General requirements for the competence of testing and calibration laboratories

ISO/IEC 17025:2017

In this presentation:
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New requirement
Interpretation / Examples / Questions
1. ISO/IEC 17025:2017
   - Change overview
   - Clause overview
   - Transition plan

2. Specific topics:
   1. Reporting statements of conformity (Decision rules)
   2. Reporting of opinions and interpretations
   3. Adressing risks and opportunities

3. Questions
ISO/IEC 17025:2017
A standard for the laboratories!
1. Laboratory standard: Purpose

- Promoting confidence in the operation of labs
- Enabling demonstration of competence in generating valid results
- Facilitate cooperation between labs and other bodies
- Facilitate acceptance of results between countries
- Improve international trade

More than 40,000 laboratories are accredited worldwide
(courtesy figures by COFRAC)
Laboratory processes
The structure of the standard

- Similar to other standards of ISO/IEC 17000 on conformity assessment
  1. Scope
  2. Normative references
  3. Terms and definitions
  4. General requirements
  5. Structural requirements
  6. Resource requirements
  7. Process requirements
  8. Management requirements (option A vs B)

Annex A – Metrological Traceability (Informative)
Annex B – Management System (Informative)

Bibliography
Main changes in approach vs ISO/IEC 17025:2005

- Process approach - focus on the outcomes of a process
- Consideration of “risk and opportunity” throughout

Interpretation: A risk based approach to management system implementation is one in which the extent and depth of the implementation of particular clauses is varied to best suit the perceived risk involved for the particular conformity assessment body

... a challenge for the labs and assessors ... since cases will seem similar, but remain different
Significant Changes in ISO17025:2017

- Scope: laboratory activities
  (testing, calibration, sampling with subsequent testing or calibration)
- Emphasis on “Impartiality” vs. “Independence”
- Process orientation
- Emphasis on result of a process instead of a detailed description of tasks and steps
- Risks and Opportunities
- Scope vs. “ongoing subcontracting”
- Information Technology: Risks, data integrity, confidentiality, validation of software, considering electronic documents
- Metrological Traceability
- Decision Rules for pass/fail (statement of conformity)

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Documentation requirements

Less prescriptive towards type of documentation:

!! Limited change !!

Past: Theory

Future:
Lab needs to provide evidence that the requirement can be fulfilled
- continuously
- in a consistent way

Less prescriptive ≠ No documentation required
BELAC practice remains valid, but “documentation” might be extended f.e. towards LIMS-protocols,…

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Clauses overview (1/19)

- 1  Scope –
- 2  Normative references
- 3  Terms and definitions

3.6 “Laboratory: a body that performs one or more of the following activities:
- calibration,
- testing,
- sampling, associated with subsequent calibration and testing”

Implications:
Sampling alone seems not accreditable, although the opposite interpretation exists and application of this clause will remain a discussion point.
3.7 Decision Rule

*rule that describes how measurement uncertainty is accounted for when stating conformity with a specific requirement*

Interpretation of decision rule: see following slides
4 General requirements

• Impartiality:

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.

• Implications:

  • Ongoing task for the laboratory
  • Attention of internal relationship as well as the relationship to externals must be paid
  • Staffing level, equipment, financial
  • Precondition: Assignment of activities and sufficient information about relationships
  • No risk management system
• 5 Structural requirements

The laboratory shall define and document the range of laboratory activities for which it conforms with this document. 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.

Implications:

Systematic subcontracting seems prohibited, although resource management will allow flexibility.

Examples: What is externally provided lab activities on an ongoing bases?
- Leasing of equipment
- Customer sampling
- Part of a test for complex test sequences that require all results for interpretation.
- DNA extraction in preparation of DNA analysis

• Laboratory management instead of top management
6 Resource requirements

6.2 Personnel: competence requirements

6.3 Facilities & environmental conditions

6.4 Equipment

6.4.1 The laboratory shall have access to equipment required for the correct performance of the laboratory activities. Equipment includes measuring instruments, software, measurement standards, reference materials, reference data, reagents and consumables or auxiliary apparatus or combination thereof necessary for laboratory activities and which can influence the result.

