



# ISO/IEC 17043:2023

## Suggestions for implementation

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**LABOPERF**

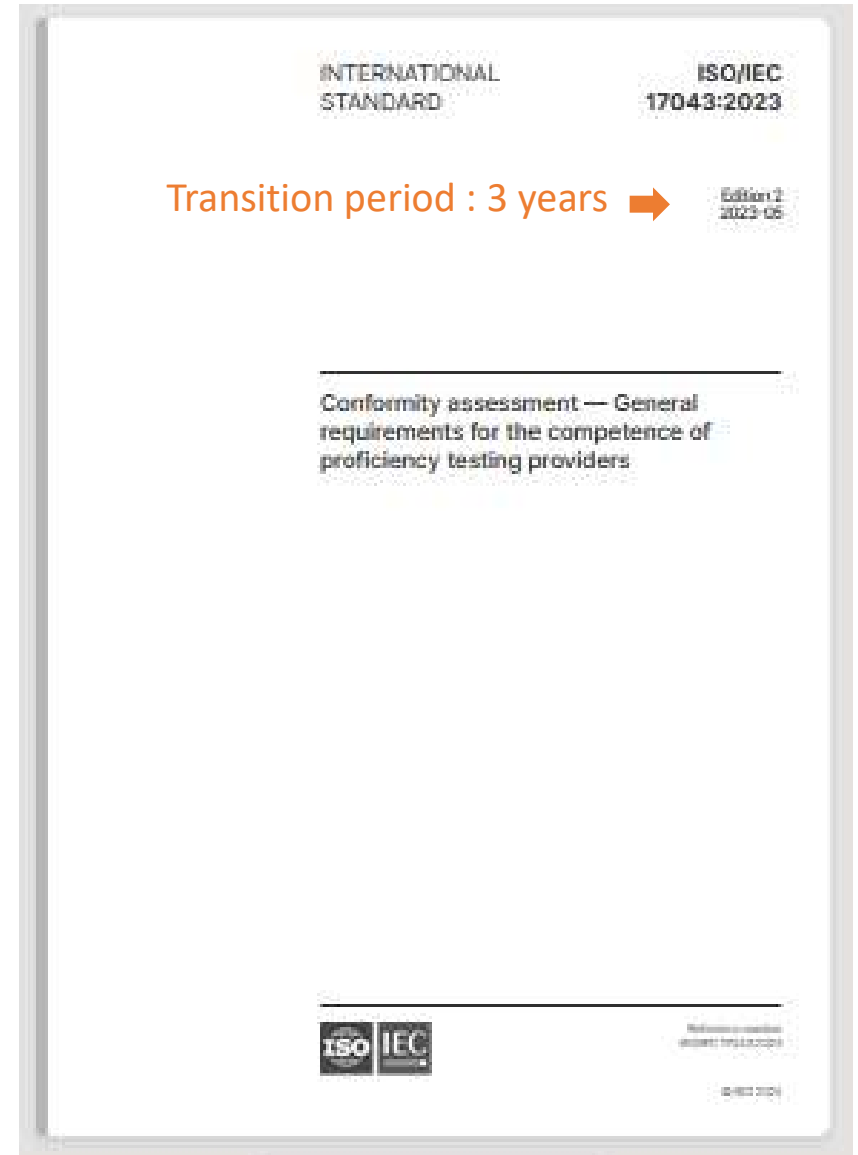
# Which use for this standard ?

- Concerns every Proficiency Testing provider (PTP) Including for External quality assessment programmes based on interlaboratory comparisons

