

Quality Assurance Guideline

for Procuring High-Quality Industrial Grade Items aimed at Supporting Safety Functions in Nuclear Facilities

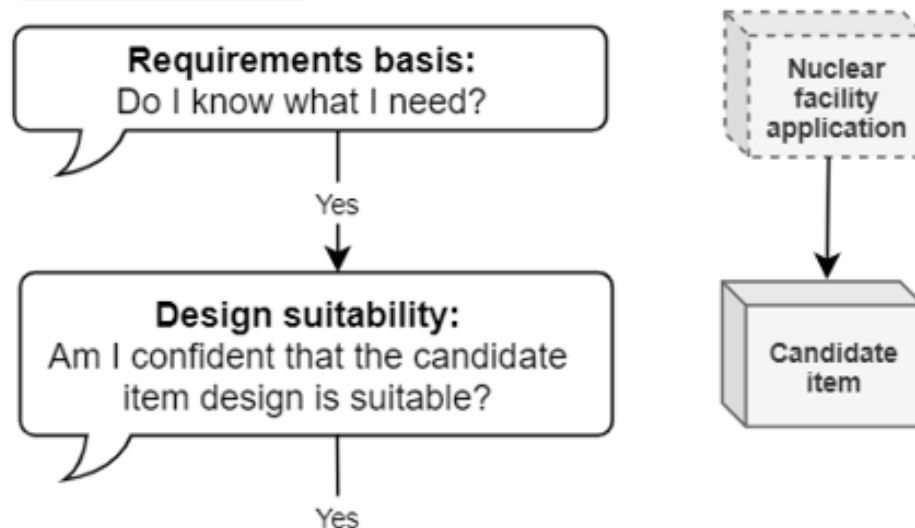
**Presentation to European
Industrial Alliance on SMR**

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European Industrial Alliance on SMR - TWG3
Webinar

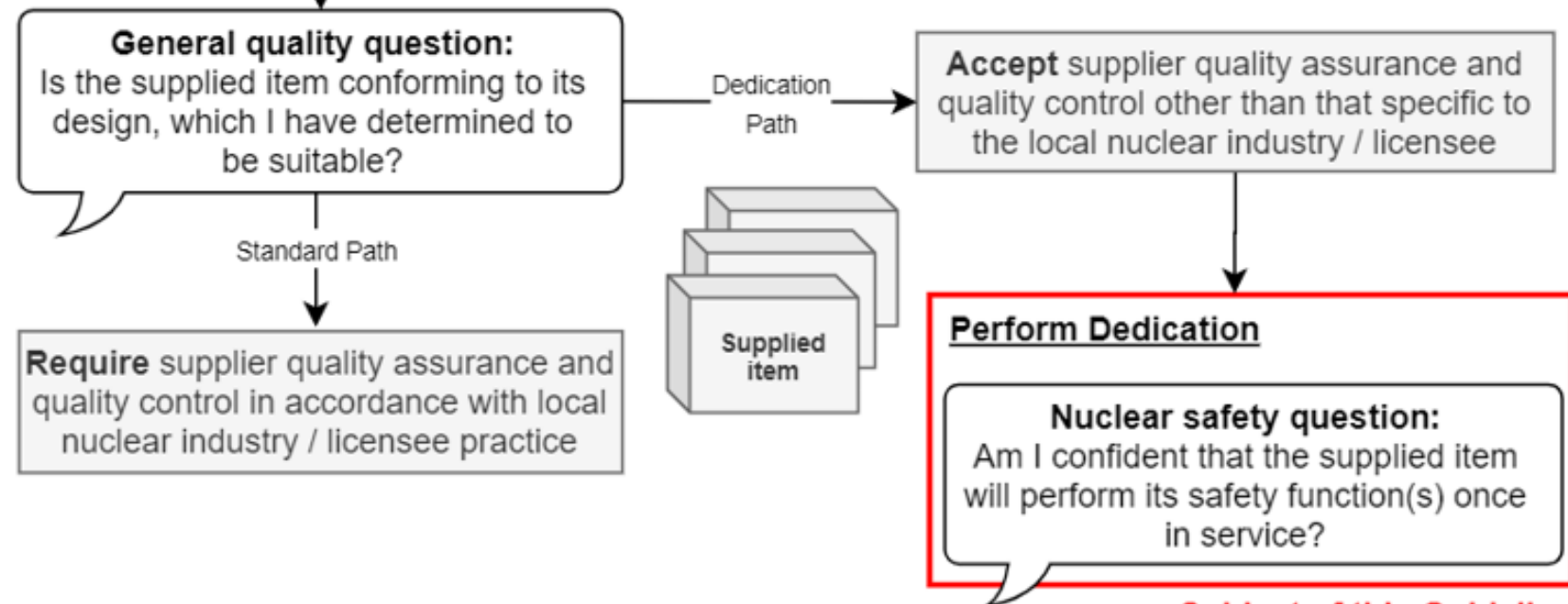
Scope

Pre-Procurement



Note that establishing the suitability of the design of an item for a given nuclear facility application may involve qualification activities performed during the initial procurement.

