FORATOM
THE VOICE OF THE EUROPEAN NUCLEAR INDUSTRY

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QUALITY ASSURANCE GUIDELINE FOR PROCURING HIGH-QUALITY INDUSTRIAL GRADE ITEMS AIMED AT SUPPORTING SAFETY FUNCTIONS IN NUCLEAR FACILITIES

VOLUME 1: METHODOLOGY

NUCLEAR

Is a low-carbon energy source

Ensures security of supply

Is environmentally, economically and socially sustainable

NUCLEAR INDUSTRY IN NUMBERS

Accounts for
25%
of electricity in the EU

Almost
50%
of low-carbon electricity

Supports around
1.1Mn
jobs

Turnover of
102bn
per year

MARCH 2022

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1 Executive Introduction

In June of 2020, the FORATOM Supply Chain Optimisation Working Group published a report entitled "*Optimising the European Nuclear Supply Chain – Use of High-Quality Industrial Grade Items in European Nuclear Installations"*. Based on the observations and recommendations within the report, FORATOM, in collaboration with the European Nuclear Installations Safety Standards Initiative (ENISS), embarked on a project to publish a *European Guideline on the Use of High-Quality Industrial Grade Items in Nuclear Facilities* (*European Guideline* or *Guideline*, for short) which is compatible with the well-established commercial-grade dedication (CGD) methodology. The European Guideline Project (EGP) was an industry-led initiative sponsored by a steering group comprised of ten European national nuclear associations, nuclear installation licensees and vendors.

The European Guideline is a publicly accessible document that offers guidance and advice for European stakeholders, primarily nuclear installation licensees, on a methodology for establishing confidence in high-quality industrial grade items intended for applications important to nuclear safety. This Guideline aims to be the foundation from which nuclear licensees and third parties develop their own processes and procedures on a voluntary basis. The Guideline supports safety in the nuclear industry by clearly describing the proven ways in which the quality of items important to safety, and their suppliers' management systems, can be verified to gain confidence in the suitability of such items for use in nuclear facilities. It supports the sustainability of the nuclear industry by creating a flexible quality assurance approach for existing and future licensed operating organizations. There is no certification scheme anticipated for this Guideline.

The drafting of this Guideline took place during 2021 and included interactions with a wide range of stakeholders inside and outside of Europe. The project and its progress was presented at various fora including national nuclear association meetings, codes and standards working groups and other nuclear industry events. During the project, two groups were given the opportunity to review drafts of the complete Guideline and provide their feedback. These were the WENRA Reactor Harmonization Working Group (RHWG), and an expert advisory group comprised of the International Atomic Energy Agency (IAEA), the European Commission Joint Research Center (EC-JRC) and Electric Power Research Institute (EPRI) representatives which was formed specifically for the purpose of collecting feedback on the Guideline. Interactions with regulatory bodies and technical support organizations facilitated by the WENRA RHWG occured multiple times over the course of 2021. All interactions which took place during the course of the project helped to improve the Guideline, ensure that it represents best practices, and upholds our industry's commitment to safety.

What is dedication?

Dedication is a quality assurance methodology related to the procurement of items and services important to safety which were not controlled under the licensee's nuclear-specific supplier quality expectations. Dedication is an acceptance process which focuses on achieving confidence that an item will fulfil its safety function(s) once installed in a nuclear facility. Dedication is not intended to establish the suitability of the design of an item, rather it furnishes evidence of the quality of the supplied item. Dedication is not qualification.

The concept of 'dedicating' items first appeared more than 40 years ago in the United States and has since been rooted in the procurement practices of the nuclear industry in many countries. In Europe, some licensees have been performing dedication activities for decades while others have only recently begun establishing or seeking to establish the process.

Why are licensees seeking to establish a dedication process?

Licensees establishing a dedication process are generally doing so in order to create a procurement path for items and services important to safety which ensures a degree quality equivalent to that which results from procurement according to established nuclear-specific rules, but which can be applied to a broader spectrum of suppliers. The methodology helps licensees to maintain or re-establish a supply chain capable of delivering the necessary engineered items and services required throughout the lifetime of their nuclear facility which helps to avoid cases of obsolescence.

Benefits of the dedication methodology include the ability to access items and services from other high-reliability industry supply chains and to accept off-the-shelf items which may include unused items from shut down nuclear facilities. By having the ability to accept items and services through a dedication process, licensees can be part of a growing network of other European licensees, suppliers and third-parties utilizing the same methodology. In other words, licensees can benefit from synergies arising from lessons learned, experience sharing, and the ever-growing range of dedication case studies which enables future dedication activities to be performed more and more accurately and efficiently.

What makes the European Guideline innovative?

Across the world, several nuclear regulators recognize one or more EPRI guidelines or local standards on the use of dedication as acceptable ways in which to meet expectations related to the quality assurance of items important to nuclear safety. However, until now there has been no generalized description of a dedication methodology which could readily be used as the basis for harmonization across Europe. The objective of the European Guideline project was to develop and publish such a methodology. The benefits of the European Guideline include:

- A dedication methodology which can be applied across the European continent and which is not tied to one country's laws, regulations, codes or standards.
- A robust and proven acceptance process in lieu of no process, many different processes or case-by-case decision-making when the item or supplier is not in compliance with nuclear-specific ways of working.
- A basis to enable regulatory stability on the subject of high-quality industrial grade item acceptance.
- The opportunity to integrate a graded, risk-informed approach to the subject of dedication which should serve to both improve the safety and the economics of the process.

2 FORATOM – European Guideline Project Owner

FORATOM is the Brussels-based trade association for the nuclear energy industry in Europe. FORATOM acts as the voice of the European nuclear industry in energy policy discussions with EU Institutions and other key stakeholders. The membership of FORATOM is made up of 15 national nuclear associations representing nearly 3,000 firms. CEZ (Czech Republic), Fermi Energia (Estonia), Nuvia (France), PGE EJ1 (Poland), Rolls-Royce led SMR and Urenco (Global) are Corporate Members.

FORATOM is represented at a number of key nuclear-related forums including the European Nuclear Energy Forum (ENEF), European Nuclear Safety Regulators' Group (ENSREG), Sustainable Nuclear Energy Technology Platform (SNETP), European Nuclear Society (ENS), European Human Resources Observatory for Nuclear (EHRON), Implementing Geological Disposal of Radioactive Waste Technology Platform (IGDTP), MEP Forum for the Future of Nuclear Energy, International Atomic Energy Agency (IAEA), OECD/Nuclear Energy Agency (NEA).

3 ENISS – European Guideline Project Support

ENISS is the European Nuclear Installations Safety Standards Initiative. Established in 2005, it represents nuclear installation license holders from 16 European countries with nuclear power units, fuel reprocessing plants or large waste storage facilities. ENISS provides the nuclear industry with a platform to exchange information on national and European regulatory activities, to express its views and provide expert input on all aspects related to international safety standards. ENISS is the common channel through which European nuclear license holders interact with WENRA (nuclear regulators), the European Institutions and the International Atomic Energy Agency (IAEA) on nuclear safety matters.

Although ENISS is hosted by FORATOM, it enjoys full autonomy with regards to its strategy, priorities and decisions as well as financing, which are discussed, reviewed and approved by its own governance bodies.

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1 Introduction

Nuclear regulatory bodies across Europe have either established requirements or published guidance about quality assurance and quality control which pertains to suppliers of items and services important to safety. Although these measures differ between European countries, sometimes to a large degree, they all aim to ensure that the procured items and services are of a high-quality. A high-quality item or service is one which is very likely to conform to the specified procurement requirements.

Today there are many industries, like the nuclear industry, which leverage well-developed regulation, codes and standards to secure high-quality items and services. There are a number of international (e.g. ISO) and regional (e.g. EN) standards recognized in Europe that could be used in the nuclear industry, after proper assessment and review. In some cases, the measures implemented by suppliers to achieve high-quality items and services when delivering to the nuclear industry are indistinguishable from those established for customers in other industries.

This Guideline describes a methodology, called *dedication*, for ensuring that items manufactured, or services provided, under non-nuclear-specific quality assurance or quality control arrangements are of a quality commensurate with the same item or service had it been furnished according to local nuclear-specific quality requirements. This approach requires that the *dedicating entity* (a licensee, for example) take on a more active role in assuring the quality of items or services important to safety. As a part of this approach the existing quality management system capabilities of the supplier can be credited.

The dedication methodology expects the dedicating entity to identify and verify *critical characteristics* of the procured item which are directly linked to the safety function(s) which the item is expected to perform in service. The conformity of the selected critical characteristics with respect to defined acceptance criteria is accomplished by well-defined quality assurance and control techniques. Dedication relates to control of the procured item or service and does not replace qualification or other design verification activities.

The dedication methodology described in this Guideline is based on the proven commercial-grade dedication methodology currently used by approximately one-third of the world's nuclear power plant licensees and a number of nuclear fuel cycle facilities. The concept of the dedication first appeared in 1979 in the United States Code of Federal Regulations. Across the world, several regulatory bodies recognize Electric Power Research Institute (EPRI) guidelines and/or local standards on dedication as allowable practice. [1] [2] [3] This Guideline has been written in order to generalize the commercial-grade dedication methodology in such a way that it is readily applicable across the European nuclear regulatory landscape. It is also intended to be largely consistent and compatible with established dedication practices in Europe.

2 Terms and Definitions

For the purposes of this Guideline, the following terms and definitions apply.

Acceptance Activities
Activities undertaken as a part of dedication in which the dedicating entity verifies item critical characteristics according to acceptance methods documented in a dedication plan.

Acceptance Method
A defined, allowable way of verifying one or more critical characteristics as a part of the dedication process.

Critical characteristics
A subset of design characteristics typically chosen by the dedicating entity, the verification of which establishes confidence that a procured item will perform its intended safety function(s) throughout its anticipated service life, or that a procured service will not negatively impact the safety function(s) of any item.

- Critical characteristics must be identifiable and measurable.

Dedicating entity
An organization which performs dedication.

- When used in this Guideline, dedicating entity usually means the nuclear facility licensee, but a dedicating entity may also be a third party or supplier.

Dedication
A planned series of actions undertaken to establish confidence that a procured item or service will perform its intended safety function(s) throughout its anticipated service life in lieu of the imposition of nuclear-specific quality assurance or quality control arrangements during the design and manufacture of the item.

- Dedication is a quality assurance methodology for procured items (and services) important to safety.

Dedicated item (or service)
An item (or service) whose critical characteristics have been verified and documented as meeting defined acceptance criteria.

- A dedicated item is an item important to safety.
- A dedicated item is a high-quality industrial grade item which has successfully been dedicated.
- A dedicated item is one whose quality is deemed suitable for use in the specified safety-classified application(s) in nuclear facilities.
- A dedicated item is deemed equivalent to an item designed and manufactured under nuclear-specific quality management system arrangements.
- The end-user of a dedicated item has confidence that it will perform its intended safety function(s) throughout its anticipated service life.

Design characteristics
Inherent attributes of an item that encompass both the item's safety and non-safety functions.

- Physical, performance and dependability characteristics are types of design characteristics.
- Critical characteristics are a subset of design characteristics typically selected by the dedicating entity.

Design suitability
The adequacy of the design of an item with respect to its intended use.

- Design encompasses all characteristics of an item including physical and performance characteristics.

- The process of establishing design suitability for items important to safety may include qualification activities.

End-user
The nuclear facility licensee who will use an item.

High-quality Industrial Grade Item (or Service)
An item designed and manufactured (or service specified and executed) under quality assurance or quality control arrangements other than those typically required by the licensee when procuring items (or services) important to safety.

- High-quality industry grade items are typically designed and manufactured under non-nuclear quality assurance and quality control arrangements, but may also be those furnished by suppliers who comply with foreign nuclear quality expectations.
- High-quality industry grade items include serially manufactured products.

Important to safety
Characteristic of an item or service whose failure could result in undue radiation exposure of people or the environment. (ISO 19443:2018) [4]

- The exact definition of the term important to safety is specific to each country's regulatory system, it may also be called safety-related.
- In this Guideline important to safety means important to nuclear safety.

