear reactors across six sites in the Carolinas. Duke Energy is one of the largest electric power holding companies in the United States, headquartered in Charlotte, North Carolina.

4.2.1.2 Current State of CGD Implementation and History

Duke Energy has been performing CGD since EPRI NP-5652 [1] was published in 1988. Today the CGD function at Duke Energy is a part of the Central Design Engineering organization. Prior to 2010, CGD was controlled by the supply chain group (at Progress Energy, with which Duke Energy merged in 2012).

4.2.1.3 Experience Summary

Duke Energy has developed a centralized, in-sourcing approach that handles large volumes of dedication activities each year, representing 25–50% of all safety-related procurements across the entire fleet. Duke Energy's Central Receiving and Dedication Facility (CRDF), located at the Harris NPP site, includes a CGD laboratory that serves as the center of CGD activities at Duke Energy. Currently, the CRDF is capable of internally performing 95% of the tests and inspections necessary to support use of Acceptance Method 1 (tests and inspections) for a wide range of items. In cases where measurement or test equipment at the lab is not sufficient, Duke Energy leverages an internal analytical chemistry and materials laboratory that operates under the same nuclear QA program. Duke Energy participates in and sometimes leads Method 2 commercial-grade surveys, usually involving joint-utility NUPIC assessment teams, as a means of accepting certain critical characteristics to support dedication of some items or families of items provided by the same suppliers. Of the acceptance methods, Duke Energy uses Method 3 (source verification) least frequently.

The dedication process at Duke Energy is one of the primary means of identifying supplier parts quality issues and potential counterfeit items. Any failures that occur during dedication or suspected counterfeit items are recorded and tracked. Duke Energy reaches out to commercial suppliers with the highest number of issues as an initial step to resolve parts quality issues and improve the compliance of future deliveries.

Over the course of three programmatic NRC CGD inspections recently completed at different plants in the Duke fleet, it has been shown that no failures of successfully dedicated items have occurred that could be attributed to CGD. Any failure would be entered into the organization's corrective action program, which would prompt screening for reporting in accordance with 10 CFR 21 [17] and actions to prevent recurrence. Dedicated items are installed in most safety systems at Duke Energy's six NPP sites, with the exception of applications requiring compliance with the ASME Boiler and Pressure Vessel Code [69], according to regulatory requirements [16] and EPRI 3002002982 [21].

Processes and procedures at Duke Energy do not limit the procurement of CGIs to cases where a nuclear-grade item or supplier is unavailable. Procurement engineering at Duke Energy is continuously seeking to improve quality, lead time, or cost by sourcing CGIs. Procurement engineering at Duke Energy continues to leverage innovation to support CGD. The CRDF is equipped for and supports the use of in-house seismic qualification, reverse engineering, failure analysis, and 3D scanning, modeling, inspection, and printing. The lab houses a tri-axial shake table, two coordinate measuring arms, three high-definition laser light point probes, and a high-definition 3D non-metallic printer. The use of these assets and tools allows Duke Energy to continue to leverage CGD as a significant option for parts procurement to support the six NPP sites. Lead time is the primary issue that drives Duke Energy to source CGIs. Given more resources and personnel, Duke Energy would be performing more CGD as it has had great success with its in-sourced CGD program to date. Senior leadership at Duke Energy is briefed by the leader of procurement engineering monthly and annually on information related to the

CGD program, including new cases of CGIs being used in a safety-related application, cost savings realized through CGD procurements, and the status of the backlog of CGD still to be performed.

Key Observation Point

CGD is used to continuously pursue improvements in parts quality, lead time, and cost.

4.2.2 Paragon Energy Solutions

4.2.2.1 Company Overview

Paragon Energy Solutions (Paragon) is a company with over three decades of experience in the nuclear industry, specializing in providing safety-related parts and components to nuclear energy facilities. The company offers a wide range of services, including CGD, seismic qualification, environmental qualification, reverse engineering, and manufacture and supply of its own critical safety instrumentation systems. Paragon collaborates with various stakeholders in the industry to address issues such as parts obsolescence, often through CGD. The company's quality management system complies with several QA regulations and standards, including 10 CFR 50 Appendix B [8], ASME NQA-1 [10], and CSA N299.1 [5].

4.2.2.2 CGD Services and Demand

Paragon performs a significant volume of CGD, both to support the production of its own safety-related equipment and as a service to licensees that wish to procure items as basic components from a supplier with a nuclear quality program instead of dedicating CGIs themselves. The company generates between 70 and 100 new CGD plans each month. The demand for CGD services has remained steady and was particularly strong immediately following the pandemic. Paragon develops its own CGD plans, rather than relying on customer-provided plans, and aims to envelop all possible or realistic safety functions of the CGIs. The company notes that it is beneficial for customers to provide information on the specific applications and requirements for the CGIs they request Paragon to dedicate.

Paragon has discovered that published data sheets from commercial suppliers should not be considered as technical specifications that the product is guaranteed to fulfill. Instead, the company often relies on documentation other than that provided by the commercial OEM to develop CGD plans, which may include information provided by the licensee about the intended application and safety-related function(s) of the item.

4.2.2.3 Acceptance Methods and CGD Item Performance

Paragon primarily uses Acceptance Method 1 (tests and inspections) to verify the critical characteristics of CGIs, but it also employs Method 2 (commercial-grade survey) and Method 3 (source verification) when appropriate. The company performs approximately 1300 CGD jobs per year (one job can include multiple lots of unique parts). Digital devices currently account for less than 5% of these jobs, although the percentage is increasing. While the failure of successfully dedicated items is extremely rare, Paragon has reported its occurrence and submitted 10 CFR Part 21 [17] reports to notify the industry when items that are accepted after successful completion of the CGD process fail.

4.2.2.4 Regulatory Oversight

The U.S. NRC does not play a significant role in Paragon's CGD activities, as it does not approve CGD plans, witness CGD activities, or regularly participate in the CGD process. The NRC Vendor Inspection Branch completed an inspection at Paragon in 2014 and one in 2024.

4.2.2.5 Supplier Management

Paragon maintains an approved suppliers list with approximately 120 commercial suppliers that support all aspects of the company's business, including its provision of CGIs, CGD as a service for licensees, and manufacture of its own safety-related product lines. Paragon has observed a high rate of turnover in the quality management staff of its commercial suppliers.

4.2.2.6 Counterfeit, Fraudulent, or Suspect Items (CFSI)

In Paragon's experience, verification of critical characteristics can occasionally result in the detection of counterfeit, fraudulent, or suspect items (CFSIs), although most CFSIs are discovered during receipt inspection and typically relate to small piece parts. Paragon aims to prevent CFSI at the procurement stage by selecting authorized distributors or reputable commercial manufacturers.

4.2.2.7 Example of a Safety-Related Assembly that Relies in Part on Commercial-Grade Items

Figure 4-1 shows an MCC cubicle that has a 34-line-item bill of materials, of which 29 require dedication prior to installation into the host system (i.e., the cubicle assembly). In this example, most components are dedicated prior to being installed. Essentially, anything with a failure mode that can't be tested once installed in an assembly is dedicated in advance of installation in the MCC cubicle. Most parts fall into this category.

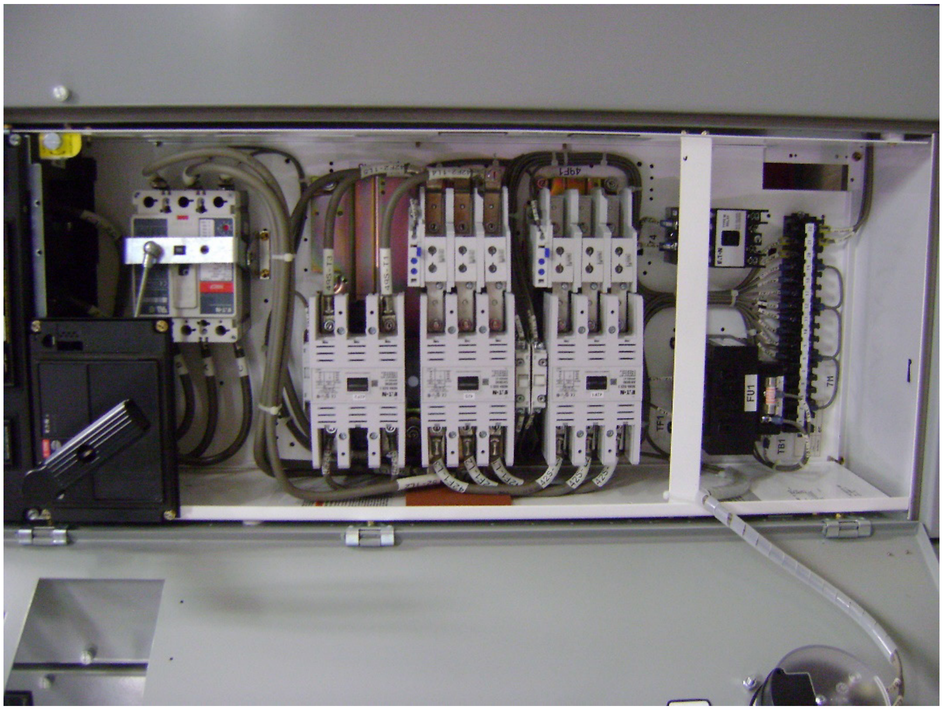

Figure 4-1. MCC cubicle composed of CGIs (courtesy of Paragon Energy Solutions)

During the factory acceptance test, the overall function and fit-up of the cubicle are tested, including verifying isolation of the terminals and lugs near the insulators. This cubicle has a RotoTract feature from Eaton that allows it to be remotely racked and de-racked from its cell. This feature was also verified via factory acceptance testing. This design has many cubicles with interconnecting wires, so much of the factory testing was verifying the operation not only of the cubicle, but of the entire system. This is an example of an electronic safety-related assembly based on many individually dedicated components.

4.2.3 United Controls International

4.2.3.1 Company Overview

United Controls International (UCI) was established in the 1960s as part of Reliance Electric's Custom Controls Division. UCI is headquartered in Norcross, Georgia, United States. The company specializes in providing safety-related materials and services for the nuclear industry. UCI's quality management program is certified to ISO 9001:2015 [11] and meets the requirements of various regulations and standards, including 10 CFR 50 Appendix B [8] and ASME NQA-1 [10].

4.2.3.2 Commercial-Grade Dedication Plans

UCI develops and utilizes its own dedication plans when performing CGD services, maintaining a library of over 2800 digitalized CGD plans covering 270 classes of parts. In rare cases, customers may provide an old dedication plan for consideration or request specific critical characteristics to be included in the UCI dedication plan. However, licensees typically do not provide UCI with information about the safety functions of the CGIs being procured.

