WEBINAR

Railway professional: How to win the trust of your customers ?

IRIS Rev.03 based on ISO/ TS 22163 : 2017

25/06/2019

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GROUPE

SPEAKERS

Mr. Bernard KAUFMANN

IRIS GENERAL MANAGER

Mrs. Angela DEHEYMER

IRIS SENIOR MANAGER

Mr. Claude BOUTEAUD

IRIS AUDITOR/ EXPERT

Mrs. Hend HOUIMEL

GLOBAL RAILWAY PRODUCT
MANAGER

OBJECTIVES OF THE WEBINAR

Understand the context of the IRIS Certification™

Understand the IRIS system

How to initiate the certification process ?

AGENDA

INTRODUCTION

1. Context and market of IRIS Certification™

2. ISO/ TS 22163 Standard

QUIZZ#1 #2

3. IRIS Certification™ rules : 2017

QUIZZ#3

4. Feedbacks from audits

5. IRIS Certification™ process

QUESTIONS AND ANSWERS

IRIS CERTIFICATION™

1. Understand the context and market of IRIS Certification™

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Understand the context of IRIS Certification™

IRIS (INTERNATIONAL RAILWAY INDUSTRIAL STANDARD) IDENTITY CARD

Homogeneous and internationally recognized evaluation tool

Developed by UNIFE (Union of European Railway Industries) with the support of major players in the railway industry

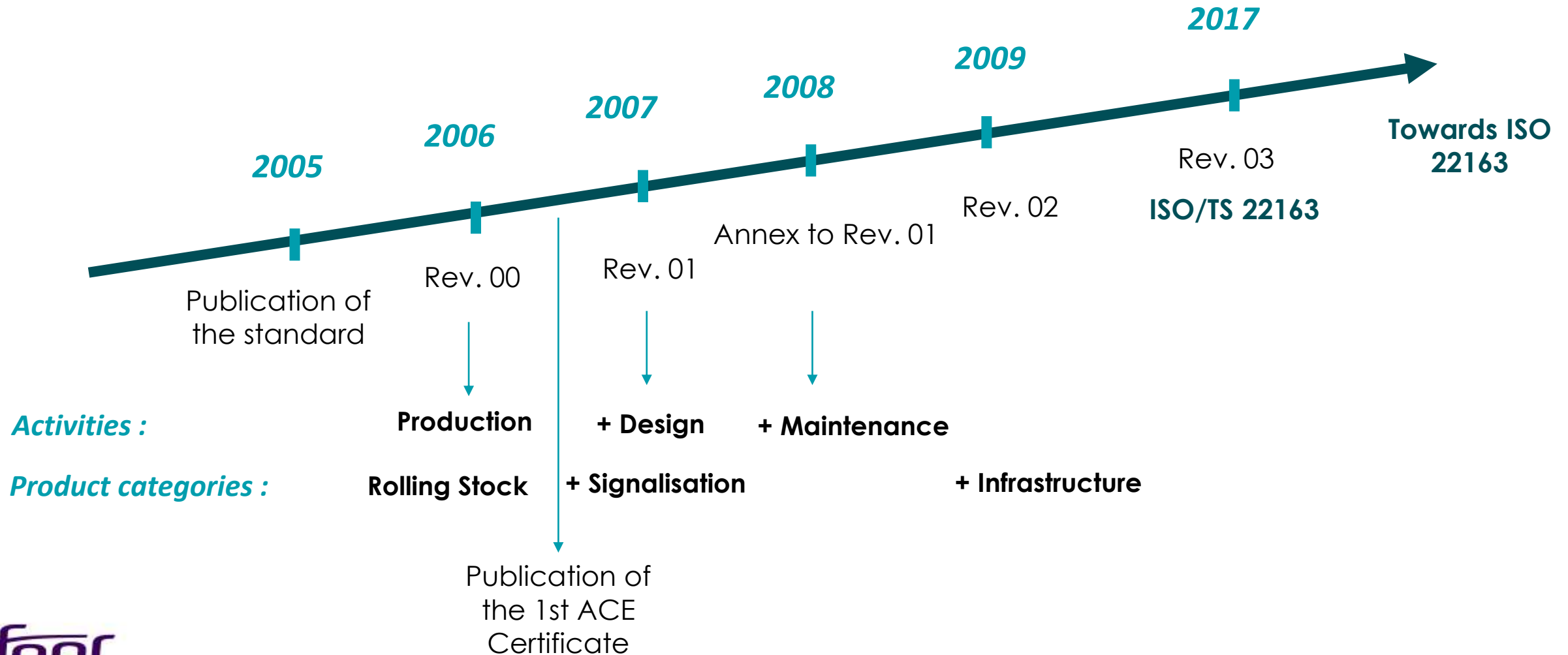**Born from dysfunctions at several levels of the supply chain**

IRIS™ Certification

Based on ISO 9001+ sector specific requirements

Applicable to all players in the rail supply chain in Europe and worldwide

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Understand the context of IRIS Certification™

EVOLUTION OF IRIS STANDARD

2005
Publication of the standard

2006
Rev. 00

2007
Rev. 01

2008
Annex to Rev. 01

2009
Rev. 02

2017
Rev. 03
ISO/TS 22163

Towards ISO 22163

Publication of the 1st ACE Certificate

Activities :

Production   **+ Design**   **+ Maintenance**

Product categories :

Rolling Stock   **+ Signalisation**   **+ Infrastructure**

Understand the context of IRIS Certification™

OBJECTIVES OF IRIS CERTIFICATION ™

- ✓ **Respond to the specific challenges of the sector:**
  - **Very small series**
  - **High technicity and security products**
  - **Projects (up to 6 years) and lifecycle (up to 35 years)**
  - **Multi-site project management**

- ✓ **Improve the quality and safety of the products**
- ✓ **Strengthen prevention and reduction of failures in the supply chain**
- ✓ **optimize costs !**

Understand the context of IRIS Certification™

STAKEHOLDERS IN THE ACCREDITATION / CERTIFICATION SCHEME

Designates the Union of European Railway Industries. This association is composed of the main manufacturers (Alstom, Bombardier, CAF, Siemens, Ansaldo ...) and operators (RZD, SNCB, SNCF etc.).

UNIFE directs the IMC created to pilot the IRIS certification scheme.

The IMC designates the IRIS Management Center and supervises the IRIS approved certification bodies in order to guarantee the conformity of the certification process defined in the IRIS certification rules.

He is the guarantor of the training program for the qualification of the auditors.

International standardization body, useful for industrial and economic organizations of all types in both the public and private sectors, which aims to produce international standards.

ISO is the owner of ISO / TS 22163.

AFNOR certification is a certifying body approved by IRIS to carry out audits and issue IRIS certification (based on ISO / TS 22163) at the request of any company in the railway sector.

Understand the context of IRIS Certification™

IRIS CERTIFICATION™ SYSTEM

**IRIS Certification™
rev.03**

→ UNIFE recognizes the accreditation of AFNOR Certification by a framework contract signed between the two parties.

ISO/TS 22163:2017
requirements for the quality management system in the railway sector

→ ISO owns and manages ISO / TS 22163;

**IRIS Certification™
rules:2017**
rules to achieve and maintain IRIS certification recognition

→ The IRIS Mangement Center (IMC) manages the rules applicable to IRIS certification

**Certification IRIS
Certification™**

→ Accredited CBs manage the certification process according to the contract and rules.

**IRIS Portal (database)
Audit tool (software)**

Understand the context of IRIS Certification™

IMC (IRIS MANAGEMENT CENTRE)

Bernard Kaufmann *
IRIS General Manager
Office: +32 2 643 70 86
Mobile: +33 7 89 21 63 21
Email: bernard.kaufmann@unife.org
* acting as representative of BK Rail

Anish Bawa
IRIS Technical Manager
Office: +32 2 643 70 84
Mobile: +32 497 05 25 57
Email: anish.bawa@unife.org

Angela de Heymer
IRIS Senior Manager
Office: +32 2 642 23 23
Mobile: +32 499 05 73 17
Email: angela.deheymer@unife.org

Vanessa Pereira
IRIS Technical Manager
Office: +32 2 642 23 21
Mobile: +32 496 83 28 84
Email: vanessa.pereira@unife.org

María Romero
IRIS Manager
Office: +32 2 642 23 26
Mobile: +32 493 40 29 81
Email: maria.romero@unife.org

Agathe Marie
IRIS Communications Manager
Office: +32 2 431 04 63
Mobile: +32 496 16 49 07
Email: agathe.marie@unife.org

Understand the context of IRIS Certification™

IRQB (INDUSTRIAL RAIL QUALITY BOARD)

18th September 2018 signature of IRQB (International Rail Quality Board) Consortium Agreement

21 signatories:
- Operators: DBAG / RZD / SNCB /SNCF / Metro de Madrid / SBB-CFF-FFS / NS / Metro de Barcelona/ JR-East / PATENTENS TALGO (from July 2019)

- System Integrators: Alstom / Siemens / Bombardier / CAF / Hitachi Rail STS

- Equipment manufacturers: HARTING / GHH / Knorr-Bremse/ Schaeffler / Voith / Faiveley

Understand the context of IRIS Certification™

THE DIFFERENT ACTORS

OPERATORS

Companies providing passenger / goods transport and carrying out the management, operation and maintenance of the railway network of which it is the owner.

