



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

Andrei Goicea – Policy Director
SNETP Forum

2 June 2022

Membership

The membership of FORATOM is made up of 15 national nuclear associations representing more than 3,000 companies.



Corporate Members: [CEZ](#) (Czech Republic), [Fermi Energia](#) (Estonia), [Nuvia](#) (France),
PEJ (Poland), [Rolls-Royce SMR](#) Ltd. (UK) and [Urenco](#) (Global)

What does nuclear contribute to the EU's economy?



106/137

NUCLEAR REACTORS
IN OPERATION IN THE EU/EUROPE



100

€ BILLION/YEAR



1 million

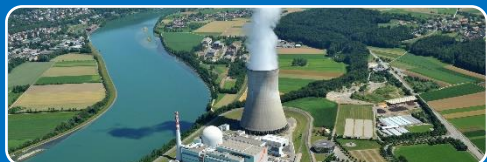
JOBS



26%

ELECTRICITY PRODUCTION

Current status & challenges of the European Supply Chain



The **safe and reliable** operation of the European nuclear fleet **requires the availability of appropriate supply chain options.**



The number of **supply chain options** have **decreased in the last few decades.**

- Many of the nuclear industry's Original Equipment Manufacturers (OEM) are no longer on the market or have stopped manufacturing their originally designed items.
- Market has become more challenging for new entrants due to the stringency and diversity of requirements across the globe



A **strong and diversified supply chain** is **essential** to ensuring the **high levels of safety, quality and reliability** required for new build projects and long-term operation alike.



The European nuclear industry could **leverage modern, high-quality and proven products manufactured by well-established suppliers** to other industries which also require high quality items.



The delivery of a **European guideline** which provides a **harmonised methodology** for use of **non-nuclear high-quality industrial grade items** would enable **consistency across Europe** and support the wider use of best practice.

Supply Chain Optimisation WG Report



OPTIMISING THE EUROPEAN NUCLEAR SUPPLY CHAIN

USE OF HIGH-QUALITY INDUSTRIAL GRADE ITEMS IN EUROPEAN NUCLEAR INSTALLATIONS

FOREWORD

FORATOM is the Brussels-based trade association for the nuclear industry in Europe. It acts as the voice of the European nuclear industry in energy policy discussions with EU institutions and other key stakeholders. Some of the key topics FORATOM deals with include security of energy supply, competitiveness, economics of nuclear, nuclear safety, nuclear liability, radioactive waste management, decommissioning, nuclear transport, environment, enabling factors for new nuclear projects, R&D, energy mix, non-proliferation, public opinion, Euratom Treaty and emergency preparedness. The membership of FORATOM is made up of 15 national nuclear associations and the companies that they represent, and three corporate members CEZ (Czech Republic), Fermi Energia OU (Estonia) and PGE EJ 1 (Poland). Overall, FORATOM represents nearly 3,000 European companies.

As the European Union's institutions are currently working on the bloc's future energy landscape, nuclear energy should have an important role to play thanks to the long-term operation of the current nuclear fleet and new build projects.

The goal of this report is to analyse the current state of play and to put forward a list of recommendations on what should be done to improve the operation of the European nuclear supply chain. This will enable a continuous development of the safety and reliability of the current nuclear fleet, which will allow it to help the EU meet its 2050 climate-neutrality goals and ensure energy security.

FORATOM plans to share the conclusions of this report with the European Commission and other key stakeholders, including national regulators and industry, in order to discuss and implement the proposed recommendations.

On this occasion, FORATOM would like to thank its members and associated stakeholders for their highly valuable contribution during the preparation of this report.

June 2020

Recommendations:



European Guideline



Harmonised Legal and Regulatory Framework



National Guidance or Endorsement Framework



Industry / Company Procedures



Additional Supply Chain Optimisation solutions led by the European Nuclear Industry

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www.foratom.org | foratom@foratom.org |

QUALITY ASSURANCE GUIDELINE

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



Project Structure Overview

Project Delivery – **Objective to publish Q1/2 2022** (open access)

FORATOM deliver project.

ENISS support interaction with regulatory community.