Key Observation Point

UCI maintains key performance indicators for its CGD process. These are:

- On-time delivery
- Sales order line (order entry) approvals
- Dedication plan approval
- Dedication report approval
- Nonconformance report (NCR) disposition approval
- NCR closure
- NCR apparent cause
- Supplier purchase order approval for material and services procured
- Supplier nonconformances

4.2.3.3 CGD Verification Methods

UCI uses Method 1 (tests and inspections) approximately 90% of the time to verify the critical characteristics of CGIs dedicated for its customers. For complex, large, or expensive items, UCI may perform source surveillance according to Method 3 (source verification). The company conducts commercial-grade surveys of some commercial suppliers to verify critical characteristics of frequently procured items. Customers occasionally request the use of specific CGD guidance documents, such as EPRI 3002002982 [21], on a case-by-case basis.

4.2.3.4 Quality of Commercial-Grade Items

Some CGIs, such as fuses, are known to have difficulty passing CGD testing due to quality issues. While suppliers may accept returns of nonconforming or non-functional products, they are often unwilling to investigate the cause of the failures. UCI has found that the best quality is achieved through procurements directly from the commercial OEM or an authorized distributor, as the quality of surplus stock from NPPs or third-party entities with warehoused stock is uncertain.

In some cases, customers may provide tighter tolerances or acceptance criteria based on the application than the item would meet based on the commercial manufacturer's published product data. In these situations, the failure of the CGI to meet the critical characteristic acceptance criteria may not necessarily be the fault of the manufacturer.

4.2.3.5 Supplier Management

UCI actively manages its supply chain of commercial suppliers. It utilizes around 100 different suppliers each year, mostly manufacturers, authorized distributors, and ISO 17025 [46] certified testing laboratories. The company maintains an approved vendor list, and listed suppliers are evaluated as needed based on their ability to meet purchase order requirements and provide satisfactory products or services. Nonconformances are reviewed as part of the evaluation process, and the authorization of distributors to supply a commercial manufacturer's products is checked annually.

More than 75% of the CGIs that UCI procures for dedication are sourced from distributors, typically authorized distributors, while less than 25% are procured directly from manufacturers. This is due to the high-volume, serially manufactured nature of many CGIs for NPPs, which are typically sold to end users through networks of distributors. Despite the importance of the nuclear power industry, some commercial suppliers express skepticism or concern about supplying to this sector.

4.2.3.6 Facilities and Equipment

For its CGD and equipment qualification activities, UCI has approximately 150 pieces of measurement and test equipment that are regularly used, with an additional 130 pieces available for occasional use in special projects. The UCI facility spans 21,600 square feet.

4.2.4 Review of 10 CFR Part 21 Reports

4.2.4.1 Background

NPP licensees in the United States, as well as any vendors supplying basic components to U.S. licensees, are required (since 1977) to submit reports to the U.S. NRC when a defect is discovered in a supplied product. 10 CFR Part 21 [17], issued by the NRC, sets forth requirements for reporting of defects and noncompliance for components and activities associated with NPPs and other nuclear facilities licensed in the United States. It mandates that suppliers and licensees promptly identify and report to the NRC defects that could cause a substantial safety hazard. This reporting is required when an item that has been accepted (as a basic component) for use in a nuclear safety-related application fails and the failure could cause a substantial safety hazard.

The regulation helps to ensure the safety and reliability of nuclear facilities by obligating entities to maintain robust processes for detecting, reporting, and rectifying safety-related issues. The regulation requires suppliers that identify such defects and noncompliance to report them to impacted customers. The reports are publicly available on the NRC's website and help to prevent recurrent failures by making the failure information available for use.

Notifications issued under 10 CFR Part 21 [17] requirements can pertain to a wide range of issues. For example, a manufacturer may learn, after supplying a component to an NPP, that an important material did not undergo testing to confirm its conformance to the requirements. In another example, a licensee would report failure of a safety-related component in service when a root cause analysis indicated failure was the result of a manufacturing defect or installation error.

4.2.4.2 Data

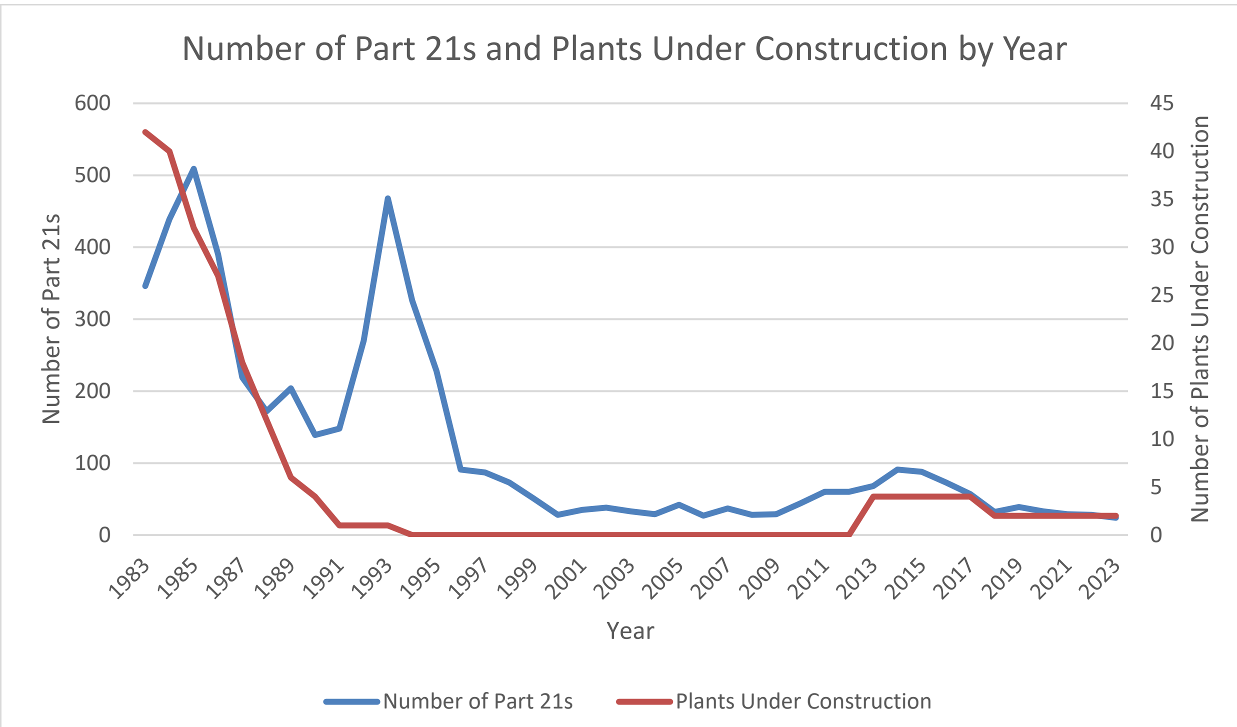

Figure 4-2. Total number of Part 21 reports (not only those related to CGD) over time, overlaid with number of plants under construction

One way of assessing the safety impact of the increased use of CGD is to look at the 10 CFR Part 21 [17] reports. This regulation applies to the supply of components, services, analysis software, and other products whose failure could cause a substantial safety hazard. In practice, most defects that would result in a product's failure to perform its intended safety function(s) are reportable. Therefore, the Part 21 reports provide a good database for looking at trends of safety-significant component failures over time.

As illustrated in Table 4-1, the annual quantity of Part 21 reports submitted to the NRC has decreased significantly over the last 40 years. In part, the decline may be due to the decreased quantity of items being provided as construction of new nuclear facilities has slowed. As illustrated in Figure 4-2 and shown in Table 4-1, the annual quantity of Part 21 reports ranged from 139 to 509 annually from 1983 to 1992. In 1996, the number fell below 100, and it has subsequently trended lower. The small increase in the number of Part 21 reports between 2010 and 2018 may correspond to the increased quantity of basic components supplied to support construction of Vogtle Units 3 and 4, completed in 2023 and 2024, respectively, and construction of the two cancelled VC Summer units.

This decreasing trend in Part 21 reports is inversely proportional to increased use of CGD over the last 40 years. The survey data collected as a part of this research indicates that use of CGD for procuring components and services for use in safety-related applications has increased over time and continues to increase, while the numbers of Part 21 reports over the same period have dropped. This supports a reasonable conclusion that the increased use of the CGD process in the United States is not resulting in a safety issue or a significant increase in the quantity of failed basic components.

Table 4-1. All Part 21 reports (not limited to those related to CGD) from 1983 to 2023

Year	Number of Part 21s	Plants Under Construction	Year	Number of Part 21s	Plants Under Construction	Year	Number of Part 21s	Plants Under Construction
1983	346	42	1997	87	0	2011	60	0
1984	439	40	1998	73	0	2012	60	0
1985	509	32	1999	51	0	2013	68	4
1986	390	27	2000	28	0	2014	91	4
1987	219	18	2001	35	0	2015	88	4
1988	172	12	2002	38	0	2016	73	4
1989	204	6	2003	33	0	2017	57	4
1990	139	4	2004	29	0	2018	32	2
1991	148	1	2005	42	0	2019	39	2
1992	270	1	2006	27	0	2020	33	2
1993	468	1	2007	37	0	2021	29	2
1994	326	0	2008	28	0	2022	28	2
1995	228	0	2009	29	0	2023	24	2
1996	91	0	2010	44				

Table 4-2 provides a summary of a detailed analysis of the individual Part 21 reports to the NRC during the last two years (2022 and 2023). In 2023, a total of 24 Part 21 reports were received, of which the 10 in Table 4-2 involved (or most likely involved) dedicated items. There were a total of 28 Part 21 reports in 2022, of which the 16 in Table 4-2 involved (or most likely involved) dedicated items. Of the 26 Part 21 reports in 2022 and 2023 that appear to have involved items accepted using the CGD process, 22 were associated with electrical or electromechanical components and 4 with mechanical components. Of the 22 that were associated with electrical or electromechanical components, 8 were associated with circuit breakers or contactors, 4 with relays, 4 with power supplies, and 6 with various other devices. These results are not unexpected as electromechanical devices such as circuit breakers and relays involve numerous piece part interfaces where small tolerance deviations can lead to random failures that are not readily detectable during typical testing performed by manufacturers with nuclear QA programs or by entities performing CGD.

Table 4-2. Part 21 reports related to CGD or CGIs from 2022 and 2023. An asterisk to the right of the event number indicates that the report didn't specifically state the items were CGD items, but they are believed to be CGD items based upon the supplier and item type.

