# Challenges in maintaining consistent high quality in an international supply chain
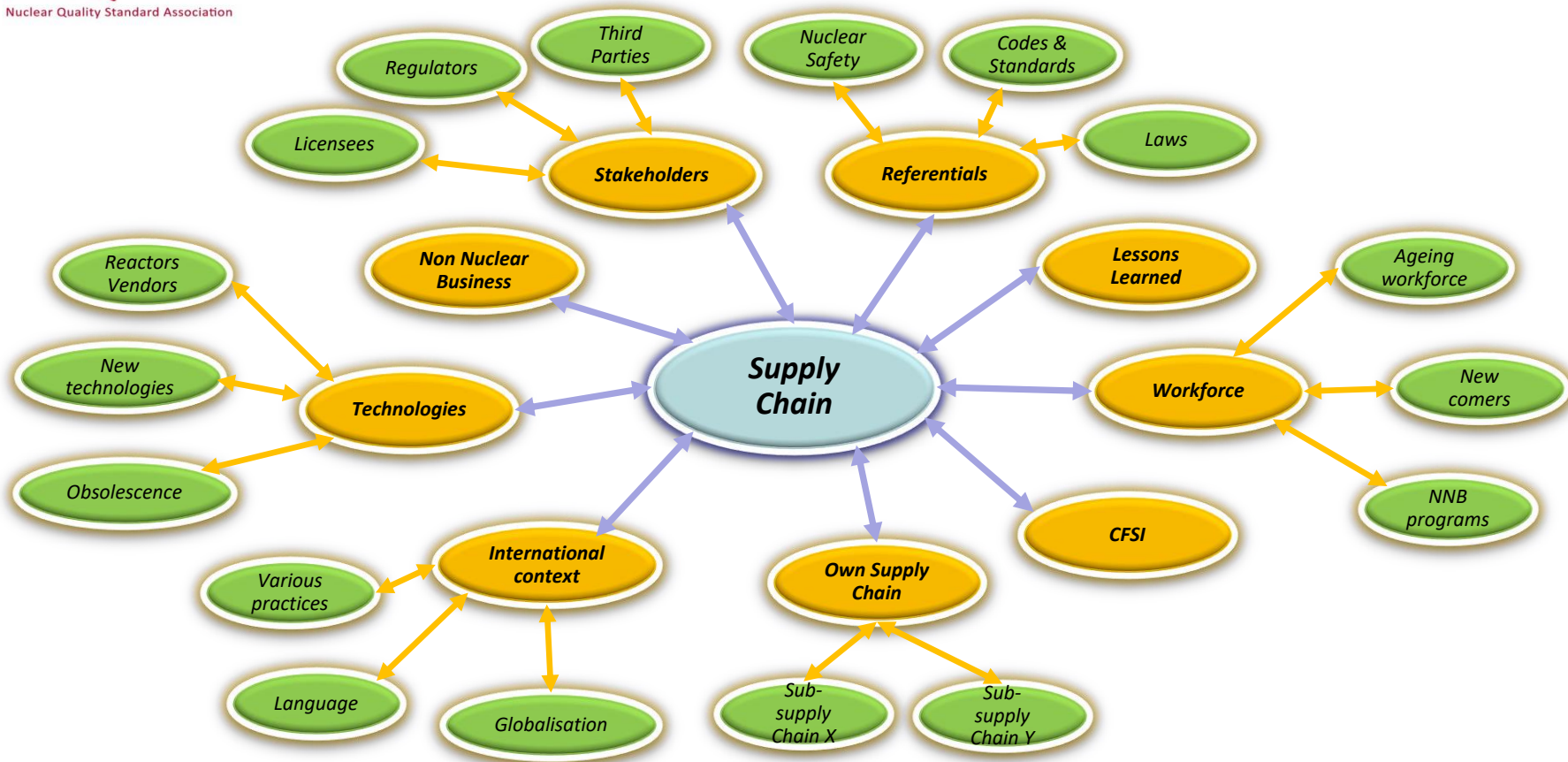
**Denis Bourguignon -  Bureau Veritas - General Secretary of NQSA**

**Betrand-Marie Nahon – Framatome – NQSA & ISO WG4 convener**

**Alain Couderc – Bureau Veritas – NQSA & ISO WG**

# Nuclear Supply Chain Challenges

*"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)**

**Not THE solution but A contribution**

# ISO 19443 - Main additional requirements

**In addition to ISO 9001, the requirements mainly focus on:**

- **Quality Management Program**
- **Safety Culture**
- **ITNS classification**
- **Graded approach**
- **Cascading requirements**
- **Independence of verification**
- **Competency management**
- **Design control**
- **Procurement control**
- **Non-conforming outputs**
- **Communication**