Steering Group provide direction, contributions and review interim drafting of guideline

(10 Members including licensees, national associations, suppliers)

Project consultant (Apollo+) support drafting of the guideline and associated actions

Steering Group Member

Sabin Sabinov

Karel Křížek

Steven Goedseels

Peter Tuominen

Virginie Calonne

Badea Martinotte

Anne-Sophie Defay

Ionut Zaharov

Magnus Arbell

Debbie Breasley

Pär Lansåker

Mat Mackay

Sponsor

BULATOM

CEZ

ENGIE

Finnish Energy

GIFEN

ROMATOM

Uniper

Urenco

Vattenfall

Westinghouse

Represented by

Selmeda Ltd.

FORTUM

EDF

Framatome

Nuclearelectrica SA



Interactions with wide range of stakeholders

FORATOM Working Groups and Members

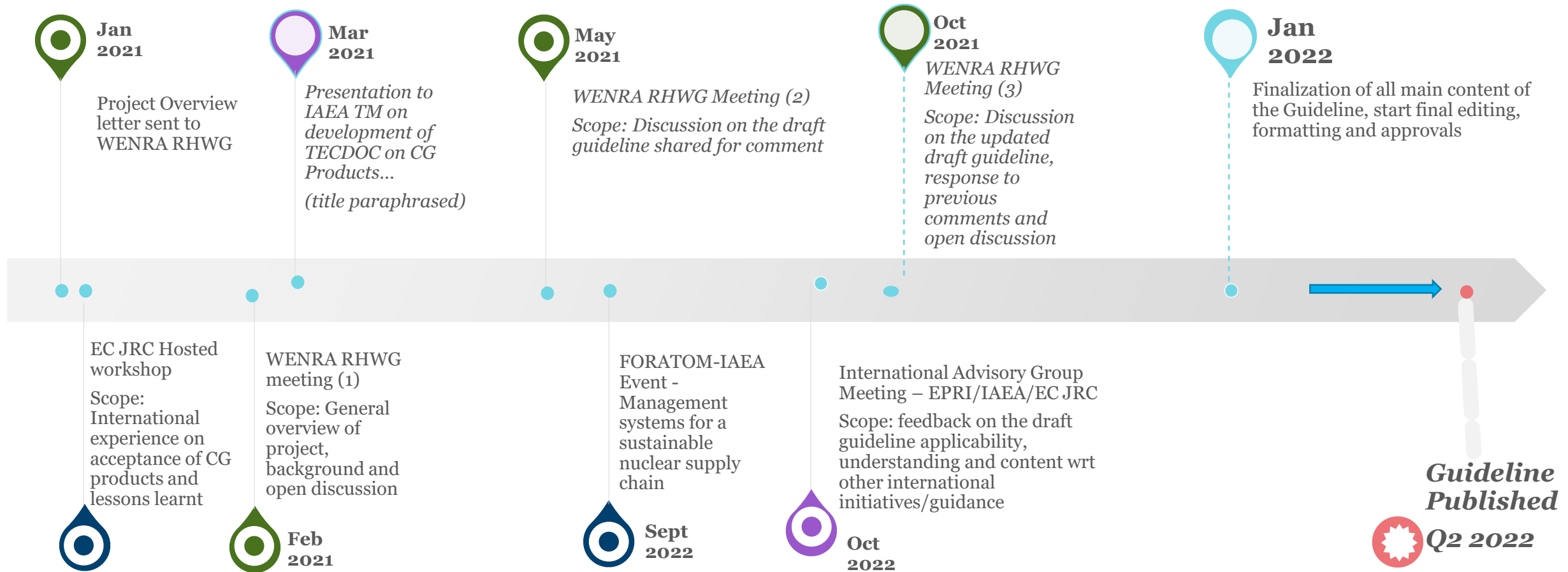
European Nuclear industry supply chain (Service providers, OEM, suppliers...)

European Nuclear regulatory community (WENRA...)

International (IAEA, EPRI, EC-JRC, SNETP, WNA)



Overview Key Interactions with WENRA RHWG and International stakeholders...



Additional outreach activities/exchanges with DG ENER, WNA SCWG, SNETP, ASME European WG on Nuclear Quality Assurance, Spanish Nuclear Society, various licensees and suppliers...