Procurement



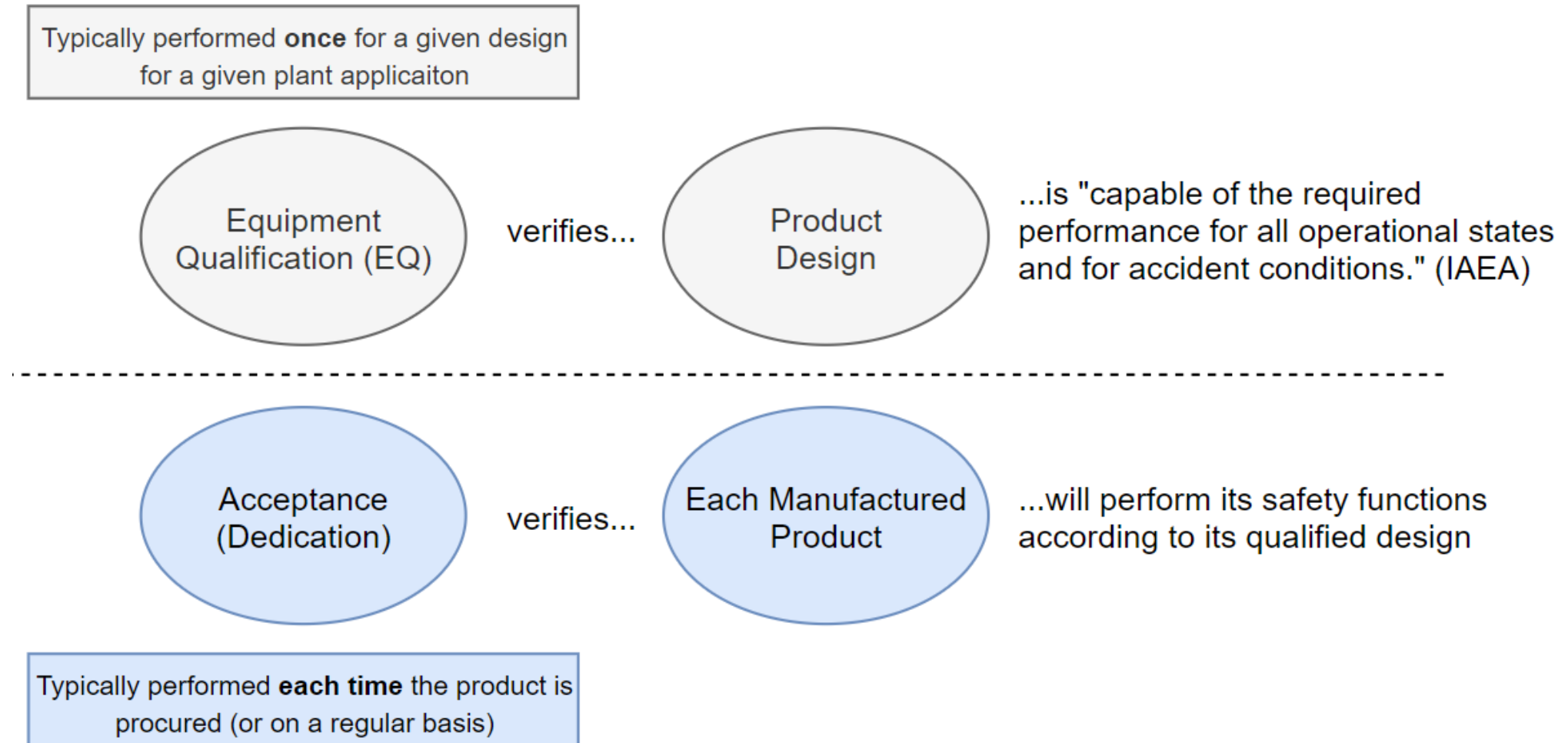
Subject of this Guideline

Dedication is...

- ✓ A 35+ year-old methodology which has been continually improved
- ✓ Applied successfully by approximately 1/3 of today's NPP licensees around the world
- ✓ Compatible with IAEA Safety Fundamentals, General Safety Requirements and Specific Safety Requirements, compatible with WENRA Safety Reference Levels (e.g. Procurement C3.17-C3.19)
- ✓ Not a means to qualify the design of an item (e.g. harsh environment, seismic, EMC)
- ✓ Applicable to all nuclear facilities, applicable to all equipment types (electrical, mechanical, digital); and services
- ✓ Ideal for, but not limited to, SC3 and SC2 serially manufactured industrial grade products
- ✓ A concept reflected in ISO 19443, for use in the supply chain
- ✓ **A way in which to Harmonize and Standardize quality assurance & quality control of procured items for NPPs, including SMRs!**

Dedication is not Qualification*

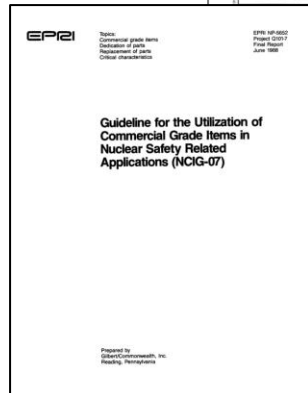
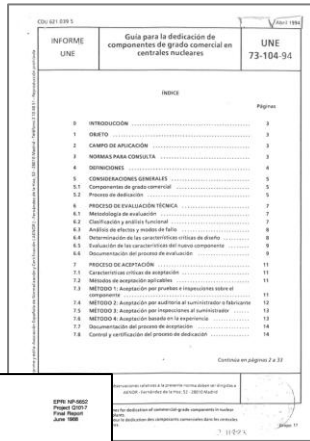
*But dedication can play a role in maintaining confidence in a qualification



National or Regional CGD Guidelines

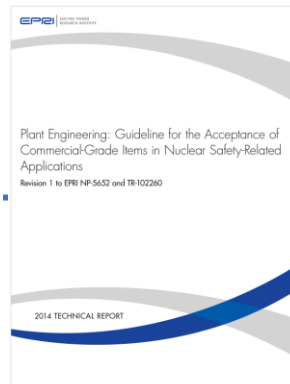
Not a new concept... Growing in popularity

Spain
(1994)



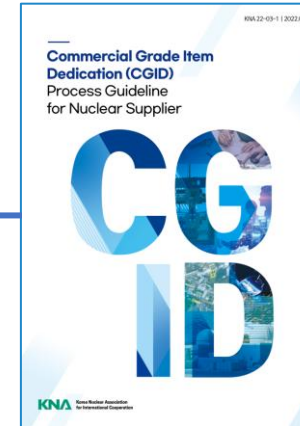
EPRI
(1988)

Europe
(2022)

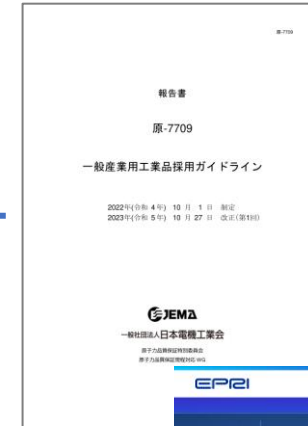


EPRI
(2014)

South Korea
(2022)



Japan
(2022, 2023)



EPRI
(2024)



Nucleareurope Quality Assurance Guideline



Quality Assurance Guideline for Procuring High-Quality Industrial Grade Items aimed at Supporting Safety Functions in Nuclear Facilities



Project steering group
2021-2022



Foundation

Leveraging proven practices

- **IAEA GS-G-3.5** The Management System for Nuclear Installations
- **IAEA NP-T-3.21** Procurement Engineering and Supply Chain Guidelines in Support of Operation and Maintenance of Nuclear Facilities
- **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
- **UNE 73104:1994** Guidelines for Dedication of Commercial-grade Components in Nuclear Power Plants
- **UNE 73403:1995** Use of Commercial Grade Items in Safety Related Applications of Nuclear Facilities
- **ASME NQA-1** Quality Assurance Requirements for Nuclear Facility Applications
- **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
- **DOE-HDBK-1230-2019** Department of Energy Commercial Grade Dedication Application Handbook



Guideline Volume 1, 54 pages

Guideline Volume 1

Methodology

The Guideline establishes a **generalized description of dedication**, one which is not linked to any individual country's practices or rules; **terminology** used in the Guideline is meant to be understood by the entire European nuclear industry.