6.4.2 In those cases where the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this International Standard are met.

6.4.8 All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

6.5 Metrological traceability: Update and explanation on traceability requirements (annex A - informative)
6 Resource requirements

- Externally provided products and services
  - Combines current Subcontracting and Purchasing
  - In all cases, have procedure + documented requirements, criteria and controls records
  - Communication with providers: products/services, acceptance criteria, competence and intended use
  - In conjunction with contract review (clause 7.1)
Clauses overview: 7. Process requirements (7/19)
7.1 Review of requests, tenders and contracts

7.1.2 The laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date.

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.

7.1.4 Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the results.
7 Process requirements

7.2 Selection, verification and validation of methods
   - Introduction of ‘verification’, applicable for all methods and standards

7.3 Sampling
   - Introduction of details on sampling plan, procedures and traceability of planning

7.4 Handling of test or calibration items
   7.4.3 Upon receipt of the test or calibration item, abnormalities or deviations from specified conditions shall be recorded. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation.

   When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating that the results may be compromised.
7.5 Technical records

7.5.2 The laboratory shall ensure that amendments to technical records can be tracked back to either previous versions and to original observations. Both the original and amended data and files shall be kept, including indication of the altered aspects and those responsible for alterations.

Implication: certain principles of Good documentation practices irrespective of the format of documentation (paper or electronic) is required.
7.6 Evaluation of measurement uncertainty

7.6.1 Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

7.6.2 A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.

7.6.3 A laboratory performing sampling or testing activities shall evaluate measurement uncertainty. When evaluating the measurement uncertainty, all components which are of significance in the given situation shall be identified and taken into account using appropriate methods of analysis.

NOTE 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result, if it can be demonstrated that the identified critical influencing factors are under control.
• **7.7 Ensuring the validity of results**

7.7.1 The laboratory shall have a procedure for regularly monitoring the validity of laboratory activities undertaken and the quality of the laboratory output. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and **shall include, where appropriate, but not be limited to:**

- a) **regular use of reference materials or quality control materials;**
- b) **use of alternative instrumentation that has been calibrated to provide traceable results;**
- c) **functional check of measuring and testing equipment;**
- d) **use of check or working standards with control charts, where applicable;**
- e) **intermediate checks on measuring equipment;**
- f) **replicate tests or calibrations using the same or different methods;**
- g) **retesting or recalibration of retained items;**
- h) **correlation of results for different characteristics of an item;**
- i) **review of reported results;**
- j) **intralaboratory comparisons;**
- k) **blind test.**

**Interpretation:** requirements for monitoring **within** a laboratory
7.7.2 The laboratory shall monitor the quality of the laboratory performance by comparing with output of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to a selection from the following list:

a) participation in proficiency testing;
   NOTE 1 ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers.
   NOTE 2 Proficiency test providers that meet the requirements of ISO/IEC 17043 are considered as competent

b) participation in interlaboratory comparisons other than proficiency testing.

– Interpretation: requirements for monitoring outside a laboratory
7.8 Reporting of results

- 7.8.2.2 The laboratory shall be responsible for all the information provided in the test report or calibration certificate, except when information is provided by the customer. When data is provided by the customer there shall be clear identification of it. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of the test or calibration results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.
7.8 Reporting of results

7.8.5 Reporting sampling – specific requirements

- Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports shall include the following, where necessary for the interpretation of results:
  a) the date of sampling;
  b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate);
  c) the location of sampling, including any diagrams, sketches or photographs;
  d) a reference to the sampling plan and sampling method;
  e) details of any environmental conditions during sampling that affect the interpretation of the results;
  f) information required to evaluate measurement uncertainty for subsequent testing or calibration.
7.8 Reporting of results

7.8.6 Reporting statements of conformity

7.8.6.1 When a statement of conformity to a specification or standard for test or calibration 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.

7.8.6.2 The laboratory shall report on the statement of conformity such that the statement clearly identifies:

a) to which results the statement applies; and
b) which specifications, standard or parts thereof are met or not met;
c) the decision rule applied (unless it is inherent in the requested specification or standard).

NOTE For further information see ISO/IEC Guide 98-4.
7.9 Complaints

7.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

Interpretation:
- All labs have to involve second persons in complaint handling, for small labs this can imply the involvement from external personnel.

7.10 Non-conforming work

More detailed
Introduction of impact and risk analysis, traceability of information

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7.11 Control of data and information management

7.11.2 The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management systems by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration/modifications to commercial off-the-shelf software they shall be authorized, documented and validated before implementation.