Publication of the European Guideline

Publication of the Quality “Assurance Guideline for Procuring High-Quality Industrial Grade Items Aimed at Supporting Safety Functions in Nuclear Facilities” after a webinar for the members on **13 May**

(Executive Summary)

Volume 1: Methodology

Volume 2: User’s Guide



FORATOM Guideline Project

Reasons behind the initiative and some foreseen benefits

- A robust and well-defined methodology for high-quality industrial grade item acceptance (dedication) which can be **applied and understood across Europe (and beyond)** in lieu of no process, many different processes or case-by-case decision-making.
- A basis for **regulatory stability** on the subject of high-quality industrial grade item acceptance.
- The opportunity to integrate a **graded or risk-informed approach** to the subject of dedication which should serve to both improve the efficacy and the efficiency of the process.

High-quality Industrial Grade Item (or Service)

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

- ① High-quality industry grade items are typically designed and manufactured under non-nuclear quality assurance and quality control arrangements, but may also be those furnished by suppliers who comply with foreign nuclear quality expectations.
- ① High-quality industry grade items include serially manufactured products.



Scope

Pre-Procurement

Requirements basis:
Do I know what I need?

Yes

Design suitability:
Am I confident that the candidate item design is suitable?

Yes

Procurement

General quality question:
Is the supplied item conforming to its design, which I have determined to be suitable?

Standard Path

Require supplier quality assurance and quality control in accordance with local nuclear industry / licensee practice

Nuclear facility application

Candidate item

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.

Dedication Path

Accept supplier quality assurance and quality control other than that specific to the local nuclear industry / licensee

Supplied item

Perform Dedication

Nuclear safety question:
Am I confident that the supplied item will perform its safety function(s) once in service?

Subject of this Guideline



Organizations performing Dedication



- The Guideline could be the basis for dedication activities performed by:
 - **Licensees**
 - **Third-party dedication service providers**
 - **Third-party laboratories** supporting testing and inspection as a part of dedication
 - **Manufacturers** of materials, parts or sub-assemblies of items important to safety which they supply (i.e. ISO 19443 suppliers)

Vol. 1 §8 Only organizations maintaining documented management systems in accordance with nuclear regulatory requirements and/or licensee expectations should perform dedication activities.