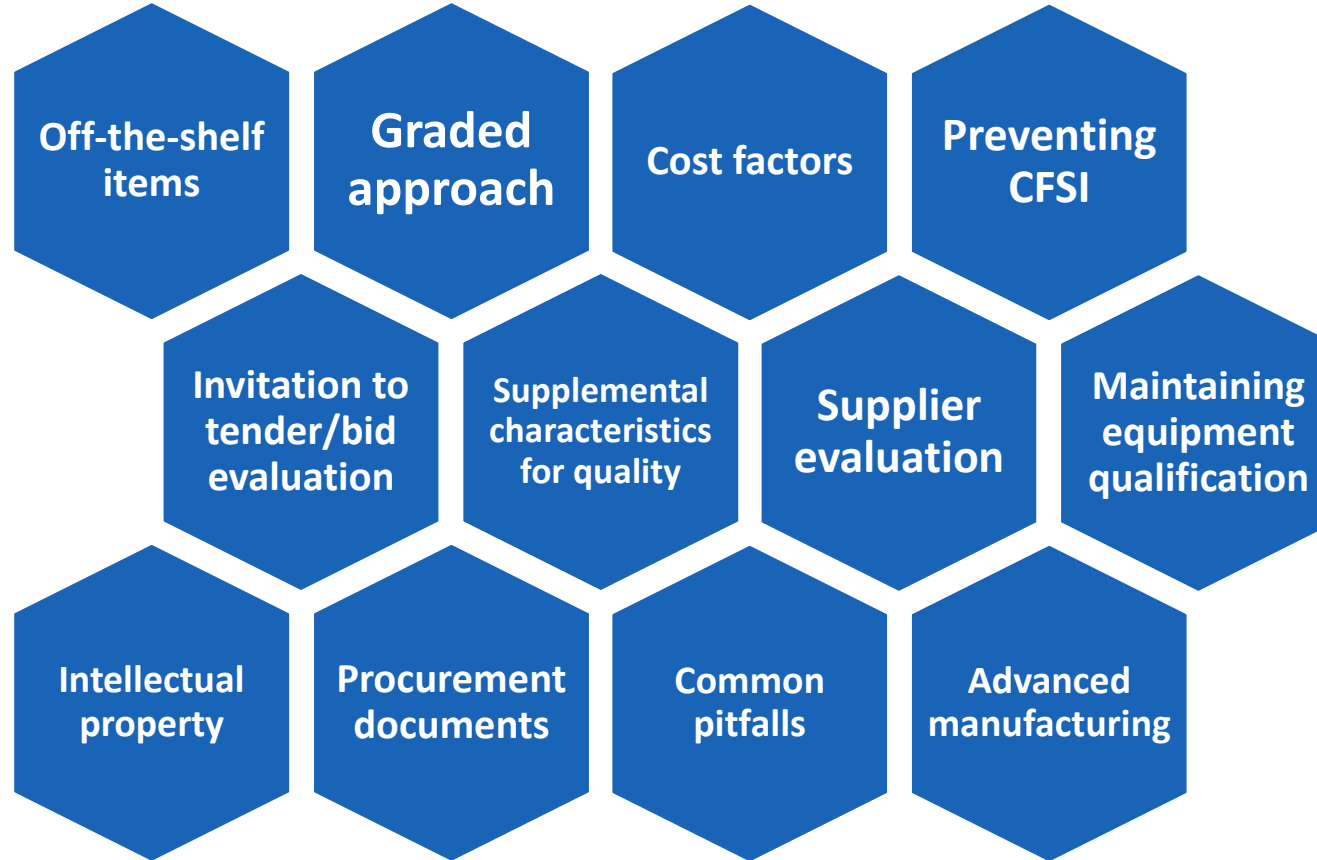
Guideline Volume 1

- A common understanding based on safety, quality and procurement nomenclature from:



