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

VOLUME 2: USER'S GUIDE

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

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1 Introduction

This second volume of the Guideline is meant to assist users of the dedication methodology outlined in Volume 1, especially those individuals responsible for implementing a dedication programme within their organization. To support organizations implementing dedication programmes and performing dedication, this Volume presents good practices, lessons learned, templates and practical examples.

In addition to a close reading of this Volume, users of Volume 1 and the dedication methodology are encouraged to consult a number of documents on the subject which have been published in the past, some of which are listed in below. These references provide useful additional context and details related to specific equipment types, elements of the dedication workflow as well as the topic as a whole.

The reader of these documents should be aware that some of their contents may not accurately reflect good or allowable practices in their domestic regulatory situation. Fortunately, much of the existing guidance is applicable to the dedication approach for Europe described in this Guideline. The wealth of existing guidance material about dedication should be leveraged by organizations building the necessary knowledge base to utilize the dedication methodology.

Licensees are encouraged to liaise with their national regulatory bodies when initially implementing this Guideline to reach a common understanding on its scope of application.

Information on the dedication methodology in general:

- 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 [1]
- DOE-HDBK-1230-2019 Department of Energy Commercial Grade Dedication Application Handbook [2]
- EPRI TR-102260 Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items [3]
- EPRI NP-5652 Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications [4]
- EPRI TR-017218-R1 Guideline for Sampling in the Commercial-Grade Item Acceptance Process [5]
- EPRI NP-6630 Guidelines for Performance-Based Supplier Audits [6]
- ASME NQA-1 Quality Assurance Requirements for Nuclear Facility Applications [7]

Dedication of specific types of equipment:

- EPRI 1009659 Generic Qualification and Dedication of Digital Components [8]
- EPRI TR-107339 Evaluating Commercial Digital Equipment for High Integrity Applications [9]
- EPRI TR-106439 Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications [10]
- EPRI TR-112579 Critical Characteristics for Acceptance of Seismically Sensitive Items (CCASSI)
- 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 [11]
- 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 [12]

Dedication in national nuclear regulation:

- (Spain) Guía de Seguridad 10.8 (Rev. 1) [13]
- (United States) 10CFR21 [14]
- (United States) Regulatory Guide 1.164 Dedication of Commercial-Grade Items for Use in Nuclear Power Plants [15]
- (United States) Generic Letter 89-02, Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products [16]
- (United States) Inspection Procedure 43004—Inspection of Commercial-Grade Dedication Programs [17]
- (South Korea) KINS/RG-N17.12 Commercial Grade Item Dedication for Commercial Grade Items for Safety-related Use [18]

European and international standards related to dedication:

- (Spain – AENOR) UNE 73104:1994 [19]
- (Spain – AENOR) UNE 73403:1995 [20]
- 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) [21]
- ISO/TR 4450:2020 Quality management systems — Guidance for the application of ISO 19443:2018 [22]

IAEA publications related to or mentioning the use and justification of commercial-grade items in nuclear installations:

- IAEA GS-G-3.5 The Management System for Nuclear Installations [23]
- IAEA NP-T-3.21 Procurement Engineering and Supply Chain Guidelines in Support of Operation and Maintenance of Nuclear Facilities [24]
- IAEA NR-T-3.31 Challenges and Approaches for Selecting, Assessing and Qualifying Commercial Industrial Digital Instrumentation and Control Equipment for Use in Nuclear Power Plant Applications [25]

2 Implementing the Guideline

2.1 In Nuclear Power Plants

Implementing a programme for dedication according to this Guideline requires management commitment as well as certain organizational and technical capabilities. Dedication is a cross-functional activity which draws upon many different competencies. To be successful, it relies on adherence to a continual improvement philosophy, trained staff, and good communication between organizational functions. Once established, a dedication programme creates an additional procurement avenue which can be leveraged to find the most suitable suppliers providing high-quality items at the best price and provides for the potential to procure and accept off-the-shelf items such as those coming from surplus inventories of nuclear facilities.

An organization carrying out dedication relies on collaboration between roles to address routine tasks. Staff chosen to lead the implementation of dedication should be aware of this fact and have the necessary knowledge, skills, attitudes and authority to effectively work across the intra-organizational boundaries. Prior to or while developing a dedication programme within an organization it can be helpful to analyse communication between the relevant roles. Mapping of interfaces between roles in terms of input/output as well as the necessary competencies needed for collaboration when performing dedication is also a valuable exercise. These activities assist in identifying gaps in the competencies of individuals or groups which can be addressed by training or reorganization. [26]

Functions typically involved in dedication within a licensee include:

- Procurement
- Engineering support
- Design authority
- Materials management
- Supply chain management
- Nuclear assurance (QA/QC/Safety)
- In-house laboratory and/or testing staff

The typical steps undertaken to implement a dedication programme at a nuclear facility cover:

- Development of policy commitment
  - The policy should outline the dedication methodology and high-level strategy for its implementation at a nuclear facility. The policy should have the commitment of senior management including the chief of engineering and site VP or similar level management at the fleet-level.
- Appointment of implementation project leaders
  - Project leaders should be provided with sufficient authority to act across functional boundaries within the licensee organization.
- Liaison with regulatory body
  - The licensee should involve the regulator in plans to implement a dedication programme. A mutual understanding should be sought regarding the process intended to be established within the licensee management system and what existing requirements dedication is intended to substitute.
- Create new processes, procedures, forms, or other instructions
- Establish a training programme
  - A training programme should be developed to indoctrinate involved staff. Training is best tailored to roles and departments. The training covers the concept of CGD and emphasizes safety. Portions of this guideline can be used to create or supplement training materials.
- Initiate the programme with the dedication of simple items for well-known applications

- ⓘ Examples of relatively simple, well-known applications could be fuses, non-pressure boundary manual valves, gaskets, O-rings, bolts, etc. A technical evaluation and dedication plan should be created for each item prior to actual purchasing as specific requirements may need to be included into purchase documents as detailed in the dedication plan. Once the staff gains some experience in implementing the dedication process, more complex items can be dedicated as required.
- Aim for continual improvement and capture lessons learned

Engineering staff play a central role in the development of dedication plans by performing technical evaluations. Selecting item critical characteristics requires an understanding of item safety functions and its safety significance. Engineering knowledge of item design, system design, interfacing SSCs, failure modes, configuration and equipment qualification may be brought to bear when developing dedication plans.

2.1.1 Gaining initial experience

Performing technical evaluations and developing dedication plans relies on a sound understanding of facility design and the item to be dedicated. When initially establishing a dedication programme within a licensee organization, it is recommended to start with the technical evaluation and acceptance of simple, well-known items and applications. A great deal of knowhow related to safety functions, failure modes, critical characteristics and the performance of acceptance activities will be built up over time. Furthermore, internal resources and manpower should be closely monitored to ensure that dedication activities are appropriately staffed and those responsible for its execution are well trained.

2.1.2 Procurement engineering

Some licensees have established a function which is meant to address the cross-functional nature of dedication, among other procurement activities. This function is called procurement engineering. Procurement engineering personnel are trained and qualified in such a way that they are knowledgeable of codes, standards, equipment qualification, fabrication processes and other requirements related to items important to nuclear safety and the procurement of those items. This includes familiarity with equipment qualification, dedication, equivalency evaluation, manufacturing processes, materials and plant design. Where the procurement engineering function is located within a licensee organization, whether as a part of supply chain or engineering, varies from licensee to licensee.

2.2 In Fuel Cycle Facilities

The implementation of a dedication programme according to this Guideline at nuclear fuel cycle facilities[1] is in many ways similar to the experience obtained at nuclear power plant licensee organizations. The implementation of a dedication programme during construction of a fuel cycle facility should follow the same steps as at any licensee organization, as described in the previous section.

Like nuclear power plants, fuel cycle facilities are comprised of structures, systems and components, some of which are important to safety. Those items have safety functions and can be dedicated to ensure suitable quality in the same manner as items for nuclear power plants. Thanks to the nature of SSC categorization and design in nuclear fuel cycle facilities, dedication is highly suitable as a quality assurance methodology, because the engineering design basis tends to rely relatively little, when compared to nuclear power plants, on nuclear-specific codes or standards which might preclude the use of dedication.

[1] Nuclear installations other than nuclear power plants, research reactors and critical assemblies. [48]

While dedication is especially well suited as a quality assurance methodology for spare and replacement parts in nuclear power plants, in fuel cycle facilities it has been leveraged significantly during the construction phase. Fuel cycle facilities have demonstrated success in implementing dedication during construction. The dedication methodology presented in this Guideline does not require any changes prior to use in the procurement process at fuel cycle facilities.

2.3 In the Supply Chain

The dedication methodology described in this Guideline is suitable for implementation by non-licensee organizations given that those organizations possess documented management systems in accordance with nuclear regulatory requirements and/or licensee expectations. Dedication can be performed by the manufacturers of items as well as by third parties who are neither the manufacturer nor the licensee intending to use the items. Licensees may need to justify the use of dedication within the supply chain in principle to the national regulatory body.

Special care should be taken when implementing a dedication programme within the supply chain. The organization doing so should ensure there is a sufficient commitment from leadership and that the necessary human resources are both made available and given the necessary tools and training to be successful.

Suppliers planning to implement dedication programmes are encouraged to follow an approach similar to that which a licensee organization would, i.e. secure senior leadership commitment, assign implementation project leaders, establish a training programme and initialize the programme using a step-wise approach.

Scenarios in which dedication programmes might be implemented in the supply chain:

- an approved nuclear supplier uses dedication to accept materials, parts, sub-assemblies or other constituent parts of the final product which support its safety function
    - ⓘ This is typically viewed as an alternative method to the sub-supplier controls that would typically be implemented by the supplier. If the sub-supplier's products do not support the safety function(s) of the final product, dedication is not necessary.
- a third party performs dedication as a service on behalf of the licensee or,
- a third party performs dedication as a service on behalf of a supplier.

When performing dedication in each of these scenarios, the dedicating entity needs to collect information from the end user for the purpose of performing the technical evaluation and preparing a dedication plan. The dedicating entity would ideally be made aware of relevant information, for example:

- nuclear facility application(s) in which the item is intended to be used;
- safety function(s) of the item;
- engineering design basis;
- item design requirements;
- technical information about the item (being aware of intellectual property);
- equipment qualification requirements;
- equipment qualification report (if present); and,
- host equipment (if present).

Experience has shown that challenges related to dedication in the supply chain often relate to the lack of knowledge transfer between the end user and the supplier.

The following are typical challenges which have been encountered during the dedication of items by third parties or by a manufacturer:

- incomplete knowledge transfer between the dedicating entity and the licensee end-user;
- dedicating entity lacks complete engineering design basis information including, for example, safety functions, equipment qualification requirements and host equipment details;
- inadequate technical evaluations;
- selected critical characteristics not sufficient to verify key safety functions of the item;
- acceptance criteria developed to verify critical characteristics not sufficient to verify safety function;
- unjustified sampling plans;
- tests and inspections not effectively verifying critical characteristics; or,
- performance of compliance-based supplier audits instead of performance-based assessment when verifying critical characteristics by acceptance method 2.

Licensees should be aware of these issues and seek to mitigate their likelihood or potential impact on quality and safety. Frequent and transparent communication between licensee and dedicating entity is an important measure to increase the likelihood of success.

2.3.1 Dedication as a service

Dedication can be performed as a service on behalf of a licensee or on behalf of an item or service supplier. When dedication is performed as a service for a licensee, the dedicating entity should be appropriately qualified by the licensee to perform activities which can impact the quality of items important to safety.

A variety of commercial and logistical constellations are possible when dedication is performed as a service. The licensee might choose to have the procured items delivered to the site of the nuclear facility for a receipt inspection prior to shipment to a third-party dedicating entity. Alternatively, the licensee may arrange for the shipment of items directly from the manufacturer to the third-party dedicating entity and only receive the items once they have successfully undergone dedication.

2.3.2 Dedication of materials, parts or sub-assemblies of items important to safety

Manufacturers may choose to implement a dedication programme to assure quality in items from sub-suppliers as an alternative method to the sub-supplier controls that would typically be implemented, and as specified within their own quality assurance programme. For example, in lieu of cascading nuclear requirements further into the supply chain, the manufacturer could use dedication to achieve the same degree of quality in items received from its suppliers.

In reality, the sub-supplier controls put in place using dedication are often similar to those implemented through conventional nuclear quality assurance programmes, with the end result being the same, in that the controls provide sufficient confidence in the overall quality of the supplied item. The acceptance methods used in the dedication process are derived from standard supplier quality control methodologies.

In some situations, sub-suppliers are required to comply with nuclear-specific requirements dictated by the end-user licensee or a regulatory body. When performing dedication in lieu of these requirements, the manufacturer should ensure that the use of dedication in this manner is permissible and inform the end-user licensee of this way of working.

This Guideline does not dictate how a licensee should qualify a supplier of items important to safety who has implemented a dedication programme for materials, parts, sub-assemblies or services furnished by sub-suppliers. Typically, the licensee would include the supplier's dedication programme within the scope of its usual auditing programme for suppliers of items important to safety. The licensee could request the supplier to share quality records generated during specific dedication activities.

2.3.3 Dedication and ISO 19443:2018

A number of industries have established sector-specific quality management requirements, some of which are based on the ISO 9001 standard. The international standard ISO 19443:2018 describes 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. [21] An associated standard, ISO/TS 23406:2020, complements existing requirements found in ISO/IEC 17021-1 for bodies providing audit and certification of quality management systems against ISO 19443. [27]

ISO 19443:2018 includes the key element of the dedication methodology as a part of the control of externally provided processes, products and services.Organizations working according to the standard are expected to consider critical characteristics of commercial-grade items or activities[2] when determining verification activities.

When customers, such as licensees, recognize ISO 19443:2018 as an acceptable management system basis for the supply of items or services important to safety, they can expect that the supplier organization may be utilizing commercial-grade items or services in the final product. In doing so, the organization performs acceptance activities to verify critical characteristics of those items or services in accordance with the standard.

Guidance for the application of ISO 19443:2018 is provided in ISO/TR 4450:2020. [22] It is recommended that this Guideline be used as a supplement to ISO/TR 4450:2020 in support of the implementation of ISO 19443:2018 by organizations in the supply chain. This Guideline provides detailed guidance on topics relevant to organizations working according to ISO 19443:2018, such as the selection of critical characteristics (see Volume 1 Section 9.3), their verification (see Volume 1 Section 10), the dedication of services (see Volume 1 Section 12.3) among many other nuances found here in Volume 2.

[2] Defined in the standard as an item or activity that affects nuclear safety and that was not designed, manufactured or performed in accordance with specific nuclear requirements.

3 Graded and Risk-Informed Approaches to Dedication

This Guideline recommends the application of a graded approach when developing a dedication programme and when performing dedication. A graded approach is fundamental to a wide range of activities in the nuclear industry, including the application of management systems as well as quality assurance and quality control activities in the supply chain. The application of a graded approach to dedication should be in line with the expectations of the IAEA and WENRA. [28] [29] [30]

Grading of the dedication process can be applied from the start of programme development by defining under which conditions dedication may be performed, for example. Dedicating entities can implement a graded approach when developing a dedication plan for a specific item, including when choosing a set of critical characteristics, when deciding on verification methods, or when deciding on sampling strategies. This section focuses primarily on ways in which a graded approach can be applied to dedication plans and to the selection and verification of critical characteristics.

As stated previously in this Guideline, the objective of the dedication process is to obtain confidence in the quality of an item as it relates to the item's capability to perform its intended safety function(s). The selection of a set of critical characteristics and their associated acceptance methods involves making engineering determinations that can be informed by considering both the nuclear safety consequences that would be created by an item's failure, as well as the additional uncertainty created around an item's performance due to its procurement from a supplier that lacks certain aspects of typical nuclear quality assurance programmes.

When developing a dedication plan for a specific item, consideration should be given to selecting a more comprehensive set of critical characteristics for items of higher risk significance or where supplier confidence is lacking. For such items, the methods chosen to verify the critical characteristics and to establish any associated sampling plans should also be more rigorous. Conversely, for items with limited risk significance or where there is higher confidence in the supplier, a smaller set of critical characteristics could be chosen for verification along with reduced sample sizes. Also, alternative approaches to verification methods could be utilized for lower risk items (for example, allowing the use of supplier data for verification for selected critical characteristics under Method 1).

3.1 Factors to be considered

The following are some specific qualitative factors related to nuclear safety risk that could be considered when selecting a set of critical characteristics and when choosing acceptance methods:

- Safety Class
  - For lower safety class items (or items classified as low risk via probabilistic risk analysis), a smaller set of critical characteristics could be chosen for verification via Methods 1, 2, or 3, and more reliance could be placed on supplier furnished data. For higher class safety items (or items classified as higher risk via probabilistic risk analysis), a more comprehensive set of critical characteristics could be chosen for independent verification including all significant characteristics that could impact the item's safety function.
  - For the purposes of this Guideline, the term safety class applies to the classification of items important to safety in accordance with IAEA SSG-30 and WENRA Safety Reference Levels Issue G, which classifies items with respect to their importance to nuclear safety and which applies to all types of equipment.

When used in this guideline, safety class is different than classes defined in nuclear pressure vessel codes which are used primarily to classify mechanical components according to their pressure retaining functions. This Guideline allows for the dedication of all items important to safety, as practical, with more stringent requirements imposed on higher safety class items, while also recognizing that most nuclear pressure vessel code class 1 components cannot be dedicated due to specific mandatory quality assurance or quality control requirements imbedded in the applicable codes.

- Design complexity
  - Items for which the design is relatively simple in nature often have less failure mechanisms that can prevent the item from performing its safety functions. Conversely, complex items can have multiple failure mechanisms, and as such present a greater degree of risk.

- Ability to monitor post installation
  - Less risk exists with items whose capabilities (to perform its safety function(s)) are continually or periodically monitored and whose failure is readily detectable during routine operation. In some instances, it might be acceptable to take credit for certain post-installation testing or monitoring as a way of verifying a specific critical characteristic. While random failures of dedicated items can occur in a similar way as those items procured from qualified suppliers, such failures can be dealt with through the facility's corrective action programme. Components that have safety functions that are never or infrequently verified once installed would generally require separate actions to verify critical characteristics. This would include components that may have to perform a safety function in a harsh accident environment (e.g. environmentally qualified components) and where defects in such components might result in common cause failures.

The following are some specific qualitative factors related to quality uncertainty risk that could be considered when selecting a set of critical characteristics and when choosing acceptance methods:

- Supplier History/Confidence
  - Identical items to those purchased previously directly from the original equipment manufacturer (OEM), or an OEM-approved distributor with traceability back to the OEM, present less risk than similar but non-identical items. Identical and/or similar items purchased from non-OEM approved distributors may require additional verification to detect counterfeit, refurbished, or sub-standard components and present a higher level of risk.

- Items with a large industrial database
  - For items where a large industrial installation database exists and where the item's safety functions and design requirements mimic those in industrial installations, defects in supplied items will likely be more readily detected. For such items operational experience, along with OEM Certificates of Conformance, might be utilized as a part of a graded approach to provide reasonable assurance regarding the verification of a specific critical characteristic.