Item
Any structure, system, component, part thereof, material or software.

- In this Guideline, item generally refers to a high-quality industrial grade item which undergoes the dedication process in order to be used by a nuclear facility as an item important to safety.

  Off-the-shelf item
  Fully fabricated, unused item which undergoes no further manufacturing or testing activities prior to sale. Off-the-shelf items include commercial-off-the-shelf-items as well as unused items from warehoused stock at nuclear facilities, for example.

Licensee
The organization holding a license to construct or operate a nuclear facility.

- The licensee is the organization which has overall responsibility for a facility.

Lot
A collection of identical or similar items procured and delivered together that are grouped for the purpose of developing a sampling plan during the performance of acceptance activities.

Nuclear facility
Facility (including associated buildings and equipment) in which nuclear material is produced, processed, used, handled, stored or disposed of. (IAEA Safety Glossary 2018) [5]

- In this Guideline, nuclear facility refers primarily to a nuclear power plant or nuclear fuel cycle facility.

Performance-based Supplier Assessment
An acceptance method (Method 2) according to which the dedicating entity assesses the supplier in order to determine if their existing quality controls are sufficient for verifying one or more critical characteristics.

Qualification
Process of determining whether a system or component is suitable for operational use. (IAEA Safety Glossary 2018) [5]

- Qualification is generally performed in the context of a specific set of qualification requirements for the specific facility and class of system and for the specific application. (IAEA Safety Glossary 2018) [4]
- Dedication is *not* a qualification process.

Quality
Degree to which a set of inherent characteristics in a procured item fulfils specified requirements.

- This definition of quality is sometimes referred to as quality of conformance and is different from the other two quality segments, namely quality of design or quality of performance.

Quality assurance
Part of quality management encompassing all those planned and systematic actions necessary to provide confidence that quality requirements will be fulfilled.

- The function of a management system that provides confidence that specified requirements will be fulfilled. (IAEA Safety Glossary 2018) [5]

Quality control
Part of quality management intended to verify that structures, systems and components correspond to predetermined requirements. (IAEA Safety Glossary 2018) [5]

Quality management (system)
Quality management can include establishing quality policies and quality objectives, and processes to achieve these quality objectives through quality planning, quality assurance, quality control, and quality improvement. (ISO 9000:2015) [6]

Requirement
Need or expectation that is stated, generally implied or obligatory. (ISO 9000:2015) [6]

Safety function
A specific purpose that must be accomplished for safety for a facility or activity to prevent or to mitigate radiological consequences of normal operation, anticipated operational occurrences and accident conditions. (IAEA Safety Glossary 2018) [5]

Source verification
An acceptance method (Method 3) according to which the dedicating entity witnesses supplier or sub-supplier activities for the purpose of verifying one or more critical characteristics.

Structures, systems and components
A general term encompassing all of the elements of a facility or activity that contribute to protection and safety, except human factors. (IAEA Safety Glossary 2018) [5]

Safety
Safety means nuclear safety and is the achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation risks. (IAEA Safety Glossary 2018) [5]

Service
Output of a supplier with at least one activity necessarily performed between the supplier and the customer. (adapted from ISO 9000:2015) [6]

Supplier
An organization supplying an item or service according to a contract. Suppliers include designers, vendors, manufacturers, contractors, subcontractors, and carriers who furnish items or services.

3 Purpose and Target Audience

The purpose of this Guideline is to provide European nuclear facility licensees and future licensees with a suitable approach to assuring quality in procured items or services in cases when the manufacturing or performance were not carried out in accordance with local nuclear regulatory requirements related to quality assurance or quality control. It seeks to provide a well-defined methodology, based on proven practices, in order to:

- Leverage an industrial supplier's robust and proven quality assurance and quality control measures.
- Utilize high-quality industrial-grade items as items important to safety.
- Demonstrate suitable quality in items whose manufacturing or testing could not be witnessed by the supplier.
- Demonstrate suitable quality in off-the-shelf items.

European nuclear facility licensees already utilizing the dedication methodology can expect to benefit from additional detailed guidance provided in this Guideline, especially in Volume 2.

The Guideline:

- is intended to be used voluntarily by European organizations involved in the procurement of items intended for use in applications important to safety in nuclear facilities;
- has been written first and foremost from the perspective of a licensee or future licensee;
- is intended to provide a basis for implementation by all entities performing dedication and a foundation from which additional guidance on various aspects of dedication can be developed;
- aims to be the foundation from which nuclear licensees and third parties can develop their own processes and procedures;
- may foster cooperation among European licensees and future licensees in the areas of high-quality industrial grade item procurement, obsolescence management, supply chain management and combating counterfeit and fraudulent items.

The Guideline has been developed as guidance for the implementation and execution of the dedication methodology in Europe. It is not a code, standard or regulation. Therefore, when purchasing items to be dedicated, contracts should not invoke this Guideline as a requirement and such procurement documentation generally does not need to reference this Guideline as doing so may lead to confusion.

4 Objective

The objective of this Guideline is to define an approach and set of expectations for item or service dedication which is applicable to Europe as a whole. The Guideline establishes a generalized description of dedication, one which is not linked to any individual country's practices or rules. The terminology used in this guideline is meant to be understood by the entire European nuclear industry.

5 Background

In accordance with IAEA specific safety requirements related to the safety of nuclear power plants, nuclear fuel cycle facilities and research reactors [7] [8] [9], the organizations involved in the design, manufacture, construction, operation, modification, maintenance or decommissioning of such installations assure that:

- the design of items important to safety follows, wherever possible, proven engineering design practices;
- the design basis of items important to safety is specified;
- items important to safety are classified on the basis of their safety function and their safety significance;
- the reliability of items important to safety is commensurate with their safety significance;
- and a qualification programme is implemented to verify that items important to safety at a nuclear power plant are capable of performing their intended functions when necessary, and in the prevailing environmental conditions, throughout their design life, with due account taken of plant conditions during maintenance and testing. [10]

The design and qualification of items important to safety ultimately ensures that they have the appropriate characteristics so that safety functions can be performed with the necessary reliability in all design basis scenarios. Steps taken to establish design suitability, such as qualification activities, are not a part of the dedication process and are not described in detail in this Guideline because they do not fall within the scope of the dedication methodology. They are expected to be carried out prior to the dedication of an item or, at the latest, prior to the use of a dedicated item.

In addition to establishing the suitability of an item's design, it is necessary to control purchased items to assure their quality, i.e. their degree of conformance with specified procurement requirements. How licensees assure the quality of a procured item is found within their management systems and quality requirements which appear in procurement documentation. Expectations related to item and supplier quality are also often described in national law, regulation or regulatory guides. [11] These sources frequently require or recommend that suppliers of items important to safety fulfill certain management system or quality control requirements. The objective of these rules is to increase the likelihood of receiving a high-quality item important to safety, which ultimately supports the fundamental safety functions of nuclear facilities.

Instead of requiring that the supplier fulfill nuclear-specific quality rules in their provision of items or services, the licensee may voluntarily decide to follow the dedication methodology in order to demonstrate that the quality of the item is suitable, assuming that doing so is acceptable to the regulatory body. Dedication encompasses those planned actions undertaken by the licensee, or third-party dedicating entity, to collect documented evidence and thereby gain confidence that the procured item will perform its intended safety function(s). Dedication is performed instead of, not in addition to, other established measures taken to ensure quality in procured items and services important to safety.

Certain elements of the dedication methodology are already performed by European nuclear licensees to gain confidence in the quality of items important to safety. These activities include witnessing different stages of supply, assessing manufacturer quality management programmes as well as performing destructive and non-destructive testing of items upon delivery. The dedication methodology outlined in this guideline leverages these existing activities in a systematic way. The methodology allows for a customized approach to verifying quality, specific to the item being procured and specific to the circumstances surrounding the item's supply and manufacture.

6 Scope

This Guideline applies to the procurement of safety-classified mechanical, electrical, digital and structural elements of nuclear facilities as well as services which can have an impact on items important to safety. The scope of this guideline is limited to the dedication methodology which is part of the procurement process.

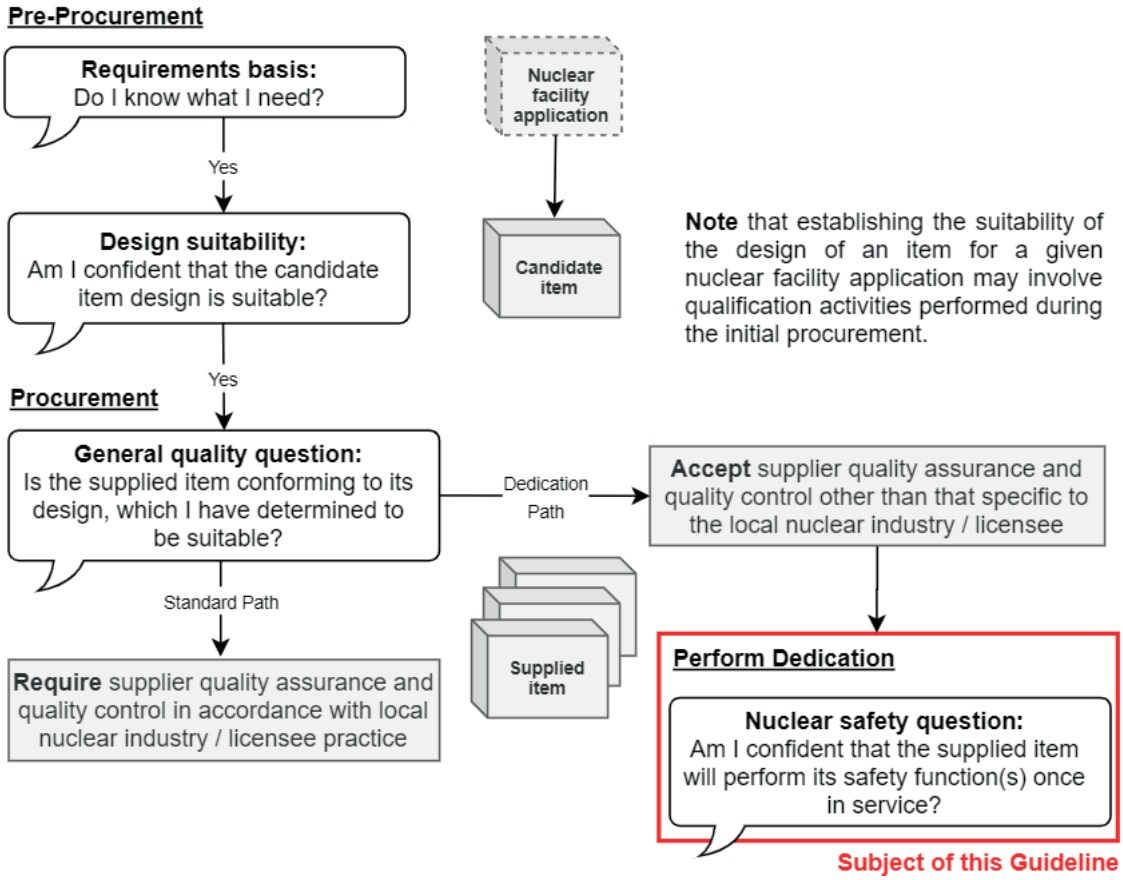


Figure 1. Depiction of the focus of this Guideline within a typical pre-procurement and procurement workflow.

6.1 Nuclear Facilities

The dedication methodology described in this Guideline is applicable to the procurement of items and services during the construction, operation and decommissioning of nuclear facilities. The application of this guideline to other nuclear facilities, for instance uranium enrichment facilities or research reactors, is possible provided that the item or service has been identified as being important to safety, classified on the basis of significance to safety, and that the safety functions of such items or services can be determined.

6.2 Item Design Suitability and Qualification

This Guideline assumes that the design basis and other requirements pertaining to the item to be dedicated have been specified and that the licensee will establish the suitability of the item's design with respect to the intended nuclear facility application, ideally prior to procurement and dedication activities. It is also assumed that the item has, or will, undergo qualification prior to use, as necessary, according to the licensee's qualification programme.