INTEGRATORS

These are the manufacturers who supply a complete assembled product (train, locomotive etc.) to operators and / or owners of rolling stock and railway infrastructure.

SUPPLIERS

These are the equipment manufacturers that supply assemblies / subassemblies (air conditioning, doors, brake systems, etc.) for their railway (integrator) customers.

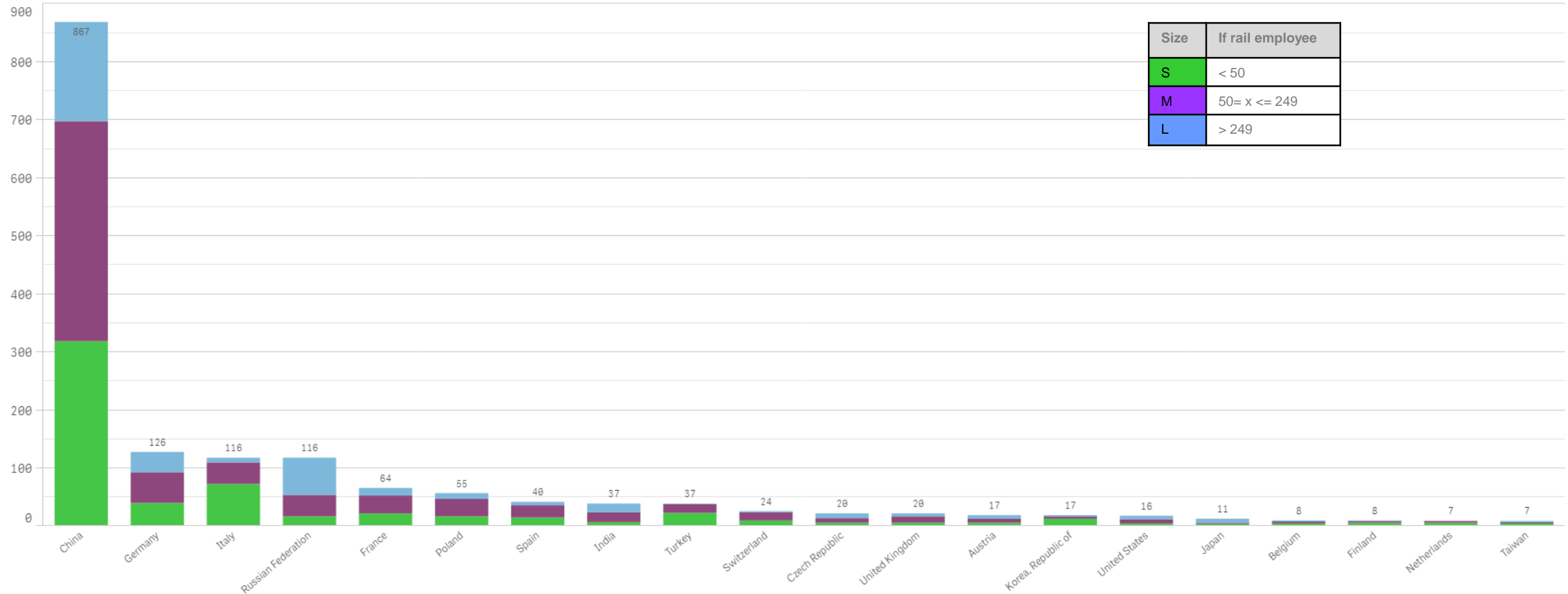# Understand the context of IRIS Certification™

APPLICATION DOMAIN

o The ISO / TS 22163 standard is applicable to **suppliers, integrators and operators** of the railway industry carrying out design-development, production and maintenance of equipment.

o IRIS Rev.03 requirements are defined in **ISO/ TS 22163 and IRIS Certification ™ rules: 2017**

o **Voluntary** certification, based on:
   All the requirements of **ISO 9001:2015** and,
   Additional requirements adapted to the QMS in the **railway**
   - Small series
   - Very long projects and life cycle

Understand the context of IRIS Certification™

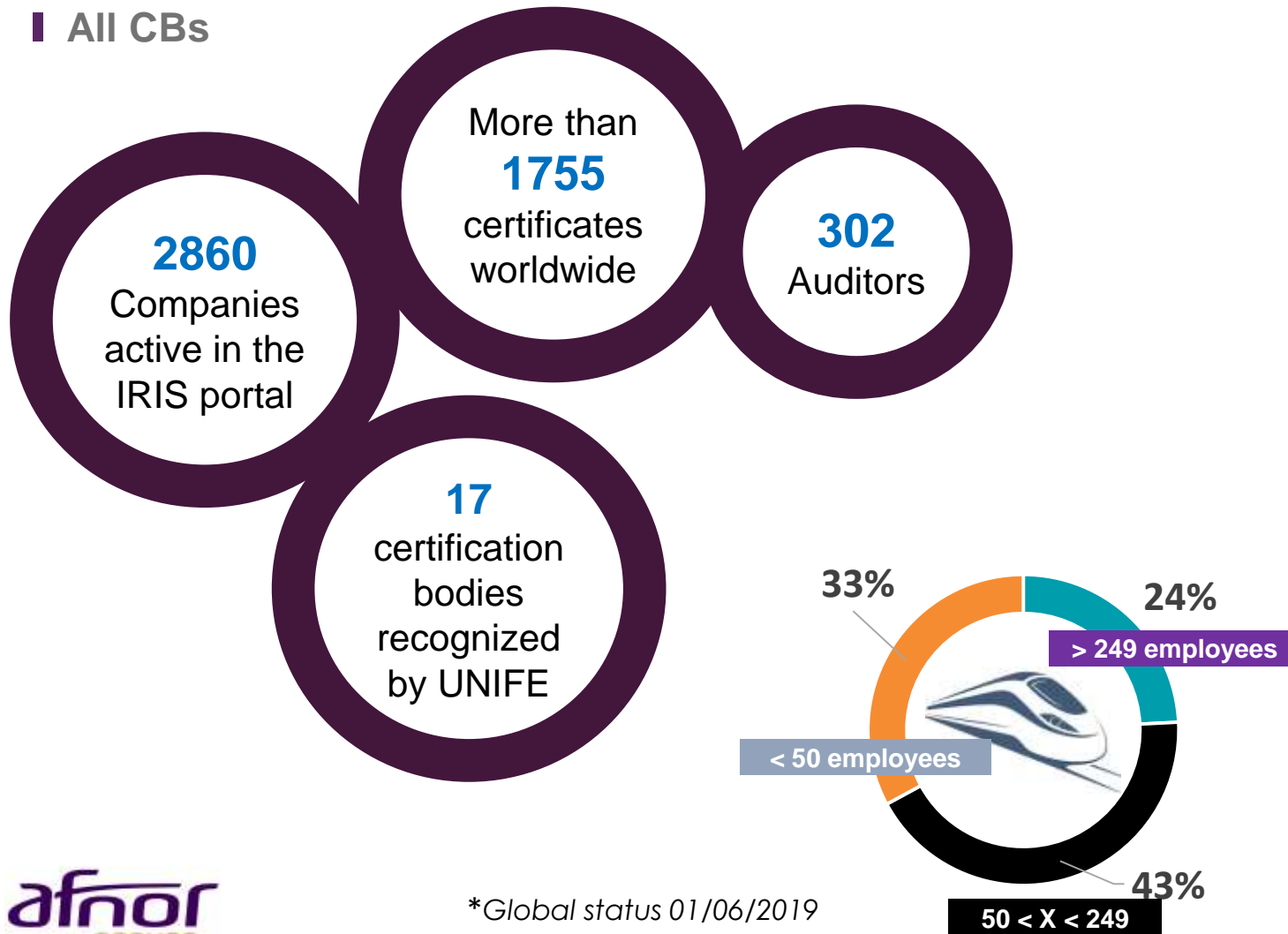## DISTRIBUTION OF IRIS CERTIFICATES IN THE WORLD

Size	If rail employee
S	< 50
M	50= x <= 249
L	> 249

China 867, Germany 126, Italy 116, Russian Federation 116, France 64, Poland 55, Spain 40, India 37, Turkey 37, Switzerland 24, Czech Republic 20, United Kingdom 20, Austria 17, Korea, Republic of 17, United States 16, Japan 11, Belgium 8, Finland 8, Netherlands 7, Taiwan 7