When implementing a graded/risk informed approach to dedication, the above factors should be considered in aggregate in order to assess the relative risk associated with the procurement of any one item. Additional or alternate factors can be developed by dedicating entities or found within other sources. For example, design maturity, significance to operation and fabrication complexity are some of the factors to be considered in the grading of quality assurance and quality control activities in the supply chain, of which dedication is a part, according to IAEA TECDOC 1740. [30] WENRA Safety Reference Levels for Existing Reactors 2020 expects that the application of management system requirements are graded on the basis of consideration for safety significance and complexity, hazards and magnitude of potential impact, and possible consequences if an activity is carried out incorrectly. [29]

3.2 Selection and verification of critical characteristics

For low-risk items (both in terms of safety significance and quality risk) and as part of a graded approach, the verification of some critical characteristics could be performed indirectly by reviewing applicable operating experience obtained from either on-site, nuclear, or commercial industries. The operating experience being used should directly relate to the item's performance with respect to the applicable safety functions and critical characteristics. Such operating experience could also be in the form of test data or certifications obtained from the supplier or from recognized third party commercial testing entities.

The indirect verification of critical characteristics should not be used in isolation or to verify all selected critical characteristics, but rather should be used only for the verification of a subset of the selected critical characteristics of lower risk items. In such cases where operating experience exists and is being credited for the verification of selected critical characteristics, normal post-maintenance acceptance testing should still be performed to verify the functionality of the item once the item is installed. Indirect verification of critical characteristics could also be used in combination with Method 2, once a performance-based assessment is performed that would evaluate the supplier's processes for acquiring and controlling the applicable test data, which would then be supplied to the dedicating entity for verification purposes.

3.3 Graded approach matrix illustration

The graded approach can be applied to many parts of the dedication process. Three main areas within the dedication process are especially well-suited for grading of dedicating entity efforts, they are: (1) the selection of critical characteristics (2) the methods chosen to verify the critical characteristics and (3) the establishment of sampling plans.

To accomplish this, the various factors as described in Section 3.1 need to be considered and aggregated. One way of accomplishing this aggregation would be to assign an importance rating or value to each of the qualitative factors that would allow for the various factors to be considered.

Safety class	**Design Complexity**	**Post-installation monitoring**	**Supplier history/ confidence**	**Commercial industry operating experience and installed base**
Class 3 Value=1	Simple Design Value=1	All item's safety functions monitored fulltime Value=1	High Supplier Confidence Value=1	Significant Operating Experience Value=1
Class 2 Value=3	Medium Design Complexity Value=2	Some safety functions monitored Value=3	Medium Supplier Confidence Value=2	Medium Operating Experience Value=2
Class 1 Value=5	Complex Design Value=3	Safety functions not monitored/not detectable Value=5	Low Supplier Confidence Value=3	Minimal Operating Experience Value=3

In the example table above, the factors associated with safety class and the ability to monitor safety functions once installed are given a higher weight than other factors. The actual weighting factors selected for use could vary based upon consensus between licensees and regulatory bodies. Using the weighting factors above, the maximum score for any one item would be 19 and the lowest possible score would be 5.

A score at the lower end of the range of between 5-9 would correspond to an item where less rigorous controls are implemented in the dedication process (in selecting critical characteristics, in verifying critical characteristics, and in implementing any sampling strategies). A score in the middle of the range of between 10-14 would correspond to an item where a medium level of controls are implemented. A score at the upper end of the range of 15-19 would correspond to an item where the maximum level of controls are implemented throughout the dedication process. The actual range of numbers considered to be in the low, medium, and high-risk categories could easily be altered based upon consensus.

The following examples are provided to illustrate the above concept.

3.3.1 Graded approach example 1

The licensee is planning to dedicate a lot of 30 fuses that protect circuits for control room instrumentation. The fuses are of the same physical size but have three different current ratings (10 of each rating). They are direct replacements for existing equipment and are classified as Safety Class 3. The fuses primary safety function is to protect the connected instrumentation from short circuits and to allow the supply of continuous current under normal conditions. The ability of the fuse to pass current during normal conditions is monitored during normal operation. However, its ability to open under specified short currents is not monitored. The design of the fuse is simple and has not changed much over many years. The item is being purchased from a distributor that the licensee has used before for multiple procurements of similar items. The distributor's quality management system has not been assessed. These exact items are used in multiple commercial industries and have a very wide installed base.

Based upon the above assumptions the total risk score associated with this item would be:

Grading factor	Value
Safety class	1
Design complexity	1
Safety function monitoring	3
Supplier confidence	2
Operating experience	1
Total	8
Low Risk	

Classifying these items as low risk would allow for certain critical characteristics to be verified using reduced sample sizes. For example, since the ability of the fuse to open under certain applied currents is a destructive test, this test could be performed on a limited number of samples. Since the fuses are not being supplied by the OEM the use of supplier furnished test data could not be used to verify critical characteristics. Had the fuses been supplied directly from the OEM, the use of OEM supplied test data to verify critical characteristics could have been considered since this was classified as a low-risk item.

If the items were classified as medium risk, the use of OEM supplied test data would not have been allowed (regardless of who supplied the items) and normal sample sizes would be used for destructive testing.

If the items were classified as high risk, more reliance would be placed on verifying all the critical characteristics using Method 1 and increased sample sizes would be used for both destructive and non-destructive testing.

3.3.2 Graded approach example 2

The licensee is planning to dedicate a batch of 25 identical O-rings that are used as a seal in the connection box of certain important to safety Class 3 transmitters used to monitor pressure post-accident in beyond design basis conditions. The seals provide a seal for moisture intrusion into the connection box and were installed on the transmitters during previous environmental qualification testing. The design of the O-ring is simple and has not changed over many years. The ability of the seal to provide its safety function is not continuously monitored. The O-rings are being procured from a distributor who purchases the O-rings directly from the manufacturer in sealed packages of 25. The licensee has good experience in purchasing other similar items from this distributor. The distributor does not repackage the O-rings. These are commercial items that are used in multiple industries. However, there is little specific operating experience with regard to the capability in this application. Based upon the above assumptions the total risk score associated with this item would be:

Grading factor	Value
Safety class	1
Design complexity	1
Safety function monitoring	5
Supplier confidence	1
Operating experience	3
Total	11
Medium Risk	

Classifying this procurement as medium risk requires critical characteristics be selected that relate to each of the O-ring's safety functions. Selected critical characteristics would include at a minimum verification of dimensions, material, and elasticity. Since the verification using Methods 2 or 3 would require access to the manufacturing facility, all critical characteristics will be verified using Method 1. The critical characteristics would be verified directly by test using Methods 1, 2, or 3. Material verification would be performed on a sample of the O-rings using a normal sampling plan. Dimensions would be verified on every item.

Had these items been classified as high risk, an enhanced sampling plan would be used for verification of materials and elasticity.

Had these items been classified as low risk, a reduced sampling plan would be used for verification of materials and elasticity. Alternatively, the use of manufacturer certifications with regard to materials could be considered as an alternative verification method.

3.3.3 Graded approach example 3

The licensee is planning to dedicate a lot of five identical molded case circuit breakers to be installed in several safety class 2 applications. They are of the same design and are direct replacements for original equipment which was seismically qualified ten years ago by the OEM for the switchgear. The circuit breakers have a safety function to allow for both a certain amount of current to be continuously supplied to the connected safety related circuits as well as to interrupt the supply of current should a short circuit occur. The ability of the circuit breaker to trip at certain values of current and to stay closed during a seismic event are features that are not monitored once installed. The design of the circuit breakers is somewhat complex but has not changed much over many years. The item is being purchased through a distributor but will be shipped directly from the manufacturer who was the original provider of the breakers. These exact items are used in multiple commercial industries, have a very wide installed base, and have commercial industry independent certification. Based upon the above assumptions the total risk score associated with this item would be:

Grading factor	Value
Safety class	3
Design complexity	2
Safety function monitoring	3
Supplier confidence	1
Operating experience	1
Total	10
Medium Risk	

Classifying this procurement as medium risk requires critical characteristics be selected that relate to each of the breaker's safety functions. Selected critical characteristics would include at a minimum the breaker's time/current response, closed contact resistance, interrupting rating, and insulation resistance. The critical characteristics would be verified directly by test using Methods 1, 2, or 3. The critical characteristics associated with ensuring no changes were made to internal parts that would invalidate previous seismic qualification would be verified by performing seismic testing on one of the breakers.

Had these items been classified as high risk, perhaps an additional breaker would be seismically tested and more reliance would be placed on verification through Method 1.

Classifying these items as low risk would have allowed for the dedicating entity to rely on third party commercial certification for verification of certain critical characteristics (for example, the interrupting rating of the breaker).

4 Guidance on Specific Topics

4.1 Replacement items

The dedication methodology does not address the equivalency evaluation of replacement items in nuclear facilities. It is recognized that European nuclear licensees have a variety of ways in which they:

- screen and evaluate replacement items;
- engage in design change (if necessary);
- maintain facility configuration control;
- develop technical requirements for replacement items;
- develop quality assurance and quality control requirements for replacement items; and
- develop procurement requirement and contract terms.

The procurement and dedication of items usually takes place only after the suitability of those items has been established by the relevant personnel within the licensee organization or design authority. Replacement items are typically sourced in the context of safety upgrades, retrofits, refurbishment or modernization projects. [31]

4.2 Supplier pre-selection

When choosing suppliers of items intended for dedication, the dedicating entity might consider their:

- performance in high-reliability industries;
- awareness of safety culture; and,
- long-term commitment to customers; and
- methods of reporting defects to customers independent of a given procurement.

When procuring expensive items, complex items, or those with high safety significance it can be beneficial to have conversations with the supplier and issue a questionnaire or request for information as a part of the evaluation described above.

During the process of supplier pre-selection, it may be useful to:

- collect specifications, technical data sheets or product catalogues which can assist in the technical evaluation process, especially the determination of the item's design characteristics (and their compatibility with the host equipment, if existing), critical characteristics and their acceptance criteria;
- determine if the supplier is in principle open to evaluations such as a performance-based assessment (Method 2);
- determine if it is possible to witness certain in-process activities (Method 3); or,
- determine if the supplier retains data related to the item's operating experience and reliability or statistical data related to quality assurance, quality control or manufacturing process stability which could be leveraged.

Clarity regarding these issues helps to mitigate potential procurement risks and better define the way in which dedication of the supplier's product could be performed.

4.3 Supplier evaluation and selection

When evaluating suppliers of items intended for dedication, the dedicating entity might consider the supplier's ability to:

- evaluate and control sub-suppliers;
- perform receipt inspection;
- demonstrate traceability during manufacturing and construction;
- control the design of their product(s); and,
- manage non-conformities

At a minimum, suppliers of items intended for dedication should be prequalified, evaluated and/or registered according to established processes, procedures and work instructions intended for suppliers of non-safety related products and services. In certain cases, a documented management system is not a prerequisite for suppliers of items intended for dedication.

4.4 Invitation to tender documentation when dedicating

In competitive bidding scenarios, multiple suppliers submit offers based on an invitation to tender (ITT) documentation. When dedication of the item being procured is foreseen, good formulation of the ITT documentation can help to mitigate project risks and provide clarity related to costs.

Firstly, it is important to recognize that if a technical evaluation has not already been completed for the item(s) to be supplied, it will be necessary to request additional information from the supplier in order to determine design characteristics. The procurement is exposed to risk if it is not known whether the supplier will provide this additional information or what the cost associated with the provision of that information may be.

Lack of sufficient design information can make it impossible to determine design characteristics and select critical characteristics. Dedication is not possible if critical characteristics cannot be determined. To mitigate the risk that a dedication fails due to lack of design information, the ITT should clearly state that design information sufficient to determine characteristics of the item important to guaranteeing certain functions will need to be furnished as a part of the contractual terms and conditions. This ensures that a dedication plan for the item can be prepared.

When requesting tenders for items which are intended to be dedicated, it is sometimes necessary to describe acceptance activities. If acceptance activities include or are expected to include verification of critical characteristics using Method 2 or 3, the ITT documentation should already describe these activities and their reliance on access to the supplier's facility or those of sub-suppliers. When all critical characteristics of an item are to be verified post-delivery (Method 1), ITT documentation does not need to acknowledge acceptance activities.

Cost positions associated with the supply of items intended for dedication can include:

- provision of item design information sufficient for the determination of critical characteristics;
- executing a performance-based assessment (Method 2) at the supplier's facility or remotely; or,
- performing source verification activities (Method 3) during manufacturing at the supplier's facility or at sub-suppliers.
  - ⓘ Typically a bid or quotation would provide a fixed daily rate for on-site witnessing.

The use of the term 'dedication' in invitation to tender documentation is discouraged because this term has a special meaning in the nuclear industry which is probably not well understood by high quality industrial-grade item suppliers.

4.5 Purchasing documentation when dedicating

Purchasing documents are legal contracts that identify requirements that items or services must meet in order to be considered acceptable by the purchaser. When an item is being procured and dedicated, the contract need only describe those aspects of the dedication plan, if any, which are relevant to the supplier. The use of the term 'dedication' in purchasing documentation is discouraged because this term has a special meaning in the nuclear industry which is unlikely to be well understood by high quality industrial-grade item suppliers.

When an item's critical characteristics cannot be determined from information collected prior to signing a procurement contract, the terms and conditions related to the supply of items intended for dedication should include:

- provision of item design information sufficient for the determination of design characteristics; and,
- conditions related to the use of item design information for the purpose of determining design characteristics.
  - ⓘ See Section 4.6.

Procurement documentation should refer to acceptance activities:

- when using acceptance method 2 to verify one or more critical characteristics;
  - ⓘ If a performance-based supplier assessment has not yet been undertaken, this activity can be made part of the contract.
  - ⓘ If a performance-based assessment has already been performed by the dedicating entity, the contract should refer to the assessment and specifically call out those supplier documents (e.g. manuals, processes, procedures or work instructions) which are to be followed to ensure the verification of critical characteristics.
  - ⓘ For more information see Section 5.15.
- when using acceptance method 3 to verify one or more critical characteristics:
  - ⓘ The contract should clearly describe what activities are to be witnesses, rules associated with hold points, and access rights to the supplier's facility for the purpose of those hold points.

The dedicating entity can, optionally, call out any number of critical characteristics (along with acceptance criteria) in the purchasing documentation. In this case, the supplier can be made liable for non-conformities discovered during verification activities.

4.6 Engineering design basis

A nuclear facility engineering design basis is the foundation upon which the overall facility is designed and includes a comprehensive set of requirements and conditions that are applicable to all plant SSCs. These requirements are agreed upon between the responsible designer, the licensee organization and (when/where required) the regulatory body. [32]

Design basis documentation for items important to safety define their necessary fit, form, function, operation, and maintenance. This documentation may include physical design, performance or dependability requirements useful for the determination of critical characteristics as a part of a technical evaluation to develop an item dedication plan.

Being an activity related to the control of procured items and services, dedication does not impact design basis documentation nor does the decision to dedicate an item typically require any kind of change to that documentation.

4.7 Dedication and intellectual property

Detailed item design information is necessary to perform a technical evaluation and prepare a dedication plan. A lack of detailed design information can make it impossible to effectively determine characteristics important to an item's safety function(s).

The dedicating entity typically collects such design information from the original equipment manufacturer. This information is sometimes non-public, proprietary or otherwise confidential. For the dedicating entity to collect design information from the supplier it may be necessary to stipulate the conditions for the release and use of the information. A non-disclosure agreement or release agreement stating how the information will be used can be useful.

Sometimes a nuclear facility relies on a third-party dedicating entity or on the supplier itself to support the technical evaluation process. Since the nuclear facility is responsible for safety, it needs to be able to assess the performance of dedication activities by third parties. Lack of such access threatens the confidence of the nuclear facility in the dedication activities and represents a risk.

Dedication plans sometimes contain information considered sensitive to either the nuclear facility, the supplier, or both. This can make the sharing or distribution of such plans difficult without well-thought-out agreements. The nuclear facility should consider this factor when interacting with suppliers of items intended for dedication or third-party dedicating entities. Ideally, the nuclear facility maintains full or conditional ownership of dedication plans.

4.8 Required information

The dedication methodology relies on a variety of mostly technical information about the item to be dedicated, its intended application in the nuclear facility and its manufacturer. The table below includes some types of information important to the dedication process and typical sources of that information.

Type of information	Typical source of information
Specification of intended item application including design basis	Nuclear facility design or system engineering
Item safety significance	Nuclear facility design authority
Item eligibility for dedication	Dedicating entity engineers
Item safety function(s)	Nuclear facility design authority or system engineering
Item critical characteristics	Supplier's item specification and/or technical drawings
Item data sheet	Supplier
Critical characteristic acceptance criteria	Supplier's item specification and/or technical drawings
Production lot formation practice	Supplier or original equipment manufacturer
Item traceability	Supplier or original equipment manufacturer

Dedication's acceptance activities can detect cases in which incorrect information has been provided. For example, if the supplier incorrectly specifies a material composition this could be detected during a verification of the material using special tests and inspections (Method 1) when that material is defined as a critical characteristic.

4.9 Selecting critical characteristics and acceptance criteria

Critical characteristics are a subset of an item's design characteristics. The set of characteristics is selected based on engineering judgement that the verification of all critical characteristics will provide adequate confidence in the ability of the item to perform its safety function(s) in service. Suitably qualified engineering personnel decide upon critical characteristics by determining if the verification of critical characteristics will provide the necessary level of confidence, according to a graded approach (discussed in more detail in Section 4 of this guideline).

In some cases, especially for more complex items that are comprised of multiple individual piece parts, verification of physical characteristics alone is not sufficient for establishing confidence in the ability of the item to perform its safety function(s). This is especially true when the safety function(s) include quantitative acceptance criteria. In such cases, it is recommended that a combination of physical and performance characteristics be considered as critical characteristics whenever possible.

Deciding which design characteristics to verify (i.e. to select as critical characteristics) and those not to verify can be made by considering factors such as:

- characteristics related to special processes (should rather be verified);
- characteristics believed to be nuclear-specific which the supplier may not be familiar with;
    - ⓘ An example of a nuclear-specific requirement can be a maximum cobalt content in steel.
- maturity of the manufacturing technology;
- maturity of the item's design;
- type testing or equipment qualification reports;
- likelihood of occurrence of failure modes which impact the item's intended safety function(s);
    - ⓘ Engineering judgement or methodologies like FMECA can be used to establish the importance of item characteristics relative to safety function(s).
- operating experience; and,
- reliability data.

Acceptance criteria are defined for each critical characteristic. Ideally, these acceptance criteria are defined in the supplier's own documentation. In rare cases the dedicating entity may choose to define acceptance criteria which deviate from the supplier's own acceptance criteria or include acceptance criteria where the supplier has not defined. The supplier should be made aware of and ideally be contractually bound to any acceptance criteria in connection with the item which deviate from those already defined by the supplier.

4.9.1 Simple Items

Critical characteristics of simple items often encompass many of the item's design characteristics. Publicly available data including supplier catalogues, technical data sheets or brochures for simple, low-complexity items can sometimes contain all meaningful design characteristics. For example, an anchor bolt's critical characteristics are likely its material, overall dimensions, thread dimensions and pull-out strength, all of which might be found in a supplier catalogue. Acceptance criteria are usually published along with design data for simple items or can be found in referenced standards. Engineering judgement needs to be used by the dedicating entity to determine if the acceptance criteria published by the supplier are suitable given the item's intended installed locations in the nuclear facility.