Guideline Volume 2

User's Guide

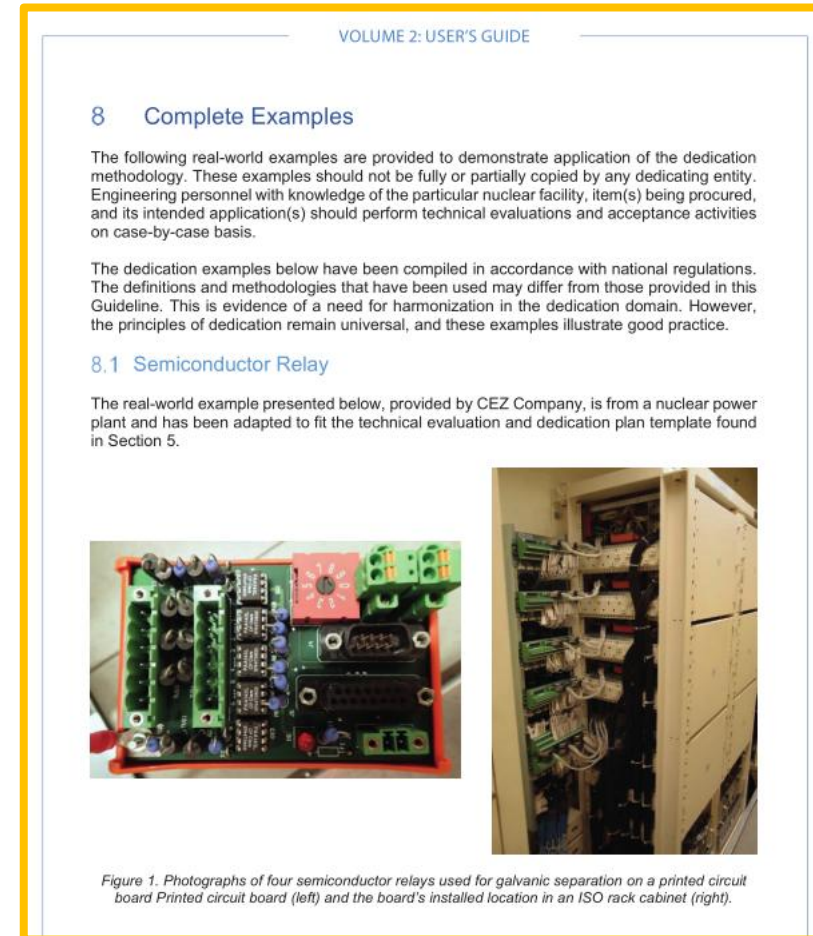


Guideline Volume 2, 88 pages

Support for Professionals

Volume 2: User's Guide

- **Implementing a dedication program** (at an operating organization and in the supply chain – ISO 19443)
- Both simplified and complete, real-world examples
- **Templates and checklists** for dedication activities
- **Graded and risk-Informed** approaches to dedication
- Overview of **regulatory approaches** to dedication worldwide

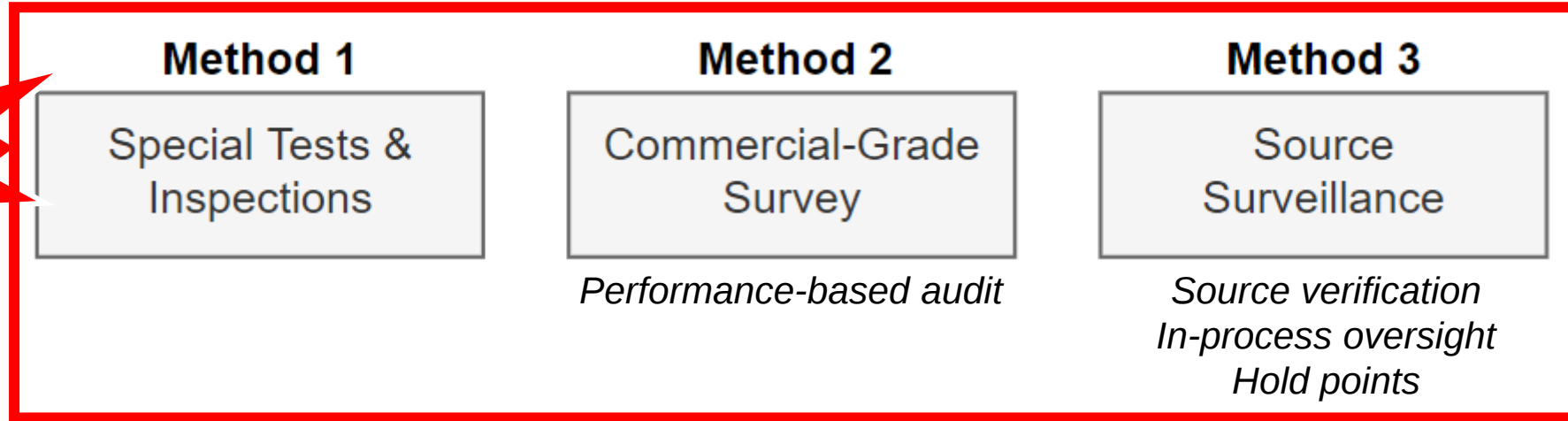


Guideline Volume 2

The Dedication Methodology

Verifying critical characteristics using defined acceptance methods...

