



Update on ISO / IEC 17043

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ISO / IEC 17043

1984 : ISO Guide 43 v1

1997 : ISO Guide 43 v2

2010 : ISO 17043 v1

Conformity assessment -

General requirements for the competence of proficiency testing providers

- ➔ A Casco standard allowing accreditation
 - multilateral agreements and mutual recognition

- ➔ 558 accredited PT providers in 2020
 - for more than 80000 accredited laboratories

Why a revision ?

Its objectives have been defined in a New Work Item Proposal :

Alignment with ISO 17025:2017

- use the ISO Casco plan
- consider sampling and other activities
- consider risk-based thinking

Deal with inconsistencies between ISO 17043 (especially annex B) and ISO 13528 (2015) : “Statistical methods for use in proficiency testing by interlaboratory comparison”

Plan of the presentation :

Introduction

- The Casco Plan
- Process approach
- Risks and opportunities
- Other changes

Conclusion

ISO/IEC 17043 development stages

Jun 2020

New work Item Proposal (**NWIP**) to revise ISO/IEC 17043 approved.
Creation of the working group 57

88 experts

ISO/IEC 17043 **CD** ballot, including the extension to review the title (2 months)

1329 comments

1st Drafting Group (DG) meeting (remote)

Help the Convenors and Secretariat to pre-scan the CD comments and prepare the full WG57 meeting

1st WG57 meeting (remote)

Review NWIP, title, deliverable, scope and develop the Committee Draft (CD) ISO/IEC 17043

2nd WG57 meeting (remote)

Review the CD ballot results and handle the comments, prepared by the DG.

Jun 2021

ISO/IEC 17043 **CD2** ballot (2 months)

844 comments

2nd Drafting Group (DG) meeting (remote)

Help the Convenors and Secretariat to pre-scan the CD2 comments and prepare the full WG57 meeting

3rd WG57 meeting (remote)

Handle the CD comments, prepared by the DG. Prepare the Draft International Standard (**DIS**).

Jun 2022

ISO/IEC 17043 **DIS** ballot + translation (5 months)

565 comments

3rd Drafting Group (DG) meeting (remote)

Help the Convenors and Secretariat to pre-scan the DIS comments and prepare the full WG57 meeting

4th WG57 meeting (remote)

Handle the CD comments, prepared by the DG. Prepare the Draft International Standard (**DIS**).

Apr 2023

ISO/IEC 17043 **FDIS** ballot + translation (4 months)

If no FDIS, publication earlier

Publication of ISO/IEC 17043:2022 after FDIS ballot

5th WG57 meeting (remote)

Handle DIS comments and prepare draft either for **publication** or **FDIS** (if any)

proficiency testing (PT) :

evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons



interlaboratory comparisons

design, performance and evaluation of measurements or tests on the same or similar items by two or more **laboratories** in accordance with predetermined conditions