Dedication, and therefore also this Guideline, cannot replace qualification activities related to establishing design suitability in items (e.g. environmental and seismic equipment qualification) or the qualification of processes or personnel. Additional discussions regarding the subject of qualification and its relation to dedication can be found under Section 12.5.

Dedication does not evaluate the impact of a change in design, nor does it provide justification for a change or for the acceptability of dissimilar replacement items. Prior to the procurement and dedication of an item for the first time, a nuclear facility's design authority should assess any such change based on established procedures for evaluating modifications or the equivalency of dissimilar parts.

6.3 Safety classifications

Structures, systems and components (SSCs) which perform or support safety functions in a nuclear facility are categorized according to safety classifications. Dedication is intended to be applied to the procurement of safety-classified items and services (which is, in this Guideline, synonymous with items and services important to safety). Strategies for the grading of dedication activities as a function of safety class are introduced in Volume 2, Section 3.

The dedication methodology described in this guideline does not prohibit the dedication of items categorized into certain safety classes, nor does it restrict dedication based on categorizations related to the severity of consequences of item failure. In other words, the dedication methodology can in theory be applied to items assigned to any safety class. However, there are other limitations which often preclude the dedication of items with high safety significance.

6.4 Codes and Standards

The dedication methodology described in this Guideline is not intended to verify that items comply with codes or standards. Instead, it is seeking to assure the conformance of an item, whose design has already been approved by the purchaser's organization, as it relates to characteristics important to its intended safety function(s). The dedication methodology is independent of codes or standards dictating an item's design, manufacturing or testing. However, items important to safety are sometimes required to comply with codes and standards which address supplier management systems and/or quality control activities. The use of dedication in lieu of certain elements of a code or standard needs to be carefully evaluated and may not be allowable without an exemption from existing regulatory/license requirements.

7 Applying the Dedication Methodology

The dedication methodology is intended to be used at the discretion of the licensee, in consensus with the regulatory body, in lieu of other quality-related requirements typically placed on the supplier of a procured item or service important to safety. Generally, dedication is already applied or is expected to be applied in Europe:

- as an alternative to the expectations of national regulation as they relate to supplier management systems or the quality control of items important to safety; or,
- instead of requirements imposed on suppliers of items important to safety specific to the dedicating entity's organization; or,
- in lieu of certain quality-related elements of codes or standards with which items important to safety are expected to comply.

As part of developing a dedication process, dedicating entities establish a clear understanding of scenarios in which dedication may be applied. Acceptable use cases can vary from organization to organization and are typically influenced by the local regulatory body. Specific national rules or organizational policies may preclude dedication in certain situations. The dedication process, whether performed by a licensee, a supplier or a third party, does not relieve the licensee of its responsibility for safety.

Dedication comprises two main activities:

Activity	Typical steps
1. Performing a technical evaluation of the item (see Section 9)	Determine if the item is eligible for dedication. Determine the safety function(s) (if not already known). Select critical characteristics. Specify acceptance criteria for each critical characteristic.
2. Perform acceptance activities to verify all critical characteristics (see Section 10)	Choose at least one acceptance method for the verification of each critical characteristic: Acceptance method 1, Special Tests or Inspection. Acceptance method 2, Performance-based Supplier Assessment. Acceptance method 3, Source Verification.

7.1 Dedicating Entities

Only organizations maintaining documented quality management systems in accordance with nuclear regulatory requirements and/or licensee expectations should perform dedication activities. The dedication workflow and the documented processes, procedures or work instructions related to it should be integrated within the quality management system of the dedicating entity and controlled accordingly. Dedication activities should be monitored to ensure correct and consistent implementation.

Although this Guideline is written first and foremost from the perspective of a licensee or future licensee, it is important to recognize that dedication also has a long history of being applied by entities other than the end-user.

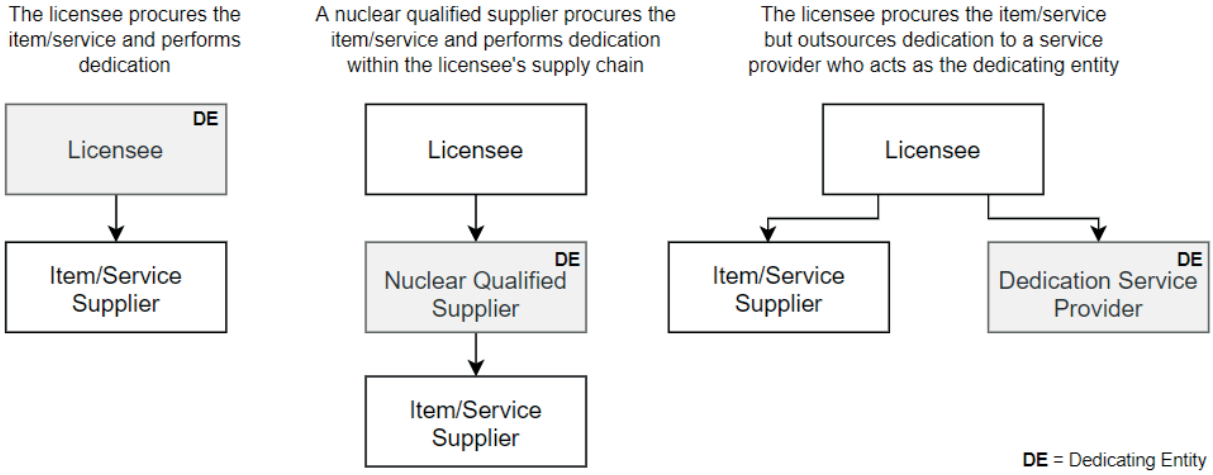


Figure 2. Three different stakeholder configurations in which the dedication methodology is typically applied. Note that in the third case (right side) the procuring entity (the licensee) is different than the dedicating entity (the dedication service provider).

Dedication is a cross-functional activity within a licensee's organization. Involved functions may include purchasing, supply chain, quality assurance, system engineering and design engineering. In applying the dedication methodology, the roles and responsibilities of different organizational functions should be well defined. All licensee personnel involved in dedication should be trained and indoctrinated to the dedication methodology. It is imperative that technically competent engineering personnel are ultimately responsible for the development of dedication plans, regardless of the dedicating entity.

7.2 Procurement Scenarios

Dedication is part of the procurement process and can be applied in a variety of procurement scenarios. Dedication provides potential for the dedicating entity to credit elements of the quality management system of the supplier, even when those are not specific to the nuclear industry. Performing dedication can be useful when procuring:

- items which have already been manufactured (including commercial-off-the-shelf items) where it is impossible to witness steps during fabrication or perform in-process tests or inspections;
- items which were not designed and manufactured under a nuclear-approved quality management system;
- items or services whose quality is controlled in a manner different than that required by the licensee (including when procuring from foreign suppliers who may maintain a nuclear-approved quality management system in their jurisdiction); or,

- items or services from suppliers who do not, or no longer, fulfill existing rules for the supply of items or services important to safety, respectively.

Dedication is applicable to the initial procurement of new items during the construction of a nuclear facility as well as in the procurement of replacement items or spare parts at operating nuclear facilities.

This Guideline describes only those procurement requirements related to dedication. Other requirements, such as compliance with or certification to codes and standards, independent oversight, equipment qualification requirements, non-conformance reporting, payment terms or those related to logistics must be developed based on prevailing organizational practices, law and regulation. This Guideline assumes that design requirements have been correctly translated into specifications which are evoked in procurement documentation.

7.3 Supplier Involvement

When procuring items or services to be dedicated the licensee or other procuring entity is an ordinary customer from the supplier's perspective, meaning that the procurement is generally made without any unique customer-specific demands with respect to quality management. This attribute of the dedication methodology enables suppliers to leverage their existing quality management systems without any significant adjustments and avoids possible risks which may arise from the introduction of novel, and often foreign, nuclear-specific quality assurance or quality control requirements. The dedicating entity may require physical access to the supplier's facilities in order to perform acceptance activities.

When performing a technical evaluation and establishing a list of critical characteristics the dedicating entity consults the supplier, if at all, in order to receive product information found in product catalogues, specifications, data sheets, high-level technical drawings or bills of materials. Volume 2 contains practical guidance related to supplier pre-selection, selection and purchasing documentation when dedication is planned.

7.4 Documentation

When an item is dedicated, records related to the quality of an item important to safety are generated. These quality records should be controlled by the dedicating entity in the same manner as other similar documentation. Documentation associated with the dedication case should be preserved as a part of the respective item dossier.

Documentation associated with dedication generated by the dedicating entity when performing a technical evaluation includes:

- description of item's safety function(s);
- description of the intended service conditions;
- assessment of the eligibility of the item for dedication;
- item critical characteristics and justification for their selection;
- identification of the selected acceptance method or combination of methods for each critical characteristic.

Dedication documentation generated during item acceptance activities includes, as applicable: (adapted from [2])

- results of a performance-based supplier assessment;
- results from source verification activities during the fabrication of the item;
- test procedures for the verification of critical characteristics, either developed by the customer or those of the manufacturer;

- reports or data sheets with the results of the acceptance tests;
- references to approved official documentation, based on which the acceptance process is carried out;
- the basis for any operating experience or manufacturer/item quality or reliability data used as a part of the acceptance activities;
- sampling plans and the basis for their selection; and,
- disposition of any anomalies observed during acceptance activities.

8 Dedication Process Starting Point

A licensee's procurement organization typically triggers the start of the dedication process when preparing to purchase an item from a supplier. This implies that the item's design has been evaluated by the licensee or its design authority as being suitable for the intended application, or there is the expectation that the design suitability will be demonstrated in connection with the procurement. Dedication cannot start before the item to be procured and its supplier are known.

9 Technical Evaluation

Performing and documenting a technical evaluation of the item being procured is the first step in the dedication process. It is generally carried out once for a specific item and intended installed location(s). It is not repeated when procuring the item multiple times but should be reviewed regularly according to a graded approach.

Once initiated, the dedication process begins with a documented technical evaluation which is carried out in order to:

1. Determine if the item is eligible for dedication.
2. Determine the item's safety function(s) based on intended installed location(s).
3. Determine the subset of design characteristics to be verified, i.e. the item's critical characteristics.
4. Determine whether any supplementary characteristics should be selected specific to the processes used during the manufacture of the item, to the extent that such processes are critical to ensuring the item's reliability

A technical evaluation is performed by suitably qualified engineering personnel who are familiar with the item to be dedicated, its intended use(s), its host equipment (if existing), the safety system to which it belongs and the design of the nuclear facility. A technical evaluation does not need to be carried out again for repeat procurements of the same item from the same supplier.

9.1 Determine Item Eligibility

The methodology described in this Guideline is meant to be applied to items which are intended for use for safety in nuclear facilities. In other words, dedication is not intended to facilitate the acceptance of items which do not perform an active or passive safety function. In practice, all items which have been assigned a safety class perform one or more safety functions in a nuclear facility. Generally, the eligibility of an item to be dedicated is not limited by safety classes, technology type or complexity (see Section 6).