QA/QC
Toolbox

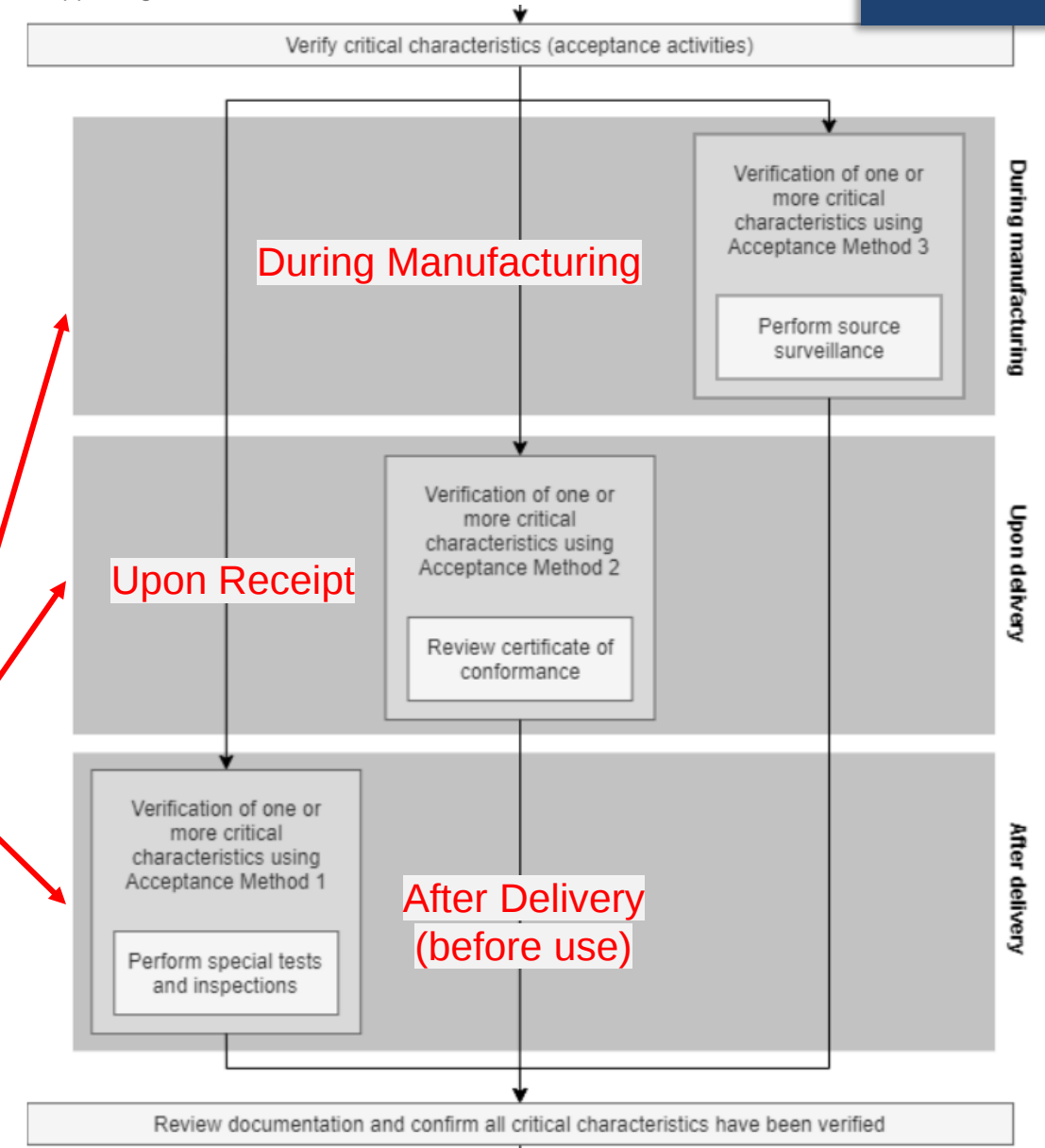


- One or more acceptance method is chosen to verify each individual critical characteristic
- The dedicating entity is free to decide which methods to use
- Results of acceptance activities are documented and treated as quality records
- Method 4, present in other dedication guidelines, does not appear in the FORATOM European Guideline. A review of the supplier/item historical performance should be carried out prior to procurement and can support a graded approach

Acceptance Methods

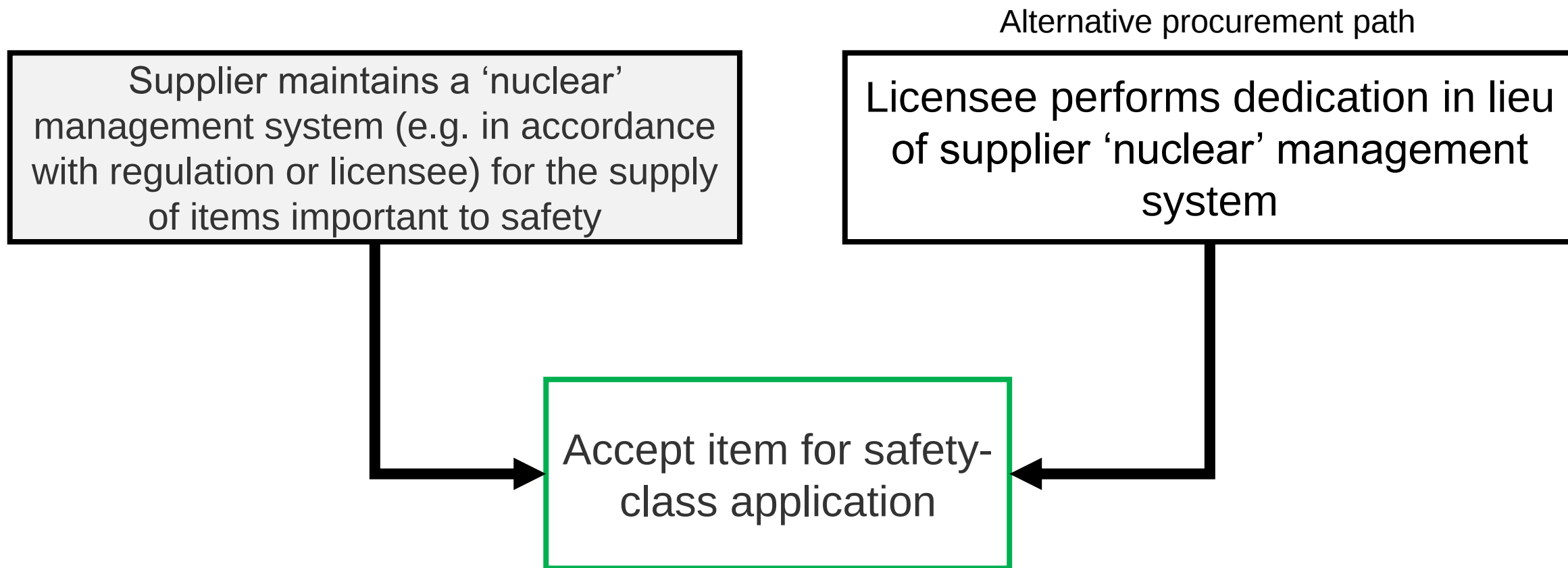
Volume 1, Annex 2 Dedication Flow Chart (excerpt)

- Acceptance methods provide for flexibility to ensure quality in various procurement scenarios
- The use of method 1, 2 or 3 depends on the particular procurement situation
- Acceptance activities take place at different stages of a procurement depending on the chosen acceptance method(s)



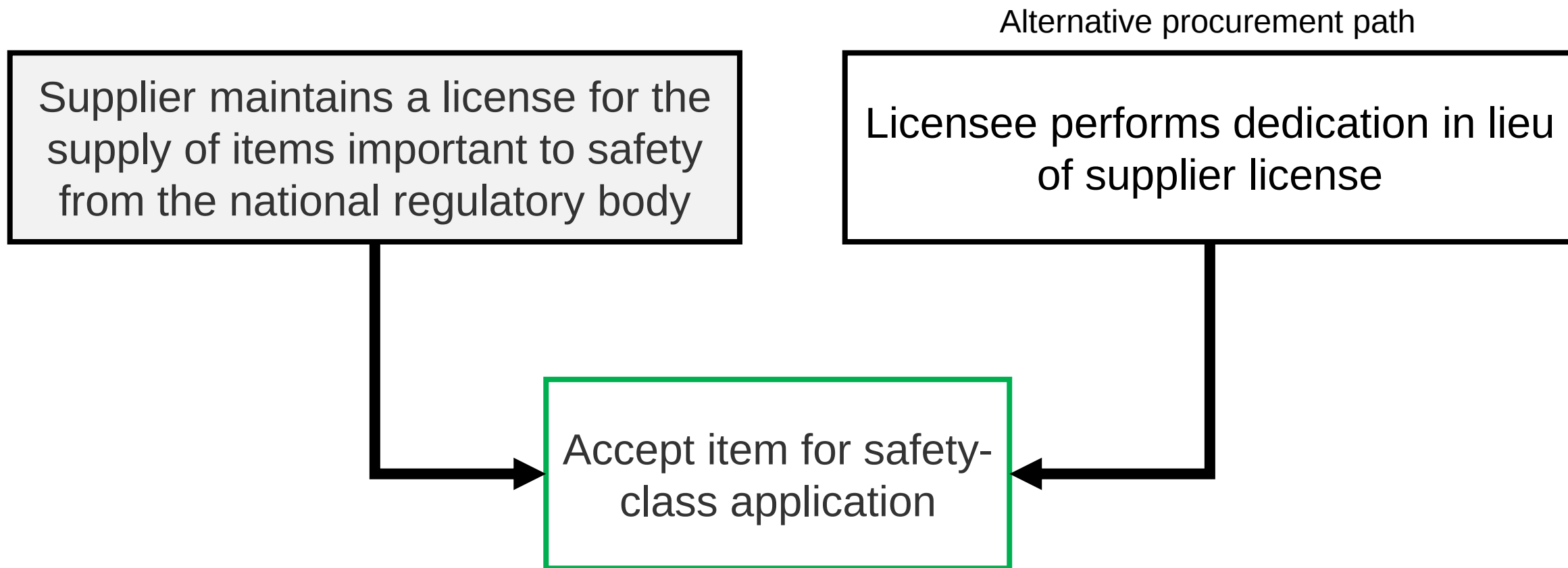
Dedication implementation in Europe today