Foundation - Leveraging proven practices

Volume 1: Methodology

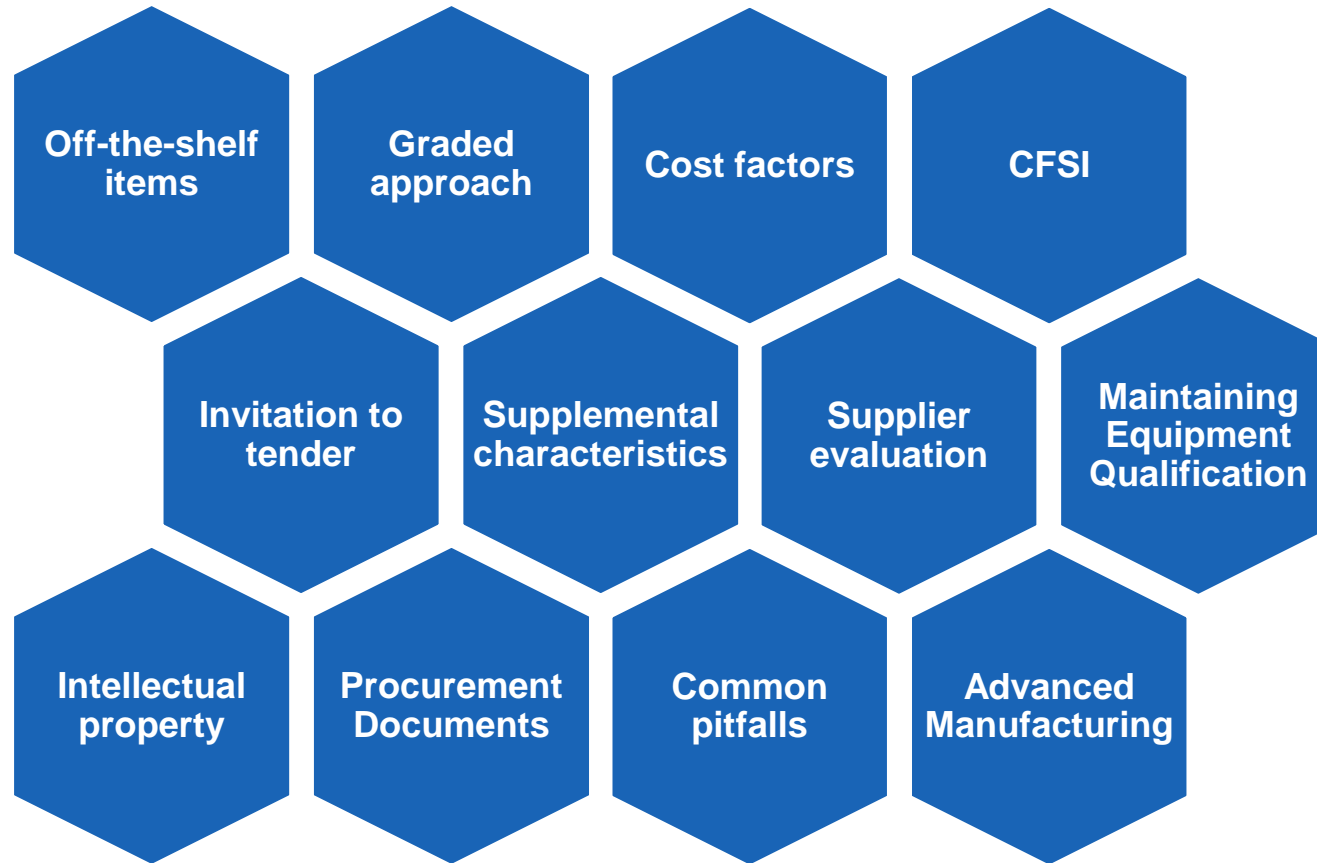


- **IAEA GS-G-3.5** The Management System for Nuclear Installations
- **IAEA NP-T-3.21** Procurement Engineering and Supply Chain Guidelines in Support of Operation and Maintenance of Nuclear Facilities
- **IAEA NR-T-3.31** Challenges and Approaches for Selecting, Assessing and Qualifying Commercial 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



European Guideline Topics

Volume 2: User's Guide



Thank you for your attention



Project Owner: FORATOM

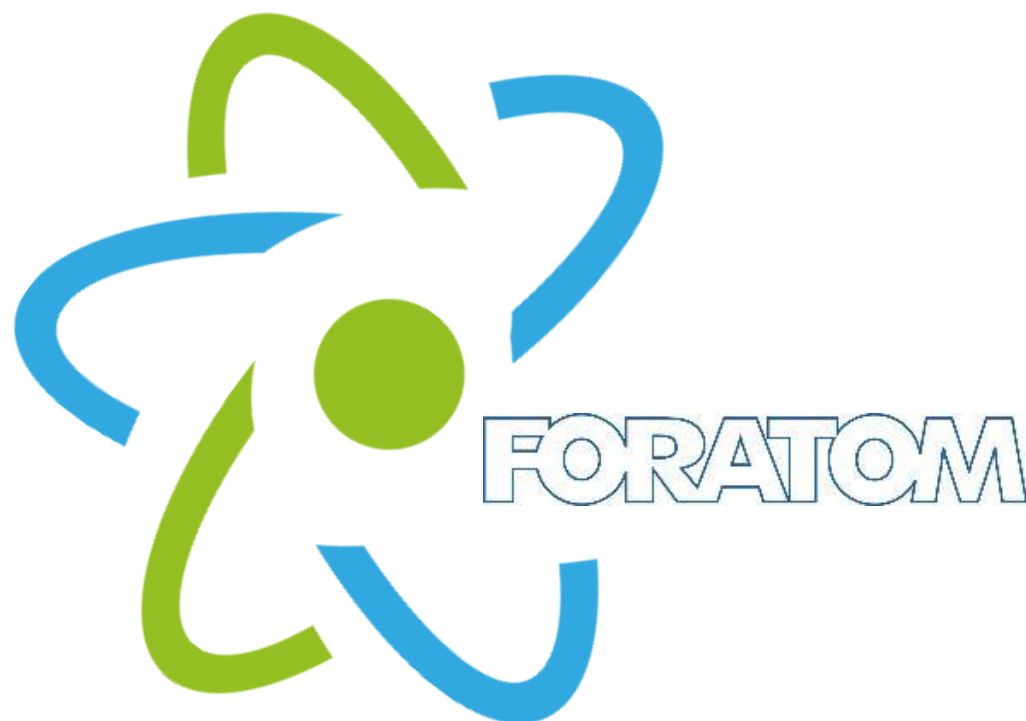
Mr. Andrei Goicea, andrei.goicea@foratom.org