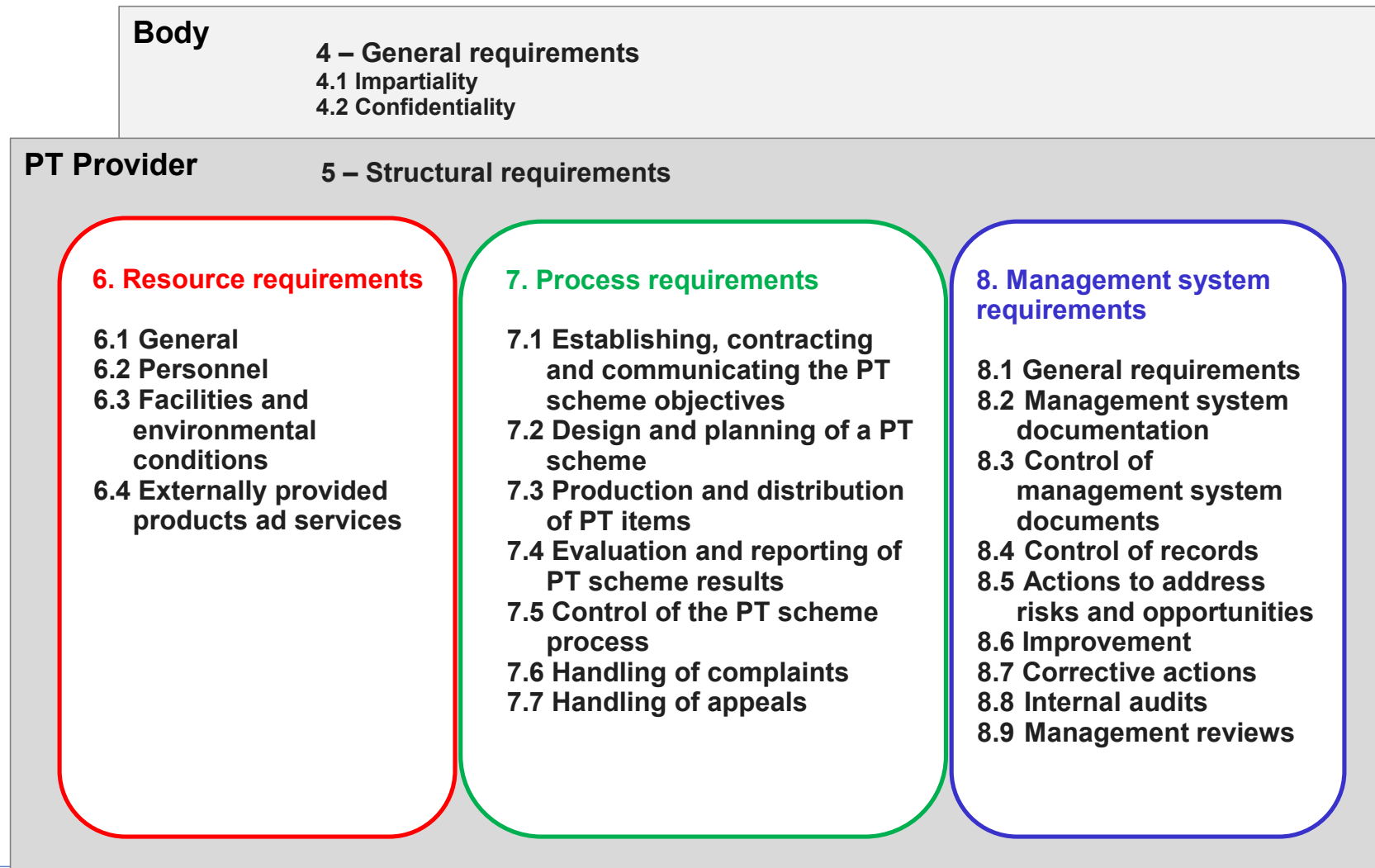
*(Laboratory : all organizations that provide information on items based on **experimental observation**, including measurement, testing, calibration, examination, sampling and inspection. )*

A PT can concern a phase/activity of the laboratory process

- Basis for the accreditation of PTP, on a defined scope
- Useful for the others...