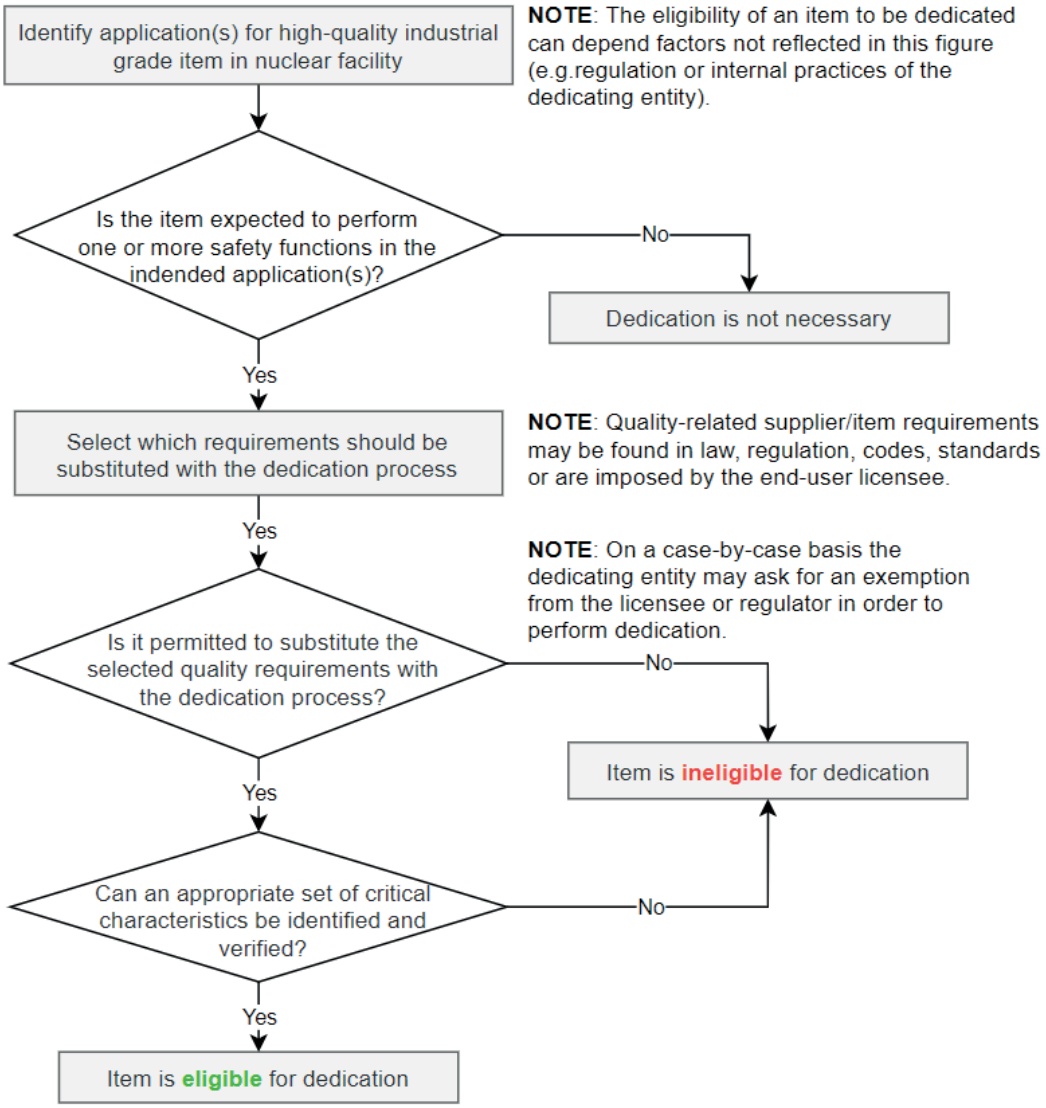


Figure 3. Key steps in determining the eligibility of an item for dedication.

A list of items which are typical subjects of dedication can be found in Annex 1.

9.2 Determine Safety Function(s)

All items important to safety in nuclear facilities perform certain active or passive functions according to their design. Some of these functions support the ability of a nuclear facility to prevent or to mitigate radiological consequences of normal operation, anticipated operational occurrences and accident conditions. These are called safety functions.[1] An item's safety functions are known to, or can be determined by, the licensee or its designer.

When procuring items such as parts of structures, systems or components for the first time, an engineering evaluation or design authority involvement may be necessary to determine if the part performs a safety function within its host. Often, not all parts which comprise a safety-classified item play a role in its safety function(s).[2] If a part does not play a role in the safety function(s) of a component, it can usually be procured without special nuclear quality requirements and is therefore not a candidate for dedication.

[1] Not to be confused with the "fundamental" or "main" safety functions of nuclear facilities themselves.
[2] Some organizations may choose to classify all parts as safety-classified if the host equipment is safety-classified.

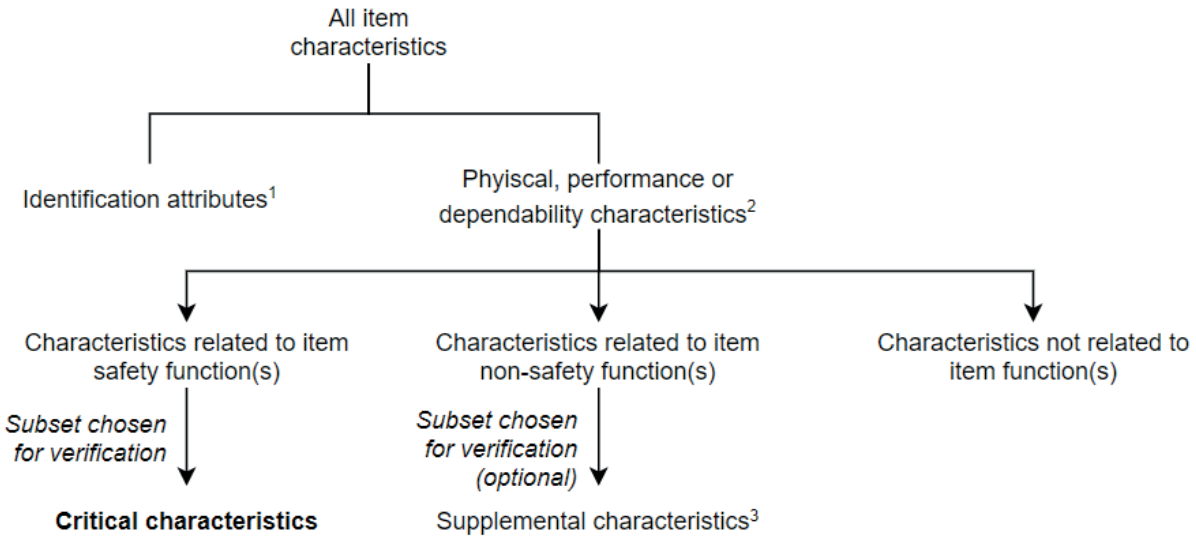
The safety function(s) of the same item may differ depending on where it is installed in a nuclear facility. All intended installation locations should be considered when determining an item's safety functions for the purpose of the technical evaluation. The intended safety function(s) of an item may be unknown to a dedicating entity who is not the end-user licensee. In such cases, all functions of the item should be treated as safety functions for the purpose of dedication, or specific controls should be implemented to limit its use to those applications that fall within the envelope of the dedication.

9.3 Select Critical Characteristics

Any item can be described by a set of characteristics. Item characteristics include identifying attributes like designation or serial number as well as design characteristics. Design characteristics are attributes of an item related to its physical form, performance or, in the case of digital equipment and software, dependability. These attributes are commonly found in supplier catalogs, data sheets or in non-public technical information provided to customers.

A subset of design characteristics, called critical characteristics, are selected by the dedicating entity for verification to provide confidence that the item will perform its safety function(s). [12] Verifying critical characteristics provides confidence that the item will perform its safety function(s) under the range of service conditions specified for the nuclear facility in operational states and in accident conditions throughout the anticipated service lifetime. Critical characteristics directly address failure modes or mechanisms which can impact the ability of the item to perform its safety function(s). In this way, the reliability of the item established during design review and qualification activities, is maintained.

In addition, there may be certain characteristics associated with the processes used during the item's manufacture that cannot be verified after the fact, but which may be important to an item's reliability. These processes should also be considered for inclusion and verification when selecting a set of critical characteristics.



[1] defined by the customer and/or manufacturer and not intrinsic to the design
[2] design characteristics; attributes intrinsic to an item's design
[3] optional; may be identified and verified to provide confidence that the item will perform its non-safety function(s)

Figure 4. Nomenclature associated with the dedication of items.

Critical characteristics are not intrinsic to an item. They are a subset of an item's design characteristics selected by the dedicating entity. Items with lower safety significance may not need as many characteristics to be verified as in the case of items with high safety significance, according to a graded approach. [12] The following list includes other potential considerations when developing the set of design characteristics chosen to be verified (i.e. critical characteristics):

- safety class of the item;
- diversity of installed components;
- number of installed locations and potential for common cause failures;
- post-installation monitoring;
- relative importance of functional characteristics [3];
- item design margins;
- host equipment design margins;
- quality assurance or quality control requirements.

An item selected for dedication may have any number of selected critical characteristics. At a minimum, one critical characteristic should be defined to address each safety function of the item. There are typical design characteristics chosen as critical for different types of items. However, since engineering judgement is involved in selecting these characteristics, different organizations may come to different conclusions regarding critical characteristics of the same item for the same intended application. The dedicating entity should provide justification for the selection of critical characteristics.

Detailed item design information can accelerate the process of selecting critical characteristics of complex items. A manufacturer's design engineering activities may have already identified design characteristics important to the item's function(s). In lieu of such information, engineering tools such as a failure mode and effect analysis (FMEA) can be utilized. If critical characteristics cannot be established, it is not possible to dedicate the item.

9.4 Specify Acceptance Criteria

Acceptance criteria are defined for every critical characteristic. For physical critical characteristics, acceptance criteria might have already been set when the item was designed. Acceptance criteria for critical characteristics can be tolerances on dimensional attributes, allowable ranges of material chemical properties (such as those dictated by a standard), performance margins or reliability criteria. Tolerances should be included in critical characteristic acceptance criteria whenever possible.

[3] A failure mode and effects criticality analysis (FMECA) can support the decision-making process when applying a graded approach to dedication for complex items. The FMECA process extends FMEA by evaluating criticality which is a relative measure of the consequences of a failure mode and the frequency of its occurrence. In this way, design characteristics can be prioritized.

10 Acceptance Activities

Performing and documenting acceptance activities to verify the item's critical characteristics is the second and final step in the dedication process. Acceptance activities are carried out each time the item is supplied.

Acceptance activities are carried out for each procurement to verify the critical characteristics of the item identified in the technical evaluation. A single method is used to demonstrate that each critical characteristic meets its respective acceptance criteria. The choice of acceptance method to be used for the verification of each critical characteristic is documented in a dedication plan based on the technical evaluation. In cases where additional confidence in the conformance of a critical characteristic is desired, and as a part of a graded approach, more than one method can be used voluntarily to verify a single critical characteristic.

A single acceptance method can verify one or more critical characteristics. Two methods of acceptance might be necessary to achieve the necessary degree of confidence in any given critical characteristic. The dedicating entity decides which acceptance methods are most suitable to verify each critical characteristic. The three acceptance methods listed below are the allowable means of verifying critical characteristics.

Method 1 verifies one or more item critical characteristics by performing special tests or inspections after delivery of the item.

Method 2 verifies one or more item critical characteristics by performing a performance-based supplier assessment to gain confidence that the manufacturer sufficiently controls quality such that one or more critical characteristics are verified.

Method 3 verifies one or more item critical characteristics by witnessing manufacturer or sub-supplier activities during the supply of the item.

Acceptance activities can take place all at once or may occur during different stages of the procurement process. The results of acceptance activities should be documented.

Historically, dedication guidance and standards have included a fourth possible acceptance method according to which the verification of one or more critical characteristics is achieved by crediting the item and/or supplier's performance record. [1] [2] This Guideline eliminates the fourth acceptance method as it relates to individual critical characteristics. A review of item and/or supplier historical performance should be carried out during the process of pre-selecting, selecting and/or qualifying a supplier prior to procurement.

High-quality industrial grade items will typically have a large installed base when compared to items manufactured and designed specifically for the nuclear industry. Correspondingly, the dedicating entity can expect that basic information related to item/supplier performance, reputation or qualitative or quantitative information about their reliability, can be furnished from the experience of the licensee, the supplier, their customers or third-party databases.

10.1 Method 1 – Special Tests or Inspection

Special tests or inspection is a method of acceptance suitable for the verification of one or more critical characteristics after the item has been manufactured. When using this method, the dedicating entity verifies one or more item critical characteristics by performing tests and/or inspections and documenting the results based on known acceptance criteria. Under certain circumstances, a qualified third party could also be used to perform the tests or inspections (see Section 14.4).

Special tests or inspection do not replace standard receipt inspection activities, however the verification of critical characteristics using this method can sometimes be integrated into those activities. [4]

Measurement and test equipment used for performing special tests or inspections should be appropriately calibrated and maintained. The suitability of measurement and test equipment resources used should consider the measuring range and measurement accuracy. Measurement traceability is required when performing special tests or inspections.