# ISO 19443 Structure
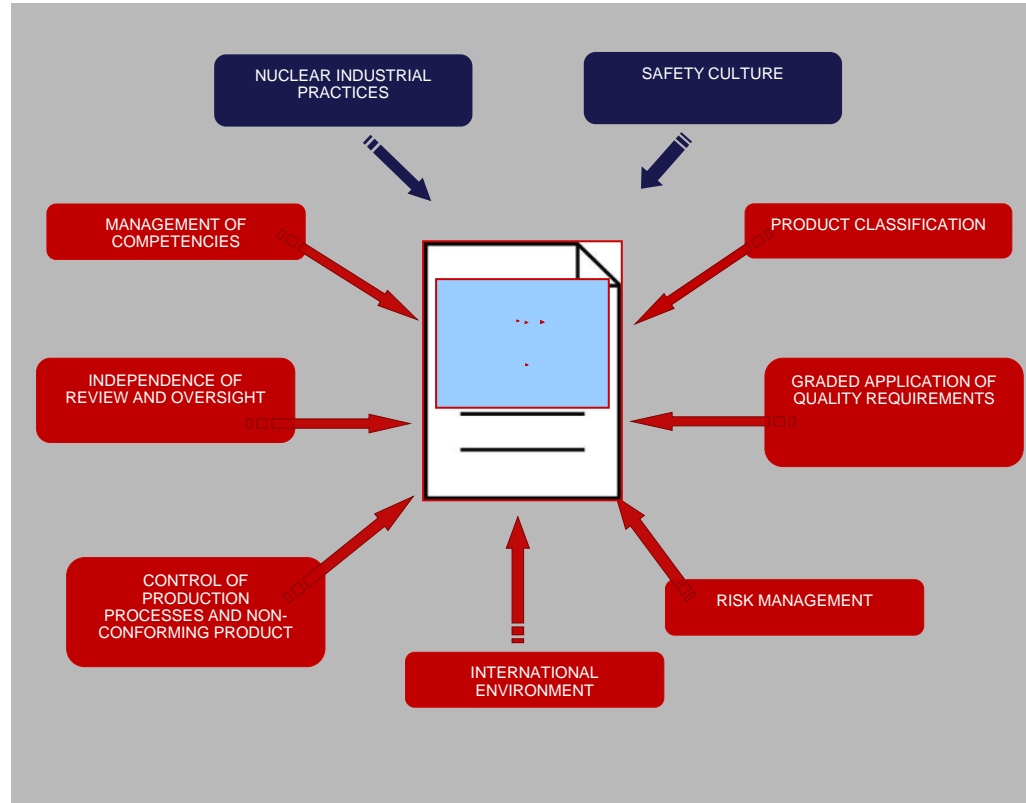
4. Context of the organization
4.1 Understanding the organization and its context
4.2 Understanding the needs and expectations of interested parties
4.3 Determining the scope of the quality management system
4.4 Quality management system and its processes
5. Leadership
5.1 Leadership and commitment
5.1.1 General
5.1.2 Customer focus
5.1.3 Nuclear safety culture
5.2 Policy
5.2.1 Establishing the quality policy
5.2.2 Communicating the quality policy
5.3 Organizational roles, responsibilities and authorities
6. Planning
6.1 Actions to address risks and opportunities
6.1.3 Determination of ITNS items and activities
6.1.4 Graded approach to the application of quality requirements
6.2 Quality objectives and planning to achieve them
6.3 Planning of changes
7. Support
7.1 Resources
7.1.1 General
7.1.2 People
7.1.3 Infrastructure
7.1.4 Environment for the operation of processes
7.1.5 Monitoring and measuring resources
7.1.6 Organizational knowledge
7.2 Competence
7.3 Awareness
7.4 Communication
7.5 Documented information
7.5.1 General
7.5.2 Creating and updating
7.5.3 Control of documented information

ISO 9001:2015 replicated as is

- text in box

Slight adaptation to complement ISO 9001 with nuclear specificities

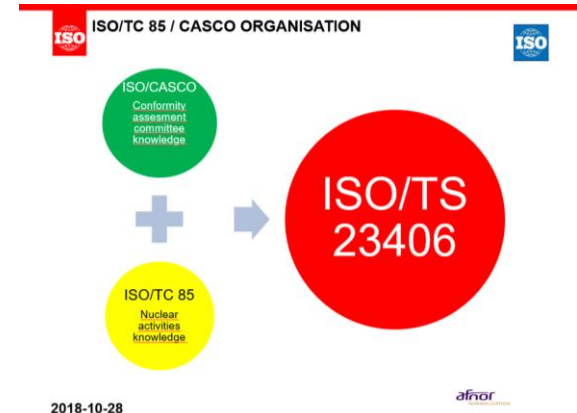New sections to comply with nuclear specificities

# ISO 19443 benefits

■ **Standardize the requirements**

 ◆ Built on industrial practices already well understood and applied in other industries