Example cases currently approved and in use (1/3)



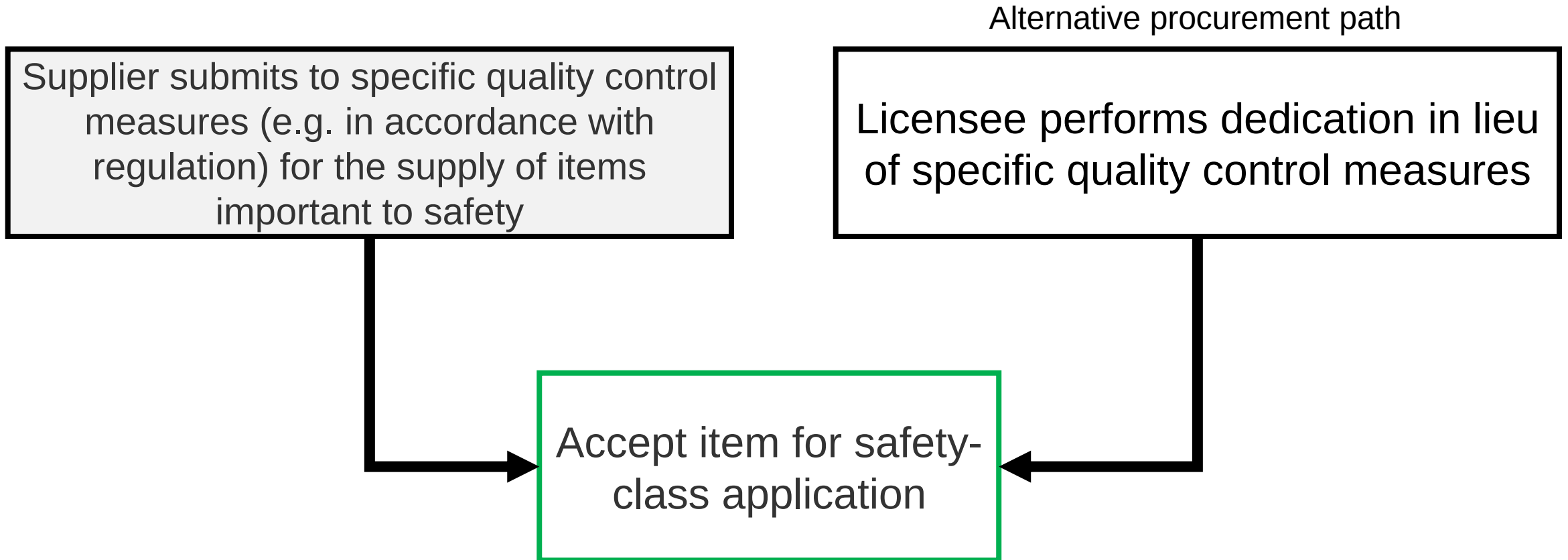
Dedication implementation in Europe today

Example cases currently approved and in use (2/3)



Dedication implementation in Europe today

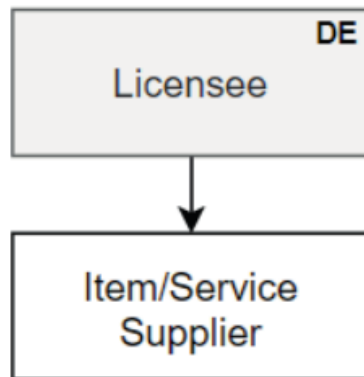
Example cases currently approved and in use (3/3)



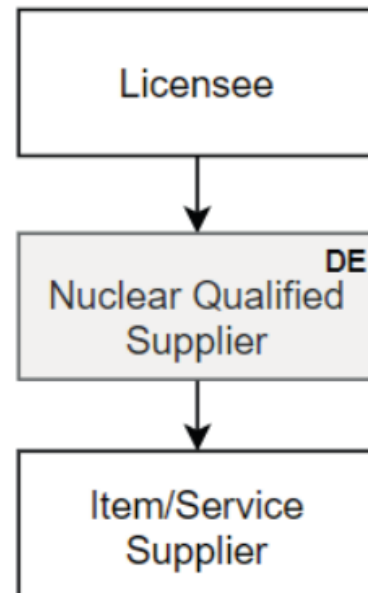
Organizations performing Dedication

Nucleareurope Guideline Volume 1: §7.1

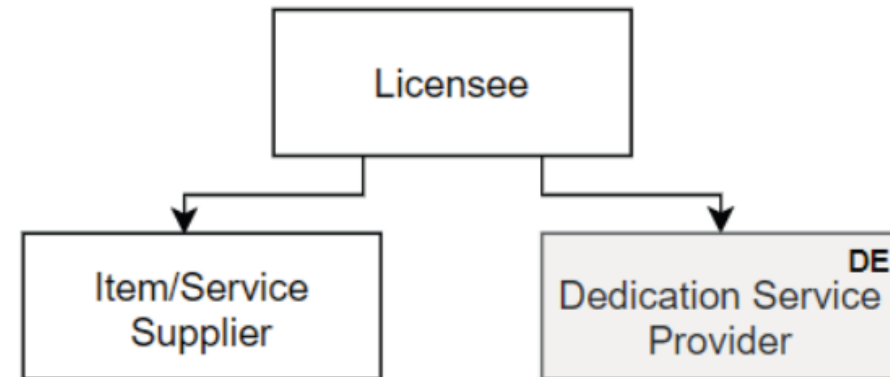
The licensee procures the item/service and performs dedication



