Physikalisch-Technische Bundesanstalt
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Revision of ISO/IEC 17025

EURAMET Webinar on Changes to ISO/IEC 17025

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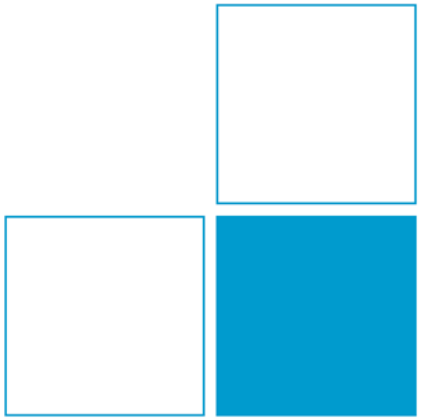


General Introduction

Major Changes

Metrological Traceability

Main reasons for the revision:

- ILAC Policies P9 (prof testing), P10 (metr. Traceability), P14 (measurement uncertainty) not incorporated
- Not sufficiently process based
- ISO 9001:2015 needs to be integrated
- Electronic media not sufficiently taken into account
- Requirements for metrological traceability not clear enough
- Too many notes
- Out dated bibliography

General Introduction

Major Changes

Metrological Traceability

New structure:

Contents

General Tendencies:

Incorporation of elements of ISO 9001:2015:

– Risks and opportunities

– laboratory management instead of quality management

– Option B allows ISO 9001 to fulfill managements requirements

• rules for statements of conformity (decision rules)

• Merge of requirements for calibration and testing laboratories

• higher requirements for testing labs concerning measurement uncertainty and metrological traceability

• takes into account modern electronic media

But: maintenance of documents and records (ISO 9001: documented information)

General Tendencies:

- Impartiality and confidentiality play a more important role
- More details on complaints and appeals
- External provided services instead of subcontracting
- More compatibility with other CASCO standards

But the reference to the principles of 9001 has been retained:

“Laboratories that conform to this document will also operate generally in accordance with the principles of ISO 9001.”

More in detail (some examples):

1 Scope

…

Laboratory customers, regulatory authorities, **organizations and schemes using peer-assessment**, accreditation bodies, and others use this document in confirming or recognizing the competence of laboratories.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*1)

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

1) Also known as JCGM 200. experts know: ISO Guide 99:2007, JCGM 200:2012

3 Terms and definitions

For the purposes of this document, the terms and definitions given in **ISO/IEC Guide 99** and **ISO/IEC 17000** and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp
— IEC Electropedia: available at http://www.electropedia.org/

9 Specific Terms and definitions:

- Impartiality
- Complaint
- Interlaboratory comparison
- Intralaboratory comparison
- Proficiency testing
- Laboratory (inclusion of sampling)
- Decision Rule (pass fail decisions)
- Verification
- Validation

Some of these terms have more importance than in ISO/IEC 17025:2005

Consequence of

„Common Elements in ISO/CASCO Standards“

Some examples for new requirements:

4.1 Impartiality

…

4.1.4 The laboratory shall identify risks to its impartiality on an **on-going basis**. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

No major problem in governmental NMIs

but we have to take the aspect into account in an appropriate way

4.2 Confidentiality

- **Legal enforcable committment** for the management of all information obtained or created during the performance of laboratory activities

- When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

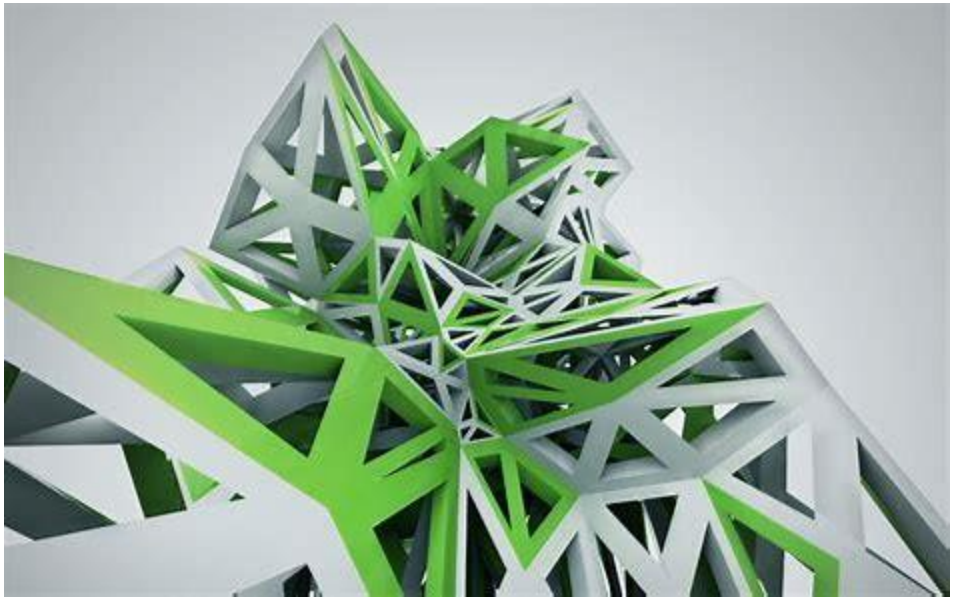
  normally not relevant for NMIs (relevant e. g. for food testing labs)

- Information about the customer **obtained from sources other than the customer** (e.g. complainant, regulators) shall be confidential between the customer and the laboratory.