Event Number	Event Date	Item Description	Dedicated by Supplier or Licensee	Discipline	Apparent Cause
#2022-03-00	29/03/2022	Diesel cylinder head	Supplier	Mechanical	OEM manufacturing quality issue
#2022-04-00/01	3/30/2022 and 5/26/2022	Poppet seal	Licensee	Mechanical	OEM manufacturing quality issue
#2022-05-00	06/04/2022	Electrical actuator	Supplier	Electro-mechanical	OEM manufacturing quality issue
#2022-07-00	11/04/2022	Electrical contactors	Supplier	Electro-mechanical	OEM manufacturing quality issue
#2022-08-00	17/06/2022	Power supply	Supplier	Electrical	OEM manufacturing quality issue
#2022-09-00/01/02/03*	6/24/2022, 7/25/22, 8/26/22, and 12/16/22	Connector cable assembly	Supplier	Electrical	OEM manufacturing quality issue
#2022-10-00	01/07/2022	Solenoid valve	Supplier	Electro-mechanical	Isolated failure
#2022-11-00	13/07/2022	Relay	Supplier	Electro-mechanical	Isolated failure
#2022-13-00*	02/08/2022	Power supply	Supplier	Electro-mechanical	OEM manufacturing quality issue
#2022-14-00*	05/08/2022	Medium voltage circuit breakers	Supplier	Electro-mechanical	Still under investigation
#2022-15-00	17/08/2022	Medium voltage circuit breakers	Supplier	Electro-mechanical	Unknown

Event Number	Event Date	Item Description	Dedicated by Supplier or Licensee	Discipline	Apparent Cause
#2022-18-00/01	8/31/2021 and 9/2/21	Stainless steel pipe	Supplier	Mechanical	Inadequate dedication/upgrading
#2022-20-00/01	10/31/2022 and 11/30/2022	Airlock equalizing valve	Supplier	Mechanical	Workmanship during dedication
#2022-21-00	01/11/2022	Power supply	Supplier	Electrical	Workmanship error during refurbishment
#2022-23-00/01/02/03*	11/4/2022, 1/3/2023, 3/3/2023, and 4/14/2023	Power supply	Supplier	Electrical	Unknown
#2022-25-00/01	11/30/2022 and 2/6/2023	Timing relay	Supplier	Electro-mechanical	No failures but undeclared digital content
#2023-02-00	25/01/2023	Medium voltage circuit breaker	Supplier	Electro-mechanical	Not clear if OEM workmanship or dedication assembly error
#2023-03-00/01*	3/6/2023 and 3/31/2023	Automatic transfer switch	Supplier	Electro-mechanical	Not clear whether error was made by OEM or by Paragon
#2023-05-00*	07/04/2023	Power circuit breaker	Supplier	Electro-mechanical	OEM manufacturing quality issue
#2023-09-00/01*	5/26/2023 and 6/23/2023	Cooling tower fan break	Supplier	Electrical	Dedication error—unauthorized design change made to allow for testing
#2023-13-00/01*	7/26/2023 and 8/24/2023	Motor-driven relay	Supplier	Electro-mechanical	OEM manufacturing quality issue
#2023-15-00/01*	8/3/2023 and 8/25/2023	Electrical contactors	Supplier	Electro-mechanical	Testing/assembly error made during dedication
#2023-16-00*	8/15/2023 and 9/6/2023	HGA relays	Supplier	Electro-mechanical	OEM manufacturing quality issue
#2023-18-00/01	9/6/2023 and 10/5/2023	Molded case circuit breakers	Supplier	Electro-mechanical	OEM manufacturing quality issue
#2023-23-00/01*	10/27/2023	Potentiometer	Supplier	Electrical	OEM manufacturing/design control quality issue
#2023-25-00*	12/13/2023 and 1/10/2023	6.9 KV circuit breaker	Supplier	Electrical	OEM manufacturing quality issue

Fourteen of the 26 CGD-associated failures reported in 2022 and 2023 were latent failures that occurred after initial installation. In such cases, once the cause of the failure was identified, corrective action was taken to perform additional testing or inspections during the dedication process to prevent similar failures. Generally, the quality of an item is not impacted by the way in which it has been accepted. For example, quality control measures applied to a finished product, whether performed by the manufacturer, by a third party, or as a part of CGD, cannot improve or reduce the quality of an item and may not be able to detect latent failures that have not been previously experienced.

4.3 Brazil

4.3.1 General Nuclear Situation

The nuclear power industry in Brazil is led by Eletrobras Eletronuclear, which operates the Central Nuclear Almirante Alvaro Alberto (CNAAA). The Angra NPP is the only nuclear power generation facility in the country and comprises:

- Angra 1: A two-loop Westinghouse pressurized water reactor (PWR) with a capacity of 609 MW
- Angra 2: A German-designed PWR with a net output of 1275 MW
- Angra 3: Currently under construction, expected to have a net capacity of 1245 MW when completed

4.3.2 Current State of CGD Implementation and History

CGD has the approval of the National Nuclear Energy Commission (CNEN) as a result of NRC conditional endorsement of EPRI guidance. CGD can be performed in Brazil by the utility, an equipment supplier, or a third party that specializes in providing CGD services. The use of CGD for accepting safety-related SSCs for Brazil's research reactor (non-power generation application) has recently been proposed [70]. Angra 1 follows eight steps in performing CGD [71]. These steps correspond with the process presented in EPRI NP-5652 [1] and 3002002982 [21]:

1. Nuclear procurement? Y/N
2. If Y, is it a safety-related item/service? Y/N
3. If Y, is it a CGI? Y/N
4. If Y, identify critical characteristics (CCs)
5. Identify acceptance criteria for ALL CCs
6. Determine method(s) of dedication
7. Implement and record verification of CCs
8. If all CCs are approved, dedication is complete

Wider adoption of CGD is seen as a means to facilitate localization of supply. It is also understood to be crucial in ensuring that Angra 1 will operate until the mid-2040s and potentially beyond [72].

4.4 Canada

4.4.1 General Nuclear Situation

Canada has a long history of utilizing nuclear energy, with its nuclear power program dating back to the mid-20th century. Canada is home to 19 operational nuclear reactors, all of which are based on the CANada Deuterium Uranium (CANDU) design, a unique heavy water-moderated reactor technology developed domestically. Canada's operating nuclear reactors are located at four nuclear power stations. Eighteen of these reactors are located in Ontario: eight at the Bruce station, four at the Darlington station, and six at the Pickering station. One reactor is located at the Point Lepreau station in New Brunswick.

Today, nuclear power plays a significant role in the country's energy mix, particularly in Ontario, which relies on nuclear energy for over 60% of its electricity generation thanks to the Bruce, Darlington, and Pickering nuclear stations.

4.4.2 Current State of CGD Implementation and History

CGD based on EPRI NP-5652 [1] has been implemented in Canada since the late 1990s as a means to accept commercial equipment for use in safety-related applications. The process began with the recognition of the need to incorporate commercial equipment into safety-related environments, particularly in light of the challenges faced by the nuclear industry in sourcing parts from nuclear-specific suppliers.

Canada, through its nuclear regulatory body, the Canadian Nuclear Safety Commission (CNSC), has adopted international best practices, including methodologies from EPRI, to standardize and regulate the dedication process. Although licensees in Canada have performed CGD internally, the majority of CGD is performed by dedication service providers.

To demonstrate compliance with regulations, codes, and standards, the CNSC expects the following information [73] in accordance with the requirements of CSA N286:12, clause 7.6, Supply Chain [74]:

- Licensee's CGD governance
- Qualification of the dedication service provider
- Purchasing requirements/quote
- Methods required for the determination of a CGD item
- Critical characteristics for acceptance
- Licensee's acceptance of the dedication service provider CGD plan
- Licensee's acceptance of the dedicated CGI's documentation and report

4.4.3 Applicable Regulations, Standards, and Regulatory Positions

The regulatory framework as it relates to CGD in Canada is based on:

- The Nuclear Safety and Control Act [75], under which the CNSC operates.
- Operating licenses for NPPs.
- CSA N286:12, Management System Requirements for Nuclear Facilities [74], which is referenced in license conditions.
- The CSA N299:2019 series of standards [5, 6, 7], which provide QA program requirements for suppliers of items and services for NPPs. However, licensees in Canada are currently committed to the 2016 series of N299 standards.

The CSA N286:12 standard [74] includes clauses related to work management, change control, design, and supply chain that are applicable to CGD. Licensees in Canada need to maintain approved procedures for CGD items in accordance with the requirements of CSA N286:12 [74]. Although not yet adopted by licensees in Canada, the CSA N299:2019 series [5, 6, 7] provides specific guidance on CGD, including requirements for different QA categories and dedication methods. The CNSC allows three dedication acceptance methods (called "control areas") based on CSA N299:

- Control Area 1: QA program augmentation
- Control Area 2: Verification activities
- Control Area 3: Supplier performance

These methods are similar but not identical to the four methods outlined in EPRI guidance commonly used in the United States. To validate all the critical characteristics:

- Control Area 1 may be used alone.
- Control Area 2 may be used in conjunction with Control Area 3.
- Control Area 3 shall only be used in conjunction with another control area.

Only suppliers qualified to N299.1 [5] and N299.2 [6] can perform dedication. A qualified dedication provider against QA program category 1 can perform CGD for items classified as QA program 1, 2, or 3. A supplier qualified to N299.2 [6] may perform CGD only for items classified as category 2 or 3 [71].

4.4.4 Experience Summary

Canada's experience with CGD has shown that it can be an effective way to qualify commercial equipment for safety-related applications when properly implemented. The CNSC has found that rigorous application of CGD processes, including thorough testing, documentation, and ongoing performance monitoring, can provide reasonable assurance that CGIs will perform their intended safety functions.

The CNSC verifies compliance with CGD requirements through inspections and reviews of licensee processes. It emphasizes the importance of both the design evaluation (ensuring the item fulfills the form, fit, and function requirements) and the acceptance process in CGD.

One example of CGD in a complex piece of equipment in Canada was the dedication of a standby diesel generator (SG) at the Bruce nuclear site [76]. Initially installed as a temporary commercial-grade generator, SG2 was later dedicated for safety-related use by employing a combination of specific tests and historical performance reviews as outlined in the EPRI NP-5652 guidelines [1]. Through the CGD process, Bruce Power demonstrated that the SG could meet the stringent safety and reliability standards required for safety-related applications. The CGD effort ensured compliance with the CNSC's regulatory requirements without the need to replace the existing generator, thus saving costs while maintaining operational safety.

Since the generator's dedication, ongoing performance and reliability monitoring has continued. The current testing regime includes:

- Biweekly tests: Each SG runs at full capacity for one hour, alternating weekly between the two units.
- Quadrennial tests: Every four years, each SG operates for four hours at rated output, with one generator tested every two years.
- Decennial mission test: A comprehensive 24-hour, fully loaded test occurs every 10 years. The inaugural test was successfully completed in 2015.