 ◆ Integrates nuclear requirements (from various origins : major stakeholders, NQA-1, IAEA GSR part 2)

 ◆ Supported by an implementation guidance

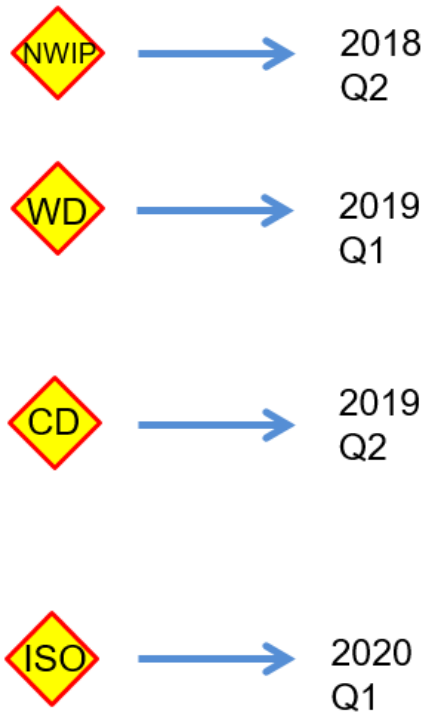■ **Help suppliers through an unique and shared quality platform**

 ◆ Over the time, represents a greater attractiveness for suppliers as an international and recognized standard, trans-project

  ⮑ **cost reduction, quality enhancement**

 ◆ Creates a capitalization of know-how and competence of supply chain

  ⮑ **create a high quality platform of nuclear suppliers**

# ISO TC85 WG4 – latest news

**NQSA**
Nuclear Quality Standard Association

- **Publication of ISO 19443 in 2018 - a major first step towards the international standardization** of nuclear suppliers assessment.

- **ISO 19443 guidance material** is under finalization: ISO Working Group held mid-October. Target for issuance of the technical report - beginning of 2019.

- Certification: **Kick Off Meeting for the ISO TS 23406** held mid-October to launch the Working Group activities. This WG will be jointly chaired by ISO & CASCO representatives. AFNOR will ensure the secretary position.



ISO/TC 85 / CASCO ORGANISATION

ISO/CASCO
Conformity assessment committee knowledge

+ →

ISO/TS 23406

ISO/TC 85
Nuclear activities knowledge

2018-10-28

afnor

ISO

# Tentative ISO TS 23406 roadmap

**F.1 Simplified diagram of options**

NWIP → 2018 Q2

WD → 2019 Q1

CD → 2019 Q2

ISO → 2020 Q1

**Contributing countries:**
- **France**
- **UK**
- **Germany**
- **Italy**
- **Russia**
- **China**
- **Canada**
- **Kenya**

| Project stage | Normal procedure | Draft submitted with proposal | "Fast-track procedure" ᵃ | Technical Specification ᵇ | Technical Report ᶜ | Publicly Available Specification ᵈ |
|---|---|---|---|---|---|---|
| Proposal stage (see 2.3) | Acceptance of proposal | Acceptance of proposal | Acceptance of proposal ᵃ | Acceptance of proposal | Acceptance of proposal | Acceptance of proposal ᵉ |
| Preparatory stage (see 2.4) | Preparation of working draft | Study by working group ᵉ | | Preparation of draft | | Approval of draft PAS |
| Committee stage (see 2.5) | Development and acceptance of committee draft | Development and acceptance of committee draft ᵉ | | Acceptance of draft | Acceptance of draft | |
| Enquiry stage (see 2.6) | Development and acceptance of enquiry draft | Development and acceptance of enquiry draft | Acceptance of enquiry draft | | | |
| Approval stage (see 2.7) | Approval of FDIS ᶠ | Approval of FDIS ᶠ | Approval of FDIS ᶠ | | | |
| Publication stage (see 2.8) | Publication of International Standard | Publication of International Standard | Publication of International Standard | Publication of Technical Specification | Publication of Technical Report | Publication of PAS |

Stages in *italics*, enclosed by dotted circles may be omitted.
ᵃ See F.2.
ᵇ See 3.1.
ᶜ See 3.3.
ᵈ See 3.2.
ᵉ According to the result of the vote on the new work item proposal, both the preparatory stage and the committee stage may be omitted.
ᶠ May be omitted if the enquiry draft was approved without negative votes.
ᵍ See ISO and IEC Supplements for details on proposals for PAS.