Project Manager: Apollo Plus

Dr. John Kickhofel, jkickhofel@apolloplus.com

ENISS support: ENISS

Mr. William Ranval william.ranval@foratom.org



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Back-up slides



Dedication is...



- ✓ A 40-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 or Specific Safety Requirements
- ✓ Compatible with WENRA Safety Reference Levels
- ✓ Neither a means to evaluate the reliability of an item (qualitatively or quantitatively) nor a means to qualify an item (e.g. harsh environment, seismic)
- ✓ Applicable to all nuclear facilities; all equipment types (electrical, mechanical, digital); and services
- ✓ Ideal for, but not limited to, SC3 and SC2 high-quality industrial grade products
- ✓ In many ways a more stringent quality assurance methodology than typical nuclear quality assurance requirements due to the focus on safety functions and licensee involvement



Implementing a Dedication Program



...at a nuclear facility, Vol 2. §3.1

- Development of policy commitment
- Appointment of implementation project leaders
- Liaise with regulatory body
- Create new processes, procedures, forms, or other instructions
- Establish a training program
- Initialize program with dedication of simple items for well-known applications
- Aim for continual improvement and capture lessons learned

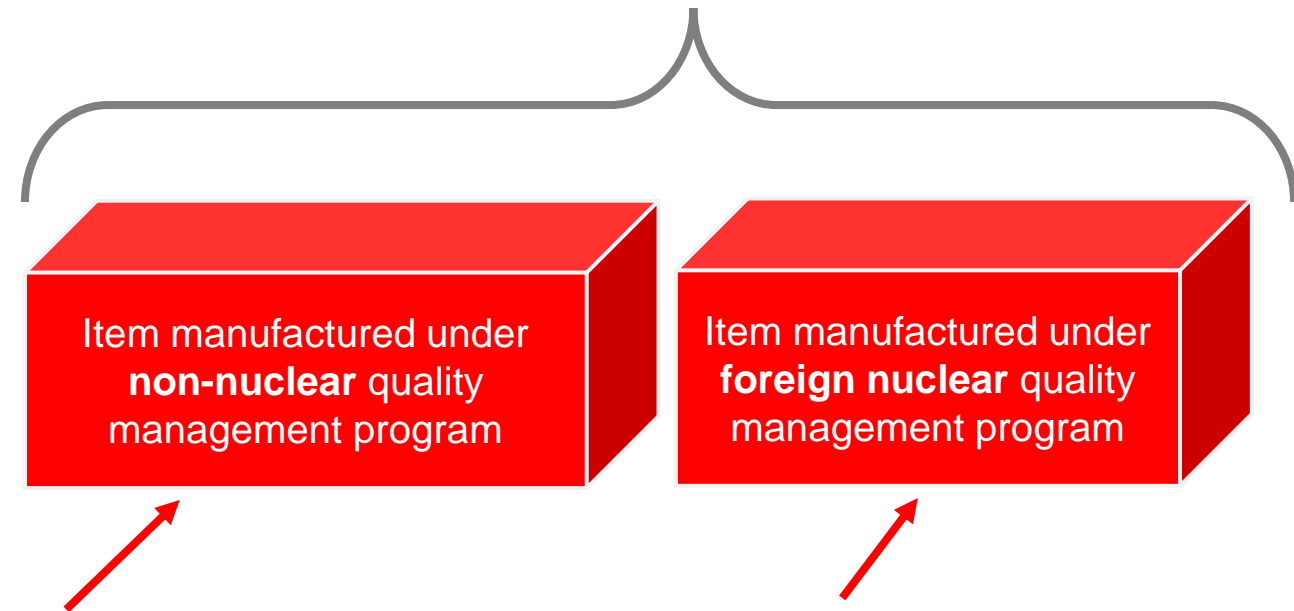


Item Eligibility for Dedication

Volume 1: §9.1

- The item (or service) should be **important to safety**, specifically, the item should have a **safety function** (or the service should have an impact on safety)
- The use of dedication as a substitute for other requirements must be allowable (e.g. agreed upon with the end-user or local regulatory body)