This testing strategy balances several factors, such as ensuring high confidence in the generators' ability to fulfill their intended safety function, minimizing environmental impact and fuel costs, and optimizing system availability by avoiding excessive maintenance-related downtime.

4.5 China

4.5.1 General Nuclear Situation

China's nuclear power industry is large and rapidly expanding. As of 2024, China operates over 50 nuclear reactors. The NPPs in China comprise a variety of technologies from France, Canada, and the United States, including four AP1000 Westinghouse reactors in Sanmen and Haiyang, which were connected to the grid in 2018. Domestic PWR technologies, such as the latest Hualong One, are also part of the Chinese NPP fleet. As of 2024, there are 27 nuclear power reactors under construction in China.

4.5.2 Current State of CGD Implementation and History

The concept of CGD is known in parts of the Chinese nuclear industry and was widely leveraged within the supply chain during the delivery of the four AP1000 Westinghouse reactors in Sanmen and Haiyang.

Around 2018, a specialized group was formed in China to advance the quality control of standardized nuclear safety equipment components. This group was established by China Nuclear Power Engineering Co., Ltd., Beijing Guangli Nuclear System Engineering Co., Ltd., and the North China Nuclear and Radiation Safety Centre (NRSC). The NRSC is a technical support organization affiliated with the Ministry of Ecology and Environment of the People's Republic of China and under China's nuclear regulatory body, the National Nuclear Safety Administration (NNSA). The group has made progress in several areas:

- Developing and trialing the CGD of components for nuclear I&C, as well as electrical equipment
- Translating and researching U.S. CGD guidelines, such as those published by EPRI
- Developing CGD technical and survey reports
- Establishing and promoting CGD standards and technical specifications

In a domestic nuclear power project, CGD was implemented for 18 categories and 154 models of commodity-level items, and test methods for 58 specific critical characteristics were developed. Furthermore, a domestic CGD system including basic standards and operating procedures has been completed [77].

4.5.3 Applicable Regulations, Standards, and Regulatory Positions

The current regulatory framework in China, including HAF 003 [78] and the rules for overseeing civil nuclear safety equipment, HAF 604 [79], do not include explicit guidelines for integrating CGIs. A licensing system exists for regulating nuclear reactors and suppliers of safety-related products, but it doesn't specifically address the procurement of CGIs.

4.5.4 Experience Summary

In 2020, the NRSC published an analysis of the CGD of emergency diesel generator liquid level transmitters. This example highlighted that while the emergency diesel generator set itself is considered safety-class equipment (with its supplier maintaining a nuclear quality management system licensed by the NNSA), the suppliers of components for the generator are not strictly required to follow nuclear quality management. The NRSC conducted CGD research, including physical tests on samples of liquid level transmitters.

The NRSC recognizes that CGD is a common practice within the U.S. nuclear industry, serving as an effective method to enhance the management of procurement and acceptance processes for equipment sets, parts, and bulk materials. Researchers at the NRSC have demonstrated that the evaluation of CGIs can improve the nuclear equipment supervision system in China, thereby improving the quality of nuclear equipment [80]. There are ongoing collaborative efforts to establish and promote CGD standards and technical specifications to ensure the quality of nuclear safety equipment in China.

4.6 Czech Republic

4.6.1 General Nuclear Situation

The Czech Republic is host to two NPPs, Dukovany and Temelín. Dukovany has four reactors, while Temelín has two. Together, these NPPs contribute to nearly a third of the nation's electricity production. Both Dukovany and Temelín are owned and operated by ČEZ, a. s., the largest utility and leading electricity producer in the country.

4.6.2 Current State of CGD Implementation and History

The ČEZ company initiated its CGD program in 2016. The primary driver for this initiative was a national legislative change that required the reclassification of certain equipment from non-safety to safety class 3. ČEZ faced the challenge of substantiating the suitability of previously procured parts for newly designated safety applications. The CGD methodology was adopted to validate the compliance of warehoused items and also to address unavailability of suppliers willing to follow nuclear industry standards.

The CGD program is centralized within ČEZ in an effort to standardize the approach across its two NPPs. A management system process is in place to control CGD and has undergone minor revisions since inception. The inaugural dedicated items were installed in 2021.

4.6.3 Applicable Regulations, Standards, and Regulatory Positions

The State Office for Nuclear Safety (SÚJB) is the regulatory body overseeing nuclear safety in the Czech Republic. The National Radiation Protection Institute (SÚRO, v.v.i.) is SÚJB's principal technical support organization, providing expert evaluations and research support.

SÚJB supervises ČEZ's CGD management system process but does not approve individual CGD plans. The regulatory body has stipulated that ČEZ should limit CGD use to scenarios where the nuclear-grade equivalent is unavailable in the supply chain. SÚJB has authorized ČEZ to employ CGD across any safety class (3, 2, or 1) but restricted its application to the part level, as opposed to the assembly or whole-component level. ČEZ will document the revised methodology in an internal procedure.

4.6.4 Experience Summary

Prior to implementing CGD, ČEZ completed staff training and developed a management system process for CGD. The adoption of CGD has offered a strategic response to obsolescence challenges in the nuclear supply chain. Since 2021, ČEZ has performed CGD on 14 lots of items for its two NPPs. A significant portion of these involved parts already in stock at the NPPs' warehouses. Items dedicated have included pump shafts and heating elements.

In all cases, ČEZ has conducted 100% of its CGD evaluations according to the criteria described in their internal procedures, which require the fulfillment of at least two of the four acceptance methods. The company maintains traceability to the CGD plan and acceptance evidence after installation in the NPPs. Maintenance staff is involved in the CGD process to ensure awareness of which parts have been dedicated. ČEZ’s experience with CGD has been positive, with no reported failures or adverse outcomes associated with the dedicated items. The company foresees an increasing volume of CGD moving forward and continued cooperation with the regulatory body.

Key Observation Point

After completing staff training and development of a management system process for CGD, ČEZ has performed CGD for its two NPPs on 14 different item batches since 2021.

SÚJB’s oversight ensures that the use of CGD, which is still relatively new in the country, aligns with the overarching objective of maintaining high safety standards within the domestic industry.

4.7 Japan

4.7.1 General Nuclear Situation

Japan has 33 operable nuclear reactors that include PWR, boiling water reactor (BWR), and advanced BWR technology. The oldest of these reactors was connected to the grid in 1974. Eleven of Japan’s nuclear reactors have restarted since the Fukushima accident in 2011.

4.7.2 Current State of CGD Implementation and History

The concept of CGIs and CGD is relatively new in Japan. It has only recently been considered by domestic nuclear licensees, despite existing regulations describing CGIs and related management system regulations from the Japan Electric Association.

In 2022, the Japanese nuclear industry’s top-tier suppliers developed the latest and most comprehensive guidelines and pilot projects related to CGD. The Nuclear Quality Assurance Special Committee Working Group for Nuclear Quality Assurance Regulations of the Japan Electrical Manufacturers’ Association (JEMA) prepared Guidelines for the Adoption of Industrial Products for General Industry, with a revised edition published in 2023 [81].

The initiative to adopt CGD in Japan is driven in part by impacts on the nuclear industry resulting from the 2011 East Japan Earthquake, such as the withdrawal of suppliers with nuclear qualifications.

4.7.3 Applicable Regulations, Standards, and Regulatory Positions

In April 2020, updated Regulations on the Standards for the System Necessary for Quality Control Related to Operations for the Safety of Nuclear Facilities (Nuclear Regulation Authority Rule No. 2, Reiwa 2nd year) were published. These regulations define “general industrial articles" as equipment, structures, and systems related to the safety functions of nuclear facilities, as well as their components, which are industrial products other than those specifically designed, developed, and manufactured exclusively for use in nuclear facilities [19].

The regulations state that for general industrial articles, the method and degree of control shall be established to obtain necessary information from suppliers to confirm compliance with requirements. In 2021, the Japan Electric Association published Management System Regulations for Nuclear Safety, JEAC 4111-2021, providing additional explanations beyond the national regulations [82].

4.7.4 Experience Summary

A project report was published based on the Nuclear Industry Infrastructure Enhancement Project: Development of Methods to Ensure Safety and Reliability in the Adoption of Industrial Products for General Industrial Use [25]. This project involved major companies like Hitachi GE Nuclear Energy, Mitsubishi Heavy Industries, Toshiba Energy Systems & Solutions, and IHI Corporation.

The project leveraged the CGD process to demonstrate the compatibility of commercial-grade products with nuclear safety and reliability requirements. Three case studies were presented:

- Manual Valve by Mitsubishi Heavy Industries: This study focused on the application and integration of a manually operated valve, highlighting the processes involved in selecting and verifying this general industrial product for use in nuclear facilities using CGD.
- Electric Valve Actuator by Toshiba ESS: This case illustrated the steps and considerations for accepting an electric valve actuator using CGD, particularly in the context of nuclear safety and reliability standards.
- Exhaust Fan by IHI: This study demonstrated the criteria and evaluation methods of CGD used to ensure that a general industrial product, in this case an exhaust fan, meets the specific requirements of nuclear facility applications.

The JEMA guideline [81] discusses the risks and challenges associated with adopting general industrial products. It notes that while these products can enhance efficiency and safety, there are inherent risks due to the difference in quality management systems between general industrial and nuclear-specific products. The guideline recommends a shared risk approach, where both suppliers and purchasers are aware of and manage these risks.

The CGD methodology is believed to be poised to play a role in sustaining the nuclear supply chain in Japan and also to support the introduction of innovative technologies, ensuring the long-term viability of Japan's nuclear industry.

4.8 Republic of Korea (South Korea)

4.8.1 General Nuclear Situation

Korea Hydro & Nuclear Power Company (KHNP) is the owner/operator of five NPPs with 26 reactors in South Korea. The fleet comprises different technologies, including Generation II and III PWRs and heavy-water CANDU reactors.

4.8.2 Current State of CGD Implementation and History

CGD was first introduced in South Korea in the 1990s by U.S. vendors supporting construction activities. KHNP has more than 20 years of experience with the CGD methodology based on the EPRI NP-5652 [1] guideline. KHNP's initial CGD procedures were developed around 2002.

The emphasis on CGD at KHNP gained momentum around 2012, coinciding with a broader acknowledgment in South Korea of the need to mitigate risks associated with counterfeit, fraudulent, and suspect items (CFSIs) in nuclear power operations. In 2013, a dedicated team was established to lead CGD efforts, aimed at enhancing the trustworthiness of procured item quality.

A significant recent development was the 2024 establishment of a Central Procurement Engineering (CPE) Section within the KHNP Central Research Institute (CRI), staffed by 11 members tasked with overseeing CGD processes. The organization has established a two-tier qualification process for personnel involved in the CGD program.