4.9.2 Complex Items

Determining the critical characteristics of complex items often requires a greater degree of engineering involvement than in the case of simple items. When sufficient design data is not available from supplier catalogues, technical data sheets or brochures, the dedicating entity should request additional information from the supplier. The provision and use of detailed item design information for the purpose of determining critical characteristics may require a non-disclosure agreement.

A design failure mode and effects analysis (FMEA) is a good tool for determining critical characteristics of complex items. The FMEA methodology used for determining item characteristics which are important to its safety function(s) is no different from a traditional FMEA used widely in the field of engineering. The supplier of a complex item may have already performed an FMEA during the design phase.

The FMEA methodology identifies credible potential item failures as well as the cause and effect of those failures. In doing so, the engineering team performing the FMEA is able to systematically identify those item characteristics which directly influence the item's ability to perform the necessary safety function(s). An FMEA performed as a part of the dedication process can be included as part of the documented evidence justifying the choice of critical characteristics.

A further possible extension of the FMEA methodology is the inclusion of a criticality analysis which provides a relative measure of the consequences of a failure mode and the frequency of its occurrence. The failure mode, effects and criticality analysis (FMECA) methodology can support the risk associated with identified failure modes and thereby support the decision-making process when applying a graded approach to dedication. In this way, critical characteristics can be weighted, and associated acceptance methods chosen most effectively.

Complex items are often dedicated by verification of performance attributes in addition to physical attributes. For example, pressure boundary integrity and seat leakage are performance attributes which may be identified as critical characteristics of a valve. Special tests could be a suitable acceptance method for verifying these critical characteristics.

4.10 When an item's intended installed location is unknown

When the dedicating entity does not definitively know the intended application(s) of the item being dedicated, so-called bounded conditions should be established that would limit the installation of the item to those applications whose safety functions are enveloped by the dedication. The dedicating entity may choose to assume that all the item's possible functions are safety functions for the purpose of dedication.

4.11 Selecting supplemental characteristics

The safety functions of an item do not typically represent all its possible functions, nor do they always encompass those functions important to the operability of the item as it relates to the purpose of the nuclear facility, for example, to generate electricity. Dedication can, at the discretion of the dedicating entity, be leveraged to verify the quality of an item more generally. For example, the dedicating entity might decide to select supplemental characteristics for verification. Supplemental characteristics are not related to the safety function(s) of the item but could be related to other functions or attributes which the end-user considers important to ensure the operability of the item.

4.12 Choosing acceptance methods for each critical characteristic

The final step in preparing a dedication plan is to select acceptance methods for each critical characteristic. The choice of acceptance methods is ideally based on a defined strategy which can help guide the decision-making process. Choosing acceptance methods requires knowledge of:

- the intended nuclear facility applications foreseen for the item;
    - ⓘ Consult knowledgeable facility design engineers
- the design of the item; and,

- ⓘ Consult experts familiar with the type of item being dedicated.
- the supplier.
  - ⓘ Consult personnel who have interacted with the supplier and are aware of nuclear supply chain good practices.

Note that this information is likely already known or compiled by the time a dedication plan is developed to the point of selecting critical characteristic acceptance methods.

The dedicating entity needs to consider many factors when choosing critical characteristic acceptance methods, all of which influence which acceptance method(s) are most suitable. These factors include:

- feasibility of verifying the critical characteristic by each acceptance method;
- safety significance of the item;
- complexity of the item;
- costs associated with verifying the critical characteristic by each acceptance method;
- procurement plan or strategy associated with the item;
- overall confidence in the supplier of the item;
- relationship with the supplier of the item;
- novelty of the item's design or its manufacturing process;
- historical performance of the item; and,
- historical performance of the supplier.

At a minimum, one acceptance method needs to be selected for each critical characteristic. In some cases, the dedicating entity may voluntarily choose to use more than one acceptance method to accept one or more critical characteristics (see Section 4.16).

4.13 Verification by acceptance Method 1

The following examples are from the perspective of a dedicating entity deciding whether to plan on verifying one or more critical characteristics of an item using Method 1 (special tests and inspection).

Method 1 can be suitable for verifying one or more of an item's selected critical characteristics when:

- it is not possible to access the supplier's facilities;
- the purchaser wants to verify critical characteristics after receiving the item;
- the item has already been manufactured;
  - ⓘ Using Method 1 to verify critical characteristics of items which have already been manufactured sometimes requires destructive testing.
- the critical characteristic is not sufficiently controlled by the supplier's quality management programme; or,
  - ⓘ A performance-based supplier assessment (Method 2) may discover that some item's critical characteristics are verified by the supplier's industrial quality management programme while others are not.
- it is not possible to verify the critical characteristics until after installation.
  - ⓘ An item cannot be relied upon to perform its safety function until all critical characteristics have been verified.

Method 1 is a good choice for verifying one or more of an item's selected critical characteristics when:

- the dedicating entity already possesses the measurement and test equipment necessary to perform the special tests or inspections;
- the item is being procured in large volumes;

    - ⓘ When verifying the critical characteristic of many identical items, sampling plans should be used according to a graded approach. Sampling plans should be defined and justified.
- the same item is procured from multiple suppliers; or,
- the item has been or may have been manufactured by multiple suppliers;
    - ⓘ For example, when procuring large volumes of commodity parts through a distributor.

Another acceptance method (2 or 3) may be more suitable for verifying one or more of an item's selected critical characteristics when:

- special tests or inspections are not capable of reliably verifying the critical characteristic;
    - ⓘ Tests or inspections are not ideal for determining if a special process like welding, soldering or heat treatment were performed with specified settings using specified equipment.
- the dedicating entity is not able or choses not to acquire and utilize the necessary measurement and test equipment to perform the special tests or inspections;
- only a single item is being procured and the critical characteristics cannot be verified without destroying the item; or,
- when using another acceptance method would be more efficient or effective.

For simple parts, dedication plans often rely solely on Method 1 to verify all critical characteristics. Special tests or inspections are sometimes performed by the licensee and sometimes are outsourced to a third-party dedicating entity. The latter may be necessary when the measurement and test equipment or capabilities are not present within the licensee organization.

4.14 Verification by acceptance Method 2

The following examples are from the perspective of a dedicating entity deciding whether to plan on verifying one or more critical characteristics of an item using Method 2 (performance-based assessment).

Method 2 can be suitable for verifying one or more of an item's selected critical characteristics when:

- the supplier maintains a documented management system;
- the supplier is willing to submit to a performance-based assessment; or,
- the dedicating entity has trained personnel available to perform a performance-based assessment either on-site or remotely.

Method 2 is a good choice for verifying one or more of an item's selected critical characteristics when:

- there will be many orders placed for the same item every year;
- more than one item is being procured and dedicated from the same supplier;
    - ⓘ A single supplier assessment can verify the critical characteristics of multiple different items (each having its own dedication plan) at the same time.
- the dedicating entity has already performed a performance-based assessment of the supplier as a part of a dedication plan for one of the supplier's other products;
    - ⓘ In this case, it is still necessary to perform the performance-based assessment with a scope which encompasses the current item of interest (as well as other items, as necessary).
- the supplier has a demonstrable track record of manufacturing high-quality, reliable items;

- the supplier's quality management programme is certified to the requirements of other high-reliability industries;
- the dedicating entity can join forces with other organizations to perform a supplier performance-based assessment, thereby reducing costs; or,
    - ⓘ As in joint-utility networks for performing performance-based assessment of common suppliers.
- the dedicating entity has a high degree of confidence in the ability of the supplier to deliver a high-quality item.

Another acceptance method (1 or 3) may be more suitable for verifying one or more of an item's selected critical characteristics when:

- access to the supplier's facility is, for whatever reason, not possible or in doubt;
    - ⓘ It is necessary to visit a supplier's facilities to perform a performance-based assessment.
- the dedicating entity does not plan to perform repeat procurements or plans to procure from the supplier infrequently;
- the dedicating entity does not intend to use this acceptance method for any other dedication activities;
    - ⓘ For the greatest cost-benefit, the training of personnel to perform performance-based assessment should be undertaken only if the dedicating entity expects to be using this acceptance method with some regularity when dedicating items.
- the supplier's business is undergoing or expected to undergo major changes; or,
    - ⓘ Changes to a supplier's business strategy or direction including mergers and acquisitions can lead to sudden changes in quality management practices.
- when using another acceptance method would be more efficient or effective.

As an example, Method 2 may be suitable for the evaluation of established quality activities at the supplier which are sufficient to provide confidence in material certificates produced according to EN 10204:2004.

Performance-based assessment can be performed independent of a supply contract, i.e. they may be performed prior to procurement or between orders. The results of an assessment determine if other acceptance activities are necessary to verify an item's critical characteristics (in the case the assessment finds that certain critical characteristics are not sufficiently verified by the supplier's quality programme).

This acceptance method is especially well-suited for joint-utility activities, see Section 10.2 for further information.

4.15 Verification by acceptance method 3

The following examples are from the perspective of a dedicating entity deciding whether to plan on verifying one or more critical characteristics of an item using Method 3 (source verification).

Method 3 can be suitable for verifying one or more of an item's selected critical characteristics when:

- the supplier is willing to allow the dedicating entity's personnel to enter their facilities;
- the supplier is able to reliably integrate hold points into the manufacturing activities of the procured item;
    - ⓘ A hold point is a point in the chain of activities beyond which an activity shall not proceed without the approval of the dedicating entity.
    - ⓘ Hold points ensure that the dedicating entity is informed in a timely manner and able to perform the source verification.

- the supplier verifies the critical characteristic effectively; or,
  - ⓘ The dedicating entity can rely on existing supplier procedures or convince the supplier to use a purpose-made procedure to verify the critical characteristic.
- the supplier does not have a documented quality management programme.

Method 3 is a good choice for verifying one or more of an item's selected critical characteristic when:

- in-process verification of the critical characteristic is necessary;
- non-conformances were detected during prior receipt inspections or other acceptance activities;
- there is a single supplier and the item is purchased infrequently;
- the item's design or manufacturing is first-of-a-kind;
- the critical characteristic is related to a special process;
  - ⓘ Method 3 is well suited for observing processes like welding, soldering, heat treatment, assembly or insulating.
- the item is procured infrequently;
- verification by this method would avoid the need to manufacture additional items for the purpose of destructive testing by Method 1;
- the critical characteristic is related to computer hardware quality; or
- the supplier has the measurement and test equipment necessary to verify the critical characteristic.
  - ⓘ A factory acceptance test bench, for example.

Another acceptance method (1 or 2) may be more suitable for verifying one or more of an item's selected critical characteristic when:

- access to the supplier's facility is, for whatever reason, not possible or in doubt;
- when using another acceptance method would be more efficient or effective.

4.16 Verification using multiple acceptance methods

As a part of a graded approach, the dedicating entity can voluntarily decide to use multiple acceptance methods to verify critical characteristics. A dedicating entity might choose to use multiple acceptance methods to verify a critical characteristic in order to gain additional confidence in the conformance of the critical characteristic. Typically, however, only one acceptance method is used to verify each critical characteristic in accordance with Volume 1 Section 10.

An example of verification of critical characteristics using multiple acceptance methods could be the use of Method 2 (performance-based assessment) to verify all critical characteristics listed in the dedication plan, followed by additional verification by Method 1 (test or inspection) of selected critical characteristics. In this example, additional confidence in the conformance of the selected critical characteristics with their acceptance criteria is provided.

4.17 When an item's handling and storage history is uncertain

In some instances, the handling and storage history of an item which a dedicating entity is seeking to accept may be uncertain. When buying warehoused inventory from other nuclear facilities, from distributors (see Section 4.25) or even when seeking to re-establish the suitability of items in one's own warehouse, for example, the handling and storage history of the item may be partially or fully unknown. In these cases, some additional considerations should be taken into during the dedication process.

As described in Volume 1 Section 11, the successful completion of item dedication is possible only when the dedicating entity is able to verify all critical characteristics of an item. The verification of all critical characteristics provides confidence that the item will perform its safety function(s) when called upon to do so in service. When handling and storage history is uncertain, engineering staff responsible for selecting critical characteristics of an item should consider this issue and include additional critical characteristics as necessary to gain the necessary degree of confidence. For example, some of the item's safety-function-related characteristics which are susceptible to environmental ageing mechanisms or physical impact shocks might be chosen as critical. Additionally, uncertainty related to handling and storage, when present, should be a factor considered as a part of a graded approach to the dedication process.

The nuclear facility's equipment qualification programme also has a role to play in establishing the suitability of an item with unknown or uncertain handling and storage history. Suitably qualified staff responsible for equipment qualification may deem an item unsuitable for use, even if staff responsible for dedication would have the ability to verify all critical characteristics.

4.18 Dedication of product families

It is not uncommon for a dedicating entity to procure many items from the same manufacturer, all of which undergo dedication to be accepted for use. The combining of acceptance activities related to each individual item can realized by using acceptance method 2. In this case, a single performance-based assessment (Method 2) is executed by the dedicating entity to verify the critical characteristics of all items within the scope of procurement, simultaneously. In other words, a single acceptance activity is performed which verifies critical characteristics across multiple item dedication plans.

When a performance-based assessment of a supplier should verify the critical characteristics arising from multiple item dedication plans, it is performed no differently than when performed when verifying critical characteristics of a single item. It is only necessary that the scope of the performance-based assessment encompasses all those supplier quality activities which control the full set of critical characteristics comprising all items to be dedicated. It should be remembered that specific purchase order requirements and a review of documentation delivered by the supplier upon delivery to confirm the assessed supplier controls were used is always necessary, even if the performance-based assessment can be performed with a periodicity independent of individual procurements (see Volume 1 Section 10.2)

When accepting multiple items from the same manufacturer in this manner, it is good practice to still develop individual dedication plans for each item to be dedicated. An exception to this might be when the critical characteristics of the items being procured are similar, this might be the case when the items are all of the same technological basis (e.g. a specific type of fastener, actuator or relay).

The use of Method 2 to verify the critical characteristics of various services furnished by the same service supplier is possible in the same manner as described above for items.

4.19 Economics of dedication

Technological obsolescence of structures, systems, components and spare parts is one of the primary challenges faced by European licensees in long-term operation. This type of obsolescence manifests itself as a lack of suppliers, spare parts, technical support and industrial capabilities. [33] The absence of suppliers (and, consequently, spare parts, technical support and industrial capabilities) is typically artificial. The suppliers are there, they are simply not able or willing to comply with the requirements of nuclear licensees, especially given the market size and uncertain market forecast. The European Commission has investigated this phenomenon in a JRC Science for Policy Report on Current Challenges of the European Nuclear Supply Chain. [34] When products are available, European licensees have reportedly paid up to ten times more for items which comply with nuclear-specific requirements compared to physically identical items manufactured according to identical processes from the same manufacturer according to industrial standards. [34]

Once a licensee has established a dedication programme, it has the potential to procure items from a larger pool of suppliers than would traditionally be possible following nuclear-specific quality assurance rules. When a greater variety of products can be sourced, competition is fostered. In some cases, only a single supplier is capable of delivering an item according to the requirements of nuclear licensees. Market economics are distorted when competition is lacking and licensees sometimes end up paying exorbitant amounts for products not because they are of a special design, but because the supplier must adhere to a nuclear-specific quality assurance and quality control regime.

4.19.1 Dedication programme cost factors

The dedication methodology places increased responsibility on the purchaser for demonstrating quality, in contrast to procurement from suppliers with management systems complying with nuclear-specific rules. This means the dedicating entity can expect some additional internal costs or resource demands to be present. The cost of an item or service, when procured without management system or quality control measures specific to the nuclear industry, is typically less, and sometimes far less, than when procured with the imposition of those measures. Any organization considering establishing a dedication programme or considering dedicating an item or service should consider the cost and resource factors which are present.

One-time cost/resource factors:

- Establishing a dedication programme
    - ⓘ (see Section 3)
- Performing a technical evaluation of the item or service
    - ⓘ (see Volume 1 Section 9)
- Preparing a dedication plan for the item or service

Repeating costs/resource factors (each procured lot of items):

- Procuring the item or service
- Performing acceptance activities
- Documenting the results of item or service dedication

One-time cost factors have a smaller impact on overall costs when procuring and dedicating an item or service more than once.

4.19.2 Acceptance activity cost factors

The performance of acceptance activities during the dedication process costs resources. Those resources may be in the form of man-hours, testing and inspection equipment, calibration of such equipment, third party services, shipping costs, additional item samples or travel expenses. The expenditure of dedicating entity resources is highly dependent upon which acceptance methods are performed. Optimizing resource expenditure is achieved primarily by evaluating the selection of acceptance methods to reduce the overall cost of item acceptance over the lifetime of anticipated procurement.

Costs and efforts associated with dedication are variable due to the high degree of flexibility provided by the methodology. Acceptance activities performed to verify the selected critical characteristics of an item are chosen based on many factors by the dedicating entity from the four allowable methods. The dedicating entity, being afforded the flexibility to choose the appropriate acceptance methods, should evaluate the costs associated with acceptance activities on a regular basis.

There are often many possible ways in which to dedicate an item by selecting different acceptance methods or combinations of acceptance methods to verify the chosen set of critical characteristics. Once a technical evaluation has been performed, establishing a list of critical characteristics and their acceptance criteria, acceptance methods need to be selected. Optimizing the dedication of a given item is primarily the intelligent selection of acceptance methods to reduce the overall cost of item acceptance over the lifetime of anticipated procurement.

Costs associated with Method 1 include:

- purchasing measurement and test equipment;
- calibrating measurement and test equipment;
- procuring tests and inspection services from a third party; and,
- test samples (destructive testing).

Costs associated with Method 2 include:

- travel expenses;
- manpower;
- assessment personnel training; and,
- potential additional fees imposed by the supplier.

Costs associated with Method 3 include:

- travel expenses;
- manpower; and,
- potential additional fees imposed by the supplier.

4.20 Supplier or item certifications

Industrial suppliers often maintain certifications related to their products, personnel or management system. These certifications are typically issued by conformity assessment bodies. Accreditation bodies can accredit the competence of conformity assessment bodies in accordance with international standards related to inspection [35], testing [36] [37], calibration [36] or the certification of products [38], persons [39] and management systems [40].

Certificates issued under an accreditation builds confidence in the quality of the corresponding products or services. When the accreditation is issued by an accreditation body who is member of international frameworks like the European co-operation for accreditation (EA) or the International Laboratory Accreditation Cooperation (ILAC), for example, additional confidence in the certificate is gained.

In the context of dedication, certificates can in certain cases be taken as evidence that critical characteristics are appropriately verified. By accepting a certificate, the dedicating entity is recognizing the certificate in lieu of a performance-based assessment (Method 2) of the supplier's quality controls. The certificate does not eliminate the need to perform a technical evaluation and develop a dedication plan, since it is only once a dedication plan is created that the design characteristics which are selected to be verified (critical characteristics) are known.

In order for a dedicating entity to consider critical characteristics to be verified by the presence of a certificate alone, the following should be performed:

- a thorough review of the standard for the certificate has been issued;

ⓘ The dedicating entity should determine if the requirements found in the standard are sufficient to verify the critical characteristics.

- a review of the certificate associated with the supplier or the item;
- a review of the validity and scope of the certification body's accreditation;
- purchasing documentation should require that the supply should be in accordance with the scope of certification and that a certificate of conformity be provided with the delivery;
- upon receipt inspection, the customer should confirm that the certificate of conformity meets the purchasing documentation expectations.