Understand the context of IRIS Certification™

IRIS CERTIFICATION™ MARKET

All CBs

2860 Companies active in the IRIS portal

More than **1755** certificates worldwide

302 Auditors

17 certification bodies recognized by UNIFE

33%
24% > 249 employees
< 50 employees
43%
50 < X < 249

Global status 01/06/2019

AFNOR Certification and its competitors

1st BUREAU VERITAS

2nd afnor CERTIFICATION

3rd DNV·GL

258 active certificates

77% AFNOR Chine/Taiwan

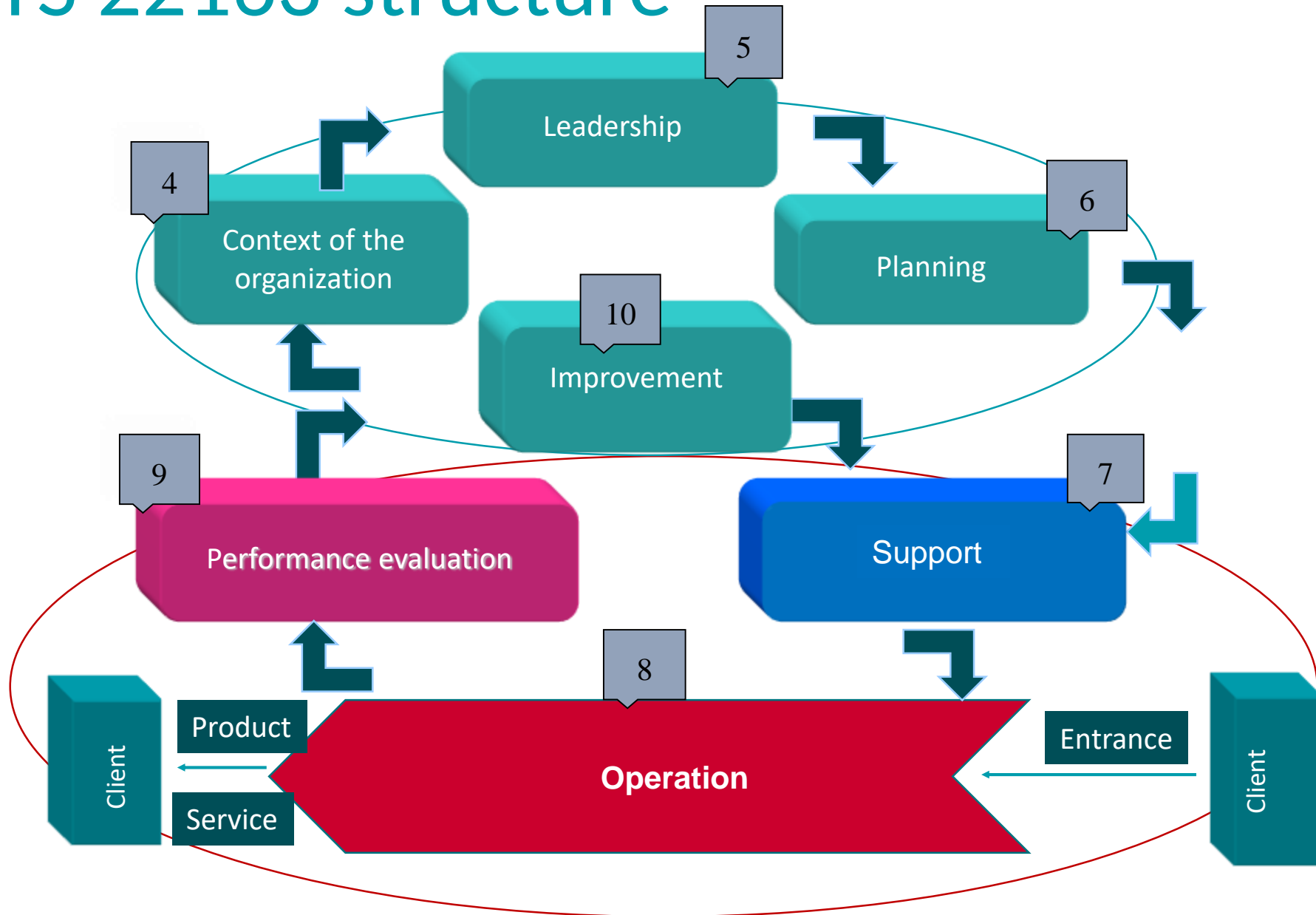**13%** AFNOR France
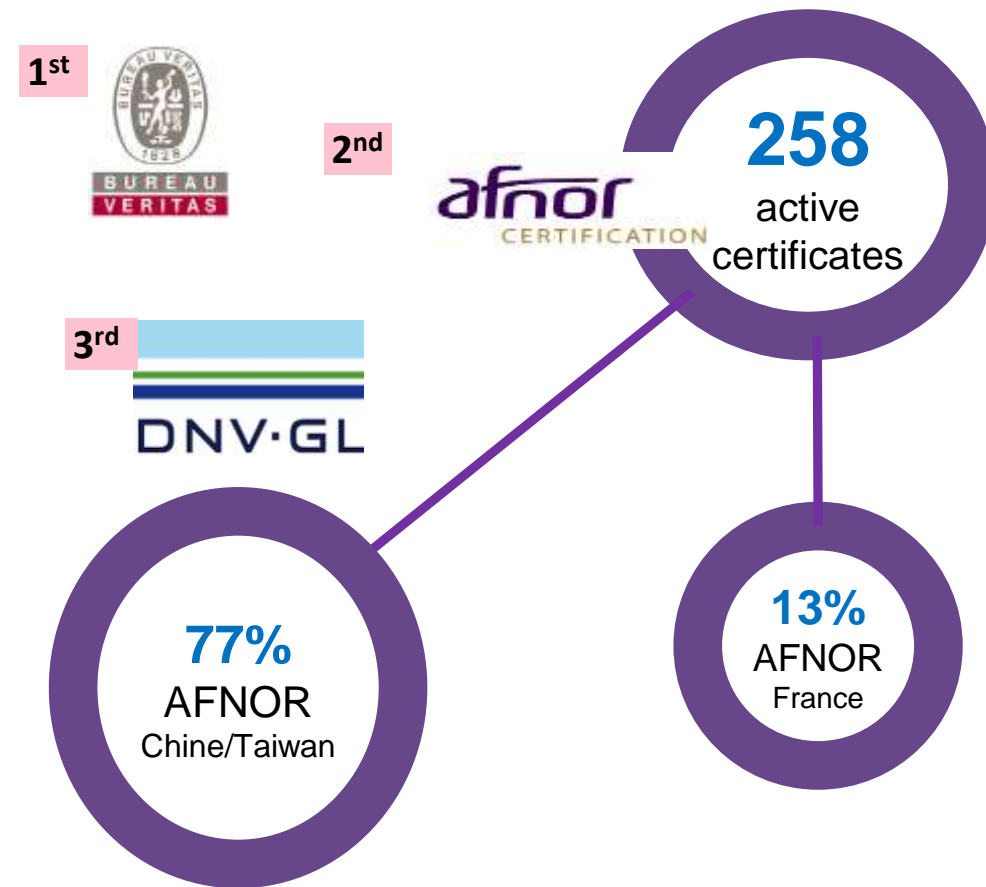
Source: IRIS Portal