Typically two types of items are subject to dedication



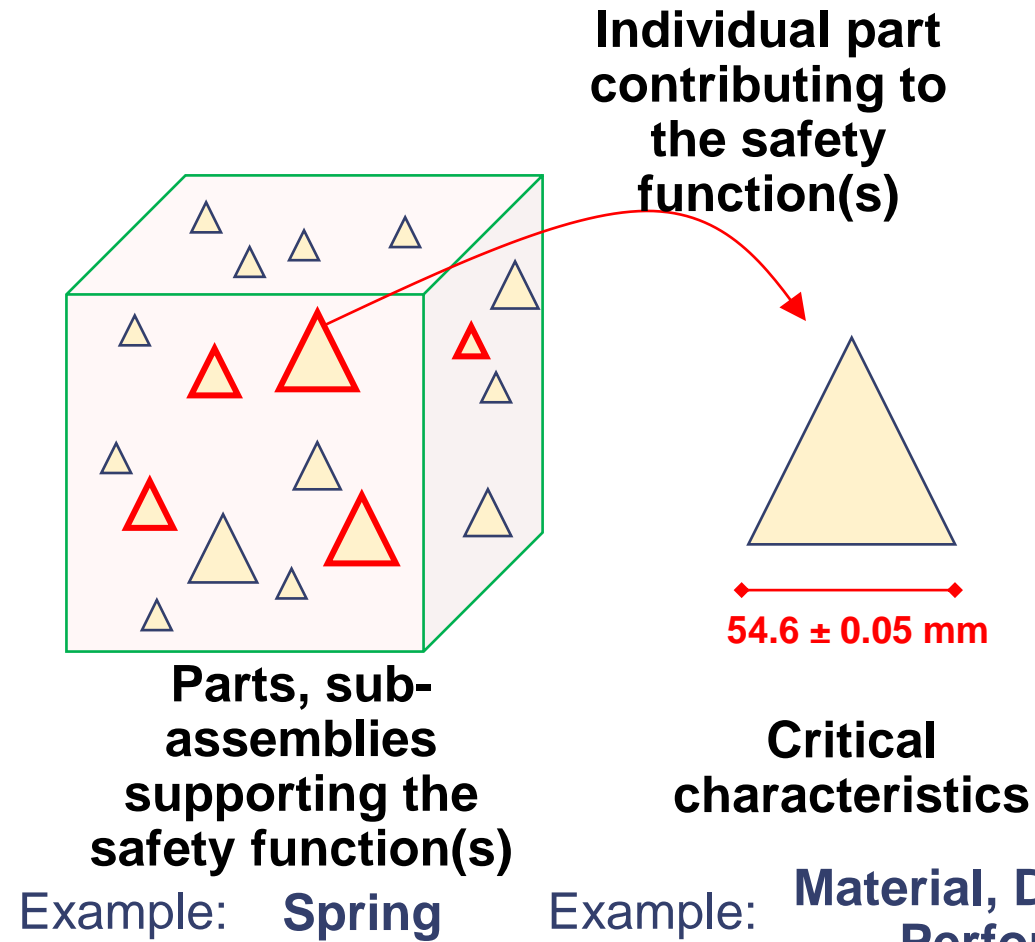
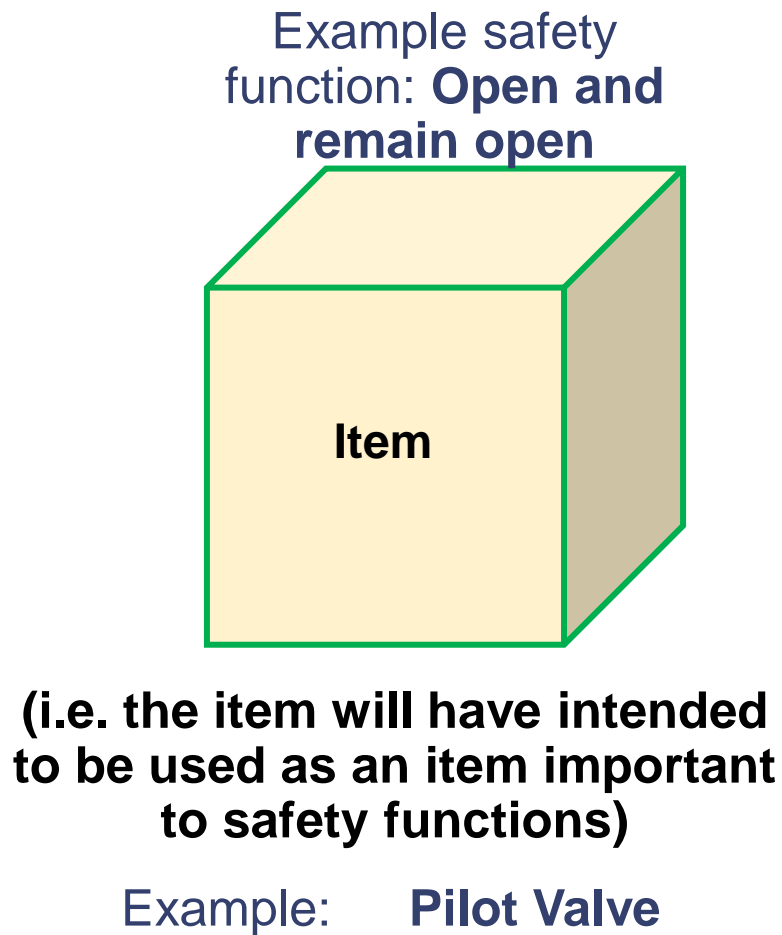
e.g. A serially manufactured item manufactured under an ISO 29001:2020 QA program for the natural gas industry