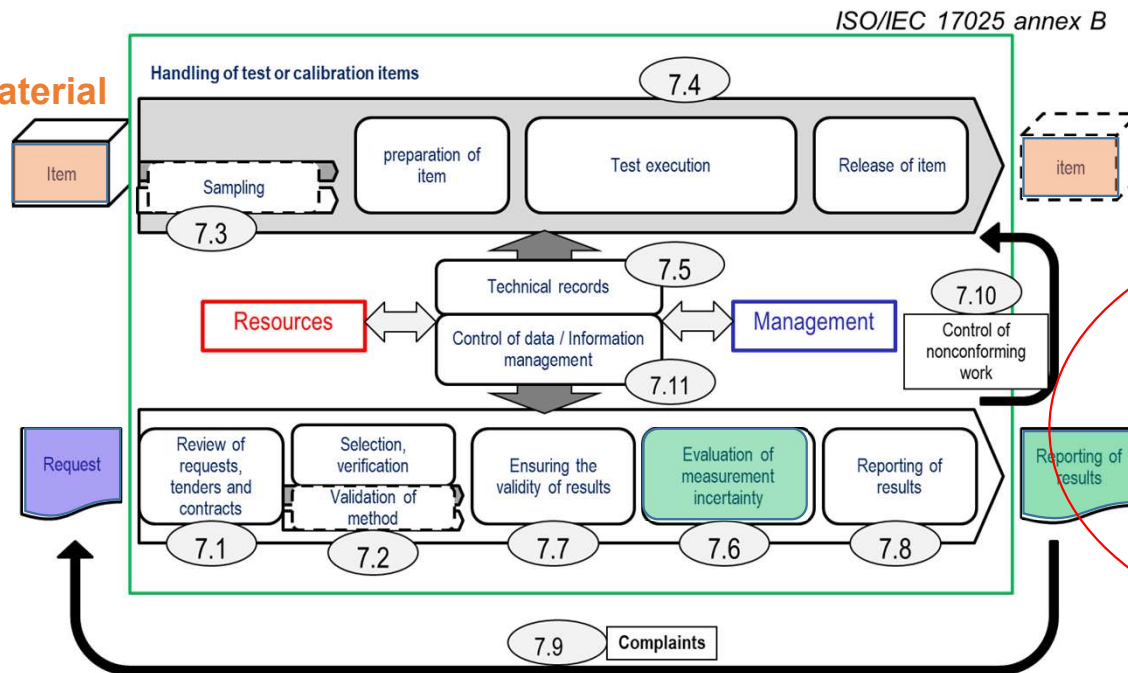
Laboratory

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

Different objectives for interlaboratory comparisons...

Characterization of a
Certified Reference Material
 ISO 17034
 Or a standard

Method validation
 ISO 5725



proficiency testing (PT) :
evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons
 ISO 17043

Definition of a PT scope of competence

- ISO DIS 17043 § 5.3 :

The PT provider shall define and document the PT schemes for which it conforms with this document. The PT provider shall only claim conformity with this document for those PT schemes.

➔ The accreditation scope would then be a part of these PT schemes

No subcontracting for :

- Design and planning of PT schemes
- The evaluation of performance
- The authorization of reports