afnor GROUPE

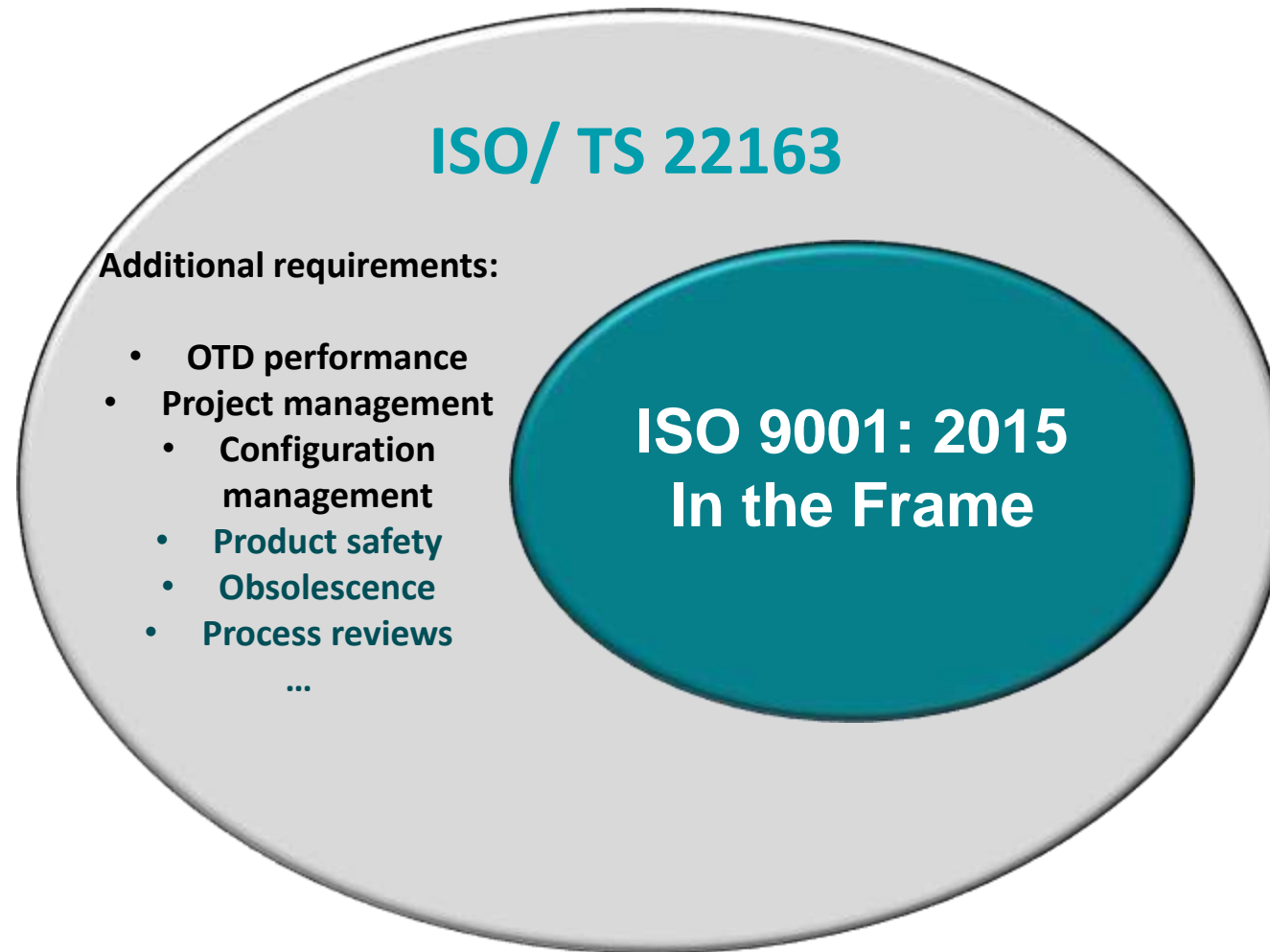# IRIS CERTIFICATION™

2. Know the ISO/ TS 22163 standard

- ISO/ TS 22163 standard and structure
- Railway specific requirements
- Major evolutions of the standard

ISO/ TS 22163 structure

ISO/ TS 22163 structure

ISO/ TS 22163

Additional requirements:

- **OTD performance**
- **Project management**
  - **Configuration management**
  - **Product safety**
  - **Obsolescence**
  - **Process reviews**
  - **...**

**ISO 9001: 2015
In the Frame**

ISO/ TS 22163 requirements

CHAPTER 4 & 5 : CONTEXT OF THE ORGANIZATION & LEADERSHIP

L E A D E R S H I P

Process approach reinforcement
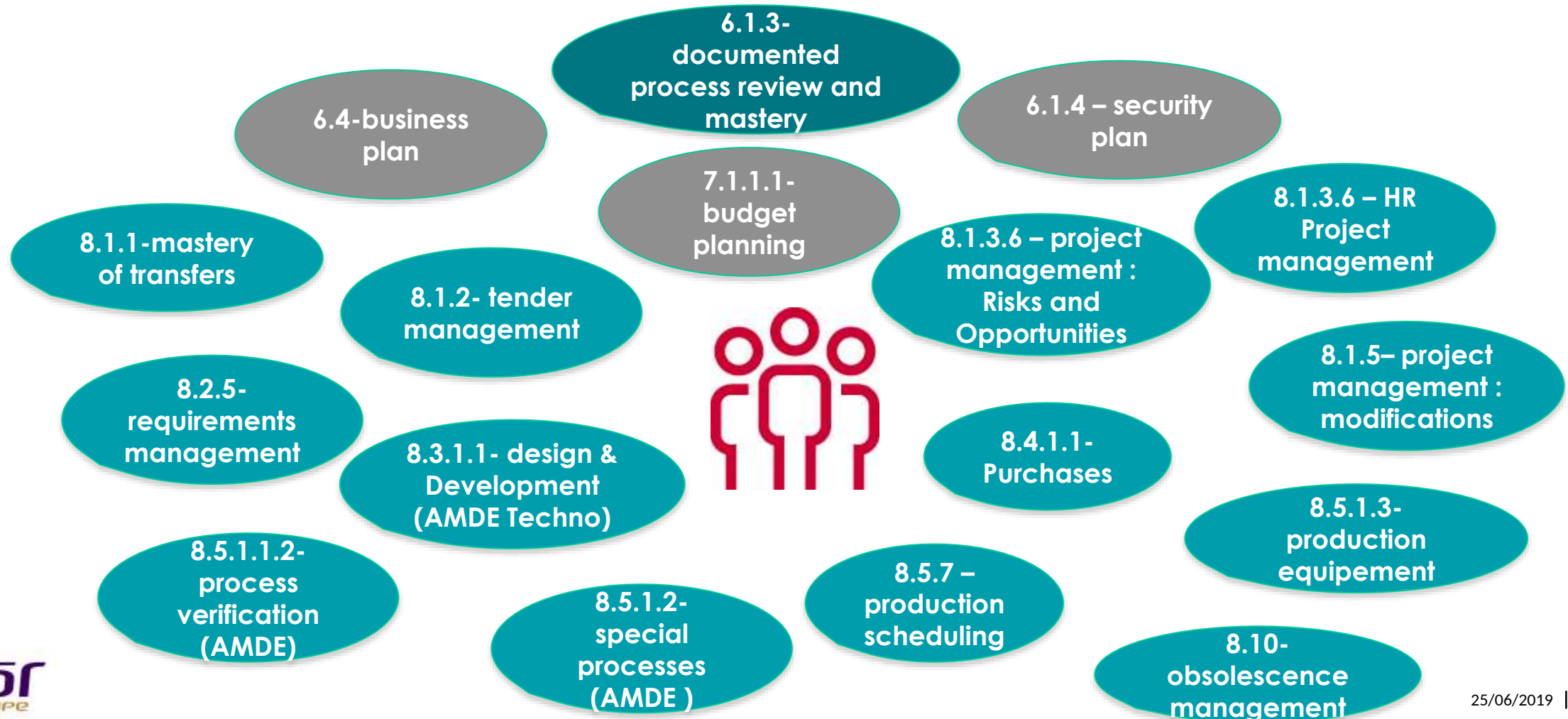
Leadership of process pilots

Process training

Conformity assessment of processes to ISO/ TS 22163

ISO/ TS 22163 requirements

« Risks and opportunities » - ISO/ TS Supplemental

6.1.3- documented process review and mastery

6.4-business plan

6.1.4 – security plan

7.1.1.1- budget planning

8.1.3.6 – HR Project management

8.1.1-mastery of transfers

8.1.2- tender management

8.1.3.6 – project management : Risks and Opportunities

8.2.5- requirements management

8.1.5– project management : modifications

8.3.1.1- design & Development (AMDE Techno)

8.4.1.1- Purchases

8.5.1.1.2- process verification (AMDE)

8.5.1.2- special processes (AMDE)

8.5.7 – production scheduling

8.5.1.3- production equipement

8.10- obsolescence management

ISO/ TS 22163 requirements

CHAPTER 6 : PLANNING

Documented Risk Management Process

a) the requirements described in 6.1.1 and 6.1.2;

b) periodic reviews and updates of risks and actions;

c) the retention of documented information from risk assessments, reviews and actions.