A good example of recognizing a certificate in lieu of performing a performance-based assessment is the third-party safety integrity level (SIL) certification process for electrical/electronic/programmable electronic safety-classified systems. Suppliers develop and manufacture products capable of a particular SIL for a defined scope of safety functions in accordance with the requirements found in IEC 61508. [41]

4.21 Dedication and CFIs

Counterfeit and fraudulent items (CFIs) have the potential to threaten nuclear safety. Nuclear facilities have addressed a variety of tools to avoid incorporating CFIs. These include sensitization programmes, bid evaluation processes accounting for CFI concerns and receipt inspection procedures which include consideration of the potential for CFIs. Although dedication can be leveraged to combat CFIs, it should not be relied upon as the sole means of preventing CFIs from entering a nuclear facility; even CFIs can appear to be of high-quality.

Engineering involvement in procurement and product acceptance is recognized by the IAEA a key aspect to be addressed in a multilayered CFI prevention strategy. [42] Dedication often increases engineering involvement in procurement by focusing quality assurance and quality control activities on an item's safety functions.

Acceptance activities in which critical characteristics are verified are valuable opportunities to detect CFIs. Real-world CFIs have been detected during the dedication process. When the dedication of an item relies on third party documentation, the veracity of that documentation should be evaluated in light of the potential for non-genuine certificates, test reports or inspection results. Personnel performing acceptance activities should be familiar with signs that an item is potentially counterfeit or fraudulent.

4.22 Off-the-shelf items

Items which have already been manufactured can be dedicated provided they are otherwise determined to be suitable for use. Since it is impossible to perform source verification activities (Method 3) on items which have already been manufactured, and reviewing supplier quality controls which were in place during manufacturing may be impractical (Method 2), it is necessary to perform special tests or inspections (Method 1).

For off-the-shelf items whose critical characteristics are verified using special tests and inspection, those tests and inspections may need to be destructive. This implies that more than one of the same item must be available. When verifying one or more critical characteristics of an item by destructive testing, the corresponding sampling plan should consider the degree of confidence in lot homogeneity.

4.23 Role of dedication in maintaining equipment qualification

The dedication process is not a substitute for verifying the suitability of an item's design but can be used to ensure that previous equipment qualification testing (or analysis) remains valid for the items being dedicated. Equipment qualification verifies that items important to safety can perform 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. [43] When dedicating an item, the verification of critical characteristics related to environmental- or seismic-resistance helps to ensure that the item intended for use is sufficiently similar to that which was qualified and thereby establishes confidence that it will perform its safety functions.

Differences between the item being dedicated and the previously qualified item could occur due to changes to the item's materials or manufacturing methods. Items are more prone to changes when a large amount of time has occurred between the time of original equipment qualification and the procurement of the items to be dedicated. Likewise, changes to an item that might render previous qualification invalid might occur when changes to the item's manufacturer or manufacturer location have taken place. Such factors should be considered when deciding on what additional critical characteristics should be included specifically to address the validity of a previous equipment qualification programme. It is not expected that an equipment qualification is to be re-performed every time a previously qualified item is supplied.

4.23.1 Environmental qualification

For electrical items important to safety that are required to be environmentally qualified, it is usually important to verify during dedication that there have been no significant changes to non-metallic materials sensitive to thermal or radiation aging. For individual piece parts, this can usually be accomplished using Method 1 in the form of non-destructive testing techniques such as Fourier Transform Infrared Spectroscopy (FTIR), provided data is available on the specific materials used in the piece parts that underwent qualification testing.

For more complex components, inspection methods that involve disassembly and inspection of internal piece parts may be necessary. Alternatively, Acceptance Methods 2 or 3 could also be utilized in combination with - or in lieu of - Method 1 testing to confirm that appropriate supplier controls are in place, as necessary, to ensure that the item's materials are the same as those originally tested as part of the qualification programme.

4.23.2 Seismic qualification

Since most items important to safety are required to be seismically qualified, it is important to ensure the selected set of critical characteristics will verify that there have been no changes to the item's design or materials that would impact its seismic qualification, and, therefore, impact the ability of the item to perform its safety function(s) in a seismic event. This would include changes that could result in damage to the item that would render it incapable of performing its safety function after exposure to a seismic event, as well as changes that could negatively impact the items performance during the event (such a relay chatter). Specific guidance on critical characteristics for the acceptance of seismically sensitive items should be reviewed by dedicating entities involved in their dedication. [44]

For most non-seismically sensitive piece parts, no additional critical characteristics need to be added to address seismic qualification provided the chosen set sufficiently verifies that there have been no major changes to the design or materials. For more complex, seismically sensitive items such as certain categories of switches, relays, motor starters and contactors, the chosen set of critical characteristics should include characteristics specifically focused on ensuring that there have been no changes to the item that could affect its seismic performance. This might involve using Method 1 techniques to verify certain seismically relevant parameters or enhanced performance testing to demonstrate similarity to previously tested items. As described above for items requiring environmental qualification, Acceptance Methods 2 or 3 could also be utilized to confirm that appropriate supplier controls are in place for aspects of the design and/or materials that could impact seismic qualification.

4.24 Dedication of equipment qualification test specimens

The guidance provided in the previous section applies primarily to replacement items for which equipment qualification has already been established. For new or replacement items that require a new equipment qualification effort but are being procured from suppliers that lack an approved nuclear quality assurance programme, both the test specimens and the supplied items can be dedicated.

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. The dedicated items would be authorized for use only after the test specimens were qualified successfully.

4.25 Distributors

Distributors frequently play a role in the sale and supply of items to nuclear facilities. As suppliers, distributors are unlike manufacturers in that they have little if any impact on the conformance of items with their specified requirements. It is for this reason that Method 2 should not be employed as the basis for accepting items from distributors unless the performance-based assessment includes the item manufacturer, and the assessment confirms adequate controls by both the distributor and the item manufacturer. [16]

When dedicating items purchased from distributors, the dedicating entity should establish confidence in the activities of the distributor as they related to quality. Distributors can affect the quality of the items they are selling depending on the ways in which items are:

- warehoused and stored;
- inspected or tested;
- traced to original manufacturing lots or manufacturers; or,
- packaged or re-packaged.

Most distributors do not influence the quality of the items they are selling.

4.26 Advanced manufacturing

Advanced manufacturing comprises the integration of new innovative technologies in both products and processes. Advanced manufacturing processes like additive manufacturing are rising much interest in the manufacturing programmes of equipment in the nuclear industry. The additive manufacturing processes can be used to manufacture prototypes, tools and fully functional end-use parts. Additive manufacturing has been proved extremely useful to accelerate the design of complex parts. The use of additive manufacturing techniques for the fabrication of items important to safety in nuclear facilities still faces many hurdles related to qualification and reliability.

In general, additive manufacturing techniques are well suited to the nuclear industry's requirements for low volume production of highly-engineered items. Raw materials, machines, tooling, equipment operators and engineers, suppliers and the manufacturing process itself, all need standards and a mechanism for qualifying or certifying against those standards to make parts with the required quality.

To address the challenge of dedicating additive manufactured items, a hybrid approach using acceptance methods 1 and 3 is recommended. Critical characteristics adapted to the nature of the manufacturing process, i.e. the characteristics based on the weaknesses of the additive process (for example porosity, imperfections), should be defined in the technical evaluation. Once the additive manufacturing process has been qualified, the dedication methodology can be used to assure the quality of the manufactured items based on an appropriately developed technical evaluation and dedication plan. Acceptance Method 2 could also become an option for additively manufactured items in the long term, once the process is fully established and fully qualified additive manufacturing processes exist.

4.27 Reverse engineering

Reverse engineered items are, by definition, not identical to the original item to which they are replacing. In general, a reverse engineered item is not manufactured by the original manufacturer and access to the item's original design information may be lacking. Therefore, in most cases, the design information associated with the item needs to be reconstituted through reverse engineering techniques before manufacture of the replacement item can commence. This is the case regardless of whether the replacement item is to be manufactured by a supplier that maintains an approved nuclear quality assurance programme or whether the item is to be dedicated.

The process of reconstituting the design requirements for an item important to safety is considered a safety-related activity that needs to be performed by a suitable organization, while the actual fabrication of the reverse engineered item could be accomplished by either an approved nuclear manufacturer or manufactured as a high-quality industrial grade item and then dedicated.

For reverse engineered items that are to be dedicated it is important to ensure that sufficient design information has been generated before beginning the dedication process, as necessary, to allow for the selection and verification of critical characteristics. For small piece parts the design information necessary would generally be limited to the piece part's design requirements with respect to how it interfaces with its host component. For larger items, the design information would be at the system level and would include the design requirements with respect to how the component interfaces with its parent system. Once the design requirements of the item have been sufficiently vetted, critical characteristics can then be selected, in a similar fashion as with any other dedicated item.

4.28 Common mistakes

The following table of typical pitfalls encountered in dedication activities are based on real examples and lessons learned. The potential solutions are provided as examples only and do not represent the best or only available resolution.

Common Mistake/Issue (of the dedicating entity)	**Potential Solution/Mitigation** (example only)
Not providing the dedicating entity with sufficient information regarding safety functions, including all service conditions (voltage ranges, environment, etc.)	Service conditions may need to be provided to the dedicating entity to allow for appropriate acceptance criteria to be developed for any verification testing. This is particularly important in those cases where the item being dedicated is a complete component and the original component is not available to provide a basis for comparison.
Not documenting the basis for the sampling strategy being used to verify critical characteristics.	Ensure the sampling strategy chosen conforms to the applicable sampling guidance. Ensure a documented basis exists that provides the rational for the sampling plan chosen including the basis for assuming a given lot is homogenous and the basis for any grouping of items.
Choosing the wrong acceptance criteria to be used for verifying critical characteristics	Ensure that any acceptance criteria chosen are sufficient to verify the acceptability of the applicable critical characteristics. In some cases, the acceptance criteria will be chosen to demonstrate that an item's performance or materials are identical to or better than the original item. In other cases, where the original item (or data from the original item) is not available, acceptance criteria should be chosen to ensure the capability of the item to perform its intended safety function under all design basis conditions.
Using test equipment/procedures that are not sufficiently sensitive to detect performance or material changes in previously qualified items including the addition of materials that were absent from the qualified specimens	Ensure that the test equipment and/or procedures chosen to verify critical characteristics are appropriate for the application being used and provide the accuracy needed for the application.
Not ensuring all critical characteristics are verified or not documenting the basis for the set of critical characteristics chosen for verification	Ensure the set of critical characteristics chosen for verification is sufficient to provide reasonable assurance that all safety functions are met under all design basis conditions. Ensure an adequate basis exists and is documented for any critical characteristics whose verification is based upon indirect methods.
Conducting performance-based assessments that focus on the overall commercial quality assurance programme but do not specifically address the critical characteristics of the item being supplier or service performed	Ensure that there is documentation in the performance-based assessment plan that ties each assessment activity to the critical characteristic being verified.
Relying on data, certificates of conformance, etc. derived from unqualified sources for use in the verification process (unless this explicitly allowed)	Ensure that any test data or certificates of conformance that are being utilized to support the verification of critical characteristic come from acceptable sources that possess the knowledge and ability to certify what is being asked.

Not implementing sufficient verification methods to determine whether there have been any material, design, or manufacturing changes have occurred in seismically sensitive items	For seismically sensitive items that were previously qualified, it is important to ensure that there have been no changes made to the item that would impact its performance during a seismic event. Any changes made to Items such as spring constants, latch mechanisms, structural integrity, etc. could impact seismic performance and would require separate analysis. Typical operational tests are not sufficient to verify whether any such changes have been made.
For generic items or commodities, failing to consider/envelop all possible applications of the dedicated item, including physical mounting, environmental conditions, etc..	Ensure that proper controls are put in place to limit the application of dedicated items to applications that conform to the assumptions made as part of the dedication process.
Failing to ensure that commercial service providers adequately control any subcontractors involved in performance of the service	Ensure that measures are put in place to limit commercial service providers from contracting out any work associated with the safety-related service being provided without prior buyer authorization.
Failing to ensure that commercial service providers have adequate controls to maintain traceability for any material provided to them by the purchaser	Ensure that measures are put in place to control and segregate any safety-classified materials either provided to or used by the service provider.
Failing to ensure that commercial service provides use measurement and test equipment that is calibrated periodically and traceable to national standards	Ensure that the measurement and test equipment used by a service provider that is specifically being relied upon as part of the verification of a safety related service is properly controlled and traceable to national standards.
Not adequately dispositioning anomalies observed in dedication testing including specific acceptance criteria that were not met	Ensure that any anomalies that occur as part of the dedication process are properly documented and evaluated, including the basis for acceptance and data that is outside of previously approved acceptance limits.
Using data from dis-similar equipment as a basis for verifying critical characteristics	Ensure that any data being used as part of verification is applicable to the item being dedicated and that the data is derived from either identical items or items that are sufficiently similar in important critical characteristics.
Deriving acceptance criteria from catalogue data as a way of ensuing the validity of previously qualified seismically sensitive components	Verifying that the commercial item meets catalogue data does not by itself ensure that there have not been any changes made to the component that might impact its qualification, as the originally qualified component may have performed better than catalogue specifications. For example, if a pickup and drop out test is going to be performed on a relay to verify no changes were made that would impact the original seismic qualification testing, the acceptance criteria for the test should be based upon the pick-up and drop out performance of the original tested and qualified relay as opposed to just catalogue specifications. This is necessary as any changes made to the commercial product that could impact seismic performance might not be detected if testing is done to solely catalogue specifications.

4.29 Typical procurement scenarios incorporating dedication

The following are various scenarios in which dedication has been pursued by nuclear facility licensees. These scenarios are intended for information only and do not represent cases in which dedication must be used to accept items for use.

Scenarios related to the manufacturer:

- The manufacturer of an item is no longer able or willing to comply with nuclear-specific quality requirements.
- The supplier does not allow access to their manufacturing facilities to witness in-process activities.
- The manufacturer is considerably more familiar with the quality controls which would be invoked if the item is to be dedicated than with nuclear-specific quality requirements.
  - When suppliers do not have a good understanding of a customer's nuclear-specific quality requirements, or are unfamiliar with them, the product is at increased risk of non-conformance during or after manufacturing.
  - For example, a licensee is sourcing items from a foreign supplier. The foreign supplier maintains a strong quality management programme which fulfils the requirements of the local nuclear industry but is unfamiliar with the licensee's requirements. The licensee verifies the quality of the items by verifying critical characteristics using hold points (Method 3) and a performance-based assessment (Method 2), quality assurance and quality control activities familiar to the supplier.
- The supplier manufactures an item which is best suited for the nuclear facility's application but is not able or willing to comply with nuclear-specific quality requirements.
  - For example, the supplier might not have the human capacity to implement nuclear-specific quality requirement or might decide against investing in implementing nuclear-specific quality requirements.

Scenarios related to supply chain factors:

- The desired product cannot be found from a supplier who fulfils nuclear-specific quality requirements.
  - In this case, performing dedication to accept the same item from a high-quality industrial grade supplier is a means to avoid item obsolescence.

Scenarios related to costs:

- The cost of the item procured when invoking nuclear-specific quality requirements is significantly higher than the sum of the cost of the item manufactured under the supplier's standard quality controls plus the estimated costs associated with dedication.

Scenarios related to project management:

- The time and effort estimated as necessary to procure an item and verify its quality using dedication is estimated to be significantly less than procuring the item according to nuclear-specific quality requirements.
- By dedicating an item, time can be saved by avoiding the need to ship its host component to a third party.

The following table describes hypothetical supply chain situations along with example licensee reactions to resolve the situation using dedication.

Situation in the supply chain (hypothetical scenario)	**Licensee reaction** (potential resolution using this Guideline)
A supplier of high-quality industrial grade items designed and serially manufactured for another industry are desired by the licensee to resolve an obsolescence issue, the result of a nuclear supplier discontinuing a legacy product line. The commercial supplier is not willing to adjust their quality assurance system to accommodate a relatively small order from the licensee.	The licensee purchases the serially manufactured item and performs dedication to ensure that the item is suitable for use in a safety-classified application and will perform its safety function.
A supplier to the oil & gas industry sells a serially manufactured ball valve according to a standardized procurement quality specification. The supplier offers to manufacture the valves for the licensee using this specification which includes an inspection and test plan (according to ISO 10005:2018) and hold points for welding and heat treatment activities. The supplier can deliver the valves in time for an important safety upgrade project.	Although the inspection and test plan is in some ways different than the inspection procedures normally followed by the licensee, the licensee can utilize dedication to accept the solenoid valves in this extraordinary circumstance. The licensee prepares a dedication plan for the ball valve and selects a combination of acceptance methods. The dedication plan takes advantage of the extensive quality assurance and quality control measures already implemented by the supplier.
A supplier to a nuclear power plant is delivering electronic sub-assemblies in large volumes to the licensee with poor quality and is experiencing non-conformances during production. The licensee and supplier determine the problem is in part due to unique nuclear requirements (e.g. hold points and new testing requirements during production) confusing and challenging the normally high-quality serial production line. The supplier has not noticed similar quality issues in producing the same products serially for the defence & aerospace industry.	The licensee accepts the supplier offer to procure the manufactured items at a lower cost according to the quality assurance and quality control the supplier implements for serially production for the defence & aerospace industry. The licensee purchases the serially manufactured item and performs dedication to ensure that the item is suitable for use in a safety-classified application and will perform its safety function.
A supplier who has historically supplied safety class 2 pumps to a nuclear power plant has decided to discontinue their nuclear quality assurance programme. The supplier will continue to offer spare parts (e.g. gaskets) for the pumps under their quality assurance programme for the chemical industry.	The licensee continues to purchase spare parts for the safety class 2 pumps, but now as commercial-grade items at a lower cost. The licensee dedicates the spares by performing its own testing of the parts (according to a sampling plan) in order to accept the commercially manufactured parts for use in the safety class 2 application.
A supplier of a high-quality industrial grade items is ready and willing to undergo a quality assurance audit by the customer but does not accept hold points and oversight during every production run.	The licensee utilizes commercial-grade dedication acceptance method 2 to perform a performance-based assessment of the supplier to gain adequate confidence that the supplier is controlling the critical characteristics of the items sufficiently. The licensee references the assessed quality management system (e.g. document identifiers and revision levels) in each purchase order and requests information if changes to key procedures or processes are made.

Situation in the supply chain (hypothetical scenario)	**Licensee reaction** (potential resolution using this Guideline)
A supplier of high-quality digital process controllers, which are desired to support the main safety functions at a nuclear waste encapsulation facility. The controllers were developed according to the process industry standard IEC 61511 and have a Safety Integrity Level (SIL) 3 certification from a certification body signatory to the International Accreditation Forum (IAF).	The licensee performs dedication to accept the controllers. The licensee follows the supplementary dedication guidance on accepting commercial-grade digital equipment [12] to take credit for the existing SIL 3 certification which demonstrates reliability and risk reduction.

5 Standardization

This Guideline has been developed to create a basic mutual understanding of a quality assurance methodology for the use of high-quality industrial grade items in European nuclear installations. It aims to be the foundation from which nuclear licensees, suppliers and third parties would to be able to develop their own processes and procedures on a voluntary basis. Standardization of the structure and contents of documentation related to dedication can bring benefits to dedication entities and suppliers alike. A set of standardized templates reduces administrative effort within organizations implementing dedication and makes understanding dedication-related documentation across the industry more feasible.