A nuclear qualified supplier procures the item/service and performs dedication within the licensee's supply chain



The licensee procures the item/service but outsources dedication to a service provider who acts as the dedicating entity



DE = Dedicating Entity

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

ISO 19443:2018

Dedication in the supply chain, Volume 2: §3.3.3

- The standard includes the concept of **dedication** (without using the term itself), but lacks detailed guidance on the matter
- The standard expects the organization to **select and verify critical characteristics of commercial-grade items or activities** which are sourced externally for products important to safety (i.e. perform dedication)
- The FORATOM European Guideline can support organizations in the implementation of ISO 19443:2018 in this area (the acceptance of externally sourced commercial-grade items and services)

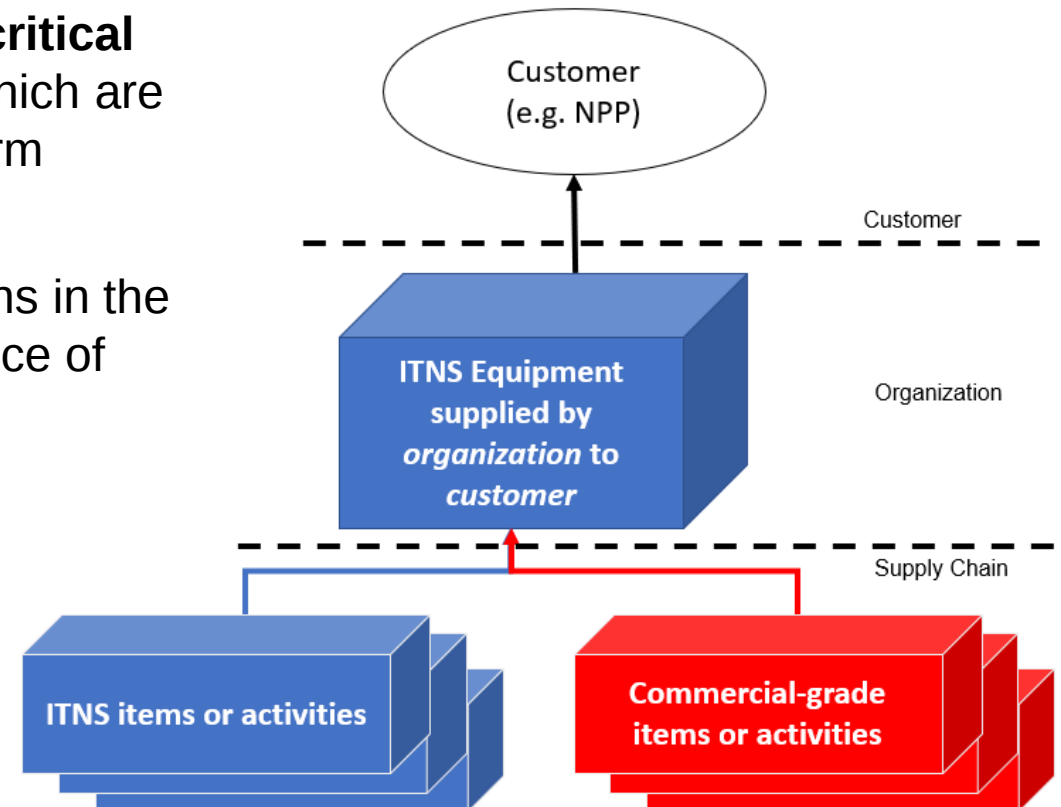


ISO 19443:2018

ISO/TR 4450:2020

ISO/TS 23406:2020

ISO 19443:2018 or
equivalent at supplier
organization



| General Information (1/2)

- Guideline is to be followed on a **voluntary basis** by licensees and other organizations; it is a basis for users to develop their own detailed processes and procedures
 - ⓘ The guideline is not a standard, it is not meant to be referenced in contractual terms during the supply of items or services
- The dedication methodology is a proven methodology which has been used for decades in parts of Europe (e.g. Spain, Slovenia)
 - ⓘ The dedication methodology is most closely related to **WENRA SRL Issue C, specifically Procurement (C3.17-C3.19)**

General Information (2/2)

- The dedication methodology described in this Guideline is not intended to verify that items comply with **codes or standards**.
 - ① When an item should comply with a code or standard, measures other than dedication should be taken to ensure this – e.g. a design review, contractual terms, or other quality checks.
- Other quality-related activities, like third-party/regulatory oversight could still take place, if necessary, even when an item will be dedicated
- The level of confidence in the quality of an item after it has been dedicated is meant to be **commensurate** to the confidence in quality of an item procured via traditional means
 - ① The dedication methodology increases engineering involvement in the procurement process

During the Guideline Development

Interaction with regulatory bodies

- **WENRA RHWG** was kept informed of the progress of the document, drafts were shared for comment
- **Two dedicated meetings** with WENRA RHWG took place during the guideline development and feedback was incorporated prior to publication
- After publication of the guideline, a new RHWG **HQIGI sub-group was established** to exchange information on the use of nuclear-grade and commercial-grade items for safety-related purposes.

Western European
WENRA RHWG
Nuclear Regulators Association

4th CORDEL Regional Workshop
18.-20. May 2022
Lyon, France

Gila Stoppa
RHWG chair

High Quality Industrial Grade Items

- Limited availability of nuclear certified components
- HQIGI already in use in some European countries/NPPs
- Dedication method already in use in some European countries/NPPs
- Common view could be usefull for Regulators
- Probably issue for harmonization



To be considered in RHWG work

18./20. May 2022

4th CORDEL Regional Workshop, Lyon

10 Western European
WENRA RHWG
Nuclear Regulators Association

Regulators Take a Deeper Look

HQIGI Task Group



Founded in May 2023 with the aim to exchange information on the different approaches concerning the use of commercial grade items for safety related purposes, based on experience in WENRA member countries.