In certain instances, a critical characteristic could be verified by performing a test after the item is installed in the facility. In such cases, the dedication is not complete (meaning that the items' safety function(s) cannot be relied upon) until the post-installation test or inspection has been successfully completed. Such tests could be integrated into existing commissioning, post-maintenance testing or surveillance strategies.

Verifying a critical characteristic by statistical sampling of a representative set can be performed when dedicating a batch of identical items. Sampling plans need to be appropriately defined and justified. Section 12.2 describes the subject of sampling during acceptance activities.

[4] A check of configuration, for example.

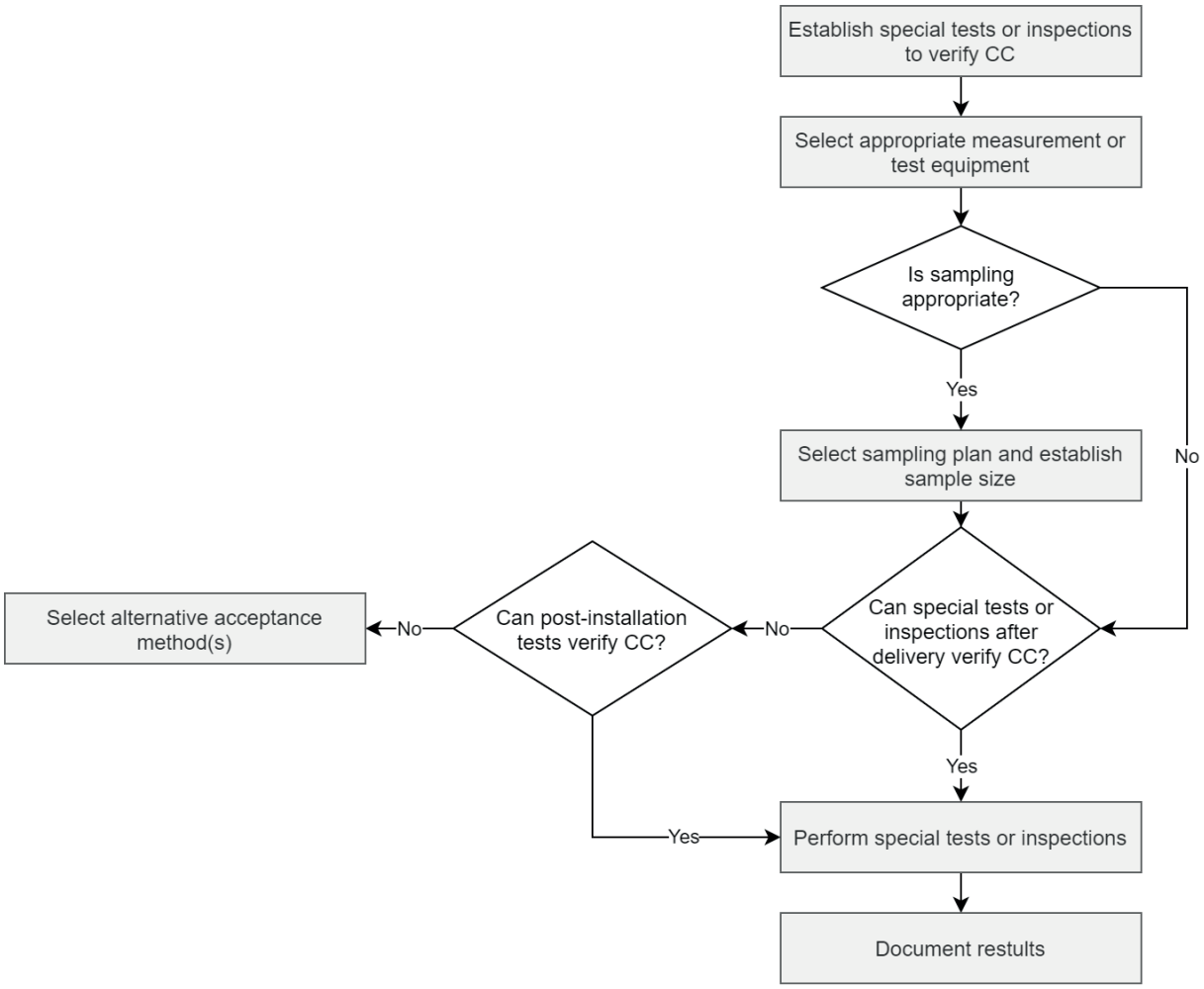


Figure 5. Performance of Acceptance Method 1 – Special Tests or Inspections

10.2 Method 2 – Performance-Based Supplier Assessment [5]

Acceptance method 2 leverages a supplier's existing quality assurance processes, procedures and work instructions to verify one or more critical characteristics when those are deemed adequate by the dedicating entity. To verify one or more critical characteristics using this method, the dedicating entity visits the supplier's premises and evaluates the supplier's quality controls to determine if they are suitable, as is, for achieving the necessary level of quality in the item intended for dedication. This method of verification is particularly useful when a specific manufacturing process has been determined to be critical to ensuring an item's reliability and the correct implementation of the process cannot be verified after the fact.

Two criteria need to be fulfilled to use this acceptance method:

- the supplier maintains a documented quality management system which is implemented effectively; and,
- the supplier's industrial quality controls adequately control the critical characteristic(s).

A supplier assessment performed as an acceptance activity for verifying critical characteristics should be performance-based and concerned primarily with documented quality activities associated with the item intended for procurement and the critical characteristic(s) of interest, rather than seeking to establish the supplier's compliance with a quality management regulation, code or standard.

A performance-based assessment is executed according to a plan which is developed by the dedicating entity specifically for the purpose of dedication. The assessment plan should seek to identify the processes, procedures and work instructions used by the supplier, or those planned to be used, to control the quality of the item which is intended to be procured and dedicated. The results of the assessment should be documented in a report, including the specific controls which are being credited as verification for any critical characteristics. If the identified controls are deemed adequate to verify the critical characteristic(s), purchasing documentation should reference the assessment report and the relevant documented controls and require that the supplier confirm, upon delivery, that the same controls were used when manufacturing or otherwise furnishing the item.

A performance-based assessment does not need to be performed prior to each procurement but should be repeated regularly with a periodicity determined according to a graded approach. Personnel participating in the planning, execution and reporting of an assessment should have the same qualifications as personnel who lead and participate in the assessment of qualified nuclear suppliers. The assessment team should include, at a minimum, an assessment team leader and a technical specialist who is familiar with the item and the technologies associated with its fabrication.

In certain cases, dedicating entities may be able to work together in order to undertake a performance-based assessment of common suppliers, when this way of working is acceptable to local regulatory bodies. Additionally, crediting traditional audits or supplier qualifications based on non-nuclear codes and standards in lieu of conducting a performance-based assessment is possible in certain scenarios.

[5] This acceptance method is commonly referred to as Commercial-Grade Survey in some countries

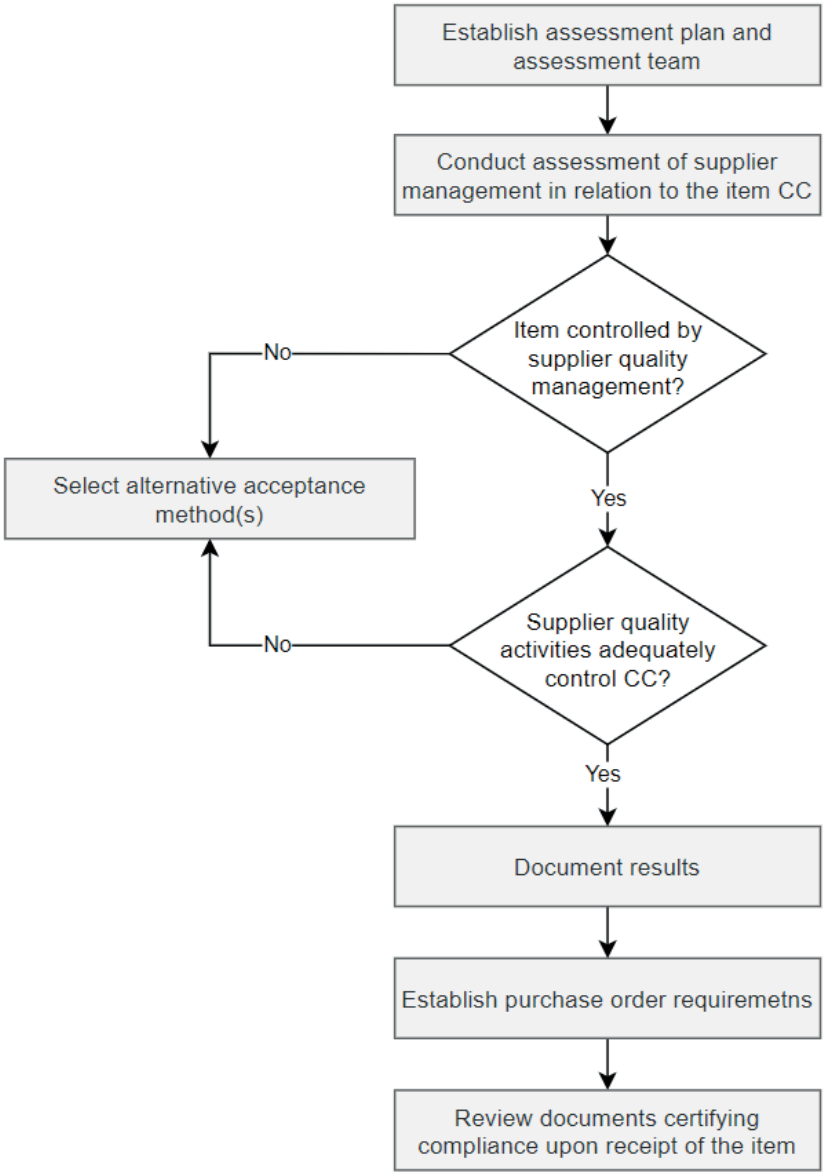


Figure 6. Performance of Acceptance Method 2 – Performance-based Supplier Assessment

10.3 Method 3 – Source Verification

Acceptance method 3 verifies one or more item's critical characteristics by witnessing supplier or sub-supplier activities. The licensee should ensure, through contractual terms, that accessibility to the supplier or sub-supplier facilities for the purpose of source verification is guaranteed. Since the failure to perform a source verification could result in an unverified critical characteristic (a failed dedication), such activities are best implemented as hold points. Hold points are points during the chain of supplier activities at which a stoppage is introduced and lifted only with the approval of the buyer.

Personnel responsible for performing a source verification should be familiar with the activities being witnessed. The dedicating entity should ensure that the activity is carried out appropriately and check for evidence that any supporting equipment has been appropriately maintained and calibrated. For batches of items, sampling methodologies can be utilized to decide on how many items within the batch will be verified by observation.