5.1 Template - Technical Evaluation and Dedication Plan

This generic technical evaluation and dedication plan template can assist personnel performing planning dedication to ensure that all important aspects of the activity have been addressed. The following template is developed based on good practice and are adapted from existing guidance on dedication so that exchange between dedicating entities might be made facilitated. [45] It should be adapted for use as necessary within a dedicating entity's individual organization.

SECTION A ITEM DESCRIPTION

MATERIAL NO:	
NOUN IDENTIFIER:	
MANUFACTURER NAME:	MANUFACTURER MODEL / PART / CATALOG NUMBER(S)

SECTION B END USE / PARENT / HOST EQUIPMENT INFORMATION

Note: If the specific end-use(s) / plant applications are not known, complete Section C of this form in lieu of Section B prior to proceeding.

☐ Not Applicable (Section C Completed Below)

EQUIPMENT ID (TAG) NUMBERS OR DESCRIPTION OF ITEM USAGE:	
PARENT COMPONENT/HOST DESCRIPTION:	
FUNCTIONAL SAFETY CLASS OF COMPONENT / HOST:	BASIS / SOURCE:
☒ Safety-Classified ☐ Non-Safety Classified (If non-safety, item is not a candidate for dedication)	
IDENTIFICATION OF PARENT COMPONENT/HOST EQUIPMENT FUNCTION(S)	

FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
☐ Active ☐ Passive		
☐ Active ☐ Passive		

PARENT COMPONENT/HOST EQUIPMENT IS (CHECK ALL THAT APPLY):	
☐ QUALIFIED	
☐ CLASS 1E	
☐ SEISMIC CLASS 1	
☐ OTHER: (see below)	

SECTION C ALLOWABLE USAGE

Only complete Section C when specific end-use of the item being dedicated is unknown.

☐ Not Applicable (Section B Completed Above)

Is the item being dedicated a commodity or standard item designed and constructed in accordance with an industry standard?	☐ Yes ☐ No
IF "YES", LIST THE STANDARD(S) BELOW	
LIST FUNCTIONS AND/OR APPLICATIONS CONSIDERED WHEN COMPLETING THIS EVALUATION	

EQUIPMENT QUALIFICATION CONSIDERATIONS / LIMITATIONS (CHECK ALL THAT APPLY):	
CONSIDERATION	QUALIFICATION BASIS / LIMITATIONS OF USE:
☐ ENVIRONMENTAL QUALIFICATION	
☐ SEISMIC QUALIFICATION	
☐ OTHER: (see below)	

SECTION D ITEM INFORMATION

ITEM DESCRIPTION:	
SAFETY CLASS OF ITEM:	BASIS / SOURCE:
☐ Safety-Classified ☐ Non-Safety Classified (If non-safety, item is not a candidate for dedication)	
IDENTIFICATION OF ITEM FUNCTION(S)	

FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
☐ Active ☐ Passive		
☐ Active ☐ Passive		

Item (Check All That Apply)	
Required to undergo equipment qualification or type testing	☐
Classified as Class 1E	☐
Required to comply with a nuclear pressure vessel code	☐
(Other's as applicable)	
Notes:	

SECTION E ELIGIBLITY FOR DEDICATION

Is the item eligible for dedication in accordance established rules? If the answer is no, this item cannot be dedicated.	☐ Yes ☐ No
BASIS FOR ELIGIBILITY	

SECTION F FAILURE MODES / MECHANISMS AND EFFECTS ANALYSIS (OPTIONAL)

CREDIBLE FAILURE MODE/MECHANISM	EFFECTS ON SYSTEM/COMPONENT FUNCTION
BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)	

CREDIBLE FAILURE MODE/MECHANISM IN USE	EFFECTS ON SYSTEM/COMPONENT FUNCTION
BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)	

SECTION G OPERATING EXPERIENCE / HISTORICAL PERFORMANCE INFORMATION

SOURCES REVIEWED AND RESULTS

SECTION H IDENTIFICATION ATTRIBUTES

IDENTIFICATION ATTRIBUTES	DESCRIPTION OF INSPECTION	ACCEPTANCE CRITERIA
e.g. Manufacturer		
e.g. Serial number		

SECTION I CRITICAL CHARACTERISTICS

CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
DESCRIPTION OF SAMPLING PLANS (if "see below" is written in the sampling plan column above)				
SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / BASIS FOR SELECTION ACCEPTANCE CRITERIA				

BASIS FOR SELECTION OF SAMPLING PLANS (IF SAMPLING PLANS ARE USED)

SECTION J REFERENCES

DOCUMENT / SOURCE	REVISION / DATE	COMMENTS

SECTION K REVIEW AND APPROVAL

Prepared by: ______________________ Date: ____________

Reviewed by: ______________________ Date: ____________

5.2 Template - Dedication Review Checklists

Checklists can assist personnel performing dedication to ensure that all important aspects of the activity have been addressed. The following checklists are developed based on good practice. They should be adapted for use as necessary within a dedicating entity. Checklists have been adapted from [45].

5.2.1 Technical Evaluation

ID	Criteria – Technical Evaluation	Yes	No	N/A
1	End-use application or scope of application of the item is identified	☐	☐	☐
2	Safety function(s) is(are) identified and functional safety classification is complete and includes active and passive safety functions as applicable	☐	☐	☐
3	Service conditions/requirements such as seismic, environmental, design code, etc. are identified	☐	☐	☐
4	A review of pertinent technical information has been performed	☐	☐	☐
4a	▪ Supplier technical information such as technical manuals, drawings, and so forth	☐	☐	☐
4b	▪ Available operating experience	☐	☐	☐
5	A failure modes and effects analysis (FMEA) has been performed to identify critical characteristics (for example, in cases where original design information / requirements are not available)	☐	☐	☐
5a	▪ The FMEA addresses failure modes/mechanisms in the applications for which the item is intended	☐	☐	☐
6	Critical characteristics are identified and address:	☐	☐	☐
6a	▪ Important physical, performance and dependability characteristics which have a direct effect on the item's ability to perform it intended safety function(s)	☐	☐	☐
6b	▪ Active and passive safety functions	☐	☐	☐
6c	▪ Ability to perform safety functions in all design basis conditions (e.g. environment, seismic, electromagnetic interference etc.)	☐	☐	☐
6d	▪ When verified, the critical characteristics selected will provide confidence that the item will perform it's intended safety function(s)	☐	☐	☐
6e	▪ The basis for selection of critical characteristics is documented	☐	☐	☐
7	An appropriate acceptance method is identified for each critical characteristic	☐	☐	☐
8	Acceptance criteria including appropriate tolerances are identified for each critical characteristic	☐	☐	☐

5.2.2 Method 1 – Special Tests and Inspection

ID	Checklist – Method 1	Yes	No	N/A
1	Special tests or inspections are conducted after the item(s) have been delivered	☐	☐	☐
2	▪ Special tests and inspections are conclusive enough to verify the characteristics they are intended to verify	☐	☐	☐
4	Special tests and inspections are documented in a plan or checklist that includes:	☐	☐	☐
4a	▪ Test methods and inspection techniques	☐	☐	☐
4b	▪ Verification of the identified critical characteristics consistent with the acceptance criteria in the technical evaluation	☐	☐	☐
4c	▪ Documentation of the inspections, tests, and results (actual values recorded)	☐	☐	☐
5	When sampling plans are employed:	☐	☐	☐
5a	▪ An adequate technical basis for the sampling plan selected is documented (factors such as lot homogeneity, complexity of the item, extent of traceability, experience with the supplier/item, etc.)	☐	☐	☐
6	When post-installation testing is employed:	☐	☐	☐
6a	▪ Measures are in place to assure post-installation testing is not waived	☐	☐	☐
6b	▪ The host equipment or system is not declared functional or operational until the dedication is complete	☐	☐	☐

5.2.3 Method 2 – Performance-based Assessment

ID	Checklist – Method 2	Yes	No	N/A
1	A performance-based assessment was conducted to verify the supplier implements adequate programmatic controls over the specific critical characteristics and items identified in the assessment plan	☐	☐	☐
2	The results of the performance-based assessment are clearly documented in the assessment plan/report	☐	☐	☐
3	The supplier's controls are documented in the manuals, processes, procedures or work instructions identified in the completed assessment report	☐	☐	☐
4	Applicable supplier controls are invoked in the procurement documents for each order (for example, by referencing document number and revision)	☐	☐	☐
5	Certification to the supplier controls (typically in the form of a certificate of conformance) invoked is also a requirement in the procurement document	☐	☐	☐
5a	▪ Documentation including the certification is verified during the acceptance process	☐	☐	☐
6	Critical characteristics that were determined not to be adequately controlled during the assessment are verified by other means according to the dedication plan	☐	☐	☐
7	Measures are in place to ensure dedication is based upon a valid, current assessment	☐	☐	☐
8	If items are provided by a distributor, the distributor was assessed or a requirement to drop-ship from the location assessed is included in the procurement document	☐	☐	☐

5.2.4 Method 3 – Source Verification

ID	Checklist – Method 3	Yes	No	N/A
1	Source verification activities are controlled by a documented plan that includes the critical characteristics to be verified	☐	☐	☐
2	Appropriate hold points are included in the documented plan and are communicated to the supplier in procurement documents	☐	☐	☐
3	The source verification witnesses activities performed on the actual items that will be shipped	☐	☐	☐
4	The results of the source verification are clearly documented in the source verification plan/report	☐	☐	☐

5.3 Template - Documenting Acceptance Activities

5.3.1 Method 2 – Performance-based Assessment

Performance-based Assessment Summary and Checklist
GENERAL INFORMATION

SUPPLIER INFORMATION		
SUPPLIER ID:		
SUPPLIER:		
ADDRESS:		
CITY:	POSTAL CODE:	COUNTRY:
TELEPHONE NUMBER:		EMAIL:
PRODUCT/SERVICE:		

SUPPLIER CONTACTS		COMPANY WEBSITE:
SENIOR COMPANY MANAGER:	TITLE: E-MAIL:	PHONE:
SENIOR QUALITY MANAGER:	TITLE: E-MAIL:	PHONE:

ASSESSMENT INFORMATION	
ASSESSMENT ID NO.:	ASSESSMENT DATES:
SUPPLIER'S PROGRAMME DOCUMENT(S):	REVISION/DATE:

ASSESSMENT TEAM INFORMATION				
ASSESMENT TEAM	NAME	PHONE	EMAIL:	CHECKLIST SECTIONS ASSESSED
TEAM LEADER				
TEAM MEMBER				
TECHNICAL SPECIALIST (SPECIFY DISCIPLINE)				

ASSESSMENT TEAM LEADER: ______ DATE:

CRITICAL CHARACTERISTICS

PRODUCT/ITEM (specify): ______

CC NO.	CRITICAL CHARACTERISTICS (CC)TO BE EVALUATED	ACCEPTANCE CRITERIA	SAT./ UNSAT.	REFERENCE CHECKLIST FIGURE

CONCLUSIONS
Do the supplier's quality controls adequately address all identified critical characteristics? Yes ☐ No ☐ (Explain any No responses)

CRITICAL CHARACTERISTICS VERIFICATION

PRODUCT / ITEM / SERVICE:

CRITICAL CHARACTERISTIC (CC)	METHOD OF CC CONTROL AND ASSOCIATED CHECKLIST ITEM(S)	ITEM REVIEWED AND WORK ORDER NO.	CONTROLLING PROCEDURE AND REV./DATE	PERSONNEL NAME/STAMP	ID NUMBER OF M&TE USED CALIBRATION CURRENT (Yes/No)

5.3.2 Method 3 – Source Verification

Source Verification Worksheet **GENERAL INFORMATION**	
SOURCE VERIFICATION NUMBER:	
SOURCE VERIFICATION DATE (PLANNED):	
SOURCE VERIFICATION DATE (ACTUAL):	
SUPPLIER ID:	
SUPPLIER:	
ADDRESS:	
PURCHASE ORDER NUMBER:	
PRODUCT(S) OR TYPE OF PRODUCT:	

SOURCE VERIFICATION PLAN	
SOURCE VERIFICATION PLAN DESCRIPTION: Describe the activity to be witnessed. Describe the acceptance criteria. Describe if the activities will be witnessed according to a sampling plan. If so, reference the sampling plan or describe it here.	
PREPARED BY:	
DATE:	
APPROVED BY:	
DATE:	

SOURCE VERIFICATION ACTIVITY	
ITEM NUMBER:	
ACTIVITIY BEING WITNESSED:	
SOURCE VERIFICATION REPORT:	
RESULTS OF WITNESSING:	
NON-CONFORMANCE REPORT REFERENCE.	
ATTACHMENTS OR REFERENCES:	
INVOLVED EQUIPEMNT:	
INOVLVED PERSONNEL:	
WITNESSING PERFORMED BY:	
DATE:	

6 Condensed Examples

The following are real-world examples from a European nuclear power plant's dedication programme. [46] Only limited information is provided for each example in an effort to provide the reader with a basic introduction to dedication. Safety functions, critical characteristics, chosen acceptance methods and sampling plans are presented for three items which were dedicated and went on to be used in safety-classified applications in a nuclear power plant. The full dedication plans for each example contain significantly more information and description of engineering justifications. Complete examples can be found in Section 7.

6.1 Fuse

Item Description	FUSE NEK Part Number: FNM-1
Supplier/Manufacturer	LICO/BUSSMANN
Supplier/Manufacturer Part Number	FNM-1
End-use(s)	125 VDC Panels No. DCT%
Quantity of items in the lot being dedicated	400

Identification characteristics:

Safety Function

The fuse must carry the design basis load current(s) without interruption. Interruption of the current would adversely affect the function of any safety-classified equipment downstream of the fuse. Additionally, the fuse may be required to isolate a fault or overload condition to prevent degradation of the 1E circuit.

Critical Characteristics

Critical Characteristic	Acceptance Criteria
Overall length (Dimension)	38.1mm ± 0.76mm
Outside diameter of ferrule (Dimension)	10.3mm ± 0.15mm
Current carrying capacity	110% rated current (15 min. minimum)
Current clearing time	135% rated current (60 min.) 200% rated current (2 min.)
Resistance	0.35 Ω - 0.45 Ω

Acceptance Methods and Sampling Plan

Acceptance Method 1 was chosen to verify all critical characteristics.

Sampling Plan

Marking and Identification	100%
Dimensions	32 of 400
Current carrying capacity	32 of 400
Current clearing time	6 of 400
Resistance	100%

Tests and inspection were performed in accordance with the sampling plan and 2 fuses were found with failures (100% inspections - lose ferrule and resistance out of tolerances). These 2 fuses were rejected.

6.2 Diaphragm

Item Description	DIAFLOTE DIAPHRAGM NEK Part Number: BR100DIA
Supplier/Manufacturer	SAVA-KRANJ
Supplier/Manufacturer Part Number	BR100DIA
End-use(s)	BRIOOTNK-001 & 002
Quantity of items in the lot being dedicated	2

Safety Function

Diaphragm must prevent air from dissolving in the water and prevents the hydrogen and fission gases in the water from mixing with the air.

Critical Characteristics

Critical Characteristic	Acceptance Criteria
Reinforcement material chemical composition	Polypropylene
Coating compound chemical composition	Natural Rubber 75-95 MV
Total weight	1668 ± 170 g/mE2
Gauge/thickness	1.9 ± 0.24 mm
Tensile strength	Min. 1325x880 N/5cm
Gas permeability (He)	Less than 4x10E-4 mbar l/s
Configuration/dimensions	Per manufacturer drawing #66864-502
Leak test	P=30cm v.st. const. per 4h

Acceptance Methods and Sampling Plan

Acceptance Method 2 and 3 were chosen to verify all critical characteristics.

All Critical Characteristics have been verified on 2 purchased items - sample 100%.

All purchased items were manufactured in accordance with the technical specification and applicable procedures for fabrication, testing and inspection. All test/inspections reports and results were accepted and in accordance with original design parameters.

7 Critical Characteristics Examples

7.1 Instrument air valve

Item: instrument valve 25.4 mm NPS.
Safety function: the valve must retain pressure, remain in its configuration (open or closed), and maintain structural integrity during and after design basis events.

Instrument air valve - Example critical characteristics adapted from EPRI 3002002982				
CC ID	Critical Characteristic	Description of Acceptance Activity	Sampling Plan	Acceptance Criteria
1	Configuration	Visual	100%	Consistent with drawing XXX Rev. X
2	Materials: Body Bonnet Stem Packing Nut (drawings attached to dedication plan)	Alloy analyzer or similar	Reduced	316 Stainless Steel
3	Dimensions: a. End connection b. Max height (inlet centerline to top of hand wheel with valve fully open) c. Bottom of valve to inlet centerline d. Hand wheel diameter e. Valve length f. (drawings attached to dedication plan)	a. Visual and direct measurement b. Direct measurement c. Direct measurement d. Direct measurement e. Direct measurement f. Direct measurement	100%	Tolerances per dimensional measurement instruction XXX Rev. X unless otherwise noted.

Instrument air valve - Example critical characteristics adapted from EPRI 3002002982				
CC ID	Critical Characteristic	Description of Acceptance Activity	Sampling Plan	Acceptance Criteria
				1. 0.855 +/- 0.050" (0.5 inch NPS) socket weld both inlet and outlet. See Note 1. 2. 3.59375 (3-19/32) inches 3. 0.625(5/8) inches 4. 2.375 (2-3/8) inches 5. 2.5 (2-1/2) inches Note 1: Dimensions of valve socket welded end ports is per ASME B16.11-2009.
4	Pressure integrity	Shell test. Using water or gas, pressure test valve in the partially open position to at least 62 bar for at least 10 minutes.	100%	Visually detectable leakage through the pressure boundary walls (body, bonnet, body/bonnet bolting) is not acceptable.
5	Disc integrity	Shell leak test. Using water, pressure test the valve in the closed position to at least 45.5 bar for 1 minute. OR Pressure test the valve with nitrogen to a minimum of 5.5 bar for at least 1 minute.	100%	Maximum allowable leakage is 5mL/h of liquid or 1.5 L/h of gas.

7.2 Terminal Lug

Item: connector, copper, terminal, ring tongue 16-14 AWG, #6 stud, PISG, blue stripe, PVF2 insulated.
Safety function: the terminal lug must maintain circuit integrity in both power and signal applications.

Terminal lug - Example adapted from EPRI 3002002982					
CC ID	Critical Characteristic	Acceptance Method	Description of Acceptance Activity	Sampling Plan	Acceptance Criteria
1	Dimensions	2	Current performance-based assessment verifies critical controls are in place to assure dimensions of the lug are controlled in accordance with design requirements.	N/A	Certification received from supplier for the purchase order indicates dimensions were controlled in accordance with supplier statistical process control instruction XXX Rev. X and XXX Rev. X.
2	Base Material	2	Current performance-based assessment verified critical controls are in place to assure base copper material is controlled in accordance with design requirements.	N/A	Certification received from supplier for the purchase order indicates base material was verified in accordance with supplier material inspection instruction XXX Rev. X and controlled per procedure XXX Rev. X.
3	Plating Material	2	Current performance-based assessment verified critical controls are in place to assure plating materials are controlled in accordance with design requirements.	N/A	Certification received from supplier for the purchase order indicates plating material was verified in accordance with supplier inspection instruction XXX Rev. X and controlled per procedure XXX Rev. X
4	Plating thickness and consistency	2	Current performance-based assessment verified critical controls are in place to assure plating is performed in accordance with design requirements.	N/A	Certification received from supplier for the purchase order indicates application of plating is controlled in accordance with supplier plating instruction XXX Rev. X.
5	Insulation Material	1	Material verification using infrared spectroscopy.	Normal	Spectral match with library spectra for insulation material.
6	Insulation Dielectric Strength	1	Dielectric resistance test at twice rating (+100VDC).	Normal	> 1600 VDC, no breakdown indicated

7.3 Air actuated ball valves

Item: air actuated on/off ball valves in accordance with ASME B16.34.
Safety functions: maintain pressure/confinement boundary (passive), return to the prescribed state on loss of pneumatic pressure by maintaining isolation for fail closed valves or maintaining fully open position for fail open valves (active), limit switches must provide an open or close indication for valves (active).