Tasks:

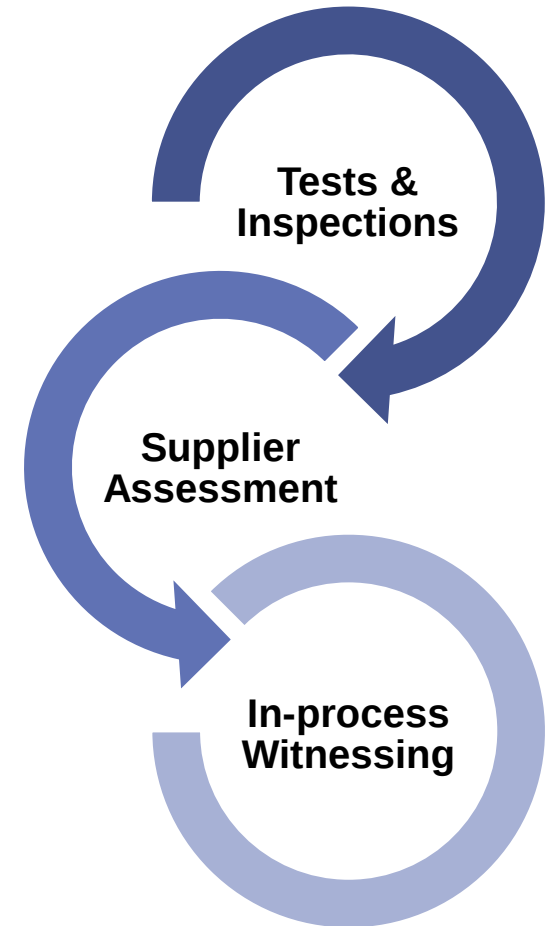
- to compile information on HQIGIs from the information already provided to RHWG
- to produce a questionnaire to gather the other member countries' experiences with HQIGIs/other approaches to this issue.

Task group members: Six European regulators

Dedication can enable procurement...

- ✓ ...of surplus stock from other nuclear (and non-nuclear) facilities
- ✓ ...of 'nuclear-grade' equipment from other jurisdictions
- ✓ ...in cases where the supplier cannot fulfill or does not accept the usual specific nuclear quality requirements
- ✓ ...of serially manufactured items instead of items as one-off special manufacturing runs

...using a basic quality assurance toolbox



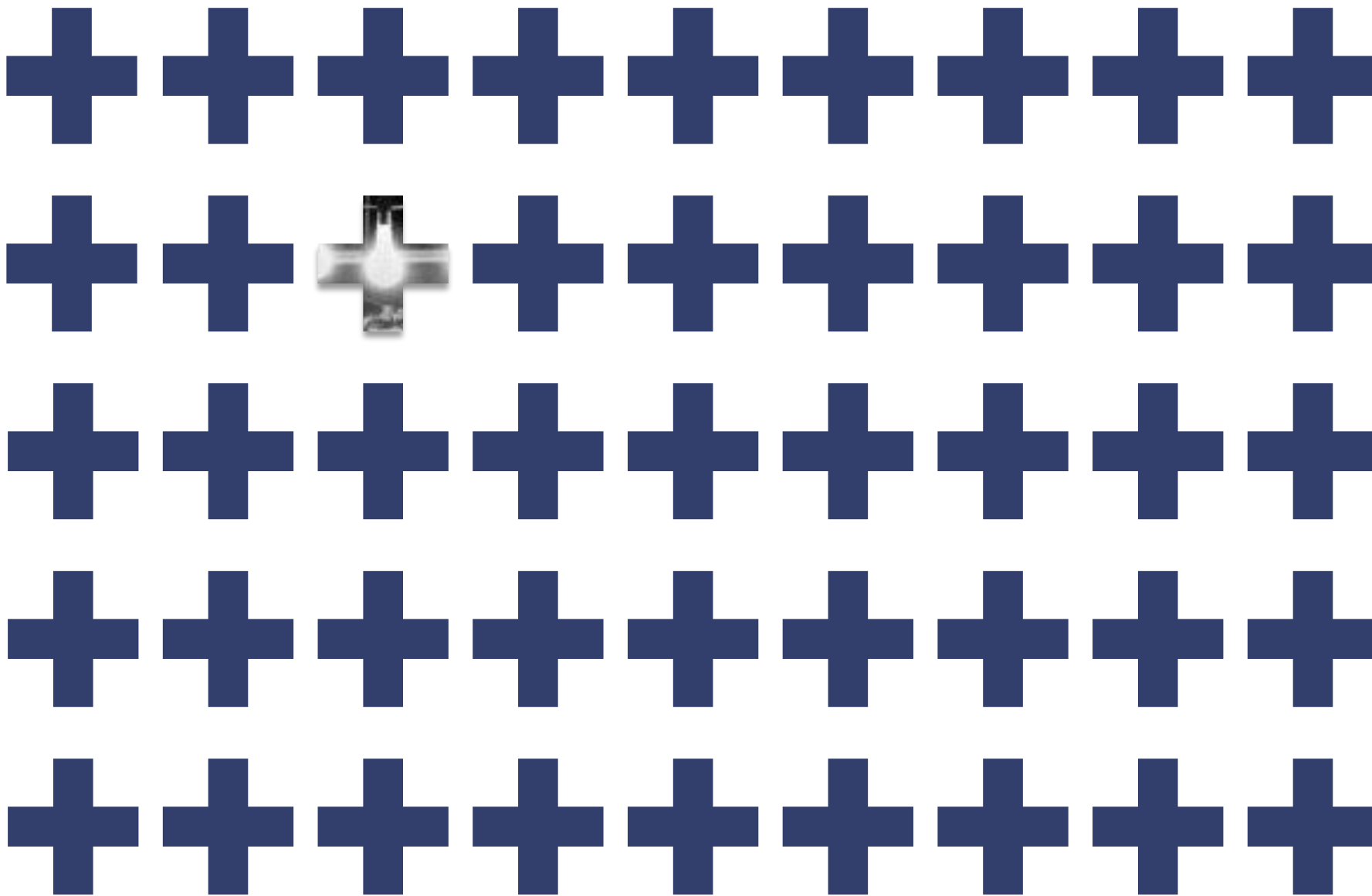
Conclusions



1. User **feedback** has been very positive – guideline has helped to bring clarity on the subject of dedication, its role in the procurement process, and how it is distinguished from qualification of items.

2. The guideline and increasing interest surrounding dedication has triggered European regulatory bodies to form a special task group **which may reach a common position on the subject.**

3. The guideline demonstrated that European stakeholders could harmonize and standardize across various jurisdictions and organizational practices.



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