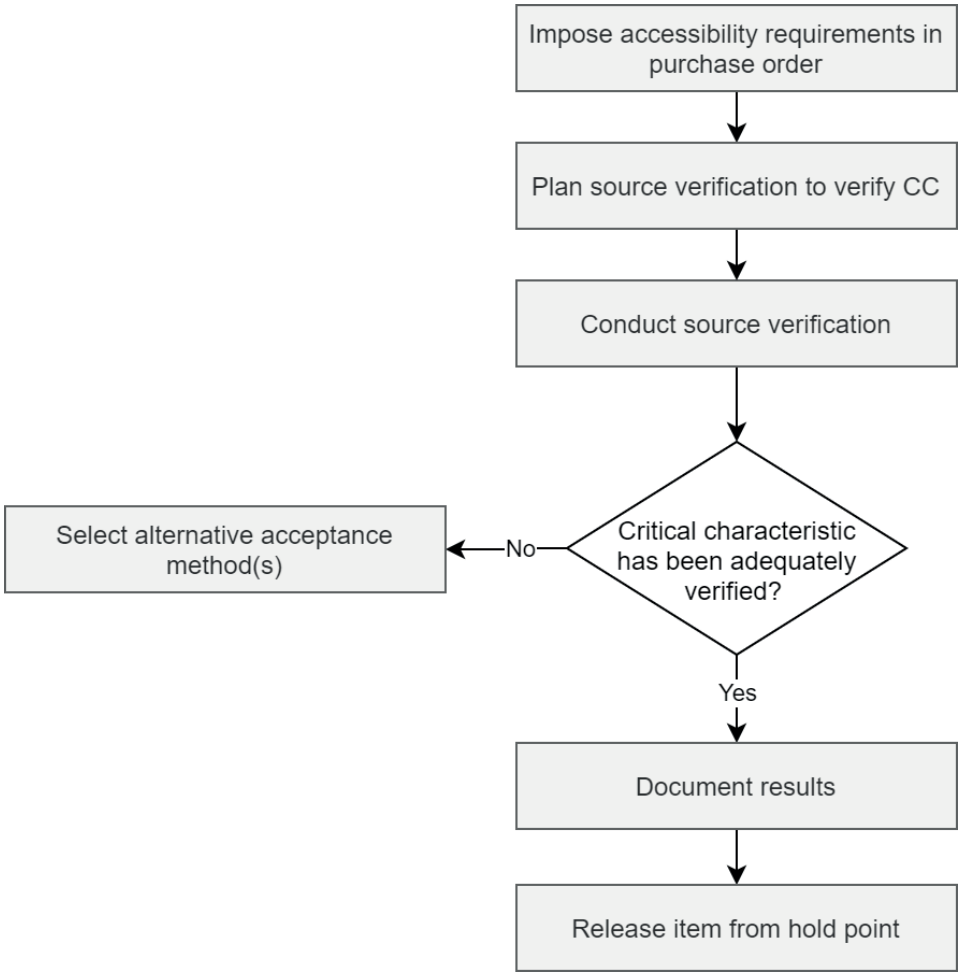


Figure 7. Performance of Acceptance Method 3 – Source Verification

11 Dedication Process Completion

Dedication of an item is completed successfully only once all selected critical characteristics are verified and their verification has been documented.

After all critical characteristics have been verified by means of one or more acceptance method, all documented evidence generated during the process should be compiled. This collection of documents should be handled and stored according to the dedicating entity's quality management system arrangements for quality records and preserved as a part of the respective item dossier.

Due to the nature of the dedication methodology, verification of individual critical characteristics may be completed at different stages in the procurement process depending on the individual dedication plan. Dedication might be finalized during the manufacturing of an item, after reviewing a certificate of conformance upon delivery of the item or after post-delivery tests or inspections.

12 Special Topics

12.1 Graded Approach to Dedication

The use of a graded approach in engineering, procurement and quality assurance is fundamental to the nuclear industry. [13] A graded approach can be particularly useful when working through the various steps of dedication and is recommended to consider both the importance of the item being dedicated with respect to safety as well as the circumstances surrounding its supply.

Specific guidance on how a graded approach might be implemented within the dedication process is contained in Volume 2 of this Guideline.

12.2 Sampling during Acceptance Activities

Lot sampling is a statistical quality control technique, the purpose of which is to ensure a high-degree of quality in a resource-efficient manner. Sampling for the quality control of manufactured products is a well-developed field founded on the mathematical domains of probability and statistics. Sampling is especially well suited for procurements in which large volumes of the same item are procured such as fasteners, seals, discrete electrical/electronic components, or consumables.

Sampling should always be performed by a random selection of representative item samples, based on documented sampling plans which include justification for their use. Sampling plans describe how many samples must be checked as a function of lot size and may differ depending on whether destructive or non-destructive checks are foreseen. Depending on the understanding or confidence in lot homogeneity, sampling plans may vary. A lot is assumed to be more or less homogeneous depending on factors such as traceability, line item (single vs. multiple), order (single vs. multiple) or supplier (single vs. multiple).

When procuring more than one item of the same design it is acceptable to introduce a sampling strategy for the verification of critical characteristics. Sampling is applicable to acceptance methods 1 or 3. Sampling is used in lieu of verifying a critical characteristic in all items in a procured lot. The sampling process is the selection of random, representative items (samples) from a lot for the purpose of verifying a critical characteristic common to the lot. Once a critical characteristic has been verified using sampling, the critical characteristic of the whole lot is considered verified.

Sampling plans may be chosen for each critical characteristic, meaning that different sampling plans can be used for each critical characteristic during acceptance activities. The dedicating entity should justify that sampling plans are appropriate and provide rationale and evidence for sampling plan selection in the technical evaluation.

Sampling strategy	Reasoning (examples)
Single	The material, mix, or batch homogeneity has been established by a single identifier (such as a heat number) and a destructive test will be used to check conformance with acceptance criteria.
Tightened	The characteristic being sampled is of high safety significance or past operating experience has identified issues in meeting acceptance criteria.
Normal	The normal sample size is the initial selection when the characteristic is expected to conform to its acceptance criteria.

Sampling strategy	Reasoning (examples)
Reduced	The item has a good performance history, a performance-based supplier assessment has established lot control or, for example, the item is being ordered as a single line-item and the supplier has ensured all pieces will be produced during a single manufacturing run.

Industrial sampling plans intended for large lot sizes may be unsuitable for use in the dedication process due to the typically small qualities of items in any one procurement. Specific guidance on the use of sampling in the dedication process should be reviewed by dedicating entities. [14]

12.3 Services

The supply of services can be subject to the dedication methodology described in this Guideline. Services important to safety performed on-site at a nuclear facility can be dedicated as an alternative to the service provider performing the work under the licensee's quality management system or under the supplier's own nuclear-specific quality management system. Services important to safety performed off-site can also be dedicated. As with the dedication of procured items according to the earlier sections of this Guideline, services are to be dedicated each time they are procured or executed.

Services which are sometimes classified as important to safety and dedicated include, but are not limited to:

- testing (see Section 12.4);
- calibration;
- maintenance;
- installation;
- equipment qualification;
- repair;
- cleaning;
- inspection; and,
- IT/software support.

For nuclear-approved suppliers that are using dedication as a way of controlling sub-suppliers, dedication can also be used as a way of controlling sub-supplier services important to safety.

12.3.1 Determine Service Eligibility

The methodology described in this Guideline is intended to be applied at the discretion of the licensee or dedicating entity to services which have the potential to adversely impact items important to safety. When the dedicating entity is the licensee, or a third-party is performing dedication on behalf of the licensee, the licensee should have a clear understanding of whether dedication is a suitable alternative to procuring the service from a supplier who fulfills typical local nuclear quality assurance expectations for the supply of services important to safety.

12.3.2 Determine Safety Impact(s)

The dedicating entity should understand the service to such an extent that it can identify the ways in which the service could impact safety if performed incorrectly. Engineering tools such as a failure mode and effect analysis (FMEA) can be utilized to determine the ways in which a service could fail and impact safety.

12.3.3 Select Critical Characteristics

A set of characteristics of a service, called critical characteristics, are selected by the dedicating entity for verification to provide confidence that the service will not have a detrimental impact on safety. If critical characteristics cannot be established, it is not possible to dedicate the service. Selected critical characteristics of services can be related to the service itself, or be attributes of items important to safety affected by the service. In the latter case, the item attributes selected as critical characteristics are verified after the service has been performed. For example, dimensions of an item important to safety can be critical characteristics of a service which, once verified after service has been performed, provide confidence that the service did not have a detrimental impact on the item's ability to perform its safety function(s).

Examples of critical characteristics for services include, but are not limited to:

- calibrated tools or equipment;
- calibration of equipment (e.g. for service providers that use calibrated equipment to verify the service was completed properly or to control in-process aspects of the service that cannot be verified after the fact);
- controls for identifying and evaluating non-conforming conditions (e.g. within a process or materials);
- controls for purchased material (e.g. for service providers that purchase material used in the performance of the service);
- controls for training/qualifying personnel to perform complex processes;
- dimensions (e.g. for machining services);
- material control/segregation (e.g. for services that rely on material provided by the licensee); and,
- procedures and work instructions.

12.3.4 Specify Acceptance Criteria

Acceptance criteria should be developed for every critical characteristic. Acceptance criteria for common service critical characteristics might include, for example, adequate documented procedures, adequate training or evidence of calibration status.

12.3.5 Acceptance Activities

The verification of each chosen critical characteristic of a service is carried out using one or more of the three acceptance methods described in Section 10. As with items, the dedication of a service is successful only if it is possible to verify all selected critical characteristics.

12.4 Use of Testing Laboratories

Laboratory testing and inspection services often play an important role in verification activities as a part of the dedication process. This Guideline recommends that the outsourcing/subcontracting of special tests or inspections as a part of dedication be performed in accordance with the following:

- the conformity assessment organization performing the special tests or inspections is accredited to ISO/IEC 17025;
- the published scope of the organization's accreditation encompasses the measurement types, measurement parameters, ranges and uncertainties associated with all verification activities;
- the accreditation has been granted by a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Agreement (ILAC MRA); and,

provided that purchasing documents require that:

- the service is provided in accordance with the organization's accredited ISO/IEC 17025 programme and within its accredited scope;
- the customer be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation (NEI);
- additional requirements as necessary according to the dedication plan and critical characteristic acceptance criteria; and

provided that upon receipt inspection it is confirmed that the laboratory's documentation certifies that:

- the contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2005 programme, and has been performed within their scope of accreditation, and
- the purchase order's requirements are met.

Specific guidance on the use of testing laboratories should be reviewed by dedicating entities. [15] The same guidance also addresses a similar workflow for the dedication of calibration services.

12.5 Qualification

Regardless of procurement arrangements (whether those arrangements include dedication or not), items important to safety should be qualified in accordance with a licensee's qualification programme. Certain processes or personnel may also need to be qualified according to local nuclear industry practices. Dedication does not include steps to qualify an item by type testing, analysis or operating experience and, therefore, cannot substitute or replace qualification requirements. Unlike dedication, the purpose of qualification is not to prevent failures caused by manufacturing quality issues. [16]

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

Figure 8. Differentiating factors between qualification and dedication

Qualification and dedication each have unique and independent roles to play in the justification for use of items important to safety. Qualification establishes the suitability of an item's design for use in its expected service conditions and for its intended application(s). An item typically undergoes equipment qualification once and measures are taken to maintain the qualified status of the item through its qualified lifetime. [10] One of those measures is ensuring that the item supplied is of the same design as the item which was originally qualified. This is accomplished through the selection and verification of critical characteristics that address the similarity between the supplied and the previously qualified item.

The dedication process should include selecting critical characteristics that will verify the similarity between the qualification test specimens and the supplied items. Since test specimens will not be supplied for installation, the qualification process itself should be sufficient to demonstrate the suitability of the design and the performance of the test specimens. The only critical characteristics that would need to be identified for the test specimens would be those that would later be used for comparison purposes. Typically, this would include any key dimensions and/or materials. The supplied items would then be dedicated like any other part that was subject to equipment qualification requirements and would generally include verification of certain performance characteristics, albeit under nominal rather than design basis accident conditions. In addition to these performance characteristics, additional critical characteristics would be selected to ensure the similarity of the supplied items to the previously tested items.

Alternatively, when procuring a batch of items for the first time that were not previously qualified, the dedicating entity may choose to procure and dedicate in a similar fashion both equipment qualification test specimens and items intended for use as a part of the same lot. In such a case, the same critical characteristics could be specified for all items, and portions of the qualification testing could be credited for verifying certain performance oriented critical characteristics, as applicable. In other words, the qualification testing could be credited as a

Method 1 test to verify certain performance oriented critical characteristics for the tested sample of items. A smaller set of critical characteristics could then be verified for the actual supplied items.

In either approach, the dedicated items would be authorized for use only after the test specimens were qualified successfully and the same dedication plan was used for all future procurements of the qualified item.