Air actuated ball valves – Example adapted from DOE-HDBK-1230-2019

CC ID	Critical Characteristic	Item	Acceptance Method	Description of Acceptance Activity	Sampling Plan	Acceptance Criteria
1	Material Chemistry	Valve: Body & End Fitting	1	Destructively examine material chemistry. Perform optical emission spectroscopy (OES) or wet chemistry equivalent.	EPRI TR-017218 Table 2-2	ASTM A351 / ASTM A479 Gr. CF8M / Gr. S31603 % weight / % weight C,0.08 max / C,0.030 max Mn, 1.50 max / Mn, 2.00 max Si, 1.50 max / P, 0.045 max S, 0.040 max / S, 0.030 max P, 0.040 max / Si, 1.00 max Cr, 18.0-21.0 / Cr, 16.0 – 18.0 Ni, 9.0-12.0 / Ni, 10.0 – 14.0 Mo, 2.0-3.0 / Mo, 2.00 – 3.00 (left column OR right column) Material selection documented in supplier drawings (provide drawing number)
2	Material Chemistry	Valve: Ball	1	Destructively examine material chemistry. Perform optical emission spectroscopy (OES) or wet chemistry equivalent.	EPRI TR-017218 Table 2-2	ASTM A479 316L (UNS S31603) (% weight): C, 0.030 max Mn, 2.00 max P, 0.045 max S, 0.030 max Si, 1.00 max Cr, 16.0-18.0 Ni, 10.0-14.0 Mo, 2.00 – 3.00 Material selection documented in supplier drawings (provide drawing number)
3	Material Chemistry	Valve: Seat	1	Destructively examine material chemistry. Perform Fourier Transform Infrared Spectroscopy (FTIR).	EPRI TR-017218 Table 2-2	Verify valve seat is Virgin TFM using FTIR Material selection documented in supplier drawings (provide drawing number)

Air actuated ball valves – Example adapted from DOE-HDBK-1230-2019

CC ID	Critical Characteristic	Item	Acceptance Method	Description of Acceptance Activity	Sampling Plan	Acceptance Criteria
4	Material Chemistry	Valve: Studs for Body/End Fitting Flange	1	Destructively examine material chemistry. Perform optical emission spectroscopy (OES) or wet chemistry equivalent.	EPRI TR-017218 Table 2-2	ASTM A 193 Gr. B8M Class 2 (% weight) C, 0.08 max Mn, 2.00 max P, 0.045 max S, 0.03 max Si, 1.00 max Cr, 16.0 – 18.0 Ni, 10.0 – 14.0 Mo, 2.00 – 3.00 Material selection documented in supplier drawings (provide drawing number)
5	Material Chemistry	Valve: Nuts for Body/End Fitting Flange	1	Destructively examine material chemistry. Perform optical emission spectroscopy (OES) or wet chemistry equivalent.	EPRI TR-017218 Table 2-2	ASTM A 194 Gr. 8M (% weight) C, 0.08 max Mn, 2.00 max P, 0.045 max S, 0.030 max Si, 1.00 max Cr, 16.0 – 18.0 Ni, 10.0 -14.0 Mo, 2.00 – 3.00 Material selection documented in supplier drawings (provide drawing number)
6	Material Chemistry	Valve: Actuator: Pinion	1	Destructively examine material chemistry. Perform optical emission spectroscopy (OES) or wet chemistry equivalent.	EPRI TR-017218 Table 2-2	ASTM A582 Gr. 303 (UNS S30300) (% weight): C, 0.15 max Mn, 2.00 max P, 0.20 max S, 0.15 min Si, 1.00 min Cr, 17.0-19.0 Ni, 8.0 -10.0
7	Material Chemistry	Actuator: Fasteners (Stop bolts, stop bolt washers, stop bolt retaining nuts, end cap screws)	1	Destructively examine material chemistry. Perform optical emission spectroscopy (OES) or wet chemistry equivalent.	EPRI TR-017218 Table 2-2	BS 6105, Gr. A2-70 (% weight) C, 0.08 max Si, 1.0 max Mn, 2.0 max P, 0.05 max S, 0.03 max Cr, 17.0-20.0 Ni, 8.00 – 10.00

Air actuated ball valves – Example adapted from DOE-HDBK-1230-2019

CC ID	Critical Characteristic	Item	Acceptance Method	Description of Acceptance Activity	Sampling Plan	Acceptance Criteria
8	Material Chemistry	Actuator: Springs	1	Destructively examine material chemistry. Perform optical emission spectroscopy (OES) or wet chemistry equivalent.	EPRI TR-017218 Table 2-2	BS EN 10270-2 Gr. VDSiCr / TDSiCr (% mass) C, 0.50 -0.60 Si, 1.20-1.60 Mn, 0.50 0.90 P, 0.025 max S, 0.020 max Cu, 0.10 max Cr, 0.50-0.80
9	Material Chemistry	Actuator: Body	1	Destructively examine material chemistry. Perform optical emission spectroscopy (OES) or wet chemistry equivalent.	EPRI TR-017218 Table 2-2	Confirm that the actuator body is composed of aluminum
10	Material Chemistry	Actuator: Pistons and End Caps	1	Destructively examine material chemistry. Perform optical emission spectroscopy (OES) or wet chemistry equivalent.	EPRI TR-017218 Table 2-2	Confirm that the actuator pistons and end caps are composed of aluminium
11	Material Chemistry	Actuator: Piston Guides & Guide Bands	1	Destructively examine material chemistry. Perform Fourier Transform Infrared Spectroscopy (FTIR).	EPRI TR-017218 Table 2-2	Confirm that material is Nylon – Sebimid 6 L02 using FTIR
12	Material Chemistry	Mounting Brackets	1	Destructively examine material chemistry. Perform optical emission spectroscopy (OES) or wet chemistry equivalent.	EPRI TR-017218 Table 2-2	ASTM A554 Gr. 304 SS (% weight) C, 0.08 max Mn, 2.00 max P, 0.040 max S, 0.030 max Si, 1.00 max Ni, 8.0-11.0 Cr, 18.0 – 20.0 Material selection documented in supplier drawings (provide drawing number)
13	Mechanical Properties	Valve: Body & End Fitting		Destructively examine tensile strength, yield strength, and elongation, OR hardness.	EPRI TR-017218 Table 2-2	ASTM A351 Gr. CF8M: Tensile Strength, 70 ksi min Yield Strength, 30 ksi min Elongation, 30% min OR Hardness, 147 – 192 Brinell OR 79 - 90 HRB Material selection documented in supplier drawings (provide drawing number)

Air actuated ball valves – Example adapted from DOE-HDBK-1230-2019

CC ID	Critical Characteristic	Item	Acceptance Method	Description of Acceptance Activity	Sampling Plan	Acceptance Criteria
14	Mechanical Properties	Valve: Ball		Destructively examine tensile strength, yield strength, elongation, and reduction of area, OR hardness.	EPRI TR-017218 Table 2-2	ASTM A479 316L (UNS S31603): Tensile Strength, 70 ksi min Yield Strength, 25 ksi min Elongation, 30% min Reduction of Area, 40% min OR Hardness, 79 - 90 HRB Material selection documented in supplier drawings (provide drawing number)
15	Mechanical Properties	Valve: Studs for Body/End Fitting Flange		Destructively examine tensile strength, yield strength, elongation, and reduction of area, OR hardness.	EPRI TR-017218 Table 2-2	ASTM A193 Gr. B8M Class 2: Tensile Strength, 110 ksi min Yield Strength, 95 ksi min Elongation, 15% min Reduction of Area, 45% min OR Hardness, 20 - 35 HRC Material selection documented in supplier drawings (provide drawing number)
16	Mechanical Properties	Valve: Nuts for Body/End Fitting Flange	1	Destructively examine proof load OR hardness.	EPRI TR-017218 Table 2-2	ASTM A194 Gr. 8M Proof Load Requirements are scaled to diameter: Nominal Size, in. / Proof Load, lbf. 1/4" / 2380 5/16" / 3930 3/8" / 5810 7/16" / 7970 1/2" / 10640 OR Hardness, 126 - 300 Brinell, OR 60 HRB – 32 HRC Material selection documented in supplier drawings (provide drawing number)
17	Mechanical Properties	Actuator: Body	1	Destructively examine tensile strength and proof strength, OR hardness.	EPRI TR-017218 Table 2-2	EN 755-2, Grades 6005A T6, 6063 T6, or 6063 T66: Tensile Strength (Rm), 195 MPa min Proof Strength (Rp0.2), 160 MPA min OR Brinell Hardness, 75 HBW min
18	Mechanical Properties	Actuator: Pistons and End Cap	1	Destructively examine tensile strength and proof strength, OR hardness.	EPRI TR-017218 Table 2-2	BS EN 1706 Gr. EN AC-46500-D-F: Tensile Strength (Rm), 240 MPa min Yield Strength (Rp0.2), 140 MPa min OR Brinell Hardness, 8- HBW min

Air actuated ball valves – Example adapted from DOE-HDBK-1230-2019

CC ID	Critical Characteristic	Item	Acceptance Method	Description of Acceptance Activity	Sampling Plan	Acceptance Criteria
19	Mechanical Properties	Mounting Brackets	1	Destructively examine tensile strength, yield strength, and elongation, OR hardness.	EPRI TR-017218 Table 2-2	ASTM A554 Gr. 304 SS Tensile Strength, 75 ksi min Yield Strength, 30 ksi min Elongation, 35% min OR Hardness, 82 HRB min Material selection documented in supplier drawings (provide drawing number)
20	Pressure Integrity	Valve Assembly	3	A Source Verification Report will document supplier control over this critical characteristic. Verify the valve may withstand its design pressure.	EPRI TR-017218 Table 2-1	Successful completion of Source Verification Report by Project Procurement Engineering. Shell Integrity: Class 150 valves constructed of CF8M or S31603 shall be tested to a minimum pressure of 425 psig hydraulically or 350 psig pneumatically for a specified minimum duration. Class 300 valves constructed of CF8M shall be tested to a minimum pressure of 1100 psig hydraulically or 900 psig pneumatically for a specified minimum duration. Valves equal or less than 2" NPS shall be tested for a minimum of 15 seconds. Valves from 2 ½" to 6" NPS shall be tested for a minimum of 60 seconds. Valves greater than 6" NPS shall be tested for a minimum of 120 seconds. Seat Leakage: In accordance with API 598, all valves shall withstand a low pressure closure test of 60 to 100 psig for a specified minimum duration. Valves equal or less than 2" NPS shall be tested for a minimum of 15 seconds. Valves from 2-1/2" NPS and greater shall be tested for a minimum of 60 seconds.
21	Functional Performance	Valve and Actuator Assembly	3	A Source Verification Report will document supplier control over this critical characteristic. Verify the valve assembly fails to its intended position upon loss of pneumatic supply pressure. Verify the limit switch indicates correct position at both open and closed states.	EPRI TR-017218 Table 2-1	Successful completion of Source Verification Report by Project Procurement Engineering. Valves shall demonstrate that they will fail in their intended position upon loss of pneumatic pressure. Valves shall demonstrate that they indicate valve position.

8 Complete Examples

The following real-world examples are provided to demonstrate application of the dedication methodology. These examples should not be fully or partially copied by any dedicating entity. Engineering personnel with knowledge of the particular nuclear facility, item(s) being procured, and its intended application(s) should perform technical evaluations and acceptance activities on case-by-case basis.

The dedication examples below have been compiled in accordance with national regulations. The definitions and methodologies that have been used may differ from those provided in this Guideline. This is evidence of a need for harmonization in the dedication domain. However, the principles of dedication remain universal, and these examples illustrate good practice.

8.1 Semiconductor Relay

The real-world example presented below, provided by CEZ Company, is from a nuclear power plant and has been adapted to fit the technical evaluation and dedication plan template found in Section 5.

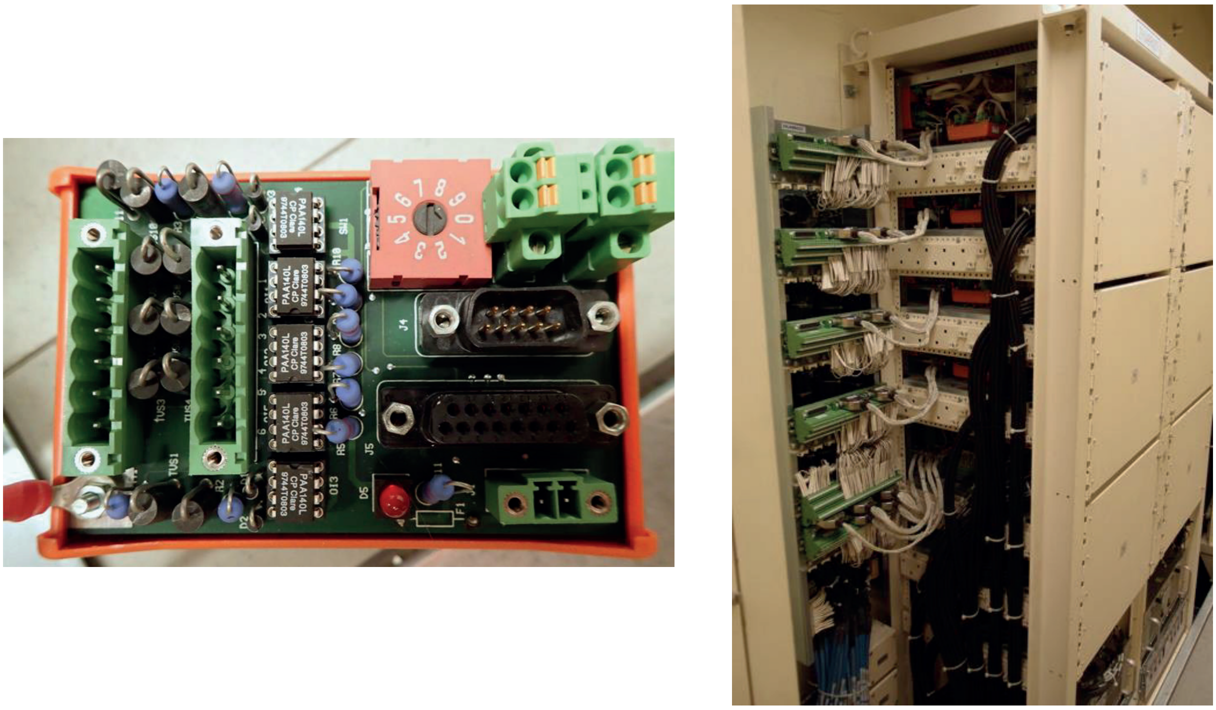


Figure 1. Photographs of four semiconductor relays used for galvanic separation on a printed circuit board Printed circuit board (left) and the board's installed location in an ISO rack cabinet (right).

SECTION A ITEM DESCRIPTION

MATERIAL NO:	PAA140, PAA140L
NOUN IDENTIFIER:	Semiconductor relay (OptoMOS Relay – normally open)
MANUFACTURER NAME:	MANUFACTURER MODEL / PART / CATALOG NUMBER(S)
IXYS Integrated Circuit Division	PAA140 Semi-conductor relay (OptoMOS Relay – normally open) PAA140L Semi-conductor relay (OptoMOS Relay – normally open)

SECTION B END USE / PARENT / HOST EQUIPMENT INFORMATION

Note: If the specific end-use(s) / plant applications are not known, complete Section C of this form in lieu of Section B prior to proceeding.

☐ Not Applicable (Section C Completed Below)

EQUIPMENT ID (TAG) NUMBERS OR DESCRIPTION OF ITEM USAGE:

Evaluated item is placed at most printed circuit boards. In case of failure of the evaluated item, it is not possible to ensure the item on the market in the required quality (meeting the requirements of Decree No. 358/2016 Coll.).

The evaluated item is a semiconductor relay (opto-relay) and serves the purpose of galvanic separation of parts connected with the control panel of the main control room (MCR) and emergency control room (ECR) on one side and with the respective control system or its parts on the other side.

- The equipment separates command signals brought from control buttons and changeover switches including feedback signals activating the signalization at modules placed in MCR and ECR (NPL2, NPL4).
- The equipment separates signals connected with signalization from the NPL (NPLSL) system as well as authorization signals for controlling by means of fix assigned controllers in MCR and ECR (ENABLE).
- The equipment separates signals connected with the LAMPTEST (LMPST) function including the lamp test function at FWC controllers placed in ECR.

Controllers in MCR and ECR are not interconnected with the control system by a direct conductor, but they are galvanically separated by means of the respective card that includes the evaluated item.

The input current is converted to infra-red light by means of a LED. This generated light is brought via optic fiber material to a light-sensitive photovoltaic cell that generates the voltage needed for switching the power output circuit. Optic fiber material is a dielectric insulation between specified parts. The galvanic separation limits spreading the unwanted overvoltage fault, if any, to the whole system.

PARENT COMPONENT/HOST DESCRIPTION:

Evaluated items are placed at following cards / in FWC controller.:
NPL2 – 8104-01-1, (5 pcs).
NPL4 – 8105-01-1 (7 pcs).
NPLSL – 8103-01-1 (42 pcs).
LAMP TEST – 8102-01-1 (24 pcs).
ENABLE – 8100- 01 -1 (4 pcs).
FWC controller (P/N 1U11898) (1 pc).

The FWC controller (P/N 1U11898) is placed on a panel of the emergency control room 1(2)HK47R004, 1(2)HK47R005, 1(2)HK47R006 (note: it is not placed in a frame or rack behind the panel).

FUNCTIONAL SAFETY CLASS OF COMPONENT / HOST:	BASIS / SOURCE:
☐ Safety-Class 1 (SC1) ☒ Safety-Class 2 (SC2) ☐ Safety-Class 3 (SC3)	Criterion of safety function (SF) category according to Decree No. 329/2017 Coll.