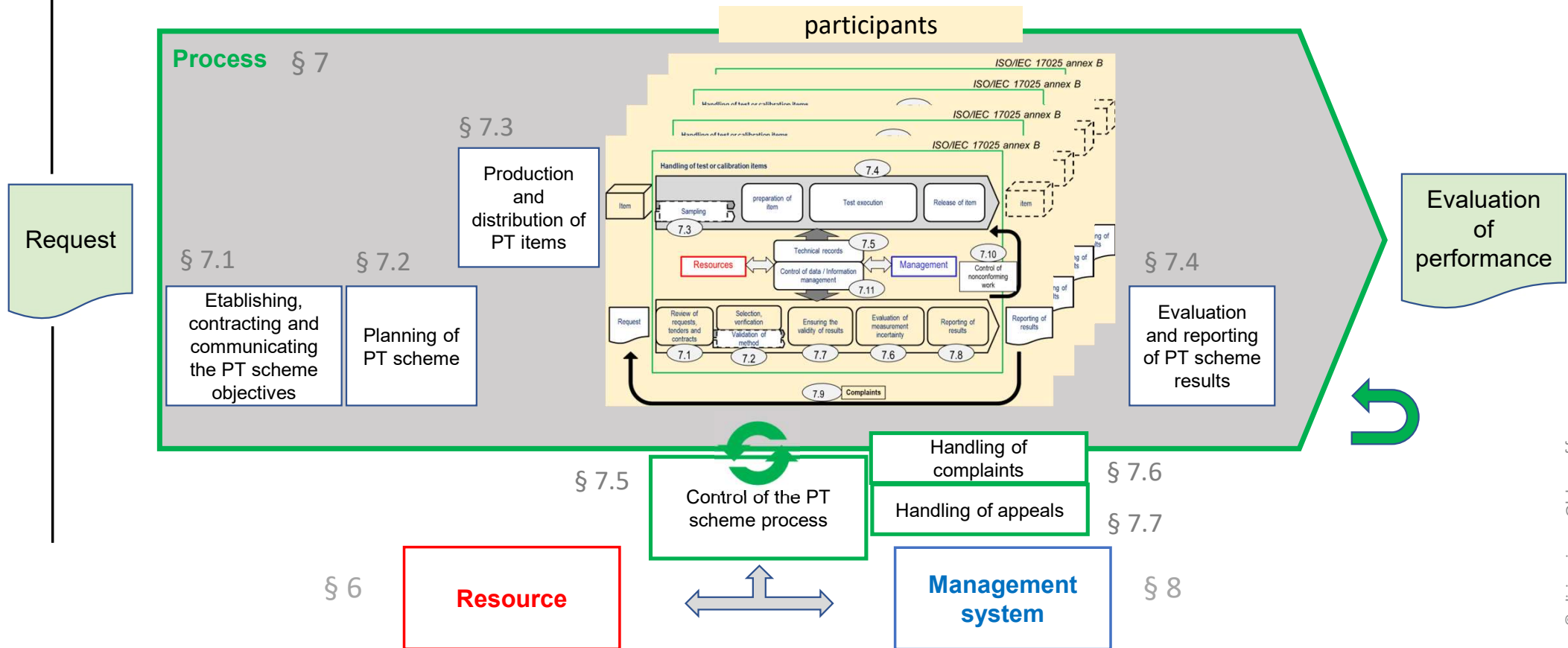
# Structure of the standard



# Process approach

General § 4

Structure § 5





# Use the process approach for the PTP management system

## Why ?

In order to :

- Benefit from the common structure with ISO 17025 and ISO 15189
- Implement the concepts of ISO 9001
- Describe the activities of the PTP in a consistent manner
- Integrate PTP activities in a more complex organisation
- Apply the plan/do/check/act principle for continuous improvement

## How ?

- Define relevant groups of activities, depending on the complexity of the organisation  
**Minimum : resource, PT process, management**
- For each of these groups, define :
  - responsibilities
  - document management
  - objectives derived from general objectives
  - an action plan
  - indicators
  - a programme of management reviews

# Risk approach



RISK :  
2 different concepts in 1



**Risk :**

consider the potential failures  
and manage them

(see ISO 15189:2010)

**Risks and opportunities :**

secure what has been planned  
by reviewing the context  
adequately

(see ISO 9001 §6.1)

# Addressing risks and opportunities



Consider the activities which should be planned in the management system (cf input data of the management review) :

- Objectives defined by the management
- Document review
- Internal audits
- Corrective actions
- PT programmes
- Seeking feedback from the customers and personnel
- Qualification of resources
- Risk identification
- Surveillance of the processes

For each of these activities, define :

- Who is in charge of the follow-up
- A frequency for reviews
- Information to consider on the context
- Sources to use
- How decisions of are made to adjust the plan
- How the effectiveness of the actions is evaluated



# Identify risks

## Why ?

To share a view of possible situations which could affect evaluations of performance in the peculiar situation of the PTP, so as to :

- Demonstrate the consistency of the management system
- Adjust the monitoring of resource (e.g. : qualification, controls,...)
- Raise awareness among staff
- Capitalise on experience



## How ?

Establish a list of risks

- based on the groups of activities / processes of the PTP
- deduced from experience of possible failures
- not redundant with the requirements of ISO 17043
- updated by means of the review of non-conforming work (for management reviews)

If also applying ISO 15189 : use the same approach...