5. Structural requirements

5.3 …The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.

But no section on subcontracting!



6.4 Equipment

- 6.4.7 The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

"should" in a comment became a "shall" requirement

New requirements for reference materials:

6.4.11 When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

The records shall include the following, where applicable:

…. f) documentation of reference materials,

6.6 Externally provided products and services

6.6.1 The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

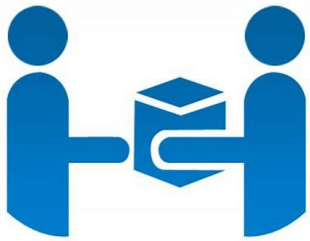
a) are intended for incorporation into the laboratory's own activities;

b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;

c) are used to support the operation of the laboratory.

NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.

→ former subcontracting , Text partly adopted by ISO 9001:2015



7 Process requirements

7.1.3 When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.

NOTE For further guidance on statements of conformity, see ISO/IEC Guide 98-4.

3.7
decision rule
rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

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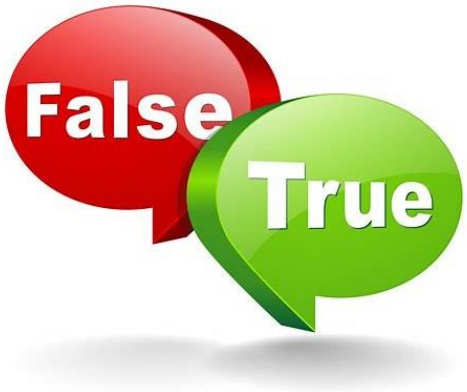
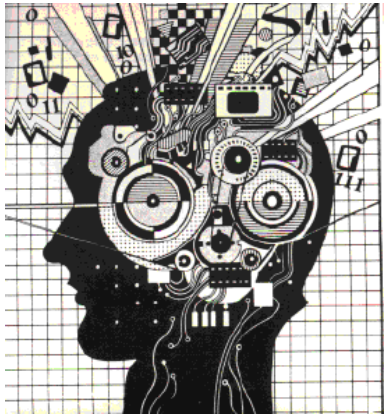


7.8.6 Reporting statements of conformity

7.8.6.1 When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.

NOTE Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary

"Statement of conformity" instead of "statement of compliance"



7.8.7.2 The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.

→ new requirements

7.7.2 The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:

a) participation in proficiency testing;

NOTE ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.

b) participation in interlaboratory comparisons other than proficiency testing..

→ stronger requirements

7.11 Control of data and information management

- Availability
- Protection from unauthorized access
- Ensurance of the integrity of the data and information
- Electronic information is normal, but paper is allowed

8 Management system requirements

- The option B of a ISO 9001 quality management system is a new concept

8.4.2 The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.

8.5 Actions to address risks and opportunities (Option A)

8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:
a) give assurance that the management system achieves its intended results;
b) enhance opportunities to achieve the purpose and objectives of the laboratory;
c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;
d) achieve improvement.

8.5.2 The laboratory shall plan:
a) actions to address these risks and opportunities;
b) how to:
— integrate and implement these actions into its management system;
— evaluate the effectiveness of these actions.
NOTE Although this document specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards. the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

8.9 Management reviews (Option A)

New required topics:

- **fulfilment of objectives**
- **status of actions from previous management reviews;**
- **effectiveness of any implemented improvements**
- **adequacy of resources**
- **results of risk identification**
- **outcomes of the assurance of the validity of results**

New minimum requirements for the management review report:

- effectiveness of the management system and its processes

- improvement of the laboratory activities related to the fulfilment of the requirements of this document;

- provision of required resources

- any need for change

General Introduction

Major Changes

Metrological Traceability

6.5 Metrological Traceability (instead of measurements traceability)

Requirements for testing and calibration labs have been merged

→ Same requirements on measurement uncertainty

6.5.1 The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

NOTE 1 In ISO/IEC Guide 99, metrological traceability is defined as the “property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty”.

NOTE 2 See Annex A for additional information on metrological traceability.

6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:

a) calibration provided by a competent laboratory; or

NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent.

b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or

NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.
NOTE 3 Details of practical realization of the definitions of some important units are given in the SI brochure.

6.5.3 When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.:

a) certified values of certified reference materials provided by a competent producer;

b) results of reference measurement procedures, specified methods or consensus standards that are **clearly described and accepted** as providing measurement results fit for their intended use **and ensured by suitable comparison.**

Annex: A Metrological traceability

A.1 General

A.2 Establishing metrological traceability

- Incorporates some of the former notes

A.3 Demonstrating metrological traceability

- CIPM MRA – KCDB is mentioned
- ILAC – MRA is mentioned

Summary:

- No revolution
- Some new aspects
- In some management systems amendments may be necessary
- 95 % are covered by ISO/IEC 17025:2005

Thank you for your attention!

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