Currently, KHNP CPE oversees the management of approximately 600 dedication packages annually, covering both operational and new construction projects. Dedication is performed both internally on the CRI campus and by local South Korean and international (primarily U.S.) CGD providers.

4.8.3 Applicable Regulations, Standards, and Regulatory Positions

The regulatory oversight of KHNP's CGD program includes biannual inspections. However, the regulatory body does not involve itself in the approval of individual dedication plans or the procurement and dedication testing of CGIs. The South Korean nuclear regulatory body, Korean Institute of Nuclear Safety (KINS), has not issued any notifications of systematic issues with CGD, installed CGD items, or implementation of CGD at KHNP. Regulatory guidance exists for licensees to follow, namely, KINS/RG-N17.12, Quality Verification for Alternating of CGIs in Nuclear Safety-Related Application [61].

4.8.4 Experience Summary

KHNP maintains a list of 21 vendors authorized to conduct CGD services. The qualification and associated supply chain management activities related to these providers are managed centrally and in the same manner as they are for other suppliers to KHNP.

KHNP CPE is equipped with a laboratory testing infrastructure capable of supporting a variety of CGD testing and inspection requirements. This infrastructure occupies approximately 200 square meters and houses over 100 pieces of measurement and testing equipment within KHNP CRI.

KHNP CPE has developed a digital management system to track CGD packages (including plans), schedules, approvals, dedicated item quantities and types, and failure data. One of the key performance indicators for KHNP's CGD process is the approval of supplier CGD plans within 14 days as part of the procurement process.

The verification of critical characteristics as a part of CGD relies primarily on Acceptance Method 1 (tests and inspections). Historically, Acceptance Method 2 (commercial-grade survey) and Method 4 (historical performance) have mostly been used as part of digital device CGD. Method 3 (source verification) has been used on items with complex configurations that require a special test, such as induction motors and medium voltage circuit breakers.

In terms of part volume, the most common CGIs dedicated for the KHNP fleet over the past decade are piece parts such as bearings, fuses, and capacitors, as shown in Figure 4-3. Whole pieces of equipment such as valves and motors are also among the most commonly dedicated items.

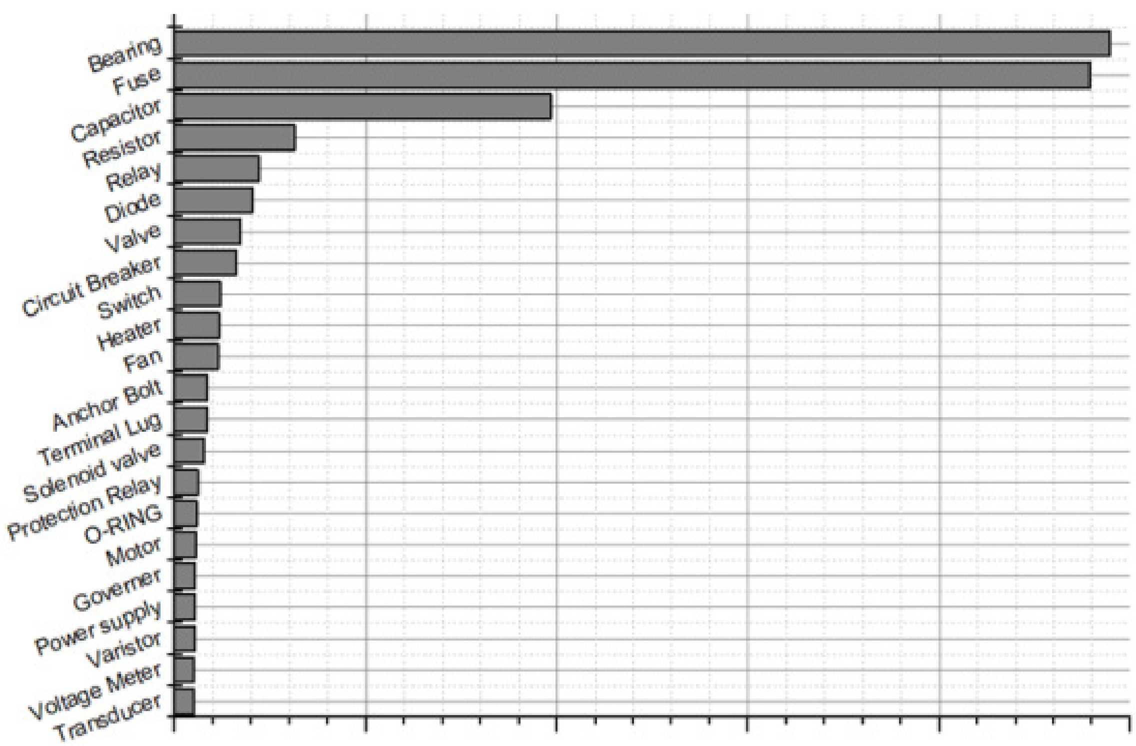

Figure 4-3. Relative volume of various CGIs supplied to South Korean NPPs over the past decade (courtesy of KHNP)

Once successfully dedicated, items subjected to CGD are marked with a sticker containing an ID linked to the complete dedication plan documentation package. Digital traceability is also ensured for cases where a label is damaged or cannot practically be adhered to the item. This system ensures that maintenance personnel can easily identify CGD items, which are treated identically to safety-related items in terms of maintenance and inspection protocols.

KHNP reports no significant failures in parts or equipment that have undergone successful dedication. It indicates that one of its key challenges is establishing appropriate acceptance criteria for the critical characteristics of CGIs. Despite this, KHNP expects an increase in CGD activities in the future, while prioritizing safety-related nuclear suppliers for the procurement of spare parts and equipment wherever feasible.

4.9 Romania

4.9.1 General Nuclear Situation

Romania has one NPP, located in Cernavoda. The plant consists of two CANDU 6 reactors, each with an electrical generating capacity of approximately 700 MW, commissioned in 1996 and 2007, respectively.

4.9.2 Current State of CGD Implementation and History

Around the mid-2010s, Cernavoda NPP faced mounting challenges in acquiring safety-class parts from qualified nuclear suppliers, due in large part to the inspection and test plan (ITP) requirement. This led the plant to develop SI-01365-T058, its first internal guidance document for performing CGD in accordance with EPRI NP-5652 [1]. Revision 0 of that guidance was reviewed and approved by the Romanian regulatory body, the National Commission of Nuclear Activities Control (CNCAN), in 2016, enabling the use of CGD. The methodology is being implemented in lieu of the ITPs normally required to be furnished and followed by the supplier of safety-class parts.

The Cernavoda NPP guidance has been revised twice since 2016 to improve the internal workflow, include CGD elements like sampling, and integrate parts of the latest EPRI guidance, 3002002982 [21]. Currently, around 8 to 12 dedication packages are being performed each year. Cernavoda performs CGD internally for simple items and tends to outsource CGD to third parties for more complex cases or items requiring measurement and test equipment not available internally. Both internal and outsourced CGD are increasing in frequency.

4.9.3 Applicable Regulations, Standards, and Regulatory Positions

There is no mention of CGD or associated terms like CGIs or critical characteristics in Romanian law or regulation. Instead, CNCAN reviews Cernavoda's CGD procedure in the same way it reviews other elements of the licensees' management system. Before performing dedication activities, CNCAN reviews and approves each dedication plan prepared by Cernavoda. Additionally, the regulatory body has the right to witness steps in the CGD process.

Qualification and selection of suppliers is a legal requirement found both in the legislation specific to sectoral procurement (Law 98/2016) [83] and in the legislation applicable to the nuclear field (CNCAN NMC-06 Rule [84], approved by CNCAN Ordin No. 70/2003 [85]). Procurement of spare parts and other equipment for Cernavoda NPP is also subject to national procurement law and the national procurement portal system.

CGD can be performed regardless of safety class, but as in the United States, items that must meet the requirements of ASME Section III Boiler and Pressure Vessel Code [69] are not eligible to be dedicated. Third-party CGD providers are nuclear qualified and authorized by CNCAN in the same way as other safety-related suppliers.

Romanian nuclear requirements are very similar to Canadian standards. When construction of the CANDU reactors started around 40 years ago, applicable Canadian standards were translated directly into Romanian regulations. Although the Romanian regulations have been revised and changed over the years, they remain similar to Canadian rules. For example, Cernavoda uses the system of four quality classes described in CAN N299.1 [5], 2 [6], and 3 [7]. A major difference between Canada and Romania is that while Canada only requires an ITP for certain safety classes, Romania requires an ITP for all safety classes, as well as regulatory approval of each ITP.

4.9.4 Experience Summary

Some of the items accepted by Cernavoda using CGD include hydrogen igniters, O-rings, fuses, quick exhaust valves, pressure-reducing valves, transducers, and transmitters. No digital items or software have yet been dedicated by Cernavoda.

Critical characteristics are being verified primarily using Acceptance Method 1 (tests and inspections). As is common practice among NPPs performing CGD, Cernavoda does not specifically track the reliability or performance of dedicated items after installation. However, if an abnormal condition were to occur, traceability to the procurement and acceptance method is always present, and the corrective action program would be activated.

The Cernavoda NPP procurement engineering superintendent, a member of the plant’s design engineering department, is responsible for managing CGD activities. The procurement engineering team comprises 12 persons with a mix of mechanical, I&C, and electrical expertise. The group has responsibility for many different activities, not only CGD.

Cernavoda NPP has historically maintained only system safety classification information. The use of CGD at Cernavoda requires an understanding of the safety class of the item being dedicated and its safety functions. In this regard, the procurement engineering team works with system engineers to evaluate the items to be dedicated.

Third-party CGD service providers are qualified and managed in a specific supplier database.

4.10 Slovenia

4.10.1 General Nuclear Situation

Slovenia has a well-established nuclear power program centered around the Krško Nuclear Power Plant (NEK). NEK is a 696 MWe Westinghouse PWR jointly owned by Slovenia and Croatia that began commercial operation in 1983. The unit provides about one-third of Slovenia's electricity and received a 20-year lifetime extension in 2023, allowing operation until 2043.

4.10.2 Current State of CGD Implementation and History

The CGD procurement process at NEK was first developed at NEK in 1996. The process was implemented to address the diminishing number of nuclear-qualified suppliers while maintaining safety standards. NEK developed its own procedures and policies, drawing on EPRI NP-5652 [1] guidance and U.S. NRC GL 89-02 [40]. The plant invested approximately $60,000 (1996 dollars) in initial setup costs, including policy development, procedure creation, personnel training, and surveys of local capabilities [86]. NEK appointed CGD coordinators across various departments and developed computer applications to support the process.