☐ Safety-classified (If non-safety, item is not a candidate for dedication) ☐ Equipment ☐ Component ☒ Part	1.3.16.1. I&C, which are necessary after reaching the stabilized subcritical state of the nuclear facility to achieve and maintain the safe state of the nuclear facility or to prevent the undesirable development of emergency conditions Control and condition signals related to the controller in MCR or ECR. see documentation – schematic diagram. TEM-I&C-0-MCR-0302 Sh. 1.2 TEM-I&C-0-MCR-0303 Sh. 1.2 TEM-I&C-0-MCR-0304 Sh. 1.2 TEM-I&C-0-MCR-0305 Sh. 1 TEM-I&C-0-MCR-0103 Sh. 1.2 TEM-I&C-0-MCR-0104 Sh. 1.2 LAMP TEST signalization at all FWC controllers in ECR

IDENTIFICATION OF PARENT COMPONENT/HOST EQUIPMENT FUNCTION(S)		
FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
☒ Active ☐ Passive	Electrical insulation	Galvanic separation of electric signals
☒ Active ☐ Passive	Status change	Switching of binary signals

PARENT COMPONENT/HOST EQUIPMENT REQUIREMENTS:		
REQUIREMENT	CRITERIA	DESCRIPTION/VERIFICATION
☒ Conformity assessment according to Decree No. 358/2016 Coll.	§12, odst. (6)	Checked by a staff member of the subdivision/dpt. of NPP Design Authority
☒ Specific requirements EQ	This concerns requirements for cards / controller, see B-1, which include the evaluated item. The following requirements related to endurance are applicable to the equipment. • against changes of external environment (temperature 15°C to 40°C, relative humidity 25 % to 95%). • against change of supply voltage level 187 V to 242 V and frequency 47 Hz to 53 Hz • against eventual seismic events represented by floor response spectra for 6.6 m level with 5% attenuation.	Specification of requirements for environment and seismicity is summarized in the document TEM-I&C-LICEN-020 Methodology for qualifying WELCO Supplied Safety Related Electrical Equipment for the NPP Temelin Instrumentation and Control Program. Checked by Specialist of NPP Engineering of Design Changes
☒ Seismic resistance	Resistance against seismic events represented by floor response spectra for 6.6 m level with 5% attenuation.	Specification of requirements for environment and seismicity is summarized in the document TEM-I&C-LICEN-020 Methodology for qualifying WELCO Supplied Safety Related Electrical Equipment for the NPP Temelin Instrumentation and Control Program. Checked by Specialist of NPP Engineering of Design Changes
☐ OTHER: (see below)		

SECTION C ALLOWABLE USAGE

Only complete Section C when specific end-use of the item being dedicated is unknown.

☒ Not Applicable (Section B Completed Above)

Is the item being dedicated a commodity or standard item designed and constructed in accordance with an industry standard?	☐ Yes ☐ No
IF "YES", LIST THE STANDARD(S) BELOW	
LIST FUNCTIONS AND/OR APPLICATIONS CONSIDERED WHEN COMPLETING THIS EVALUATION	
EQUIPMENT QUALIFICATION CONSIDERATIONS / LIMITATIONS (CHECK ALL THAT APPLY):	

CONSIDERATION	QUALIFICATION BASIS / LIMITATIONS OF USE:
☐ ENVIRONMENTAL QUALIFICATION	
☐ SEISMIC QUALIFICATION	
☐ OTHER: (see below)	

SECTION D ITEM INFORMATION

ITEM DESCRIPTION:

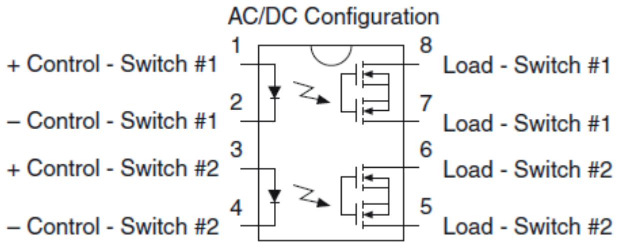
PAA140 - Dual Single-Pole, Normally open, OptoMOS Relays
Double optic semiconductor (OptoMOS) relay, placed in eight-pin housing of 1 cm x 0.5 cm approximate size.

Control current for activation max. 5mA, Control current for deactivation min. 0.4-0.7mA, Maximum output voltage 400 V, Maximum output current 250 mA rms/mADC, electric resistance at closed output 6 ohm, maximum 8 ohm, Parasitic current at open condition 1 microA, Insulating voltage between input and output 3750 Vrms.

PAA140L - Dual Single-Pole, Normally open, Current Limiting, OptoMOS Relays
Double optic semiconductor (OptoMOS) relay with current limitation, placed in eight-pin housing of 1 cm x 0.5 cm approximate size.

Control current for activation max. 5mA, Control current for deactivation min. 0.4-0.7mA, Maximum output voltage 400 V, Maximum output current 200 mA rms/mADC, electric resistance at closed output 10 ohm, maximum 13 ohm, Parasitic current at open condition 1 microA, Insulating voltage between input and output 3750 Vrms.

The optic semiconductor relay with current limitation limits the value of current passing through the output circuit in closed state.



SAFETY CLASS OF ITEM:	BASIS / SOURCE:

☐ Safety-Class 1 (SC1) ☒ Safety-Class 2 (SC2) ☐ Safety-Class 3 (SC3) ☐ Non-Safety Related (If non-safety, item is not a candidate for dedication)	See Section B on Parent Component/Host Description

IDENTIFICATION OF ITEM FUNCTION(S)		
FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
☒ Active ☐ Passive	Electrical insulation	Galvanic separation of electric signals
☒ Active ☐ Passive	Status change	Switching of binary signals

ITEM REQUIREMENTS		
REQUIREMENT	CRITERIA	DESCRIPTION/VERIFICATION
☒ Qualification of environment	This concerns documents proving properties of card / controller, see B-1, which include the evaluated item.	TEM-I&C-EQ-3783 SC Equipment Qualification Report for the Isolation Rack,
☒ Seismic resistance	This concerns documents proving properties of card / controller, see B-1, which include the evaluated item.	TEM-I&C-EQ-3783 SC Equipment Qualification Report for the Isolation Rack, TEM-I&C-EQ-3837 SC Equipment Qualification Report for Main and Emergency Control Room Standup Panel and Mounted Devices.
☒ EMC	This concerns documents proving properties of card / controller, see B-1, which include the evaluated item.	TEM-I&C-EQ-3783 SC Equipment Qualification Report for the Isolation Rack, TEM-I&C-EQ-3837 SC Equipment Qualification Report for Main and Emergency Control Room Standup Panel and Mounted Devices.
☐ OTHER: (see below)		

SECTION E ELIGIBLITY FOR DEDICATION

Is the item eligible for dedication in accordance established rules? If the answer is no, this item cannot be dedicated.	☒ Yes ☐ No

SECTION F FAILURE MODES / MECHANISMS AND EFFECTS ANALYSIS (OPTIONAL)

CREDIBLE FAILURE MODE/MECHANISM	EFFECTS ON SYSTEM/COMPONENT FUNCTION
Temperature	Although the temperature range recommended for storage is -40 °C to +125°C, reaching the limit values represents - figuratively speaking - a “stress” for the stored component that is degrading it. Incorrect storage temperature may cause function degradation. This degradation mechanism is effective to a very limited extent in case of the standard / usual way of storage in frost-free environment and in the packing recommended by the manufacturer.
Humidity	The evaluated item is of the MSL-1 moisture sensitivity level according to the international criteria of semiconductor component manufacturers IPS/JEDEC J-STD-020, i.e. the period is not limited, in which the component or evaluated item may be exposed to environment of 85% (30°C) relative humidity. Higher storage humidity may cause function degradation. This degradation mechanism is effective to a very limited extent in case of the standard / usual way of storage in frost-free environment and in the packing recommended by the manufacturer.

Electrostatic field	Evaluated item is ESD (Electrostatic Discharge Sensitive). This degradation mechanism is effective to a very limited extent, in case of storage in accordance with recommendations according to JESD-625 Requirements for Handling of Electrostatic Discharge Sensitive Devices, i.e. in antistatic packing.
BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)	
Source document for selection of degradation mechanisms during storage is attached to the plan.	

CREDIBLE FAILURE MODE/MECHANISM IN USE	EFFECTS ON SYSTEM/COMPONENT FUNCTION
Operational temperature	Although the temperature range recommended for storage is -40 °C to +85°C, reaching the limit values represents - figuratively speaking - a "stress" for the stored component that is degrading it. The evaluated item is part of card / controller, see B-1, that is situated in the main control room AE341 and the emergency control room AE052. Climatic parameters of both control rooms are +25°C with +55% humidity at normal as well as emergency conditions. (See the document of Nuclear Research Institute Rez, a. s. – division Energoprojekt Prague, Up-date of the list of equipment for qualification with regard to environment conditions and seismicity based on the Basic Design Amendment 414). The environment is basic 311 here according to CSN 330300. See CEZ_ME_1093 Inspection of Electric Equipment in NPP), free annex C – Book of Environment in Temelin NPP. This degradation mechanism influences the design position in MCR and ECR environment to a very limited extent only.
Humidity	Considerably high humidity during operation may cause function degradation. The evaluated item is part of card / controller, see B-1, that is situated in the main control room AE341 and the emergency control room AE052. AE052. Climatic parameters of both control rooms are +25°C with +55% humidity at normal as well as emergency conditions. (See the document of Nuclear Research Institute Rez, a. s. – division Energoprojekt Prague, Up-date of the list of equipment for qualification with regard to environment conditions and seismicity based on the Basic Design Amendment 414). The environment is basic 311 here according to CSN 330300. See CEZ_ME_1093 - Inspection of electric equipment in NPP, free annex C – Book of Environment in Temelin NPP. This degradation mechanism influences the design position in MCR and ECR environment to a very limited extent only.
EMC	The evaluated item is part of card / controller, see B-1, that is situated in the main control room AE341 and the emergency control room AE052. Electromagnetic field may cause function degradation at a design position in the environment of MCR and ECR. The effect of this degradation mechanism was verified within the qualification tests (see the documents TEM-I&C-EQ-3783 SC Equipment Qualification Report for the Isolation Rack, TEM-I&C-EQ-3837 SC Equipment Qualification Report for Main and Emergency Control Room Stand-up Panel and Mounted Devices).
BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)	
Source document for selection of degradation mechanisms during storage is attached to the plan.	

SECTION G OPERATING EXPERIENCE / HISTORICAL PERFORMANCE INFORMATION

SOURCES REVIEWED AND RESULTS
The total number of installed electronic opto-relays is 4142 pcs in both units. In total 4 pcs of defective NPL2 cards and 7 pcs of defective NPL4 cards, i.e. in total 11 defective electronic opto-relays were registered since 2001 according to information of the I&C administrator of System Engineers Section (SED). Calculation of MTBF for 19 years = 6935 days = 166440 hours $MTBF = \frac{total\ number\ of\ installed\ items\ x\ number\ of\ run\ hours}{number\ of\ faults}$ $MTBF_{NPP\ Temelin} = \frac{4142\ x\ 166440}{11} = 62672225.45 = 6.3\ x\ 10^{7} hrs$

SECTION H IDENTIFICATION ATTRIBUTES

IDENTIFICATION ATTRIBUTES	DESCRIPTION OF INSPECTION	ACCEPTANCE CRITERIA
Manufacturer/type	Visual	IXYX Integrated Circuits Division / PAA140, PAA140L
Production number/other identification symbol	Visual	Ddoes not exist

SECTION I CRITICAL CHARACTERISTICS

CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
Switching capability with adequate reliability (the switching capability is a dominant factor of transmitting the required signal through the galvanic separation that is part of this electronic component).	1, 2 & 4	The product/item reliability is indicated by MTBF parameter. The value of this calculated statistical quantity is specified for the DOL card of selected components in the document TEM-I&C LICEN-027 "Topical Report, I&C Reliability Analysis Report". The DOL card is placed in the same type of frame /rack placed right next to the frame where the evaluated item is placed in the environment of the main and emergency control rooms. DOL card reads the conditions of individual controllers and switches at control room panels; it means that it has similar function like the NPL2/4 card, at which the evaluated item is located. Value MTBFDOL=1.4 x 10^5 hrs.		Functional capability and parameters of the evaluated item are declared by catalogue sheet of the manufacturer and by operational experience in Temelin NPP.
Insulating property (the insulating capability of electronic component influences the capability of the whole module to prevent the spread of failure condition caused e.g. by short circuit).	1 & 3	The evaluated item is part of the card, see B-1. The manufacturer specified following maximum possible faulty levels of voltage during the qualification tests. The modules ENABLE, LAMP TEST of the controller are connected to internal circuits of control panels in MCR and ECR. The maximum possible failure voltage based on the analysis carried out within qualification tests is 30 V DC.		The manufacturer declares the value of 3750 Vrms for the insulating capability between input and output in the catalogue sheet of evaluated item.

Resistance against EMC impacts (the evaluated item is part of equipment, to which these requirements apply within its qualification).	3	Required EMC resistance is verified during qualification tests prepared in accordance with the requirements, see TEM-I&C-LICEN-021 Electromagnetic Compatibility Guidelines for Type Testing, by the system supplier. Evaluated item is part of the card / controller see B-1, the equipment was connected to testing panel provided with switches and signalization during the test. The signalization state was monitored during the simulation of EMC interference according to requirements of the testing procedure. The functionality of controllers and switches was verified between individual EMC tests. Fulfilling requirements is registered for cards placed in ISO rack in the document TEM-I&C-EQ-3783 SC Equipment Qualification Report for the Isolation Rack. Fulfilling requirements is registered for FWC controller in TEM-I&C-EQ-3837 SC equipment Qualification Report for Main and Emergency Control Room Stand-up Panel and Mounted Devices. (see Annex 7.,8.)		Evaluated item is part of the card / controller see B-1. Requirements for SC equipment as regards EMC are based on the document TEM-I&C-LICEN-021 Electromagnetic Compatibility Guidelines for Type Testing. The following requirements related to endurance are applicable to the equipment. • against electrostatic discharge (Contact Discharge 8kV). • against radiated high frequency electromagnetic field (10V/m frequency 20 MHz to 1GHz. • against fast electric transient phenomena / impulse groups (I/O Cables 2kV).
DESCRIPTION OF SAMPLING PLANS (if "see below" is written in the sampling plan column above)				
SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / BASIS FOR SELECTION ACCEPTANCE CRITERIA				

BASIS FOR SELECTION OF SAMPLING PLANS (IF SAMPLING PLANS ARE USED)

SECTION J REFERENCES

DOCUMENT / SOURCE	REVISION / DATE	COMMENTS
1.Catalogue sheet PAA140 – IXYS Integrated Circuit Division	DS-PAA140-R10	File attached to plan
2.Catalogue sheet PAA140L – IXYS Integrated Circuit Division	DS-PAA140L-R05	File attached to plan
3.Certificate ISO9001:2015	US09/74450	File attached to plan
4.Certificate TUV SUD Product Service	No. B 082667 0007 Rev.00.	File attached to plan
5a. Reliability Report (IXYS IC Division SSR-Form-A Relay Family by DIP Styla Package)	No. 2012-017, Date 2/27/18	File attached to plan
5b. Specification of MTBF from results of manufacturer's type tests	11/2019	File attached to plan
6.TEM-I&C-EQ-3791 Isolation Test Report for Isolation Modules.	Rev. 0 / May 2000	File attached to plan
7.TEM-I&C-EQ-3783 SC Equipment Qualification Report for the Isolation Rack.	Rev. 0 / June 2000	File attached to plan
8.TEM-I&C-EQ-3837 SC Equipment Qualification Report for Main and Emergency Control Room Stand-up Panel and Mounted Devices.	Rev. 1 / February 2001	File attached to plan
9.IXYS Integrated Circuits Division Counterfeit Parts Policy	Date 6/30/17	File attached to plan

SECTION K REVIEW AND APPROVAL

Prepared by:	Staff member of the System Engineers Section or Specialist of NPP Engineering of Design Changes
Reviewed by:	Head of the professional subdivision/dpt. of the author
Reviewed by	Head of Quality Control Dpt.
Approved by	Head of Section of System Engineers Section

8.2 Ring Tongue Terminal

The real-world example presented below, provided by URENCO, is from a nuclear fuel cycle facility and has been adapted to fit the technical evaluation and dedication plan template found in Section 5.

SECTION A ITEM DESCRIPTION

MATERIAL NO:	N/A
NOUN IDENTIFIER:	Ring Tongue Terminal
MANUFACTURER NAME:	MANUFACTURER MODEL / PART / CATALOG NUMBER(S)
Burndy LLC	Ring Tongue Terminal, 16-14 AWG, #8 - #10 Stud, Tin Plated Copper, Vinyl Supplier P/N: Insulated, Color Blue, P/N TP14-10 Bulk Packaging # BA 14E10, UL Listed

SECTION B END USE / PARENT / HOST EQUIPMENT INFORMATION

Note: If the specific end-use(s) / plant applications are not known, complete Section C of this form in lieu of Section B prior to proceeding.

☒ Not Applicable (Section C Completed Below)

EQUIPMENT ID (TAG) NUMBERS OR DESCRIPTION OF ITEM USAGE:		
PARENT COMPONENT/HOST DESCRIPTION:		
FUNCTIONAL SAFETY CLASS OF COMPONENT / HOST:		BASIS / SOURCE:
☐ Safety-Classified ☐ Non-Safety Classified (If non-safety, item is not a candidate for dedication) ☐ Equipment ☐ Component ☐ Part		
IDENTIFICATION OF PARENT COMPONENT/HOST EQUIPMENT FUNCTION(S)		
FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
☐ Active ☐ Passive		
PARENT COMPONENT/HOST EQUIPMENT REQUIREMENTS:		
REQUIREMENT	CRITERIA	DESCRIPTION/VERIFICATION
☐ OTHER: (see below)		

SECTION C ALLOWABLE USAGE

Only complete Section C when specific end-use of the item being dedicated is unknown.

☐ Not Applicable (Section B Completed Above)

Is the item being dedicated a commodity or standard item designed and constructed in accordance with an industry standard?	☒ Yes ☐ No
IF "YES", LIST THE STANDARD(S) BELOW	
UL 486A-486B 2013 Standard for Safety Wire Connectors UL 486E 2009 Equipment Wiring Terminals for use with Aluminium and/or Copper Conductors	
LIST FUNCTIONS AND/OR APPLICATIONS CONSIDERED WHEN COMPLETING THIS EVALUATION	
Commodity material CGDP (commercial-grade dedication plan) for the use of the referenced Ring Tongue Terminal in all applications where called for in approved Engineering documents, procedures and/or work plans. Used in all applications where called for in approved Engineering documents, procedures and/or work plans. This Ring Tongue Terminal is required to carry design current and maintain electrical circuit integrity. This is a passive safety function when used within safety-classified circuits. function when used within safety-classified circuits.	
EQUIPMENT QUALIFICATION CONSIDERATIONS / LIMITATIONS (CHECK ALL THAT APPLY):	

CONSIDERATION	QUALIFICATION BASIS / LIMITATIONS OF USE:
☐ ENVIRONMENTAL QUALIFICATION	
☒ SEISMIC QUALIFICATION	Compression lugs considered to be seismically rugged for nuclear application. Verification of the listed critical characteristics for acceptance is sufficient without requirement of seismic qualification needed.
☐ OTHER: (see below)	

SECTION D ITEM INFORMATION

ITEM DESCRIPTION:	
Ring tongue terminal 16-14 AWG, #8 - #10 Stud, Tin Plated Copper, Vinyl Insulated, Color Blue	
SAFETY CLASS OF ITEM:	BASIS / SOURCE:
☒ Safety-Classified ☐ Non-Safety Classified (If non-safety, item is not a candidate for dedication)	Called for in approved engineering documents.
IDENTIFICATION OF ITEM FUNCTION(S)	

FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
☐ Active ☒ Passive	Carry design current	This Ring Tongue Terminal is required to carry design current. This is a passive safety function when used within safety-classified circuits.
☐ Active ☒ Passive	Maintain electrical circuit integrity	This Ring Tongue Terminal is required to maintain electrical circuit integrity. This is a passive safety function when used within safetv-classified circuits.