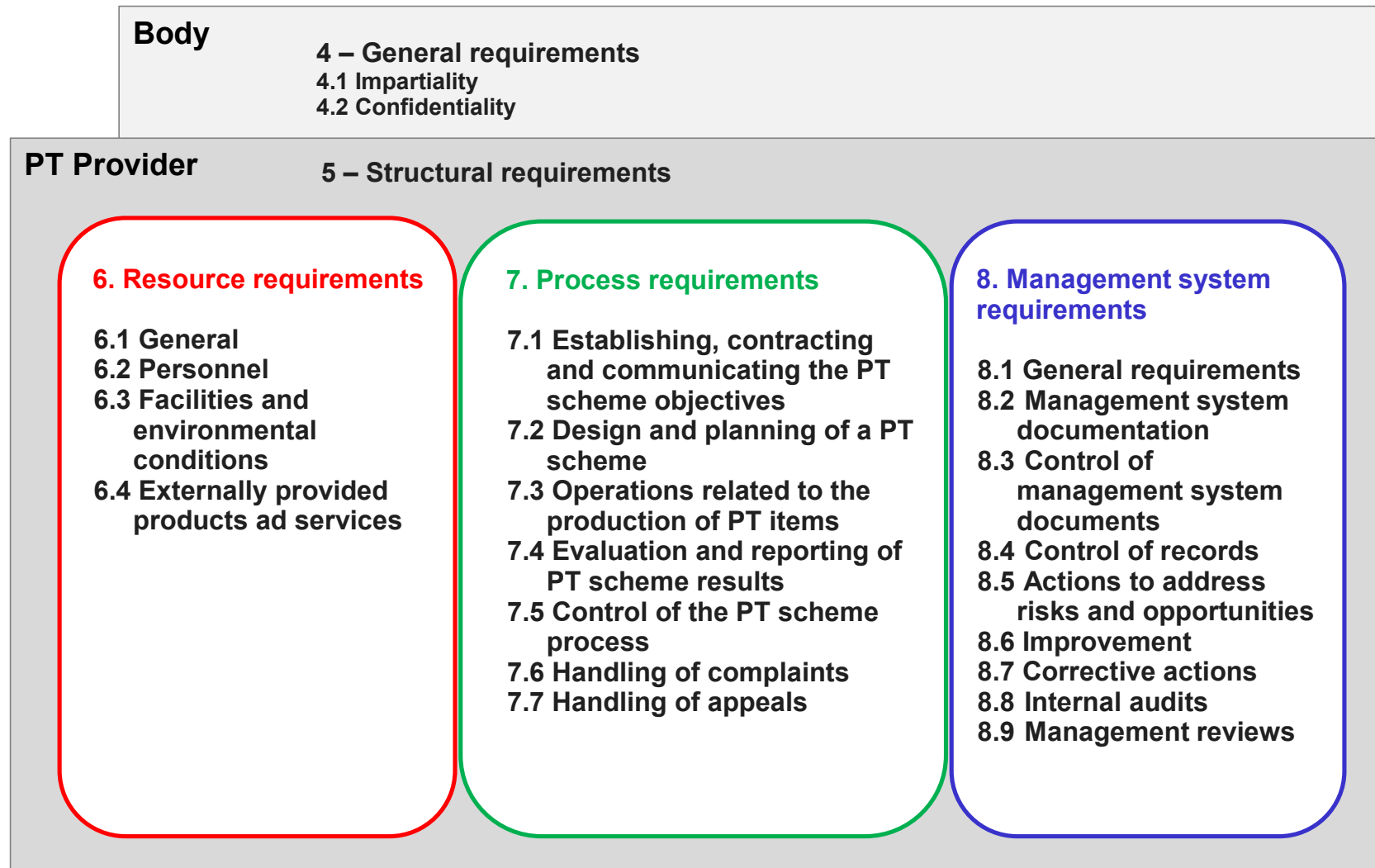
unchanged

... but external expertise may be used

Use of the Casco plan

- Designed to ensure the validity of the results of the assessment, impartiality, consistent operation
- Very consistent with the process approach
- Convenient for the PT providers who also apply ISO 17025 (and ISO 15189 soon)
- Convenient for PT provider applying ISO 9001
- No changes allowed for some parts of the text (e.g. appeals)

Structure of the new standard



General § 4

Structure § 5

Process § 7

Request

§ 7.1

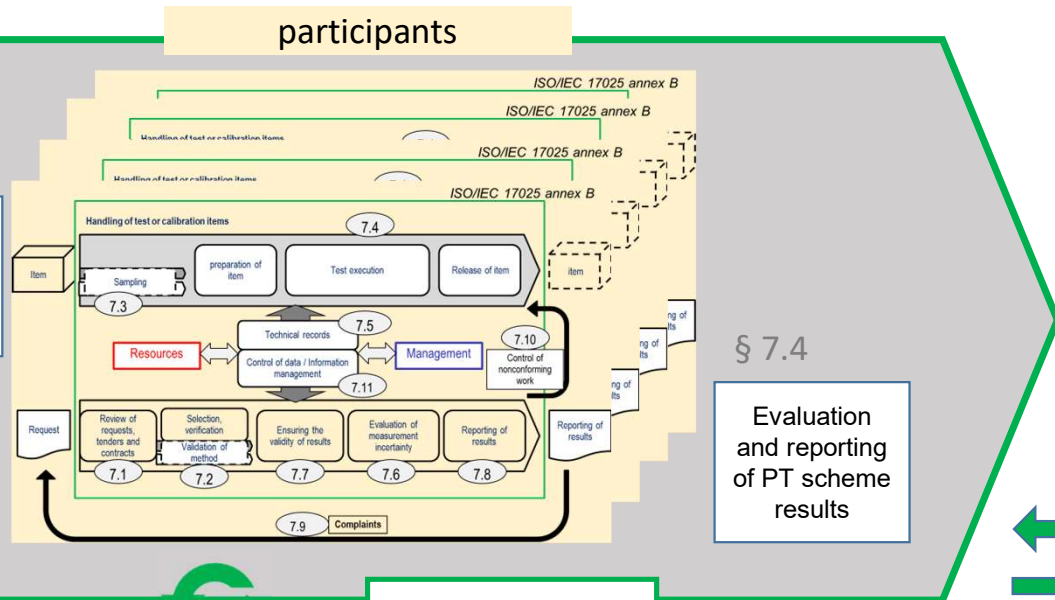
Establishing, contracting and communicating the PT scheme objectives

§ 7.2

Planning of PT scheme

§ 7.3

Operations related to the production of PT items



Evaluation of performance

§ 7.5

Monitoring of the PT scheme process

Handling of claims

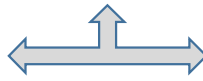
§ 7.6

Handling of complaints

§ 7.7

§ 6

Resource



Management system

§ 8

Alignment with ISO 17025 (and ISO FDIS 15189) : the risk-based approach



Risk :

consider the potential failures
and manage them

(see current ISO 15189)