Interpretation:
- E.g. Externally maintained software on equipment under supplier maintenance contract shall be controlled for the interface with the laboratory information management system.
- Question: What is the impact of changes on data integrity management?
8 Management requirements

Management system:
- Option A: using ISO/IEC 17025 directly as before
- Option B: using ISO 9001 but ensuring that the MS meets the technical needs of ISO/IEC 17025

Alignment was made with the ISO 9001:2015
Includes actions to address risks and opportunities.
Quality manual is no longer required (in that format)

BELAC practice: will remain the same: Audit MS + technical aspects.
Implementation of ISO/IEC 17025:2017: BELAC transition plan (1/3)

• Benchmarking: BELAC has participated in the “train the trainer” event on ISO/IEC 17025:2017 organised by EA in January 2018.

• BELAC ISO/IEC 17025:2017 Community event 22, 29/03/2018
  • Refreshing training for BELAC assessors
  • Communications with laboratories

• Transition to accreditation according to ISO/IEC 17025:2017
  • Transition plan was published.

General principles for the transition to new or revised standards

- It is BELAC’s intention to undertake the assessments for transition purposes with scheduled surveillance or renewal assessments. If this is not possible, a case-by-case approach will be used to schedule the transition assessment.

- A self assessment report will be requested: Module C filled out by the Lab.

- Findings raised against new or adapted requirements:
  - will be classified according to the provisions in BELAC 3-11 (type A or B non-conformity) but the CAB will be given more time to take corrective actions.
  - corrective actions will need to be verified and closed out before a final decision on transition can be taken. In order to allow BELAC to complete the decision making process in due time, evidences of corrective actions taken will need to be submitted to BELAC before a predetermined date.

**In practice ……**

**01.07.2018:**
- all initial assessments according ISO/IEC 17025:2017
- other assessments according to ISO/IEC 17025:2017 on a voluntary basis

**01.01.2019:**
- all assessments according to ISO/IEC 17025:2017

**01.12.2020:**
- End of transition period: all accreditation certificates according to ISO/IEC 17025:2005 cease to be valid
Abbreviations

- BELAC: Belgian Accreditation Organization
- EA: European co-operation for accreditation
- IEC: International Electrotechnical Commission
- ISO: International Organisation for Standardisation

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ISO/IEC 17025: 2017
(clause 7.8.6)

Statements of conformity
Decision rules
3 Terms and definitions

3.7 Decision Rule

Rule that describes how measurement uncertainty is accounted for when stating conformity with a specific requirement
Decision rule

- ISO/IEC 17025:2005
  a statement of compliance takes uncertainties into account.

- ISO/IEC 17025:2017
  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.

Decision rule based on:
- Model
- Simple pass/fail ?
- In specification
- In legislation
- Industry expectation
- Client required
- Others,

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Customer makes widgets and wants an average of 95% of his widgets to meet the specification of \( \geq 100 \) mm height.

The laboratory can measure to an uncertainty of +/- 5 mm at 95% confidence. For this “single tailed” at 95% confidence the coverage factor is 1.64. The acceptance threshold for 100 mm is therefore 104.1 mm (at \( u = 2.5 \) mm)

He tells the laboratory to pass all samples that appear to be at least 104.1 mm height. They have agreed a decision rule. If he wanted less wastage he could have the measurement made more accurately and reduce his PFR.

Courtesy: T. Thompson - UKAS

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Decision rule implementation: example 2

- A Police Force considers prosecuting a driver who was measured to have driven at 34 miles per hour in a 30 mph limit.
- The uncertainty of the equipment is +/- 3 mph at 95% (ie 2σ) confidence. They could confidently suggest that 95 out of every 100 drivers caught like this were guilty.
- They must never lose a case on technical grounds or else the whole system will be discredited so they agree a decision rule to give 99.95% confidence, (ie 4σ) so all results have 6 mph deducted before a prosecution case is made.

Courtesy: T. Thompson - UKAS

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ISO/IEC 17025: 2017
(clause 7.8.7)

Opinions and interpretations
Opinions and interpretations

- Stakeholder demand
- No significant changes in the 2017 version of the standard
- No change towards the BELAC policy:
  When they are used, they need to:
  - Have a clear and sound bases
  - Need to be identified in the report
  - Shall not be confused with inspection or product certification.