By April 1998, NEK had prepared and implemented 10 generic instructions and 70 dedication packages for various components, leading to cost savings and increased technical know-how among plant personnel. The implementation was approached step by step, starting with simpler items and gradually increasing in complexity as experience was gained. In 2014, NEK integrated its existing CGD tracking program into a universal electronic business suite. All CGD items at NEK receive a unique identifying code that easily links them back to their specific dedication plan and associated procurement and quality control documents.

NEK performs CGD primarily internally based on Acceptance Method 1, using its own measurement and test equipment. Maintenance department personnel perform testing under quality control supervision. Outsourcing of testing sometimes takes place when the appropriate measurement or test equipment is not available internally; NEK still controls the dedication activities under its quality program. NEK sometimes performs Method 2 (commercial-grade surveys) in combination with Method 1 (tests and inspections). Although Method 4 (historical performance) is not used in accordance with restrictions discussed in NRC GL 89-02 [40], historical performance is considered when developing sampling plans used for Method 1.

NEK has no practice of completely outsourcing the dedication of CGIs; however, third parties with approved 10 CFR 50 Appendix B [8] programs are sometimes contracted for dedication and qualification of CGIs that are then furnished to NEK as basic components. NEK does not dedicate ASME Section III [69] items, items that are required to be environmentally qualified, or digital items.

Approximately 30 people across the procurement engineering, QA, quality control, and maintenance departments are currently involved in CGD at NEK. A role in the CGD process is only one responsibility of these individuals.

4.10.3 Applicable Regulations, Standards, and Regulatory Positions

The Slovenian Nuclear Safety Administration (SNSA) does not publish any specific rules or guidance about CGD and is not involved in day-to-day procurement business. The SNSA references NRC rules and Institute of Nuclear Power Operations documents and regularly audits management system elements, including the CGD program. NEK is free to choose CGD as the acceptance process during procurement of safety-related items, even if the original item is still available from a nuclear-qualified supplier. The decision to dedicate is based on available knowledge and resources within NEK and the item's lead time and cost. NEK takes a conservative approach and prefers to dedicate only those items for which it has the necessary engineering expertise to confidently perform technical evaluations.

NEK proactively monitors regulatory information and available operating experience related to CGD. While the CGD program at NEK was originally based on EPRI NP-5652 [1], NEK updated its guidance to be consistent with EPRI 3002002982 [21] shortly after it was published in 2014.

4.10.4 Experience Summary

NEK has steadily increased its CGD know-how and capabilities since it began utilizing the methodology in 1996. In the early days, NEK dedicated simple commodity items, which helped the staff to become familiar with the process, the components themselves, and the standards that dictate their design and function. Over time, NEK began to acquire the necessary knowledge and measurement and test equipment to dedicate more items, such as breakers and contactors. Over the last decade, NEK has performed 543 instances of dedication on 361 unique part numbers. Figure 4-4 shows the fractional breakdown of those items by type.

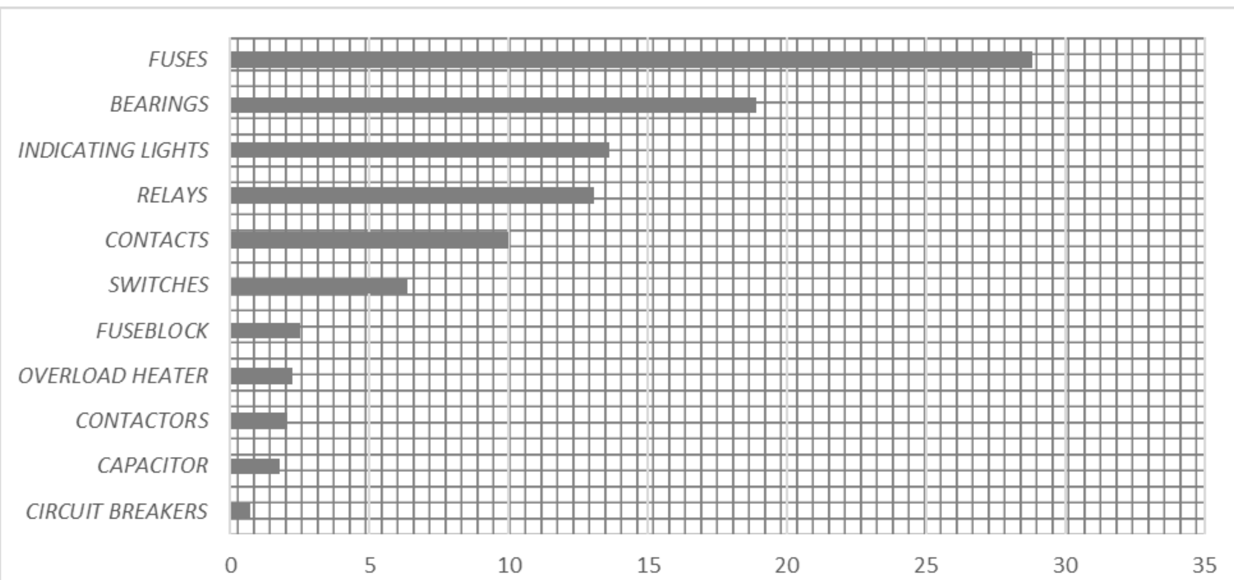

Figure 4-4. Types of items dedicated by NEK over the last 10 years as a percentage of all dedicated items

NEK has had a very successful history of applying the CGD methodology with no reported incidents. If defects were to arise, they would be reported to the QA department, which would report to NUPIC. Once dedicated, CGD items are inspected, maintained, and monitored in the same way as items procured as basic components from nuclear-qualified suppliers. NEK has never detected CFSI during the dedication process, likely because it procures CGIs from the original manufacturer or authorized distributors.

4.11 Spain

4.11.1 General Nuclear Situation

Five NPPs comprising seven nuclear reactors are operated in Spain: Almaraz (Units I and II), Ascó (Units I and II), Cofrentes, Trillo, and Vandellòs (Unit II). These plants employ a mix of German PWR and American PWR and BWR technologies and contribute more than 20% of Spain's domestic electricity production. The NPPs are owned by a consortium of companies including Endesa, Iberdrola, Naturgy, and EDP. CNAT operates Almaraz and Trillo, ANAV operates Ascó and Vandellòs, and Iberdrola operates Cofrentes.

4.11.2 Current State of CGD Implementation and History

CGD has a long history in Spain and is currently performed in large volumes. At one NPP, dedication makes up 50% or more of all safety-related procurements on an annual basis. Spanish procurement engineers view dedication as a technical activity rather than a quality activity.

Collaboration among Spanish NPPs on CGD began in the mid-1990s with a working group. This group was later dismantled and restarted around 2016–2017. Currently, the Spanish Nuclear Industry Forum (Foro) hosts a working group including ANAV, CNAT, and Cofrentes that focuses on CGD. Representatives from Spanish NPPs meet every two months to discuss CGD-related matters and share documentation.

4.11.3 Applicable Regulations, Standards, and Regulatory Positions

The Spanish Nuclear Safety Council (Consejo de Seguridad Nuclear, CSN) is the regulatory body overseeing the safety and security of nuclear operations within the country. The CSN publishes Safety Guide 10.8, Rev. 1, Quality Assurance for the Management of Elements and Services for Nuclear Facilities [60], which establishes how NPPs should perform dedication. This guide references UNE 73-104 [23] and EPRI-5652 [1].

The CGD methodology cannot be used for items subject to the requirements of ASME Section III class 1, 2, or 3 [69]. It can only be used for CGIs that fulfill the requirements of 10 CFR 50 Appendix B [8], 10 CFR 21.3 [17], and U.S. NRC RG 1.164 [42].

The CSN does not participate actively in CGD procurements and does not have approval authority over CGD activities while they are taking place. Instead, CSN reviews CGD activities as part of regular inspections and audits of the licensee's management systems.

4.11.4 Experience Summary

Spanish NPPs have successfully dedicated many types of mechanical, electrical, and I&C items. Complex pieces of equipment such as a Boron analyzer, a battery charger, and high voltage breakers have been dedicated. Digital component dedication, although challenging, has been performed successfully on items such as digital registers for the main control room at Almaraz, protective relays, and thermal-override relays.

The majority of CGD acceptance activities in Spain are performed using Method 1 (tests and inspections) (internally or outsourced). When Method 1 is uneconomical or impossible, Method 2 (commercial-grade survey) or Method 3 (source verification) is used, typically in conjunction with Method 1. Method 4 (historical performance) cannot be used alone to verify critical characteristics due to Spain's adherence to U.S. NRC GL 89-02 [40].

Spanish licensees perform CGD internally or using third parties to varying degrees. At CNAT, for example, 30% of CGD is performed internally in its own laboratories and 70% is outsourced. When developing CGD plans for in-house dedication, software from the company APIS Informations-technologien GMbH (https://www.apis.de/en) is used to perform failure modes and effects analysis for developing a list of critical characteristics.

Like those in the United States, Spanish licensees treat safety-related and dedicated items the same when it comes to maintenance, monitoring, and traceability. They do not specifically track the reliability of CGIs and report that they have not seen evidence that indicates special tracking of successfully dedicated items is necessary. In their survey responses, Spanish utilities reported no notable cases of successfully dedicated products failing in service.

From a supplier quality management perspective, Spain is highly harmonized despite having different owner/operator organizations. The utilities share qualified supplier lists, which include CGD service providers, and they perform safety-related supplier qualification activities together, in accordance with the Spanish UNE 73-401 standard [87].

Procurement strategies vary among Spanish NPPs. CNAT attempts to buy from nuclear-qualified suppliers whenever possible, otherwise using CGD. ANAV is not required to buy safety-related items if available, but it often finds it easier to do so. It is noted that CGIs are of at least the same quality as nuclear-grade items, if not higher, and better technologies are often available on the commercial market, which can then be dedicated.

4.12 Taiwan

4.12.1 General Nuclear Situation

In Taiwan, six nuclear reactors were connected to the grid at three sites on the island between 1977 and 1985. Currently, PWR's Maanshan 1 and 2 are the only operating reactors.

4.12.2 Applicable Regulations, Standards, and Regulatory Positions

The Nuclear Safety Commission (NSC) of Taiwan serves as the principal regulatory body overseeing the implementation of CGD practices, ensuring that they align with international standards and contribute to the overarching goal of nuclear safety.

The CGD process in Taiwan, as regulated by the NSC and implemented by entities such as Taipower, involves several steps: selection, evaluation, verification, and acceptance of CGIs for use in nuclear safety-related applications. This process is underpinned by a framework based on the Regulations on the Dedication of Commercial Grade Items and Certification of Dedication Agency (CGD regulation) [88], which outlines the criteria and methodologies for CGD.