RISK :
2 different concepts in 1



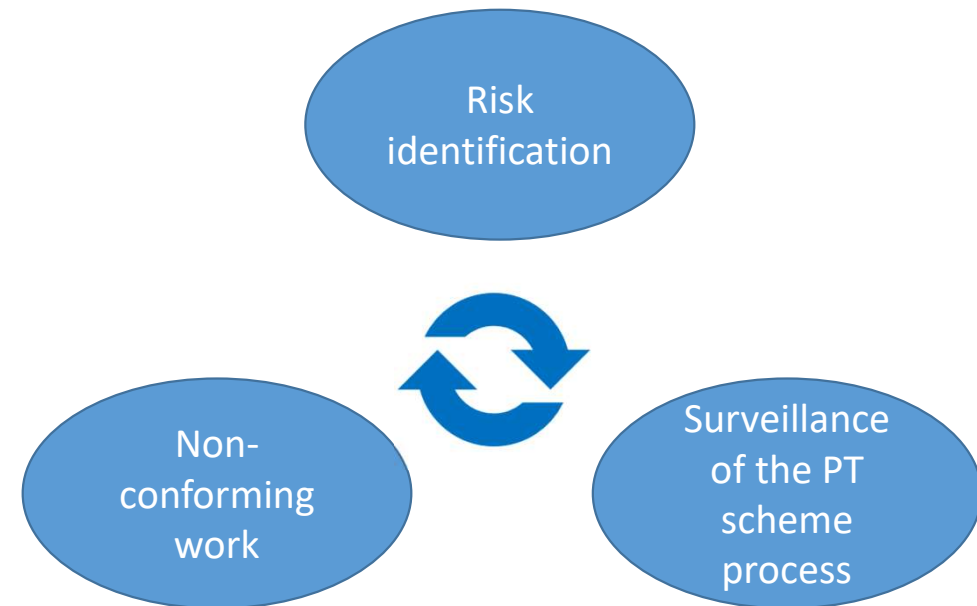
Risks and opportunities :

secure what has been planned
by reviewing the context
adequately

(see ISO 9001 §6.1)

Risks

- Risks have to be identified, but no requirement of risk evaluation
- Risks to impartiality have to be specifically considered
- Change control is introduced :
§ 7.2.1.2 When a PT provider intends to introduce significant changes to activities which can affect the validity of the PT scheme, the PT provider shall identify and manage the risk to ensure the validity of the PT scheme is maintained.
(examples given in a note)
- Internal audits are risk-driven

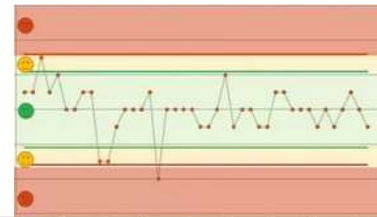


Surveillance of the processes *(discussions in progress for the wording)*

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.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



Other requirements aligned with ISO 17025

- Less requirements that impose means
 - e.g. No more list of records to retain
 - e.g. No more mandatory functions (such as coordinator)
 - e.g. Procedures : .. *document its procedures to the extent necessary to ensure the consistent application and validity of its PT activities.*
 - But some procedures are required.
- Requirements on control of data and information management
- Relevant requirements of ISO 17025 (or ISO 15189) have to be applied for PT item characterization or for assessing homogeneity and stability

Alignment with ISO 13528:2022

- Editorial corrections of annex B of ISO 17043

- Introduction of the possibility **not** to test homogeneity and stability for every PT round but the PT provider has to :
 - Perform an assessment of homogeneity and stability
 - Provide experimental evidence for this assessment
 - Consider the effects of conditioning, storage, transport, ... and their changes.

See annex B, clause B2 of ISO 17043, ISO 13528 and Guide 35

Content of key documents

PT scheme plan :

- ⊖ name of the coordinator
- ⊖ name and coordinates of the PTP
- ⊖ critical external service providers instead of subcontractors
- ⊕ q) the treatment of results from different measurement or test methods, where permitted by the PT scheme;

Information to participants :

- ⊕ objectives of the PT scheme
- ⊕ critical timeline

Report :

- ⊖ name of the coordinator
- ⊕ reported measurement uncertainties (participants)

Conclusion



- The revision is a great occasion to bring simplifications to the management system, whereas it should increase the competence of PT providers.
- The step is higher for the PT providers whose management system is not aligned on ISO 17025 or the next ISO 15189 :
 - ✓ Risks and opportunities,
 - ✓ Impartiality
 - ✓ Surveillance of the processes
- For accreditation, a 3 year transition period is very likely



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THANK YOU FOR YOUR ATTENTION