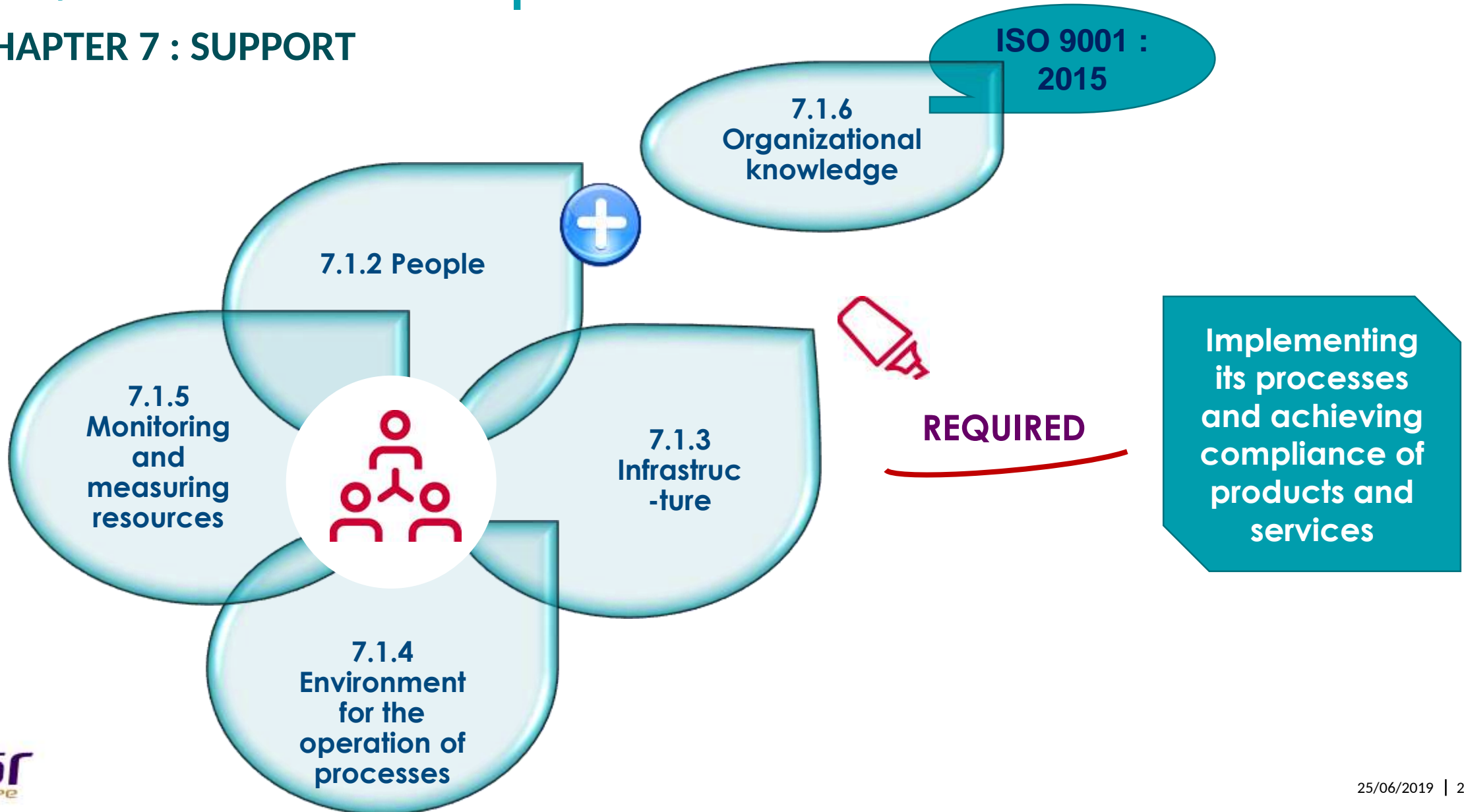**Documented strategic planning**

Reviewed annually

Elements to be taken into account at least

ISO/ TS 22163 requirements

RESSOURCES

7.1.6 Organizational knowledge

ISO 9001 : 2015

7.1.2 People

7.1.5 Monitoring and measuring resources

7.1.3 Infrastruc-ture

7.1.4 Environment for the operation of processes

REQUIRED

Implementing its processes and achieving compliance of products and services

QUIZZ #1

ISO/ TS 22163 requirements

QUIZZ #1

1- About process approach do you have to Train people to process and Appoint process owners ?

YES   NO

2- For risk management do you need to have a formal methodology (process) ?

YES   NO

ISO/ TS 22163 requirements

CHAPTER 8 : OPERATION

Significant differences between ISO/ TS 22163 and ISO 9001:

Documented processes requested on :

- ► Transfer planning
- ► Tender management
- ► Project management
- ► Change Management
- ► Configuration Management
- ► Requirements for products and services
- ► Control of externally provided processes, products and services (PPSPE)
- ► RAM and LCC
- ► Obsolescence Management

ISO/ TS 22163 requirements

CHAPTER 8 : OPERATION

8.1.2. TENDER MANAGEMENT

A documented tender management process is required.

- This process must include in particular :
    - requirements management (see 8.2)
    - their financial evaluation;
    - the contribution of organizational knowledge
    - **planning deliverables, costs included (eg, dates, price)**
    - **planning resources dedicated to the contract**

- The organization shall define the types and levels of skills required for requirements management for the persons handling the offers.

ISO/ TS 22163 requirements

CHAPTER 8 : OPERATION

8.1.3. PROJECT MANAGEMENT

The organization shall establish, implement and maintain a process documented project management.

The requirements have been reorganized and clarified especially the project management but overall no huge change.

8.1.3.1 - Project integration management (reinforcement)
8.1.3.2 - Project scope management
8.1.3.3 - Project time management
8.1.3.4 - Project Cost Management
8.1.3.5 - Project Quality management (simplification)
8.1.3.6 - Project Human Resources Management (Strengthening)
8.1.3.7 - Project communication management (reinforcement)
8.1.3.8 - Project Risk and opportunity management
8.1.3.9 - Project procurement management **(added but not consequential)**

ISO/ TS 22163 requirements

CHAPTER 8 : OPERATION

8.2.5 - Requirements for Products and Services - Supplemental

Requirement of a documented requirements management process.

This process shall :

Be applicable for:
- **design and development of new products and services**
- tender management
- **project execution**
- change control.

Performed in a multidisciplinary approach
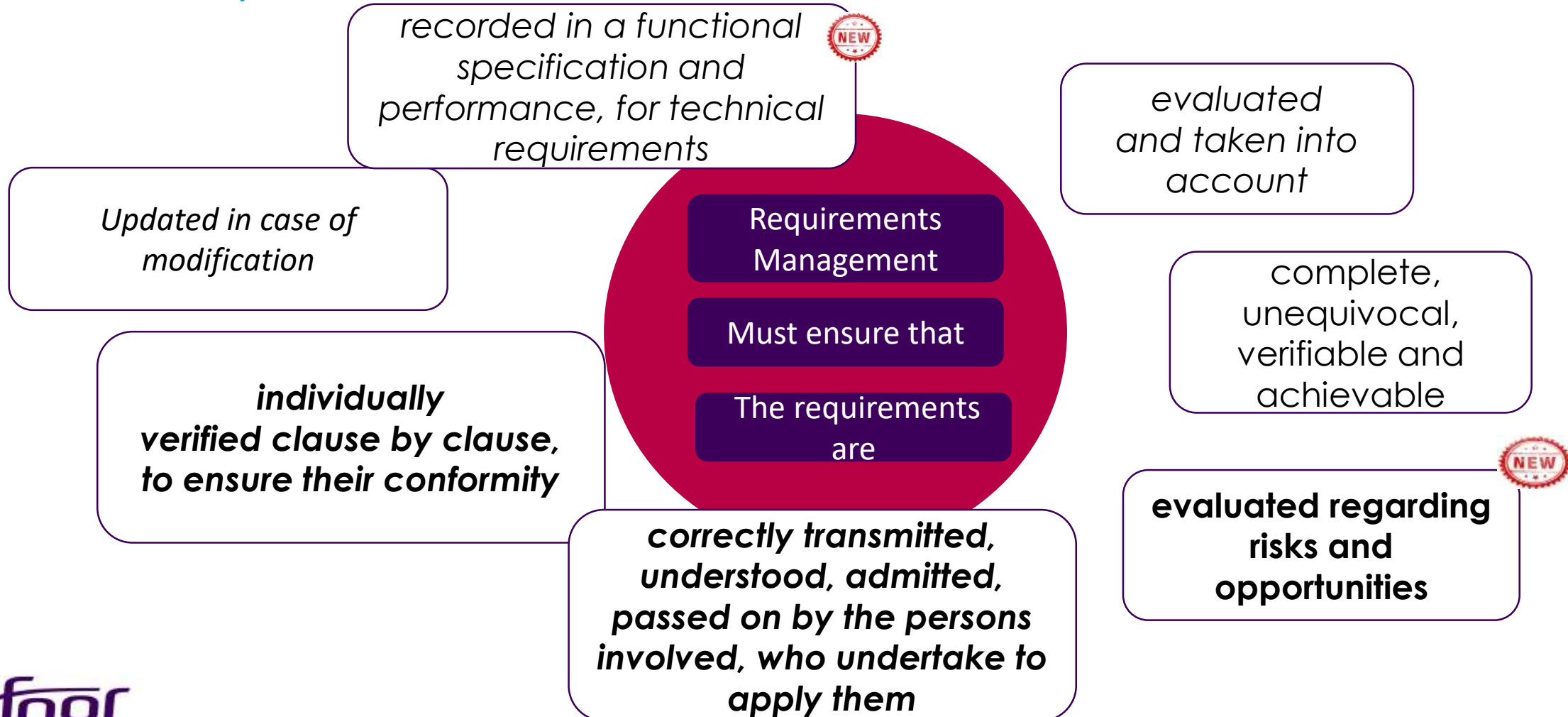
Include at least the following steps:
- **determination**
- **and review**
- **Verification and**
- **Validation**