12.6 Digital Equipment

Commercial-off-the-shelf digital equipment is sometimes used in safety applications in nuclear facilities, especially in instrumentation and control systems. The IAEA has addressed challenges and approaches associated with assessing and qualifying this type of equipment for use in nuclear power plants, including the dedication methodology. [17] Specific guidance on the dedication of digital equipment should be reviewed by dedicating entities as necessary. [18]

Dedication of digital equipment is undertaken to verify the critical characteristics of hardware and, if present, integrated software such that confidence in the ability of the devices to perform their safety function(s) is achieved. International standards in the area of functional safety, and specifically the IEC 61508:2010 SIL certification scheme, provide for a similar methodology. [19] Specific guidance on the use of IEC 61508:2021 safety integrity level (SIL) certificates in lieu of a performance-based supplier assessment (acceptance method 2) for verifying critical characteristics should be reviewed by entities intending to dedicate certified digital equipment. [20]

12.7 Design and Analysis Software

In addition to embedded software contained within installed items important to safety (as described in the previous section), software within the nuclear industry is also often used to design or analyze the adequacy of a design with respect to certain important to safety aspects of a component's or system's performance. For example, software is commonly used to design and analyze piping systems (including determination of seismic loads), analyze structural loads on building components (walls, floors, etc.), analyze performance of the on-site and off-site electrical system (voltage drops, transient performance, etc.), analyze environmental conditions due to postulated design basis accidents, as well as in many other applications important to safety. If such software is purchased commercially without the imposition of nuclear quality assurance requirements and the design and/or analyses software is the primary means for verifying the adequacy of the design, the software could be a candidate for dedication. If alternative means that meet nuclear quality assurance requirements are always used to verify the adequacy of the design, the software could be purchased commercially and would not need to be dedicated.

Specific guidance on the dedication of software should be reviewed by dedicating entities as necessary. [21]

13 Ensuring Reliability Through Dedication

The reliability of an item is a function of both the adequacy of its design and of its manufacturing. For an item to be reliable from the design perspective, the design needs to be suitable for the item's potential operating environments, interface requirements and consider internal tolerances, materials, and other key parameters. The adequacy of an item's design is typically verified by licensees through either analytical or testing methods, including when required, by the licensee's qualification programme. These activities provide confidence that the item is capable of performing its intended safety function(s), when needed, under the specified service conditions and throughout its anticipated service life.

In addition to ensuring suitable conformance to design basis requirements, the manufacturing process also needs to be sufficiently controlled in order to achieve a reliable item by consistently replicating the approved design. For items important to safety that are procured utilizing typical nuclear-specific quality requirements, confidence in an item's reliability (from a manufacturing perspective) is generally obtained through specific quality-related requirements imposed on the supplier. Typically, there are no specific reliability or testing programmes imposed on suppliers of items important to safety once the design of the item which they are furnishing has been validated.

Alternatively, for dedicated items, quality is assured by selecting and verifying the critical characteristics of an item against its design requirements. If properly implemented, the dedication process includes controls that should provide confidence in an item's reliability. These controls include the initial selection of an item's supplier (i.e. only selecting suppliers that have a history of supplying reliable items, both commercially and/or to the nuclear industry), verification by the dedicating entity of an item's critical characteristics (including steps within the manufacturing process that are critical to ensuring reliability), and follow-up monitoring of the reliability of dedicated items through the licensee's non-conformance programme.

In the case of items that already have a large industrial installation base, confidence can be gained by the expectation that any item reliability issues will likely surface outside the nuclear industry and will be acted upon and corrected by the supplier. Furthermore, on an ongoing basis, licensee non-conformance programmes should be able to flag any reliability issues associated with a specific dedicated item, as well as the population of dedicated items in service in general. In aggregate, these steps taken prior to, during, and after completion of the dedication process should provide a level of reliability for the dedicated item comparable to that which would be expected had the item been procured utilizing conventional nuclear-specific quality requirements.

14 References

[1] EPRI 3002002982 Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications Revision 1 to EPRI NP-5652 and TR-102260.

[2] UNE 73-104-94 "Guía para la dedicación de componentes de grado comercial en centrales nucleares".

[3] UNE 73-403-95 "Utilización de elementos de calidad comercial en aplicaciones relacionadas con la seguridad de instalaciones nucleares".

[4] ISO 19443:2018 "Quality management systems — Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)".

[5] IAEA Safety Glossary Terminology Used in Nuclear Safety and Radiation Protection 2018 Edition.

[6] ISO 9000:2015 "Quality management systems — Fundamentals and vocabulary".

[7] IAEA Safety Standards Series No. SSR-2/1 (Rev. 1) "Safety of Nuclear Power Plants: Design".

[8] IAEA Specific Safety Requirements No. SSR-4 Safety of Nuclear Fuel Cycle Facilities.

[9] IAEA Safety Standards Series No. SSR-3 "Safety of Research Reactors".

[10] IAEA Safety Standards Series No. SSG-69 "Equipment Qualification for Nuclear Installations".

[11] IAEA TECDOC-1910 "Quality Assurance and Quality Control in Nuclear Facilities and Activities".

[12] DOE-HDBK-1230-2019 "Department of Energy Commercial Grade Dedication Application Handbook".

[13] IAEA-TECDOC-1740 "Use of a Graded Approach in the Application of the Management System Requirements for Facilities and Activities".

[14] EPRI NP-7218 "Guideline for Utilization of Sampling Plans for Commercial-Grade Item Acceptance".

[15] NEI 14-05A Rev. 1 "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services".

[16] IEEE Std 627-2019 "IEEE Standard for Qualification of Equipment Used in Nuclear Facilities".

[17] IAEA Nuclear Energy Series 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".

[18] EPRI TR-106439 "Guideline on Evaluation and Acceptance of Commercial-Grade Digital Equipment for Nuclear Safety Applications".

[19] IEC 61508-1:2010 "Functional safety of electronic/electrical/programmable electronic safety-related systems. General Requirements".

[20] 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 B.

[21] EPRI 3002002289 "Guidelines for the Acceptance of Commercial-Grade Design and Analysis Computer Programs used in Nuclear Safety Related Applications: Revision 1 of 1025243".

Annex 1 Items Typically Suitable for Dedication

List adapted from EPRI Joint Utility Task Group[6] Commercial Grade Item Technical Evaluations. This list does not encompass all items potentially suitable for dedication nor is it meant to imply that dedication is restricted to the following items.

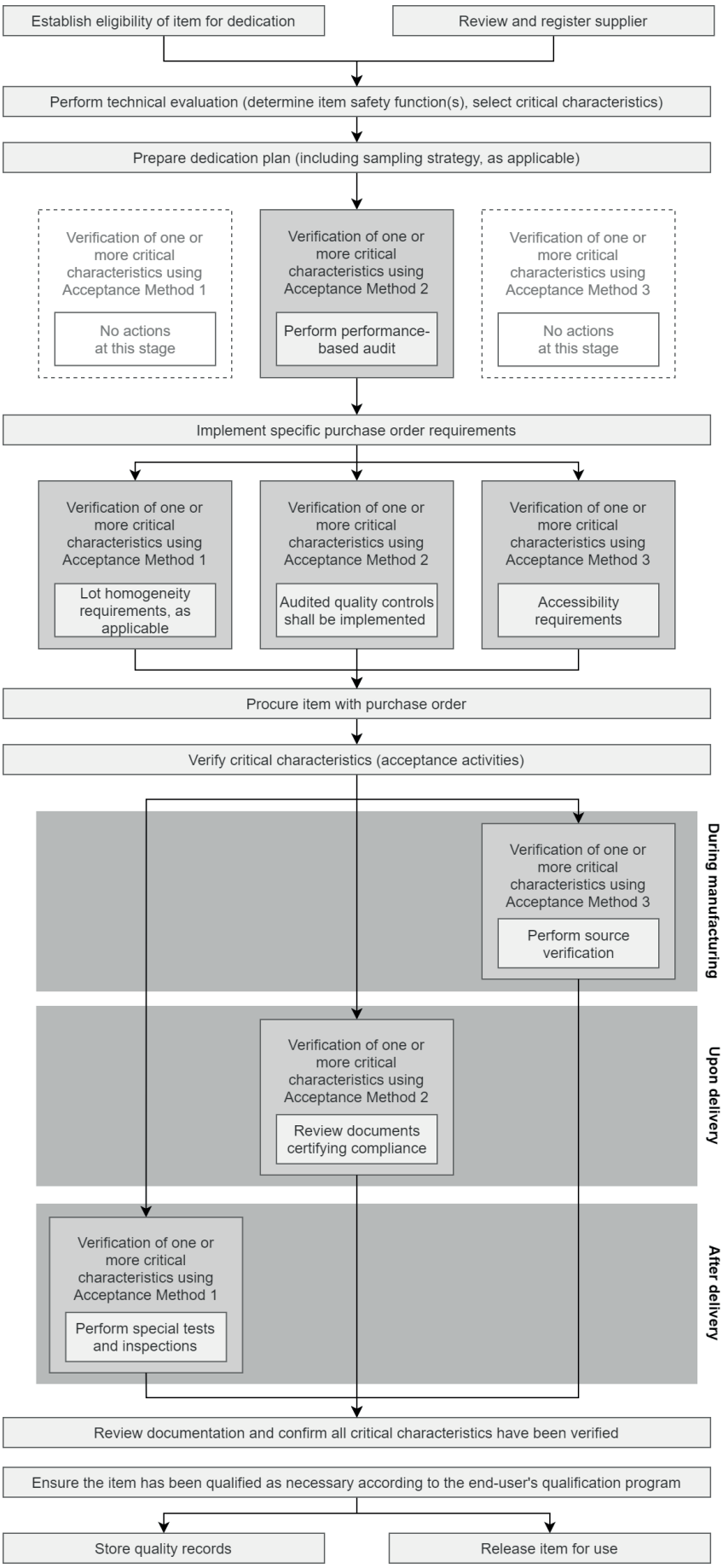
Item	Description
Actuators	Air Diaphragm Actuators
Actuators	Air Piston Actuators
Adhesives	Adhesives
Batteries	Lead Acid Batteries/Battery Cells
Battery Chargers	Battery Chargers
Bearing	Camshaft Thrust Bearing
Bearings	Bearings - Rolling
Belts	Drive Belts
Bolts	Expansion Anchor Bolts
Bolts	Bolts (e.g. DN8 and Above)
Breakers	Molded Case Circuit Breaker
Cable	Power and Control Wire and Cable
Cable Assembly	Umbilical Cable Assembly, Strip Chart Recorder
Cable Tray	Metallic Cable Tray System
Capacitors	Fixed Capacitors
Cement	Cement
Circuit Board	Printed Circuit Board Assembly
Circuits	Integrated Circuits
Connectors	Pin and Socket Connectors
Contactors	AC/DC Contactors
Controller	Pneumatic Controller
Couplings	Rigid Couplings
Couplings	Lubricated Flexible Couplings
Couplings	Non-Lubricated Flexible Couplings
Couplings	Elastomeric-Element Flexible Couplings
Cylinder	Cast Iron Cylinder Head
Detectors	Resistance Temperature Detectors
Diodes	Silicon Voltage Regulator Diodes
Expansion Joints	Expansion Joints (Metallic & Non-Metallic Without Tie-Rods)
Filters	Filters
Fittings	Compression Fittings
Fittings	Conduit Fittings
Fuse Blocks	Fuse Blocks
Fuses	Various
Gaskets	Gaskets, Non-metallic (and Spiral Wound)
Governors	Woodward Governors
Greases	Greases
Grout	Grout (Cement-Based)
Heat Exchangers	Heat Exchangers
Heaters	Bimetallic Overload Heaters

[6] The Joint Utility Task Group (JUTG) was formed in late 1989 under the sponsorship of the Electric Power Research Institute (EPRI).