One of the unique aspects of the CGD practices in Taiwan is the control over third-party CGD service providers, referred to locally as dedication agencies. The dedication agencies are authorized by Taipower, under the oversight of the NSC, to perform dedication activities. These entities are evaluated and approved based on their technical competence, QA programs, and ability to adhere to specified CGD processes and procedures. The NSC CGD regulation includes a template for an Application for Certification of Dedication Agency for Commercial Grade Items, which mandates that dedication agency applicants provide their quality manual, CGD procedures, description of capabilities, and three years of CGD records. Additionally, the dedication agency must guarantee the NSC right of access to its facilities.

To specifically monitor the performance of CGD items, the NSC CGD regulation includes a template for Abnormality Report of Dedicated Commercial Grade Item. It is the responsibility of the dedication agency and the licensee to file this form to report an abnormality of the dedicated CGI to the regulatory body within one month of detecting the defective item or unsuitable condition of the item.

5 RELATED PROJECTS AND WORKS

5.1 KELPO

In 2017, the Finnish Radiation and Nuclear Safety Authority (STUK) recognized a need to study the efficiency and effectiveness of the regulatory approval process for SSCs in safety-related applications. This was based on STUK's experience, license holders' feedback, and interviews with organizations in the supply chain.

In 2017–2018, STUK conducted two studies to better understand challenges in the approval process. The first study was focused on the approval process for SSCs. During the study, it became obvious that the traditional nuclear supply chain had become less willing and able to deliver products to the shrinking nuclear market in Europe. Several traditional suppliers had stopped delivering to the nuclear industry or no longer existed. The study resulted in two main conclusions [89]:

- The existing approval process was seen as burdensome, especially regarding documentation and inspections during manufacturing.
- License holders had identified an increased need to use high-quality industrial-grade products in safety-related applications to maintain a high level of nuclear safety and reliability in the longer term.

The second study was focused on getting feedback from the main domestic nuclear supply chain. The conclusion was that the manufacturing industry saw the existing regulatory guides as advantageous, because they provide a solid basis of requirements, but questioned the value of additional requirements that differ from those for other industries. Further, the supply chain identified that the license holders had different requirements and approval criteria for the same SSCs, even when they were based on the same regulatory framework and requirements.

In 2018, the Finnish license holders, Fortum and Teollisuuden Voima Oyj (TVO)—later joined by the new Finnish utility, Fennovoima—started a project called KELPO to better enable the use of high-quality industrial-grade products in safety-related applications. This use was seen as a prerequisite for maintaining continuous development of nuclear safety in the long term. STUK participated in KELPO as an observer with the intent of furthering both purposes.

KELPO was intended to develop a new process for internal and regulatory approval of SSCs (see Figure 5-1). It was also meant to solicit input on the renewal of the regulatory framework (YVL-guides). The intent was to go from a detailed compliance-based approach to a more performance-based approach, highlighting the license holder's full and ultimate responsibility for nuclear safety and implementing a graded approach to make inspections and other processes more risk based. An additional key objective was to develop collaboration between the licensees, the regulator, and the suppliers.

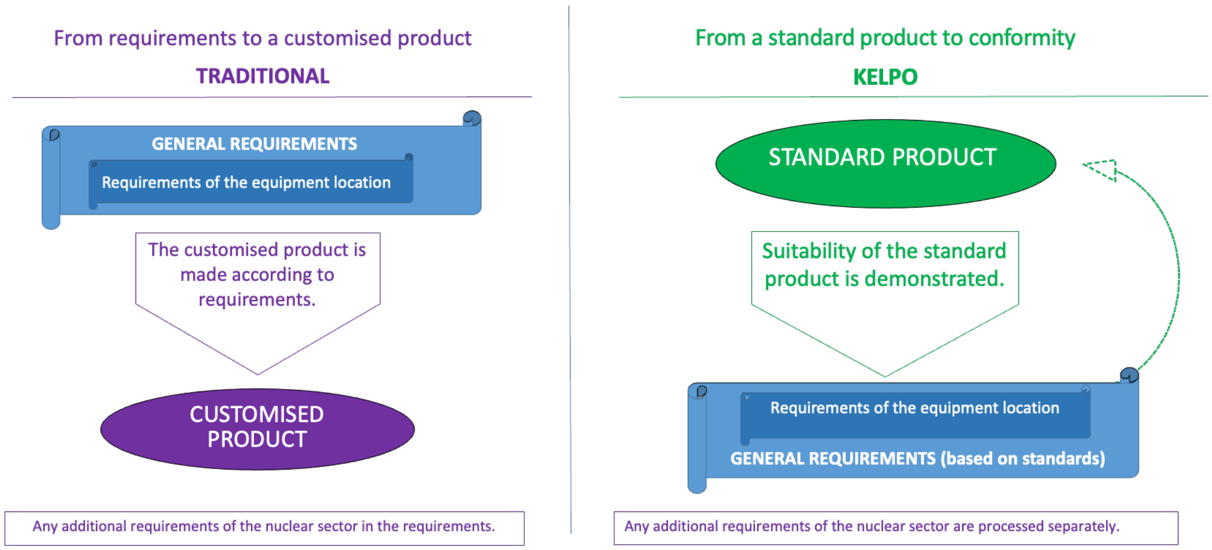

Figure 5-1. The KELPO approach

KELPO sought to learn from other industries with high volumes and lots of experience and to go from tailor-made, often "first of a kind" items to serially manufactured items. This meant developing a process and related instructions for approval of safety-classified items according to joint procedures and requirement specifications, utilizing a digital data platform co-owned by all license holders and accessible to the regulator.

The first step in developing this process was to focus on the approval of mechanical items in the lower safety classes. Working groups were established, with the regulator participating as an observer and offering the regulatory perspective. A new process resulted from this phase and was reviewed by the regulator. A pilot project was then started with a real procurement of safety-related manual valves, which later were installed at the Olkiluoto NPP. The utilities also developed joint general technical characteristics, including templates, to which the license holder adds necessary site/place-specific technical characteristics. It is estimated that some 80% of the approval is handled through the joint general technical characteristics, with site/place-specific characteristics covering the remaining 20%.

The final KELPO process was developed based on feedback from the utilities, the regulator, and the supply chain. The pilot projects included the following main steps:

- Definition of general technical characteristics and site/place-specific characteristics
- Identification of industrial-grade items
- Audit and approval of the supplier of the industrial-grade item
- Procurement of the item
- Verification and approval of the delivery and documentation
- Installation
- Testing and operational use
- Documentation in the joint digital data platform depicted in Figure 5-2

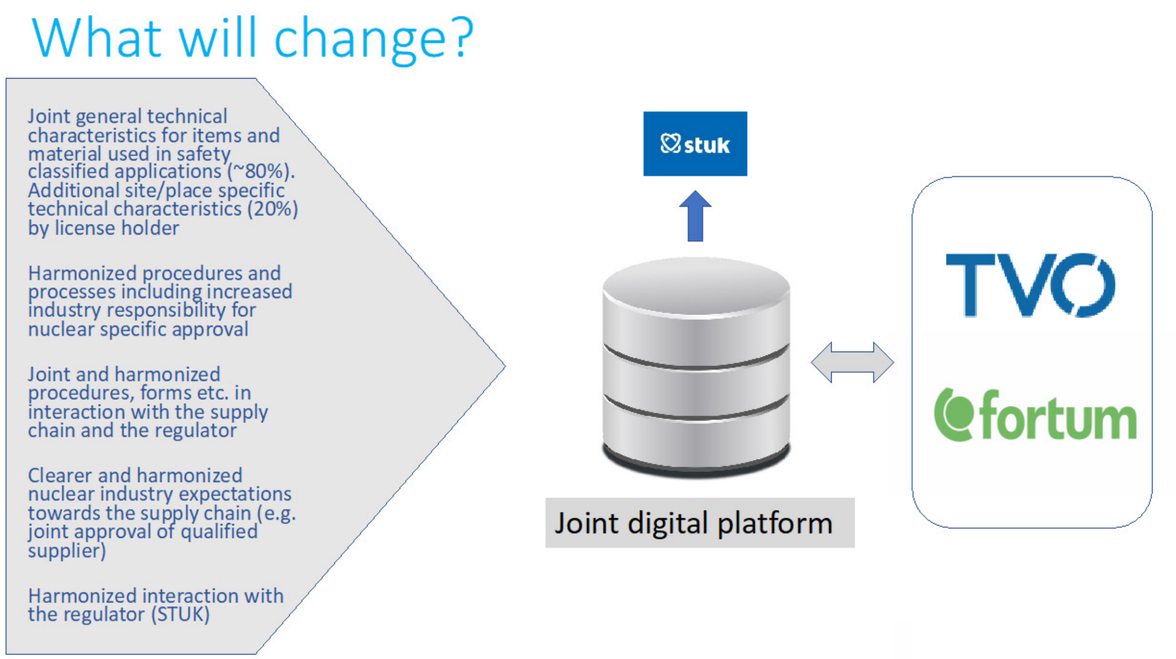

Figure 5-2. KELPO joint digital platform

The KELPO approval process was approved by STUK, and the license holders incorporated it, with related process descriptions, approvals, documentation, etc., into existing management systems.

The KELPO process has been in use for three years and has been utilized for purchase of more than a hundred components. The experience has proved that the process delivers expected quality and lives up to the original expectations for KELPO. No major deviations of KELPO-purchased items have been identified by license holders or the regulator.

Based on these positive experiences, the KELPO approach is extended to a Nordic KELPO approach (other Nordic jurisdictions). The KELPO experiences are also being utilized in the ongoing renewal of the Finnish nuclear energy legislation.

5.2 ISO 19443:2018

The international standard ISO 19443:2018 [4] specifies the quality management system requirements for organizations in the supply chain of the nuclear sector, particularly for the supply of products and services important to nuclear safety (ITNS). It is derived directly from ISO 9001:2015 [11] and incorporates additional nuclear-specific requirements. The standard applies to organizations involved in the design, development, production, installation, and servicing of products and services that directly affect nuclear safety, ensuring that suppliers at all levels adhere to stringent quality requirements to maintain safety and reliability. It mandates that top management demonstrate leadership and commitment to the quality management system and emphasizes the importance of a safety culture within the organization. The standard integrates risk-based thinking, requiring organizations to identify and address risks and opportunities that could impact product and service quality, with a specific focus on nuclear safety-related risks and processes so as to manage them effectively.

Since its inception in 2018, the number of suppliers certified to the ISO 19443:2018 [4] standard is growing rapidly. Presently, the majority of certified suppliers are located in France and elsewhere in Europe, with fewer in North America, Asia, and Africa.