ISO/ TS 22163 requirements

CHAPTER 8 : OPERATION

8.2.5 - Requirements for Products and Services - Supplemental

recorded in a functional specification and performance, for technical requirements NEW

evaluated and taken into account

Updated in case of modification

Requirements Management

Must ensure that

The requirements are

complete, unequivocal, verifiable and achievable

individually verified clause by clause, to ensure their conformity

evaluated regarding risks and opportunities NEW

correctly transmitted, understood, admitted, passed on by the persons involved, who undertake to apply them

ISO/ TS 22163 requirements

CHAPTER 8 : OPERATION

8.1.4 – Configuration management

The organization shall establish, implement, and maintain **a documented configuration management process appropriate to the product.**

This process shall consider :

- ✓ **configuration management planning**
- ✓ the product breakdown structure (PBS) to the smallest replaceable unit
- ✓ **identification of configuration items, at least the safety ones**
- ✓ configuration baselines to be established, at least for "as designed", "as built" and "as maintained"
- ✓ change control
- ✓ configuration status accounting
- ✓ **criteria for identification of traceability**

ISO/ TS 22163 requirements

CHAPTER 8 : OPERATION

8.1.5 – Change management

The documented change management processes shall include the requirements for :

- changes to requirements

- changes in the design and development

- changes to production and service delivery processes

These processes shall include in particular:

- the change request

- cause analysis in the event of changes caused by failures

- an impact analysis of changes

- verification of the proposed changes in order to avoid the negative effects;

These processes must be supported by application software.

ISO/ TS 22163 requirements

CHAPTER 8 : OPERATION

8.4.1.1 - Control of externally provided processes, products and services –
General - Supplemental

The organization must determine the type and extent of the 8.4 requirements that apply to service providers
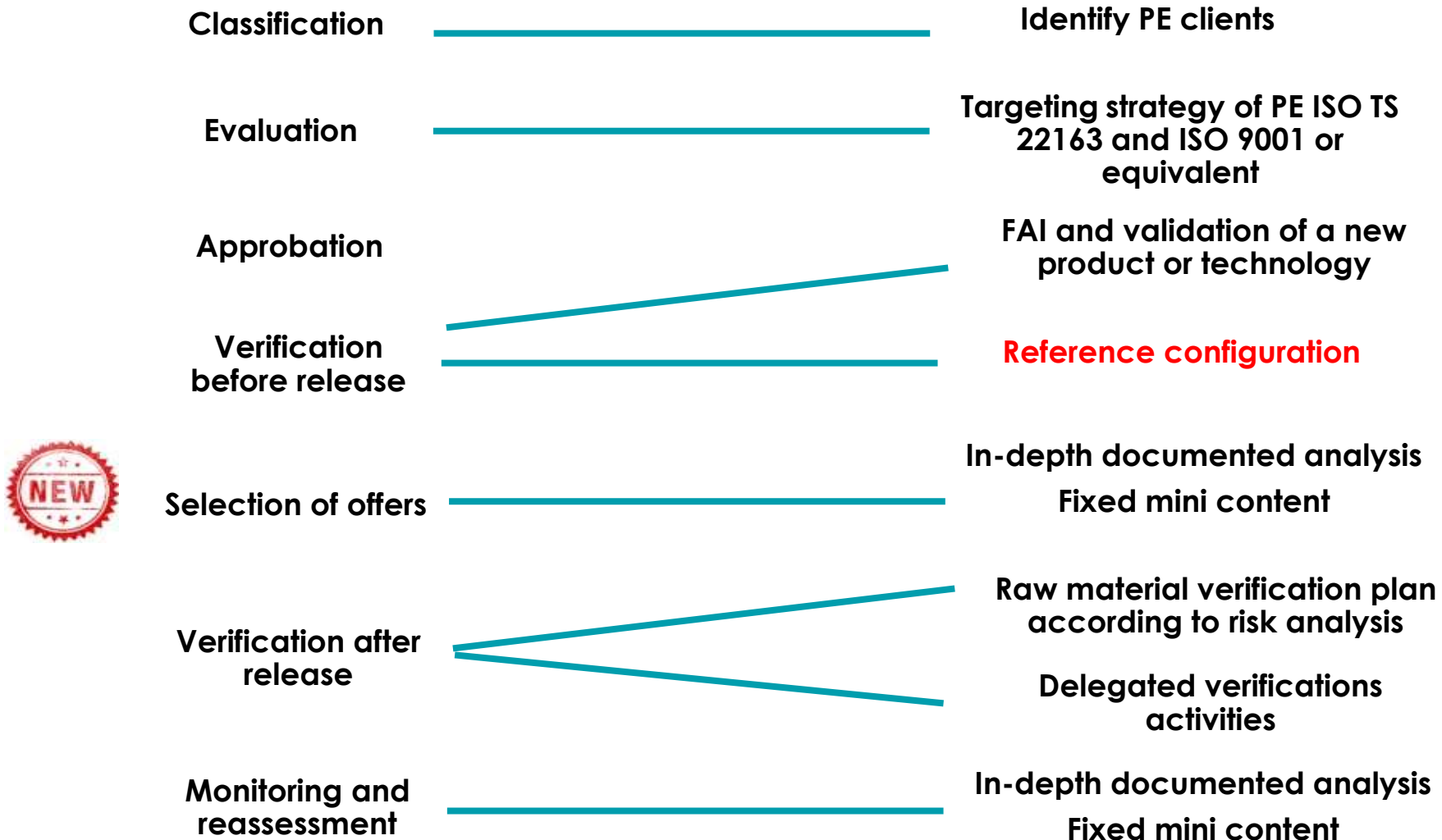
- internal and External providers
- **using risk analysis based on defined criteria.**

➔ Requirement for **a documented process** for processes, products and services provided by external service providers (EPPPS)

ISO/ TS 22163 requirements

CHAPTER 8 : OPERATION

8.4- Control of externally provided processes, products and services

Classification	Identify PE clients
Evaluation	Targeting strategy of PE ISO TS 22163 and ISO 9001 or equivalent
Approbation	FAI and validation of a new product or technology
Verification before release	**Reference configuration**
Selection of offers	In-depth documented analysis / Fixed mini content
Verification after release	Raw material verification plan according to risk analysis / Delegated verifications activities
Monitoring and reassessment	In-depth documented analysis / Fixed mini content

ISO/ TS 22163 requirements
CHAPTER 8 : OPERATION

8.5.1.1 - Control of production and service provision - supplemental

Requirement of a documented process of production and service delivery.

This process shall:

<table>
<tr>
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a) include requirements for:
    1) scheduling of production (see 8.5.7);
    2) activities ensuring the control of conditions (see 8.5.1.1.1);
    3) verification of the production and service delivery process (see 8.5.1.1.2);
    4) validation of the production and service delivery process (see 8.5.1.1.3);
    5) control activities of production equipment (see 8.5.1.3);
    6) activities ensuring identification and traceability (see 8.5.2);
    7) the management of the assets of customers or external service providers (see 8.5.3);
    8) preservation (see 8.5.4);

</td>
<td>

b) refer to:
    1) **to first article inspections (see 8.9);**
    2) configuration management (see 8.1.4);
    3) change management (see 8.1.5);
    4) release of goods and services (see 8.6);
    5) control of non-compliant output elements (see 8.7);
    6) special processes (see 8.5.1.2).

</td>
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</table>

ISO/ TS 22163 requirements

CHAPTER 8 : OPERATION

8.5.1.2 Special processes

The organization shall establish, implement and maintain a documented process for managing special processes, including:

• the identification of special processes that the organization plans to use;

• **for each special process,** the definition of:
- responsibilities and authorities
- applicable standards
- **Risk Assessment (FMEA)**
- work instructions according to a 6M approach:
  - Management, Manpower, Machine, Methods, Material, Mother nature (Environmental conditions)
- staff skills and qualifications;
- control methods and related documented information;
- the qualification of the special process;
- validation of each specific application;
- revalidation after the modifications;

ISO/ TS 22163 requirements

CHAPTER 8 : OPERATION

8.8 RAM and LCC

Documented processes are requested for the management of RAM and LCC activities. (No safety).