Item	Description
Hoses	Hoses (Metallic And Non-Metallic) Single Line
Impellers	Pump Impellers
Indicators	Pressure/Differential Pressure Indicators (Local Gages)
Liner	Un-plated Cylinder Liner
Lugs	Lugs, Compression, Insulated
Lugs	Lugs, Compression, Un-Insulated
Meters	Electrical Analog Indicating Meters
Motor Assembly	Drive Motor Assembly, Strip Chart Recorder
Motors	Three Phase Squirrel-Cage Induction Motors, A) Continuous Duty B) Intermittent Duty (Excluding Motor Operated Valves)
Motors	Single Phase Fractional And Integral Horsepower Motors - Squirrel Cage Induction - A) Continuous Duty B) Intermittent Duty (Excluding Motor Operated Valves)
Motors	Direct Current Fractional And Integral Horsepower Motors - A) Continuous Duty, B) Intermittent Duty (Excluding Motor Operated Valves)
Motors	Diesel Engine Air Start Motors
Nozzle	Nozzle and Holder
Nuts	Machine Screw Nuts
Nuts	Nuts (DN8 and Above)
Oils	Industrial Oils (Petroleum Based)
Oils	Motor/Engine Oils
Oils	Diesel Fuel Oil
O-Rings	Circular Cross Section O-Rings
Packing	Graphite Packing
Pins	Cotter (Split) Pins
Piston	Piston Assembly
Power Supplies	DC Power Supplies
Power Supplies	Uninterruptible Power Supplies
Pulley Assembly	Bracket 3-Pulley Assembly, Strip Chart Recorder
Pump	Water Pump Complete w/Gear
Pumps	Rotary Pumps
Pumps	Reciprocating Pumps
Radiation Monitor	Radiation Monitor Detector Assemblies
Recorders	Recorders, Strip Chart
Rectifier	Silicon Controlled Rectifier
Refrigerants	Refrigerants
Regulators	Pressure Regulators, Single Stage
Relays	Electromagnetic Relays - Control
Relays	Electromagnetic Relays - Protective
Relays	Electrically Activated Time-Delay Relays
Relays	Solid State Relays - Protective
Relays	Bimetallic Thermal Overload Relays
Resistors	Resistors (Fixed and Mounted by its Leads)
Rods	Connecting Rods
Rotor	Turbocharger Rotor Assembly
Screws	Machine Screws
Screws	Sheet Metal Screws
Sealants	Silicon Rubber Adhesive Sealants
Seals	Mechanical Seals
Servo amplifier	Servo amplifier, Strip Chart Recorder
Sheaves	Sheaves
Shell	Main Bearing Shell

Item	Description
Solder	Solder, Resin or Rosin Core or Solid, Tin-Lead Alloy
Splices	Splices, Compression, Insulated
Splices	Splices, Compression, Un-Insulated
Springs	Coiled Springs
Steam Traps	Metallic Steam Traps
Steel	Structural Steel
Strainers	Metallic Strainers
Struts	Strut Metal Framing System
Switches	Pressure/Differential Pressure Switch
Switches	Limit Switches
Switches	Test Switches
Switches	Control and Transfer Switches
Switches	Hand Switches
Switches	Level Switches (Float Type)
Switches	Temperature Switches
Tape	Electrical Tape
Terminal Blocks	Terminal Blocks - 600 V Power and Control
Thermocouples	Thermocouples
Thread Insert	Screw Thread Insert (Heli-Coil)
Transducers	Electro-Pneumatic Transducers Current Input (I/P)
Transformers	Transformers - Control Power, Single Phase, 500 VA Or Less, 600 Volt Or Less, Dry Type
Transformers	Current Transformers
Transistors	Switching Transistors
Transmitters	Pressure And Differential Pressure Transmitters
Tubing	Tubing (Metal)
Turbocharger	Turbocharger
Valve Diaphragms	Valve Diaphragms and Seats
Valve Discs	Metallic Valve Discs (Including Wedge, Ball And Plug
Valve Stems	Safety-Related Non-Pressure Retaining Valve Stems And Hinge Shaft
Valves	DN50 And Smaller Metallic Gate And Globe Manual Valves For Pressure Boundary Applications Only
Valves	Non-Externally Assisted, Bolted Bonnet, Metallic Swing Check Valves
Valves	Manual, Metallic Ball Valves
Valves	Non-Modulating Solenoid Valves
Valves	Manual, Metallic Plug Valves
Valves	Manual, Metallic Diaphragm Valves
Valves	Manual, Metallic Gate Valves
Valves	Manual, Metallic Globe Valves
Valves	Manual, Metallic Butterfly Valves
Valves	Metallic Folding Disc Check Valves
Valves	Non-Externally Assisted, Bolted Bonnet, Metallic Piston Lift Check Valves
Valves	Metallic Relief Valves (Excluding Pilot And Power-Operated Relief Valves)
Varistors	Varistors
Washer	Flat Washer
Washer	Lock Washer (Tooth Type)
Washer	Lock Washer (Helical Spring Type)

Annex 2 Dedication Flowchart



Annex 3 Typical Item Safety Functions

List adapted from [1].

Item Safety Function	Description
Maintain pressure integrity	Mechanical function. Pressure integrity is required to prevent the escape or entry of an unacceptable leakage rate or quantity of fluid past the pressure boundary. It applies to both active and passive equipment, inclusive of the item that contains a fluid.
Open	Mechanical function. Active components are normally closed and required to perform a mechanical movement to achieve and maintain an open position, thereby allowing the minimum design flow.
Remain open	Mechanical function. Passive components are normally open and required to maintain an open position, allowing the minimum design flow.
Close and isolate	Mechanical function. Active components are normally open and required to perform a mechanical movement to achieve and maintain a closed position, thereby stopping process flow. (Absolute sealing is not considered part of this function.)
Remain closed and isolate	Mechanical function. Passive components are normally closed and required to maintain a closed position, thereby stopping process flow. (Absolute sealing is not considered part of this function.)
Provide directional control	Mechanical function. Active and passive components are required to govern the direction of process fluid or gas movement, which is determined by the operating parameters of the system.
Activate or modulate	Mechanical function. Active components are required to perform continuing mechanical movement (for example, a component that modulates the position in order to regulate flow).
Maintain structural integrity	Mechanical function. Active and passive components are required to maintain their structural form. The component does not collapse, disassemble, or disintegrate. Failure of a part confined internally to the component does not constitute a violation of structural integrity.
Provide pressure and flow	Mechanical function. Active components are required to provide minimum design pressure/flow of process fluid or gas through component movement.
Provide containment isolation	Mechanical function. Active or passive components are required to be closed for containment isolation (not to be used as a replacement of component function to close and isolate).
Provide combustible gas control	Mechanical function. Combustible gas control is required in order to prevent the buildup of volatile fluids within containment.
Blend	Mechanical function. This applies to blenders or mixers that combine ingredients or chemicals by mixing.
Provide support and secure	Mechanical function. This is required in order to restrict movement or provide damping to ensure dynamic stability.
Maintain circuit integrity	Electrical function. Maintain intact electrical state such that the design current flow is accomplished through the component and excess current flow caused by shorting does not occur. Components that must distribute or allow rated current flow include buses, distribution panels, fuses, and circuit breakers. This function applies to all electrical components to prevent excess current flow and shorts.
Maintain electrical isolate	Electrical function. Applies to components that prevent excess current flow, usually caused by short circuit, from propagating through the circuit and impeding the operation of other components. Components with this function are typically used to isolate non-Class 1E circuit failures from Class 1E circuits.

Item Safety Function	Description
Change state	Electrical function. Changes state to perform a control function. State changes include normally energized to de-energized and normally de-energized to energized state. Modulate between these states. Examples of devices that change state in order to function are relays, circuit breakers, and solenoid-operated valves.
Transform or supply energy	Electrical function. This applies to components required to provide voltage/current to appropriate power levels for use by other components.
Provide signal	Electrical function. This applies to components that generate or transmit a process signal used for control or indication purposes. It applies to transmitters, elements, and signal conditioners.
Provide control	Electrical function. This applies to components whose primary function is to control other components. This function is typically accomplished through a change in contact position(s) and applies to switches
Provide filtering	Mechanical or electrical function. Passive components are required to remove particles or debris from process fluid or gas.
Provide motive force	Mechanical or electrical function. Active components are required to provide motive force, start and commence a performance or operation, and continue such operation as required.
Provide heat control	Mechanical or electrical function. This relates to the process of heating or cooling a fluid, gas, or other component. Mechanically, this function is typically accomplished by a heat exchanger or cooling coil. Electrically, this function is accomplished by an electrical heater.
Provide indication	Mechanical or electrical function. This is required to provide indication, either local or remote, to operations or maintenance personnel.
Provide torque transmission	Mechanical function. This changes the speed and torque (and sometimes direction) of motor output.

Annex 4 Typical Physical Characteristics

List adapted from [1], [12].

General	Mechanical	Electrical
Balance	Behavior (cleavage, peel)	Amperage
Chemical content	Breaking strength	Capacitance
Cloud point	Composite material hardness	Dielectric strength
Colors	Cover Adhesion	Impedance
Concentration	Durometer hardness	Inductance
Continuity	Elasticity	Leachable halogen content
Density/specific gravity	Fatigue resistance	Leakage current
Dimensions	Shear strength	Load rating
Drop point	Spring constant	Plating
Ductility	Strand Pattern	Polarity
Durometer hardness	Surface hardness	Resistance
Finish	Tensile strength	Working voltage
Flammability		
Flash point		
General configuration		
Material of construction		
Melting point		
Mounting connections		
Nil-ductility temperature		
Oil/water separation		
Permeability		
Physical configuration		
Pour point		
Purity		
Resilience		
Solubility		
Surface finish		
Thermal conductivity		
Torque		
Viscosity		
Weight/mass		

Annex 5 Typical Performance Characteristics

List adapted from [1], [12].

Accuracy
Adequate lubrication path
Air consumption
Bias current
Calibration
Chatter
Contact Interrupt Capability
Contact/connection resistance
Current Rating
Current rating
Cycle time
Dielectric strength
Direction of shaft rotation
Dissipated power
Flow rate
Freedom of rotation
Input/output voltage
Interrupt rating
Isolation resistance
Leakage
Leakage current
Noise levels (output levels, input susceptibility)
Ohmic resistance
Operability (fail open/close, stroke)
Pickup & drop-out voltage
Post-installation vibration, noise and heat
Pressure integrity/ Hydrostatic testing
Pressure rating
Relief range
Repeatability
Ride out
Rotor Balance
Set point stability
Speed (rpm)
Tension (Pullout)
Time / current curve
Torque
Voltage drop
Volume Resistivity

Annex 6 Typical Dependability Characteristics

Dependability characteristics are typically selected only for digital equipment and software.

Built-in quality (systematic integrity) Quality of design Quality of manufacture Failure management Compatibility with human operators Compatibility with human maintainers
Reliability
Maintainability

Annex 7 Examples of Critical Characteristics

The following is a table of design characteristics that can be selected as critical characteristics of typical serially produced bulk items.

Item	Critical Characteristics
Bearing	Configuration, dimensions, load rating, material, model number
Bolt	Configuration, dimensions, pitch, material, tensile strength, hardness, plating
Cable	Conductor resistance, insulation resistance, insulation breakdown levels, insulation material
Cotter pin	Configuration (point type), dimensions, material, finish, hardness
Crimped terminal connector	Configuration, material, dimensions (wire size, ring tongue size), voltage rating, continuity, tensile pullout strength, color
Drive belt	Dimensions, cross-sectional shape, fatigue resistance, load rating, material, tensile strength
Fitting	Material, dimensions
Flange	Material, dimensions, sealing surface flatness and finish, bolting arrangement
Framing device	Configuration, shape, dimensions, material, tensile strength, coating
Fuel oil	Density, flash point, cloud point, pour point, kinematic viscosity, chemical composition, BTU rating, viscosity
Fuse	Configuration, current rating, interrupt rating, time/current response, dimensions
Lubricating grease/oil	Color, specific gravity, viscosity, drop point, cone penetration, pour point, chemical composition, cloud point
Structural material (plate, bar, rod, etc.)	Dimensions, shape, material, tensile strength, hardness, ductility, coating
O-ring	Dimensions, material, durometer hardness, elongation, leachable halogens
Pipe	Material, dimensions
Relay	Configuration, pick-up/drop out voltage, voltage rating, current rating, chatter, response time, coil and other non-metallic materials
Resistor	Configuration, resistance, power rating
Spiral wound gasket	Configuration, dimensions, style number, materials (filler and windings), pressure rating, leachable chlorides, spiral density
Temperature switch	Configuration, dimensions, material, voltage rating, response time, accuracy, nameplate data, temperature range, wire rating, enclosure type dielectric strength (insulation), dead band width
Terminal block	Configuration, voltage rating, current rating, materials, dielectric strength

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