SECTION E ELIGIBLITY FOR DEDICATION

Is the item eligible for dedication in accordance established rules? If the answer is no, this item cannot be dedicated.	☒ Yes ☐ No

SECTION F FAILURE MODES / MECHANISMS AND EFFECTS ANALYSIS (OPTIONAL)

CREDIBLE FAILURE MODE/MECHANISM	EFFECTS ON SYSTEM/COMPONENT FUNCTION
BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)	

CREDIBLE FAILURE MODE/MECHANISM IN USE	EFFECTS ON SYSTEM/COMPONENT FUNCTION
BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)	

SECTION G OPERATING EXPERIENCE / HISTORICAL PERFORMANCE INFORMATION

SOURCES REVIEWED AND RESULTS

SECTION H IDENTIFICATION ATTRIBUTES

IDENTIFICATION ATTRIBUTES	DESCRIPTION OF INSPECTION	ACCEPTANCE CRITERIA
Markings / Color	Visual Verification of the package and item marking will provide reasonable assurance that the item ordered is the item received.	Package/Box marked with following information: 16-14 (AWG), 8·10 (Stud Size), TP1410 (Part Number) or Bulk Packaging # BA 14E10, UL Listed. In addition, verify the terminal ring is physically marked with 16-14 with Blue Insulated Barrel.
Terminal lug marking	Visual	This item will be physically marked with the AWG size "16-14". The manufacturer's name will not be marked on the physical item. Verification of the manufacturer will be verified by the first identification attribute.

SECTION I CRITICAL CHARACTERISTICS

CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
Insulation material	1	Non-destructive	100%	Consistency of thickness, no surface voids or through wall deformity
Barrel inside diameter	1		EPRI-TR-017218-R1, Table 2-1 (Normal Plan)	Lug acceptance of 14 AWG wire
Stud size	1		EPRI-TR-017218-R1, Table 2-1 (Normal Plan)	0.204 Inch +/- 0.015 Inch
Ring diameter	1		EPRI-TR-017218-R1, Table 2-1 (Normal Plan)	0.312 Inch +/- 0.015 Inch
Plating material	1	Visual	100%	Tin plating (silver in colour) shall completely cover the surface of the conductor material.
Base material	1		EPRI-TR-017218-R1, Table 2-2 /Recommended Destructive Test and inspection Sampling Plan for Line-item/Single Product Manufacture Lot Formations.	Remove a section of the plating and verify the base material is copper in appearance.

DESCRIPTION OF SAMPLING PLANS (if "see below" is written in the sampling plan column above)

SAFETY FUNCTION(S) SUPPORTED / BASIS FOR SELECTION OF CRITICAL CHARACTERISTICS / BASIS FOR SELECTION ACCEPTANCE CRITERIA
The two most critical **dimensions** associated with this lug are stud size and AWG size applicability. Where higher power applications are used tongue thickness may be considered critical. However, since this part number is used on a maximum of 600 volts the tongue thickness is not considered a critical characteristic. Since the insulation of the lugs extends beyond the barrel, an alternate verification of AWG size is to ensure the lug accepts a conductor of the "Maximum" size when a range is given. This would adequately assure an acceptable inner barrel diameter. Verification of **insulation material** type is only required of those EQ applications for which there are no additional qualified insulations applied at installation. Verification of insulation material is not required for most non-EQ applications. For the location where these components are to be used; no environmental qualification exist. Therefore, the verification of insulation material type is not required. Due to the relative simplicity of terminal lugs and the minimum number of different base materials used in their construction (i.e. copper, brass, or aluminium), are easily distinguishable from one another by visual inspection. Verification of **base material** may be performed following the removal of a portion of the plating. Note: Removal of the plating material to verify base material is considered a destructive test. Verification of exact **plating material**, in most instances, is not critical for acceptance. Most manufactures only use tin plating, for UL listed lugs, with the exception of high temperature applications, which in most application is nickel plating. For the application at UUSA, no high temperature applications are required. Therefore, a visual inspection of the existence and uniformity (no base material showing) of tin plating is sufficient. Installation requirement: Crimping of the lug is a vital aspect of both its design as well as its ability to perform its intended safety function. Crimping pressure shall neither overstress nor understress the lug's barrel, and a controlled crimp is necessary to ensure the resulting termination is free of contamination, resistant to shock, and its tensile strength approaches that of the wire itself. This dedication is based on the assumption that maintenance incorporates specific plant approved document, procedure and/or work plan for the installation of this lug, which includes the use of proper calibrated crimper and reasonable inspections, to provide assurance that the lug is crimped in accordance with its design. The combination of the installation plan and the acceptance methods, as specified above, adequately assure that the lug meets its design requirements following final installation.

BASIS FOR SELECTION OF SAMPLING PLANS (IF SAMPLING PLANS ARE USED)
The different sampling sizes are based on EPRI-TR-017218-R1.

SECTION J REFERENCES

DOCUMENT / SOURCE	REVISION / DATE	COMMENTS
UL 486A-486B	2013	Standard for Safety Wire Connectors
UL 486E	2009	Equipment Wiring Terminals for use with Aluminium and/or Copper Conductors
QAPD	34a	Quality Assurance Program Description

SECTION K REVIEW AND APPROVAL

Prepared by: CGD Engineer

Reviewed by: Independent CGD Reviewer
Reviewed by QA Manager (or Designee) Reviewer
Approved by CGD Manager (or Designee)

9 Regulatory Approaches to Dedication

National law and regulations dictate requirements which nuclear licensees must comply with. Nuclear regulatory styles tend to rest somewhere on the spectrum between prescriptive and goal setting. Goal-setting regulation establishes outcomes to be achieved while prescriptive regulation describes in some detail the means and ways to be followed in order to achieve the desired objectives. [47] Some regulatory bodies publish non-binding guidance on how licensees can address requirements. Regulatory bodies might also endorse or conditionally endorse codes or standards as acceptable ways in which to comply with requirements.

The SSC quality assurance methodology described in this Guideline, known as Commercial-Grade Dedication, is applied by licensees and their suppliers in several regulatory regimes. Those regimes acknowledge the subject of dedication to varying degrees. National law, regulation or regulatory guidance might explicitly address the subject of dedication or might not depending on the country. In either case, the regulatory body possesses the authority to inspect the management system of nuclear licensees and thereby oversees the dedication programme of licensees.

This Section briefly describes the control and oversight of item dedication practices in selected countries.

9.1 U.S.

In the United States, items important to safety, called safety-related items or 'basic components,' are those which have been designed and manufactured under a quality assurance programme complying with 10CFR50 Appendix B or items which were not and have instead successfully completed the dedication process.

The term dedication has existed in the U.S. Code of Federal Regulations since 1979. The dedication methodology as applied in the United States has evolved over the last 40 years. In 1988 the first guideline on dedication, NP-5652 "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications," was published by the U.S. non-profit Electric Power Research Institute (EPRI), whose members include nuclear utilities. The objective of the guideline was to provide a guideline for procuring and using commercial grade items in safety related nuclear power plant applications. EPRI NP-5652 was conditionally endorsed by the U.S. Nuclear Regulatory Commission (NRC) in Generic Letter 89-02.

Today, the subject of dedication, its definition and description are found in 10CFR21 on "Reporting of Defects and Noncompliance."

> *Dedication. (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys[3]; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of*

[3] Referred to as performance-based assessments in this Guideline.

10 CFR Part 50, appendix B. The process is considered complete when the item is designated for use as a basic component.

(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component.

Regulatory Guide 1.164 "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants" issued June 2017 describes the methods which the U.S. NRC considers acceptable in meeting regulatory requirements for dedication of commercial-grade items and services used in nuclear power plants. In this Regulatory Guide, the U.S. NRC endorsed, in part, EPRI 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items In Nuclear Safety-Related Applications" (2014) with respect to commercial-grade dedication of items and services to be used as safety-related items in nuclear power plants. The U.S. NRC also publishes inspection procedure 43004 on the "Inspection of Commercial-Grade Dedication Programs."

9.2 Czech Republic

Starting in 2016 the Czech nuclear utility CEZ began developing and localizing a dedication methodology. CEZ prepared the CGD methodology in close cooperation with the State Nuclear Regulatory Authority (SUJB). The methodology was applied to pilot cases in which technical evaluations were performed for simple items such as cables, relays and breakers. Changes of nuclear regulations or guides were not necessary and the scope of ČEZ CGD programme today is implemented within the current Czech legal framework.

This methodology is applicable to parts only. The dedication of components and equipment is currently not allowed. CGD oversight is included to the SUJB standard inspections in the areas of management system, purchasing, modifications, safety assessment, operation experience feedback, quality assurance and technical safety and assessment and verification of conformity of safety-classified equipment.

9.3 Spain

The Spanish nuclear regulatory body CSN reviews licensees' dedication process and dedication plans as part of its inspection activities. The regulatory guide Guía de Seguridad 10.8 (Rev. 1) describes national standards UNE 73-403-95 and UNE 73-104-94 as adequately describing the criteria on which the use of commercial-grade components in safety-related applications should be based and the methodology to be followed, respectively. [13] [19] [20] The same regulatory guide describes EPRI-5652 "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications" as an acceptable alternative to UNE 73-104-94 under the condition that Acceptance Method 2 and Method 4 are not used alone to determine the suitability of a commercial-grade item.

Commercial-grade dedication has been widely used by Spanish nuclear licensees since the 1990's. Most dedication-related activities are outsourced to third parties.

9.4 Canada

In Canada, national regulation does not directly address dedication of items or services, nor does the Canadian nuclear regulatory body (CNSC) have a formal position on dedication. However, dedication is an acceptable practice and is performed in line with EPRI guidelines by third parties in Canada. Canadian nuclear licensees do not themselves perform dedication.

CSA N286-12 "Management system requirements for nuclear facilities" provides the licensee's fundamental verification criteria of the supply chain. While N286-12 does not directly address the dedication methodology, the CNSC staff has in the past concluded (on a case-by-case basis) that EPRI-5652 "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications" provided reasonable assurance that SSCs will perform their safety function(s).

The Canadian Standards Association (CSA) standard N299 "Quality assurance program requirements for the supply of items and services for nuclear power plants" is intended specifically for use between licensees and their suppliers. The N299 standard includes the subject of dedication. The CNSC supports the use of the N299 standard but does not mandate it.

9.5 South Korea

Dedicated items have been utilized in South Korean nuclear power plants since the 1990's when reactor vendors from the U.S. delivered electrical I&C devices and parts which had undergone the dedication process. Korea Hydro & Nuclear Power (KHNP), operator of the South Korean nuclear power plant fleet developed its own dedication programme in the early 2000's at the request of the national regulatory body. KHNP maintains processes for in-house and third-party dedication of commercial-grade items. Dedication is most often performed on bearings, fuses, capacitors and relays. New-build nuclear power plant projects in South Korea are also utilizing the dedication methodology.

Locally, the general dedication guideline EPRI NP-5652 as well as TR-106439 for digital equipment has been endorsed by the regulator and the Nuclear Safety Committee Notice No. 2018-2 defines commercial-grade item. The South Korean regulator published regulatory guide KINS/RG-N17.1. The dedication methodology can also be found in the Korean Electric Power Industry code on requirements for quality assurance programs of nuclear reactor facilities, KEPIC QAP-1.

9.6 Slovenia

A commercial-grade dedication programme has been in place at Krsko NPP in Slovenia since 1995. The Slovenia regulatory body, SNSA, regularly performs inspections of the Krsko NPP management system which includes the programme for the procurement and dedication of commercial grade items. The Krsko NPP management system complies with both 10CFR50 Appendix B and Slovenian national requirements. Being closely aligned with U.S. regulation, Krsko NPP is a member of the Nuclear Procurement Issues Corporation (NUPIC) for the purpose of participating in joint-utility supplier audits and performance-based supplier assessments (Method 2).

The subject of dedication is not addressed in national law (the 2017 Act) or in national nuclear regulation (Rules on radiation and nuclear safety factors (JV5) and Rules on operational safety of radiation and nuclear facilities (JV9)).

9.7 Romania

Based on a special nuclear requirement, a management system license issued by the national regulatory body, CNCAN, is required to supply items important to safety to Romanian nuclear facilities. In special cases, Cernavoda NPP is using dedication in lieu of the CNCAN supplier license to accept items for use in safety-classified applications. Dedication plans are issued and applied by Cernavoda NPP using internal expertise and tools. Romanian national nuclear law and standards did not require major changes to accommodate the dedication methodology since the dedication procedure is part of Cernavoda's authorized management system approved by the regulatory body.

Cernavoda NPP first issued a procedure for dedication in 2016. CNCAN reviews and approves the Cernavoda NPP dedication procedure on a regular basis as it does with any part of the licensee's management system. Quality plans are used by Cernavoda NPP for all safety-related deliveries. Quality plans describe the chronology of tests and/or inspections to be performed on the item(s) being procured as well as the processes and procedures guiding them. They are not unique to dedication but used for any safety-classified procurement. Quality plans for safety related products are approved by CNCAN (and by ISCIR in the case of pressure-retaining equipment or components, however, dedication is not applied to pressure-retaining equipment in Romania).

When acceptance activities are carried out during the manufacturing process, they are integrated into the quality plan approved by the client and nuclear regulator. In some instances, the dedication plan acts like a quality plan in terms of acceptance by the Cernavoda and CNCAN based on the established dedication procedure.

10 Joint-Utility Strategies

It is recommended that licensees across Europe who are planning to establish item dedication capabilities according to this Guideline:

- focus on harmonizing and standardizing the implementation of this Guideline between nuclear facilities and other dedicating entities;
- share and pool engineering resources to develop generic critical characteristics for various item types and typical technologies;
- seek and foster opportunities to jointly perform acceptance activities like performance-based assessments of common suppliers; and,
- promote meetings, workshops, conferences and other events where experience can be shared, training can take place and lessons learned can be exchanged.

This list is based on good practices from countries with successful and well-established dedication programmes. This section describes two possible joint-utility strategies which could be leveraged to increase the efficiency and effectiveness of the use of this Guideline across Europe.

10.1 Generic dedication plans for specific technologies

The European nuclear power plant fleet is comprised of only a handful of reactor types and for this reason it has many pieces of equipment in common, especially commodities or items important to safety of low safety significance.

This Guideline recommends the development of generic dedication plans for items, since the dedication of the same item at different nuclear facilities can differ only in relatively limited ways. Such generic dedication plans could be a strong basis for a dedicating entity developing their own site-specific plans, including defining acceptance criteria or selecting acceptance methods.

A nuclear facility, in adhering to its responsibility for safety, should use generic dedication plans only once its own engineers have evaluated such plans and confirmed that they are technically sound and applicable to the specifics of the facility application for the item. The selection of acceptance activities performed to verify each critical characteristic and their associated acceptance criteria (as applicable) are best chosen by each dedicating entity.

Application specifics to consider when using generic dedication plans would include:

- the item's safety function(s) in the intended application(s); and,
- the specifics associated with the intended installation environment including both seismic and environmental qualification requirements.

The structure of a generic dedication plan library could include a variety of common item types and sub-types, as well as typical applications and associated safety functions. Included in the library could be specific items from common suppliers.

10.2 Network for performance-based supplier assessments

Acceptance Method 2 is especially well-suited for cooperation between dedicating entities. A performance-based assessment of a supplier is performed in order to verify one or more critical characteristics of one or more items intended for dedication being procured from the supplier.

Benefits of cooperative performance-based assessment networks for licensees can include:
- efficient use of human capital;
- information sharing between licensees with common suppliers;
- reduction in costs associated with performing performance-based assessments; and,
- increased influence in interactions with suppliers.

Benefits of cooperative performance-based assessment networks for suppliers can include:
- consistent customer expectations;
- increased visibility in the marketplace; and,
- a unified 'voice of the customer' with respect to quality expectations.

Baseline requirements can be developed by cooperative performance-based supplier assessment networks for:
- minimum assessment team size and experience;
- assessment personnel initial qualification and ongoing training;
- developing an assessment plan; and,
- reporting assessment results.

Networks for performance-based supplier assessment efforts have been established for licensees and for members of the supply chain. A limited number of European licensees have joined these international groups. These efforts have been successful in capturing synergies and increasing efficiency for both dedicating entities and suppliers. Depending on local regulation, it may not always be possible to perform Acceptance Method 2 as a joint-utility activity.

11 Recommended Next Steps for the European Nuclear Industry

The following recommendations have been developed in the interest of promoting the implementation of this Guideline and ensuring the deployment of the dedication methodology among European nuclear licensees and within their supply chains is successful and sustainable.

The following steps are presented as good practice, in addition to the discussions in Section 2.1 and 2.2, for licensees interested in implementing this Guideline:

1. Determine needs: In order to determine if there is a need for a dedication programme in the first place, the licensee should review their supply chain situation, SSC sourcing needs and obsolescence issues. Based on an understanding of dedication gained through this Guideline, the licensee should be able to determine if there is a benefit or need to implement the methodology within their organization.

2. Analyse requirements: As a first concrete step towards establishing a dedication programme, the licensee should analyse the various requirements they impose on suppliers of items/services important to safety and the products/services themselves, especially those related to quality.
   - ⓘ These requirements may originate in laws, regulations, codes, standards or the licensee's own organizational practices.

3. Define applicability: As a part of developing a dedication process, the licensee should establish a clear understanding of the procurement scenarios in which they would like to use dedication. These 'use cases' can vary from organization to organization and are typically influenced by local law and regulation relating to the quality of items/services important to safety and their suppliers.

- The licensee can seek to learn more about established dedication programmes within Europe to better understand successful dedication use cases.
- The licensee may already recognize that their supply chain struggles to comply with certain requirements (e.g. a management system according to local nuclear regulation or quality-assurance expectations specific to the licensee's organization). These requirements may be good candidates for substitution.

4. Reach consensus: As a next step, licensees should, within their own organization and together with their local regulatory body, reach consensus on which typical requirements could be substituted by the dedication process (i.e. ensure the 'use cases' determined in the last step are acceptable to the regulator). Once the licensee and regulator have reached agreement on the use of the Guideline/dedication methodology, licensees are encouraged to develop their own processes and procedures according to the Guideline dedication methodology.
    - Consider performing a pilot project in which the regulator can act as an observer and provide feedback.
    - Consider approaching the regulator together with other local licensees who have interest in applying the Guideline/dedication methodology.

5. Engage suppliers: Once consensus with the regulatory body has been reach on the use of the dedication methodology, licensees should liaise with the supply chain. The use of dedication by manufacturers or service suppliers should be clarified as well as the qualifications for the performance of dedication or dedication activities by third parties.
    - Consider performing a pilot project in which interactions between suppliers, third-party dedicating entities and the end-user can be trialled.

Regulatory bodies play an important role during the initial phases of the implementation of the dedication methodology within a country. For this reason, regulators are encouraged to have access to technical support on the subject of the dedication methodology and this Guideline and to be prepared to review implementation avenues proposed by licensees. Once established, the regulatory body may continue to play a role in overseeing the dedication process or activities as a part of existing licensee management system reviews. Should licensees seek to establish internationally harmonized ways of working, such as those joint-utility strategies described in Section 10, European regulatory bodies will likely work together in overseeing such activities.

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