These processes must include:

- › a) the calculation of RAM and LCC objectives
- › b) implementation of RAM and LCC requirements in design and development and throughout the supply chain
- › c) data collection
- › **d) analysis and comparison with field data from similar earlier products (FRACAS);**
- › e) transmission of feedback on RAM and LCC data to relevant operational teams to improve design principles,
- › **f) Sharing with external providers of the results of RAM and LCC data analyzes on the elements provided;**
- › g) If the objectives are not achieved, the organization must
  - • give priority to field data,
  - • carry out the corrective actions required in 10.2 and
  - • monitor field data until targets are met.

ISO/ TS 22163 requirements

CHAPTER 8 : OPERATION

8.10 Obsolescence management

A documented process to ensure the availability of supplied products and their spare parts, at least **until the end of the warranty.**

This process shall include:

a) the definition and regular review, for the purpose of updating, of a plan covering:

› a second procurement strategy;

› the applied storage approach;

› the FIT FORM FUNCTION referring to the change management process (see 8.1.5);

b) the risk management of obsolete parts

c) communication with the customer.

ISO/ TS 22163 requirements

CHAPTER 9: PERFORMANCE EVALUATION

9.4 Process review

Regarding process reviews, the organization shall:

a) review the mandatory processes required by this document every 12 months at a minimum;

b) ensure that:

1) process owners participate in process reviews, as well as **management representatives of process stakeholders;**

2) the compliance of processes with the requirements of 4.4.1 is raised during process reviews;

3) the actions of previous process reviews are monitored;

4) decisions are made and actions are taken if needed;

5) results of process reviews are reported to management;

6) the input and output of process reviews are documented and maintained;

7) non-conformities resulting from the process concerned are monitored;

8) The resources needed to execute the process are available and effective.

QUIZZ #2

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Understand the context of IRIS Certification™

QUIZZ #2

1- Do you need to have a formal process for project management covering all the different aspects of the project

YES   NO

2- Requirement management: Do you need to do a clause by clause

YES   NO

3- Do you need to have a strategy to enable targeting of external providers compliant to ISO TS

YES   NO

4- Do you need to perform Process FMEA for all type of special processes.

YES   NO

5- Do you need to cover all mandatory processes by process reviews.

YES   NO

IRIS CERTIFICATION ™

2. Feedbacks from audits

25/06/2019

Transition Audit feedbacks

- Very **short transition time** to correctly handle new requirements, which are fortunately often identified in Readiness review (Step 1)
  - ex 22 processes covered by process review elements,
  - Competency management process confused with the training process (former ISO 9001 procedure),
  - Consistency of turtle diagrams,

- Not understanding the scope of the requirements management process (often confused with the business process),
- Difficulties in addressing the documentation of all special processes,
- Difficulties in formalizing a supplier development or incentive strategy for ISO/ TS.

Initial Audit feedbacks

- Difficulties in defining a relevant architecture of scopes
  Definitions of "remote" functions and extension sites.

- Major NCs on Classic Aspects ISO 9001 with re-audit obligation :
  - o On the operational part
  - o On leadership
  - o Staff awareness
  - o Mastery of special processes
  - o Process Reviews
  - o Methodological approach for risk management

But also :
- Outstanding initiatives to use ISO/ TS 22163 to structure the Multi-site Special Processes approach

Combined audits

AUDIT APPROACH SUCCESSFULLY COMBINED:

ISO/ TS 22163 and CMMI Devpt:
Requiring good coverage of software aspects

ISO/ TS 22163 and EN9100:
With different approaches for the product risk approach

More traditional approaches to combined audits:
ISO/ TS 22163 and ISO 14001 / OHSAS 18001 / ISO 45001

Sometimes highlighting the confusion between the notion of "Product Safety" and the notion of health and safety at work.

IRIS CERTIFICATION ™

3. Know the IRIS certification™ rules : 2017

Know the IRIS certification™ rules : 2017

AUDIT PROCESS

1- A reinforced audit method at the request of the parties interested I the evaluation objectified by the data provided on points of "Customer focus" of the repository defined.

2-Performance evaluation of processes with the turtle:

> 8.2 Requirements for products and services
> 8.1.3 Project Management ..
> 8.4 Control of processes, products and services provided by external service providers
> 8.3 Design and development of products and services.
> 8.5.1 Control of production and service delivery.

3- Recognition and visibility of the results:

Beyond the IRIS certificate of conformity, a quality performance statement will be awarded progressively with 3 levels of performance: Bronze, Silver, Gold.

Gold

Silver

Bronze
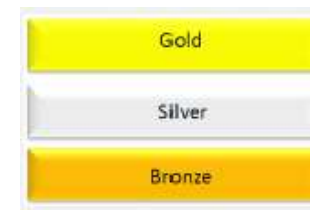
Know the IRIS certification™ rules : 2017

AUDIT PROCESS

The audit process is supported by a tool that contains different elements of the classic ISO 9001 process:

- **KO items** (yes / no answer) on key points of the standard
- **Closed yes / no answer items** in general positioned on standard ISO 9001 requirements

NB: Any answer No is considered as an NC MAJ.

➔ This greatly reduces the application of classic ISO 9001 requirements.

- **Open-ended items** with different levels of maturity allowing a scale of progress

Know the IRIS certification™ rules : 2017

ASSESSMENT METHODOLOGY

CONFORMITY – CUSTOMER PERCEPTION– PERFORMANCE EVALUATION

CONFORMITY ISO/TS 22163

Evaluation based on a maturity level observed on each of the requirements of the standard

Optimized	4pts	
Qualified	3pts	
Defined	2pts	
Poor	1pt	NC min
Insufficient	0pt	NC MAJ

NC = corrective action required

CUSTOMER PERCEPTION

Evaluation of taking into account:
- *expectations and needs of stakeholders,*
- *customer orientation,*
- *satisfaction / claim*
- *KPI defined by the organization to monitor the effectiveness and quality of the products provided*

PERFORMANCE

Evaluation of the 5 mandatory processes (if applicable - confirmed at the opening meeting) following a matrix 5 levels (A, B, C, D, E) of performance evaluation

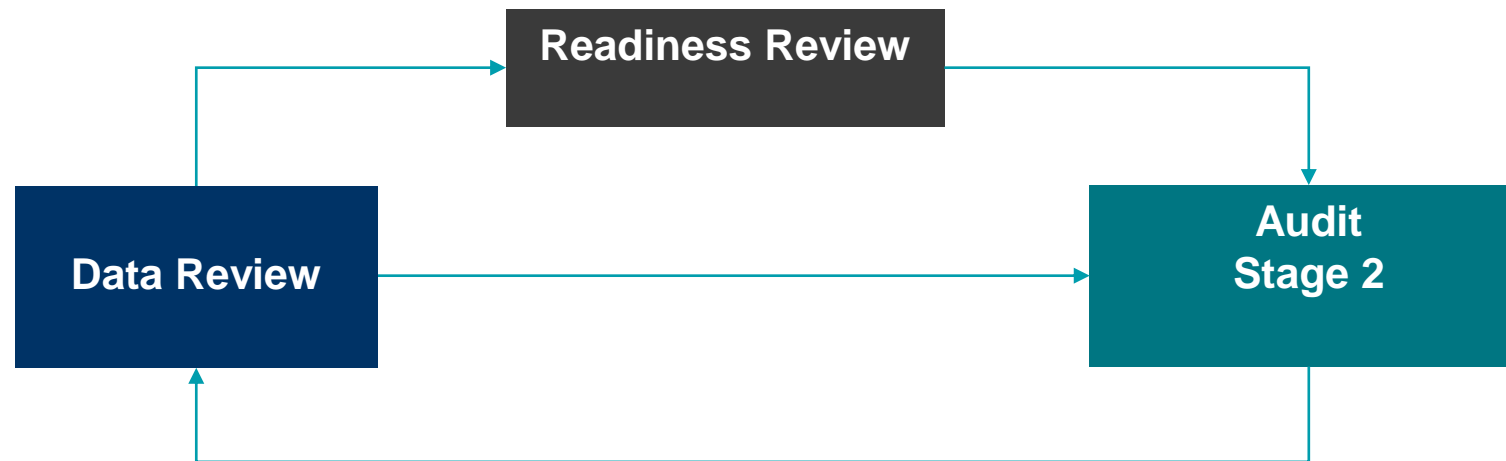| D	B	A
D	C	B
E	D	D

Know the IRIS certification™ rules : 2017

AUDIT CYCLE

A CERTIFICATION SCHEME OF 3 YEARS:

- **Initial audit year N**
  → Data review + Readiness Review + audit stage 2 (initial)
- **Surveillance audit 1 (year N+1) than 2 (year N+2)**
  → Data review + audit stage 2 (surveillance)
- **Recertification audit (year N+3)**
  → Data review + Readiness Review (optional) + audit stage 2 (recertification)