The ISO 19443:2018 [4] standard considers the control of externally provided processes, products, and services. It describes how the quality management system should control the supply of items, including those that may be important to nuclear safety in the final product being supplied. In this context, the standard refers to critical characteristics and to commercial-grade items (or activities). The standard defines a commercial-grade item or activity as:

> Item or activity that affects nuclear safety and that was not designed, manufactured or performed in accordance with specific nuclear requirements.

Although the standard never uses the terms "dedication" or "CGD," the concept of verification of critical characteristics of CGIs indicates that the CGD methodology as described by EPRI could be used to support meeting ISO 19443:2018 [4] requirements related to acceptance of CGIs. Like suppliers' use of CGD discussed in Section 3.9 of this report, performance of CGD by an ISO 19443:2018 [4] certified supplier is for the purpose of accepting materials, parts, or sub-assemblies of the final product.

5.3 IAEA TECDOC-2034

The IAEA published TECDOC-2034, Suitability Evaluation of Commercial Grade Products for Use in Nuclear Power Plant Safety Systems [90], in 2023. The objective of this technical document is to provide information about evaluations and acceptance activities used to enable use of commercial-grade products in safety-related applications at NPPs and other types of nuclear facilities. The document includes guidance on establishing suitability of CGIs and provides reference information about practices in different jurisdictions as a basis for adoption, continued use, and discussion of the evaluation and acceptance process for commercial-grade items and services.

In addition, as part of its Nuclear Harmonization and Standardization project's work to enable use of standard, proven serially manufactured industrial/commercial-grade items, the IAEA maintains a collection of documents from different jurisdictions and organizations that discuss acceptance of these items as part of the Management, Supply Chain and Quality Network of Excellence website [91]. Access to the site is free of charge but requires membership. Registration for membership is available from the iaea.org home page.

6 SUMMARY/GLOBAL OVERVIEW

The CGD acceptance methodology developed by EPRI members in 1988 has been used successfully for over 35 years. It was developed and used first in the United States, but its use has rapidly expanded throughout the global nuclear industry. Figure 6-1 presents an overview of jurisdictions that have used CGD and their amount of experience doing so. A wide breadth of experience data, both quantitative and qualitative, exists regarding the implementation of CGD, both in the United States and abroad. Over the years, the practice of CGD has evolved, and operating experience has been used to develop and revise extensive industry and regulatory guidance, further enabling the practice. The goal of this report was to capture and analyze this operating experience and form conclusions regarding the efficacy of the CGD process.

Based upon a review of available data (including data on safety-significant failures) on the performance of safety-related items, a review of higher-tier safety system performance data, and surveys and interviews with licensees and suppliers of CGD items, it is reasonable to conclude that components procured using the CGD process can continue to be relied on to provide adequate performance, comparable to that of components procured from suppliers with nuclear quality management and assurance programs. While some failures of components procured using CGD have occurred, the rates of failure do not appear to be significantly higher than those of items procured from suppliers with nuclear programs. Furthermore, while the use of CGD items continues to expand, overall safety system performance indicators remain steady or continue to improve. Lastly, other required quality programs, such as corrective action and surveillance programs, can provide real-time feedback on the performance of installed equipment and can be used to detect a negative trend in the performance of installed items (including CGD items), should one occur.

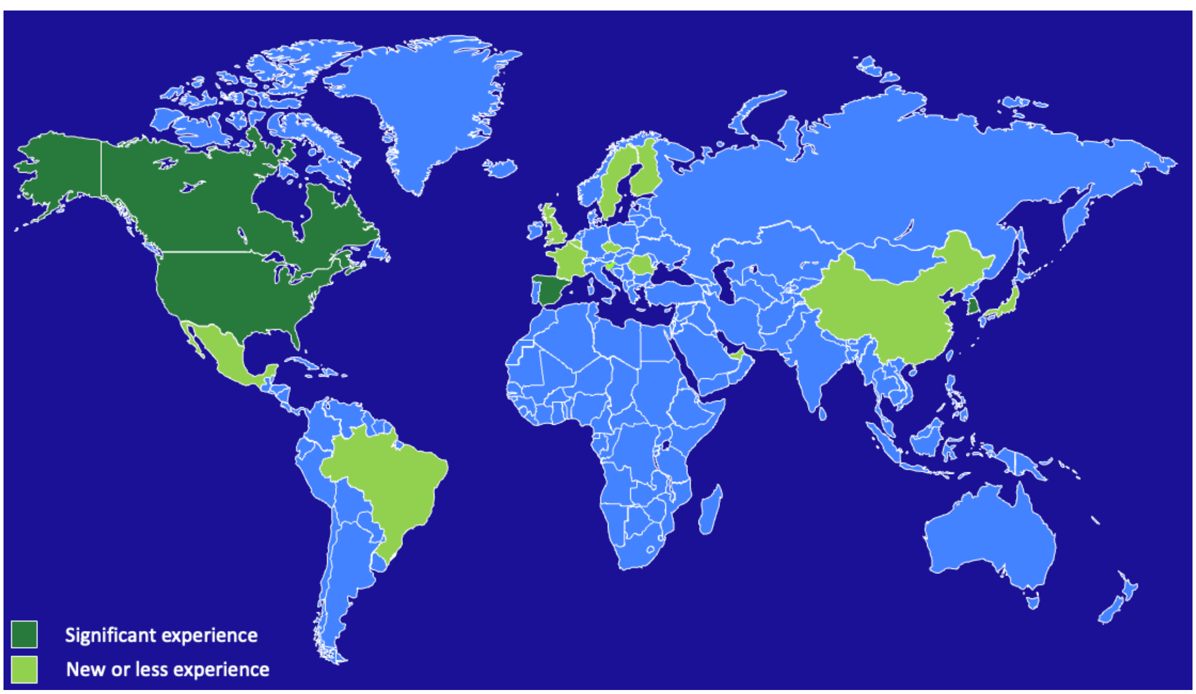

Figure 6-1. Map illustrating adoption of CGD around the world

The relative CGD experience of different jurisdictions is presented in Table 6-1. This evaluation is based on the amount of time since the inception of CGD in the particular jurisdiction and the volume of CGIs estimated to be accepted by licensees each year using the CGD methodology.

Table 6-1. Relative CGD experience, as a function of years of experience and number of procurements

Jurisdiction	Degree of Experience
Belgium	Low
Brazil	Mid
Canada	Mid/High
China	Low
Czech Republic	Low/Mid
Finland	Mid
France	Low
Japan	Low
Mexico	Mid
Republic of South Korea	High
Romania	Mid
Slovenia	High
Spain	High
Sweden	Low
Taiwan	Low
United Arab Emirates	Low
United Kingdom	Low
United States	High

CGD has been implemented and used for different reasons in different jurisdictions. Table 6-2 summarizes applications of CGD worldwide as reported in surveys and benchmarking visits conducted pursuant to this report, as well as in available documentation.

Table 6-2. Applications of CGD methodology in different jurisdictions based on survey results, interviews, and review of available documentation

Jurisdiction	Accept Items Not Available from Nuclear Suppliers	Reduce Lead Time/Localize Supply Chain	Detect CFSI	Establish Quality of Previously Procured Items	Manage Obsolescence	Enable Use of Updated Technology	Improve Quality
Belgium	X				X		
Brazil	X	X			X		
Canada	X			X	X		
China		X					X
Czech Republic				X	X		
Republic of South Korea	X		X			X	X
Japan	X				X		
Mexico	X				X		
Romania	X				X		
Slovenia	X	X	X		X		X
Spain	X				X		X
Taiwan	X				X		
United States	X	X			X	X	X

In summary, CGD can be used as an effective tool in supporting the long-term operation of a nuclear facility, as well as potentially enabling the use of serially manufactured industrial-grade items for construction of advanced and small modular reactors.

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A CGD EXPERIENCE SURVEY PARTICIPANTS

EPRI sincerely appreciates the licensees and suppliers that participated in the surveys and provided the responses used as the basis for parts of this report.

A.1 Licensee Survey Participants

The Utility Experience with the Commercial-grade Dedication Process survey, which was issued to utilities as a part of this research, is a structured inquiry designed to gather qualitative and quantitative information on the utilization of CGD by utilities across various jurisdictions in North America, Europe, and Asia. The survey delves into the practical aspects of CGD and explores a range of topics, from the basic demographic details of the participating organizations, such as location and type of nuclear facility, to more nuanced aspects, such as the specific guidelines followed for CGD, the historical usage of the process, the proportion of safety-related items accepted through CGD, and any failures of these items in service. Additionally, the survey seeks insights into the decision-making factors influencing the adoption of CGD, challenges encountered in its implementation, and any regulatory implications or violations related to the process.

The survey's design aimed to capture a comprehensive view of CGD practices, highlighting trends in its application, internal versus outsourced dedication processes, and the impact of organizational and regulatory policies on its use. Table 7-1 shows the 12 organizations, representing 96 nuclear reactors, that participated in the survey.

Table A-1. Licensees that received and completed the Utility Experience with the Commercial-grade Dedication Process survey

Name	Country	# of NPPs	# of Reactors
Asociación Nuclear Ascó-Vandellós II, A.I.E. (ANAV)	Spain	2	3
Centrales Nucleares Almaraz-Trillo, A.I.E. (CNAT)	Spain	2	3
ČEZ, a. s.	Czech Republic	2	6
Comision Federal de Electricidad	Mexico	1	2
Constellation	United States	11	23
Duke Energy	United States	6	11
ENGIE Electrabel	Belgium	2	7
Iberdrola Generación Nuclear, Cofrentes NPP	Spain	1	1
Korea Hydro & Nuclear Power (KHNP)	South Korea	5	26
NextEra Energy	United States	3	7
NPP Krško (NEK)	Republic of Slovenia	1	1
SN Nuclearelectrica S.A. (SNN)	Romania	1	2
Vistra Corp.	United States	3	4

A.2 Supplier Survey Participants

The data and findings in this report are also based on a survey of suppliers, including third-party CGD service providers. It is estimated that more than 30 companies worldwide offer CGD services related to the inspection and testing of CGIs. The Supplier Experience with the Commercial-grade Dedication Process survey was completed by seven such service providers in North America, Europe, and Asia. The survey explores the historical experience of their CGD service provision, types of items most commonly dedicated, trends in CGD business, and volume of items dedicated annually. Additionally, it investigates the primary methods used for verifying critical characteristics, the geographic markets served, experiences with item failures, and the challenges encountered in implementing the CGD process. Table A-2 shows the suppliers that participated in the survey.

Table A-2. CGD providers that received and completed the Supplier Experience with the Commercial-grade Dedication Process survey

Name	Country
Kinectrics Inc.	Canada
Nucleonova S.L.	Spain
Paragon Energy Solutions	USA
SGS	Spain
United Controls International	USA
Westinghouse Nuclear, WPB	USA
YPP Corporation	South Korea

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PROGRAM

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