2019 · 2020

1 2 3 4 5 6 7 8 9 10 11 12 1 2 3 4 5 6

2018-10-28

- ▶ **Association founded by Framatome & Bureau Veritas**

- ▶ **7 companies are full members, WNA is associated member**

- ▶ **Our aim : promote the standardisation of supplier oversight**

  - First standard NSQ 100 published by NQSA in 2010 *(based on ISO 9001-2008 & IAEA GSR-3)*

  - 8 guidelines published in 2011 for NSQ100 implementation

  - NSQ 100 was used as a first draft for ISO 19443, proposed in 2015

- ▶ **Actively supporting the ISO19443 published in May 2018**

# Challenges for the Nuclear Industry
# in the implementation of ISO 19443

■ **Nuclear Industry should increase cooperation to get prepared for the implementation of the new standard ISO 19443 and open a dialogue to review the way of using this standard at an international level :**

1. ISO 19443 requirements can be simply used in the supplier assessment process, without any certification request,

2. ISO 19443 accredited certificates can be requested by the Nuclear Industry according the use of specific ISO TS 23406 to include nuclear requirements for certification process,

3. ISO 19443 certification scheme could be controlled by the nuclear industry, with an approach similar to other industry models : aeronautics, automotive, rails

# NQSA approach for ISO 19443 certification

- Meeting/Workshop to exchange and discuss views on "Towards a nuclear Industry Controlled Certification scheme for the implementation of ISO 19443?",

    - was held in June 2018 in Paris

    - NQSA members : Framatome, Bureau Veritas, Rolls Royce, VO Safety, MHI, ENGIE, ROSATOM, WNA

    - EDF, ORANO

    - UK Safety Directors' Forum, AFCEN, OECD/NEA

- **Presentation** of solutions experimented by other Industrial sectors:

    - Automotive - IATF,

    - Aerospace - ICOP,

    - Rail – IRIS.

**11 companies & organisations participated to discuss possible certification schemes**

**Large support to ISO ongoing work:**

▪ to draft a technical report providing <u>guidance for the implementation</u> of ISO19443 (target publication: Beginning 2019)

▪ to draft an ISO19443 accreditation standard (<u>ISO TS 23406</u> target for 2020)

**However:**

▪ **Detailed matrix-comparison with existing other standards or regulations would be useful** (NQA1, GSR-part 2, YVL guides, RCC codes, Russian standards, Korean standards, etc).

*NQSA is setting an open-working group for performing this job.*

▪ ISO traditional accreditation process won't be enough to ensure that certification audits meet Industry expectations.

*There is room for Industry oversight in addition to future ISO accreditation processes*

An Industry Controlled Certification Scheme could be an **opportunity to improve performance in the implementation of ISO19443** => **objective : greater confidence and recognition in the certification**

- ❑ Efforts should be joined at international level to work on reviewing possible schemes (Industry main stakeholders, IAEA, Foratom, WNA, NQSA, Vendor Inspection Cooperation Working Group, reactors' owners' groups, WANO, etc.)
- ❑ A close dialogue with Regulatory Safety Authorities should also be established

The **competence/experience of auditors is key** for ensuring performance of audits, where ISO accreditation processes don't include any specific requirements?

- ❑ A particular focus for Industry oversight complementary to ISO accreditation could be given on auditors' performance (training, qualification, supervision)

*Proposal to work on a cooperation roadmap to set up working groups and analyse a potential Nuclear Industry-Controlled Certification Scheme*

# Cooperation Roadmap Proposal
## Nuclear Industry-Controlled Certification Scheme

***3 topics of cooperation***

❑ To cooperate on defining **the most adequate scheme**: scope, participants, rules, governance, functioning, and interface with other organisations (such as regulators or accreditation bodies) or nuclear industry associations (for example, reactor owners' group, WANO, NUPIC, CANPAC).

  ❑ The working group will address topics such as national practices for accreditation, unified approach for recognition of certification bodies under the scheme, scheme recognition by national legislations, national organisation, international coordination, funding, and oversight arrangements.

❑ To cooperate on a **scheme to strengthen the competence of the ISO 19443 auditors** by:

  ❑ Reviewing the competency expectations and independence of auditors and the mechanisms through which the industry will ensure these expectations are met;

  ❑ Collecting good practices on the performance of quality auditors;

  ❑ Reflecting on a training-qualification-supervision scheme for auditors under ISO 19443 that can be controlled by the industry.

  ❑ With a clear objective of not duplicating the ISO TS 23406 WG activites

❑ To cooperate on information exchanges and mutual recognition of national certifications.

  ❑ Existing exchange platforms that exist in the aeronautics, automotive and the railway industries can be used as input data. Consideration will be given to topics such as: shared data base, what information can be shared and with whom.

# Cooperation Roadmap Proposal
# Nuclear Industry-Controlled Certification Scheme

**Bureau Veritas**

**EDF**

**ENERGOATOM**

**ENGIE**

**FRAMATOME**

**NQSA**

**ROLLS-ROYCE Civil Nuclear**

**ROSATOM**

**SAFETY DIRECTORS' FORUM**

**URENCO**

**WORLD NUCLEAR ASSOCIATION**

# *Thank you for your attention*