Know the IRIS certification™ rules : 2017

SOME SPECIFICITIES …

o The IRIS Certification Process follows a **Site-by-Site** certification approach:

→ The multi-site certification approach as it exists in other certification schemes (eg ISO 9001) does not apply to IRIS.

o The last day of the initial audit sets the **reference date** of the cycle

→ The dates of the following **successful** audits must not exceed 12/24/36 months

o All durations (audit activities) are governed by the IRIS Certification ™ rules: 2017

→ IRIS recognizes the 9001: 2015 / IATF 16949: 2016 / EN9100: 2018 certifications

o An ISO 9001 certificate can be issued independently of the IRIS certificate, even if the conditions for awarding the IRIS certificate are not fulfilled;

o **A quality performance statement** is issued annually by the IMC after each successful audit. This recognition is displayed on the IRIS portal.
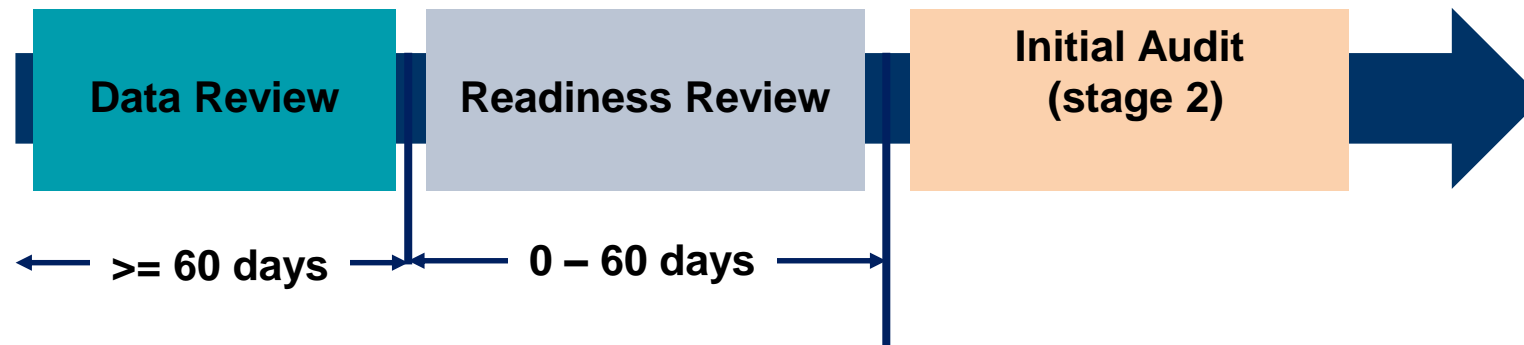
IRIS certification™ process

THE DIFFERENT AUDIT PHASES IN THE CERTIFICATION PROCESS:

➜ **At the initial certification:**

- **A data review conducted off-site;**

- **A readiness review conducted on site;**

- **The certification audit (step 2) carried out on site.**

Data Review	Readiness Review	Initial Audit (stage 2)
>= 60 days	**0 – 60 days**	

IRIS certification™ process

THE DIFFERENT AUDIT PHASES IN THE CERTIFICATION PROCESS:

➜ **During the follow-up audit (1 or 2) and recertification :**

    ➜ **A data review conducted off-site;**
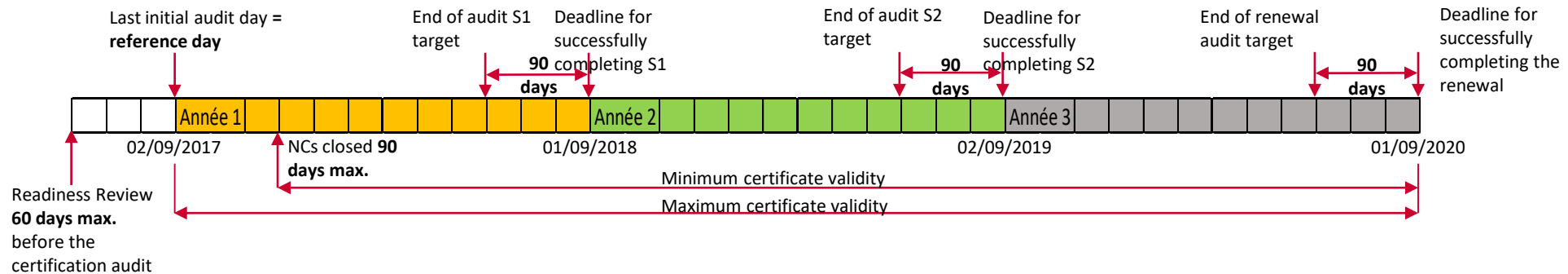   ➜ **The stage 2 audit carried out on site.**

| Data Review | | Initial audit (stage 2) | |

←—— **>= 60 days** ——→

Know the IRIS certification™ rules : 2017

AUDIT CYCLE

Specific features imposed by the IRIS certification™ scheme:

The last days of the certification audit is called the **reference date**.

The audit successfully completed date **must not exceed 12 (S1)/24 (S2)/36 (R) months** from the last day of the certification audit.

QUIZZ #3

afnor
GROUPE

ISO/ TS 22163 requirements

1- IRIS Assessment process content closed items mainly on ISO 9001 requirements ?

YES   NO

2- Specific assessment will be done during the audit using the turtle diagram for requirement management process ?

YES   NO

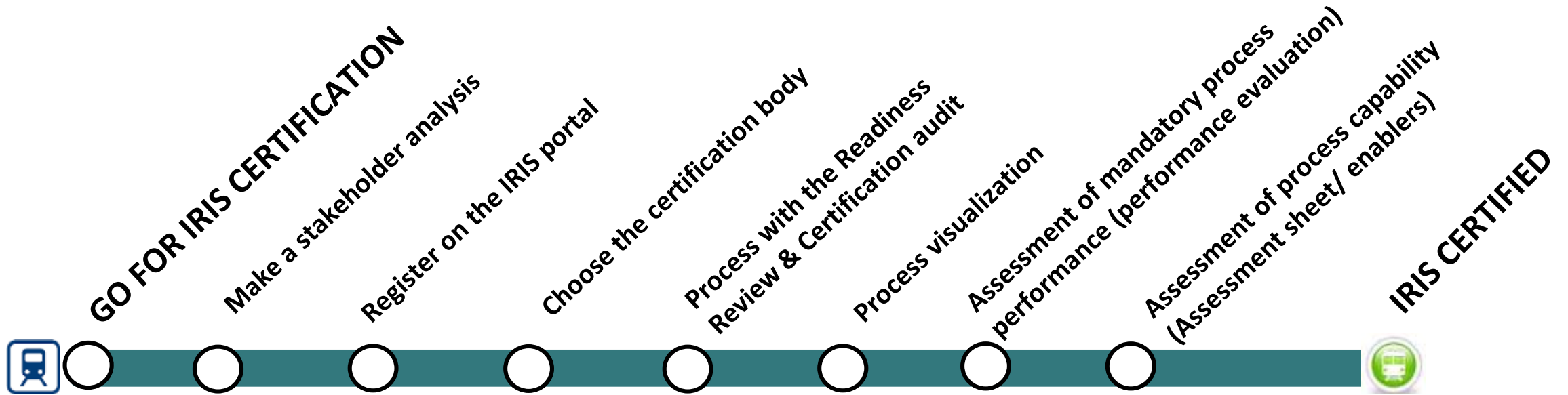3- IRIS assessment process content maturity evaluation ?

YES   NO

IRIS CERTIFICATION™

4. IRIS certification™ process

On track for quality

GO FOR IRIS CERTIFICATION

Make a stakeholder analysis

Register on the IRIS portal

Choose the certification body

Process with the Readiness Review & Certification audit

Process visualization

Assessment of mandatory process performance (performance evaluation)

Assessment of process capability (Assessment sheet/ enablers)

IRIS CERTIFIED

IRIS CERTIFICATION™ PROCESS

CERTIFICATION REQUEST

To start the IRIS Rev.03 certification™ process, the organization must:
- be a legal entity or belong to a group and,
- have a global Quality Management System and,
- have at least one eligible IRIS activity: design or manufacture or maintenance, and
- be eligible for one of the applicable fields of application, and
- to be located on a single site.

The customer must register on the IRIS portal (www.iris-rail.org) to:
- get all the information you need for IRIS Rev.03 certification™,
- be able to purchase the Audit Tool,
- choose your CB,
- initiate the IRIS Rev.03 certification™ process

Official documents needed :
- ISO/ TS 22 163 : 2017
- IRIS CERTIFICATION RULES : 2017
  - ➔ To purchase these documents via AFNOR BOUTIQUE, Click HERE

QUESTIONS & ANSWERS

CONTACT

Hend HOUIMEL

+33(0)1 41 62 62 29

hend.houimel@afnor.org

www.afnor.org