e.g. Krsko NPP (Slovenia) procures from a supplier qualified to supply items important to safety to EDF Energy (UK)



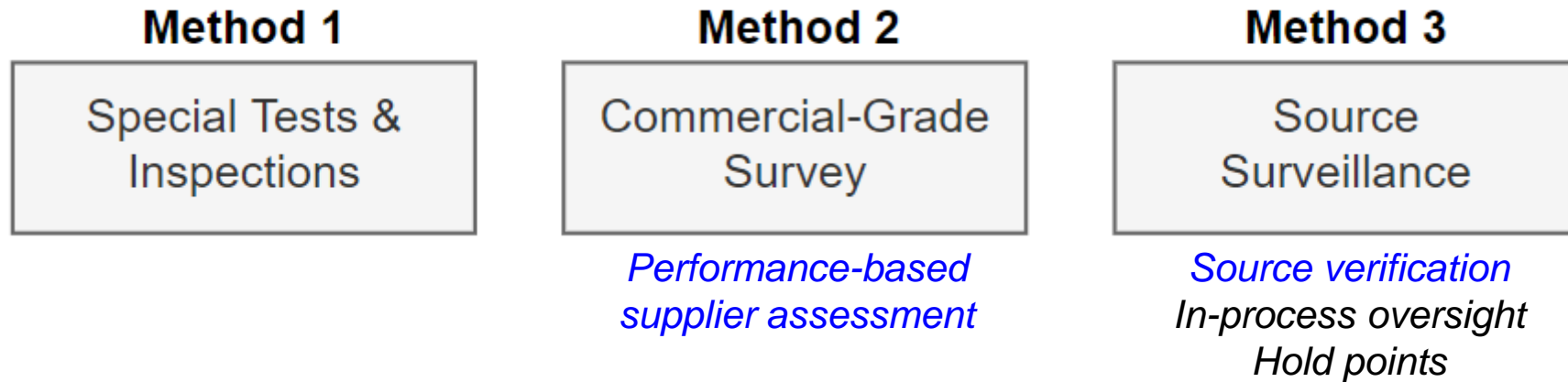
The Dedication Methodology (1/2)

Define a set of **critical characteristics** which support the safety function(s) of the item...