It is recommended to take into account the EA informative document EA-INF/13:2015

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Opinions and interpretations

ISO/IEC 17025:2017 clauses to be considered in relation with opinions and interpretations

- 6.2.6 authorization of personnel
- 7.8.3 content of test reports
- 7.8.4 content of calibration reports
- 7.8.7 reporting opinions and interpretations

Opinions and interpretations under ISO/IEC 17025:2017 cannot be ignored!
ISO/IEC 17025:
Risks and opportunities
Risks and Opportunities (1/14)

Purpose

– enable some reduction in prescriptive requirements and their replacement by performance-based requirements;
– Improve flexibility in the requirements for processes, procedures, documented information and organizational responsibilities;
– establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects

Requirement

– requires the laboratory to plan and implement actions to address risks and opportunities. The laboratory is responsible for deciding which risks and opportunities need to be addressed
There is mention of risk throughout the whole Standard example: section on 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.....

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

This type of consideration applies to most lab features and to everything it does.
Risk based approach - The General Case

A risk based approach to management system implementation is one in which the breadth and depth of the implementation of particular clauses is varied to best suit the perceived risk involved for the particular laboratory.
### Risks and Opportunities (4/14)

<table>
<thead>
<tr>
<th>Less prescription</th>
<th>More output consideration</th>
</tr>
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<tbody>
<tr>
<td><strong>ISO/IEC 17025:2005</strong>&lt;br&gt;Lab shall have <em>policies and procedures</em> to ensure protection of confidential information…</td>
<td><strong>ISO/IEC 17025:2017</strong>&lt;br&gt;The lab shall <em>ensure the protection of confidential information</em>….</td>
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The relaxation of prescription makes it essential for each lab to consider the risk for each clause

- To discuss and agree what measures are required
- To implement in a known/controlled way for consistency
- To keep under review
Risk for a given clause:
How likely that a given area of compliance might lead to problems, ie non-compliance with the Standard, taking into account, the circumstances of the body, like

- Technical nature of the work
- Cultural, geographical and social environment
- Ownership
- Customer base
- Employees
The requirement for impartiality is a good example of where the risk and measures necessary can vary greatly:

A privately owned lab, with many customers, where the owner has no other activities or ownerships is unlikely to need extensive measures to protect impartiality.

Consider alternatively:

- A lab with only one customer
- A lab where the owner owns some customers
- A lab of a manufacturer also taking on third party work
A technical example:

6.4.10 *When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.*

- The complexity of this varies according to risk. A gauge block used as a reference may need little by way of intermediate checks but a sensitive electronic item exhibiting drift may need frequent checks, plotting and calculation from comparisons resulting in a drifting reference value being derived.

- All according to risk; similarly with calibration intervals
This philosophy is not new!

It has always been a requirement to take appropriate steps but a tendency to compare activities in dissimilar risk laboratories lead to some difficulties. Accreditation Bodies were criticised for “requiring” activities in some labs but not in others. Now it is quite clear that the extent of activity to comply with a particular clause will vary and it is the responsibility of the lab to achieve and demonstrate this appropriately.

Clause 8.5 of the new 17025 describes the purpose……...
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 can achieve 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; and

d) achieve improvement.
The laboratory shall….

8.5.2 The laboratory shall plan:
   a) actions to address these risks and opportunities;
   b) how to:
      - integrate and implement the actions into its management system;
      - evaluate the effectiveness of these actions.

8.5.3 Actions taken to address risks and opportunities shall be proportionate to the potential impact on the validity of laboratory results.
Making risk and opportunity consideration happen

- Ensure a culture in which risk and opportunity can be safely considered openly and honestly
- Provide a mechanism for all staff (whose activities can affect the output of the lab) to consider this, discuss and bring forward any ideas
- Agenda item on departmental meetings and reviews.
- Major item on MS Review agenda
- Expected of all staff by their managers
Why is this a good thing?

- Gives opportunity to be a better lab!
- Can reduce risk (or share it)
- Can provide opportunity to save effort and/or money
- Can encourage development, new techniques, quicker or easier calibrations, lower prices, higher profit, happier customers, better reputation
- Not all labs are the same so they should not all have the same features in their management systems
What is not required?

- There is **no expectation of adherence to Risk Management formal standards like ISO 31000** although these may make useful reading in setting up enhancements in a 17025 laboratory environment.

  ➔ It is more expected that the features will be inherent in the normal operation of the laboratory using 17025 with the enhancements appearing in several places in the management system.
SUMMARY

- Throughout the Standard
- An embedded philosophy
- Less Prescription – More Consideration
- Not all labs are, nor should they be, the same
- An opportunity to be a better lab