# Surveillance of the processes

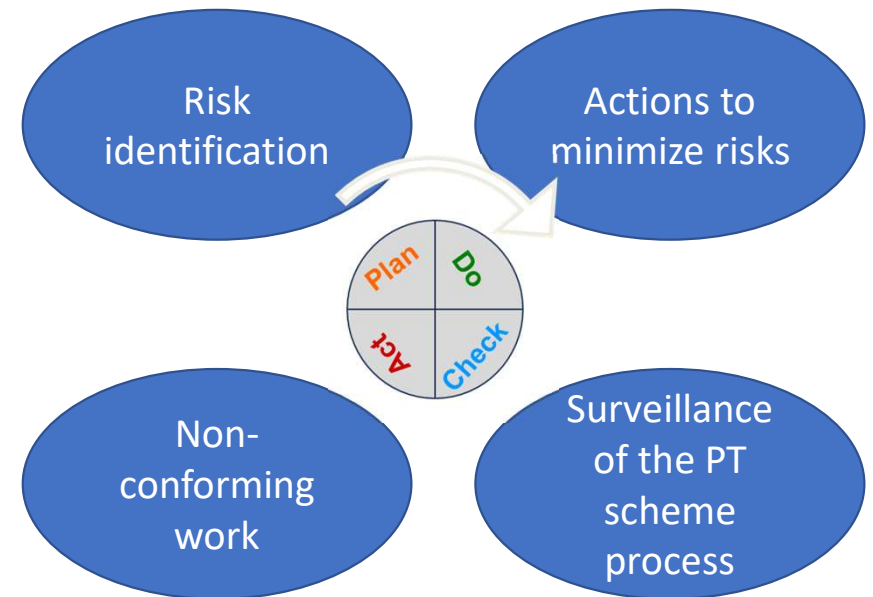
## 7.5.3 Surveillance of the processes

The PT provider shall have a procedure to ensure the validity of the PT scheme. Surveillance activities shall be planned and reviewed [see also [8.9.2](#) item n)], and the resulting data shall be recorded for the continuous improvement process.

NOTE Depending on the PT scheme, surveillance activities can include:

- evaluation of externally provided products and services;
- use of reference materials or other control items;
- the transmission of results from participants;
- control of statistical conditions to confirm the validity of performance evaluation;
- checking of reports;
- for continuous schemes, comparisons against previous PT rounds.

 **Secure evaluations of performance**





## start with the risk list

PT scheme	Risk	Surveillance of the PT scheme	when	Records
PT1	Possible uncontrolled change of the software used for stats	Test with a set of reference data	Before each round	R12-01
PT1	Information transmitted by participants not copied in the report	Check list for review pointing at possibly missing information	For each report	R11-04
PT2	Possible drift of the characteristics of the reference material from which the entities are derived	Statistical analysis of the results obtained by a reference group of participants	Every year	R13-02
PT3	Possible overheat of the entity during transportation	Use of a color indicator to detect overheats	Each participant	Result form
PT3	...			

- + define how the resulting data are used
- + review of the adequacy of surveillance activities for the management review

# Change control

Changes which have an impact on the general competence of the PTP :

- PT item production
- Assessment of homogeneity and stability
- Determination of the assigned value,
- Statistical analysis
- New types of PT activities



Impact on the (accreditation) scope



General approach :

- Detection of potential changes (who, how)
- Analysis of the impact (e.g. Ishikawa diagramme)
- Action plan
  - Decision
  - Communication
  - Follow-up

*Project mode if required*



# Lack of impartiality : a peculiar risk

## Plan

- PT provider structured and managed so as to safeguard impartiality
- Responsibility defined
- top management commitment to impartiality (see also § 8.2.1)

## Do

- PT activities shall be undertaken impartially (see also aussi § 6.2.4)

## Check

- monitor its activities and its relationships to identify threats to its impartiality

## Act

- If a threat to impartiality is identified, its effect shall be eliminated or minimized



## Impartiality : an example of tool for risk identification

Type of threat	Possible situation	Actions to minimize the risk
Self-interest	The coordinator could have members of his/her family among participants	The coordinator doesn't know the participant Ids and the assigned value is consensual
Self-review	The lab who assesses homogeneity and stability is also a participant	Only one characteristic of the entity used among several
Advocacy	/	
Familiarity	The PTP is also participant	Confidentiality required, separation of access to data ...
Intimidation	/	
Competition	/	

# Other requirements which have been strengthened

- Treatment of results from different measurement or test methods, where permitted by the PT scheme (§ 7.2, 7.3, 7.4);
- Handling of complaints and appeals (§ 7.6 and 7.7)
  - Description of a process, which ensures :
    - Traceability of the processing
    - Impartiality
    - Timely information of the claimer
  - Difference made between complaints and appeals (which concern results)

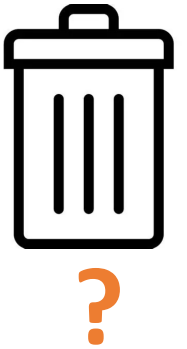


## Control of data and information management (§ 7.5.2)

- Alignment with ISO 17025:2017 and ISO 15189:2010
- Map of the information system useful
- validation of software “for functionality, considering data availability, data integrity, confidentiality, and traceability of operations

# Requirements deleted or simplified

- Name a coordinator and a quality manager
- Details / activities which require an authorization
- Details / records which have to be kept
- Only one policy required
- Quality manual not required



# As a conclusion...

An EQALM TFG ISO 17043 was created

- remote meeting in september
- meeting on oct 17th

## Objectives :

- Run a survey
- Retrieve and share information from the first accreditation assessments
- Work on some parts of the new version
- Write a paper



# Thanks for your attention



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