The Dedication Methodology (2/2)

Verify critical characteristics using defined acceptance methods



- One 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

ISO 19443:2018

Dedication in the supply chain, Volume 2: §3.3.3

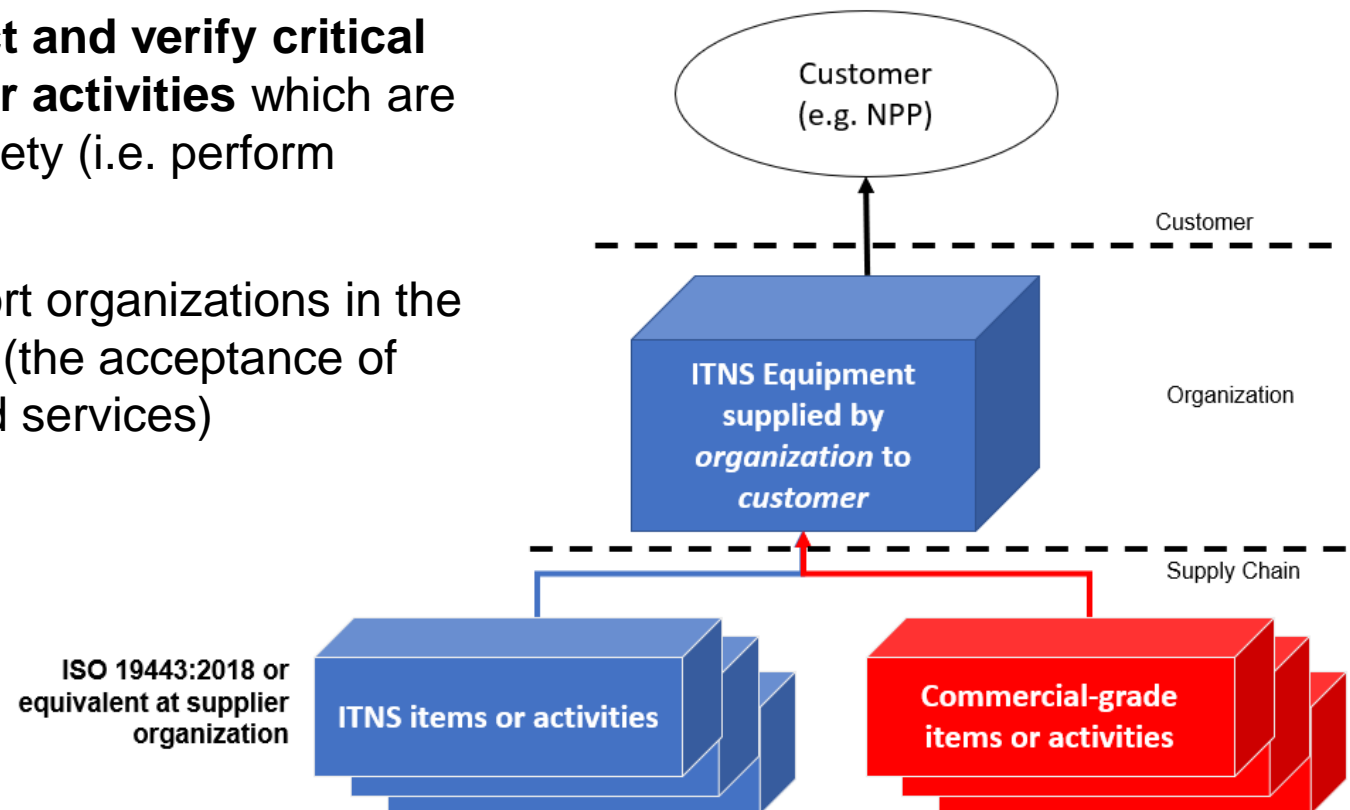
- The standard includes the concept of **dedication** (without using the term itself), but lacks detailed guidance on the matter
- The standard expects the organization to **select and verify critical characteristics** of **commercial-grade items or activities** which are sourced externally for products 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



Guideline Volume 1: §4 - Objective

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

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



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 described in the Guideline is **applicable to all types of nuclear facilities**, in all lifecycle phases and to all types of items important to safety (mechanical, electrical, digital, I&C...) and 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

