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EN ISO/IEC 17025

General requirements for the competence of testing and calibration laboratories

AGENDA

- Introduction
- History and development of accreditation
- General considerations of EN ISO/IEC 17025
- Requirements of the Standard

Quality Management System (ISO 9000)

Quality

The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs

Management System

Set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives

Quality Management System (ISO 9000)

Quality management systems serve many purposes, including:

- Improving processes
- Reducing waste
- Lowering costs
- Setting organization-wide direction

International Standard Organization (ISO)

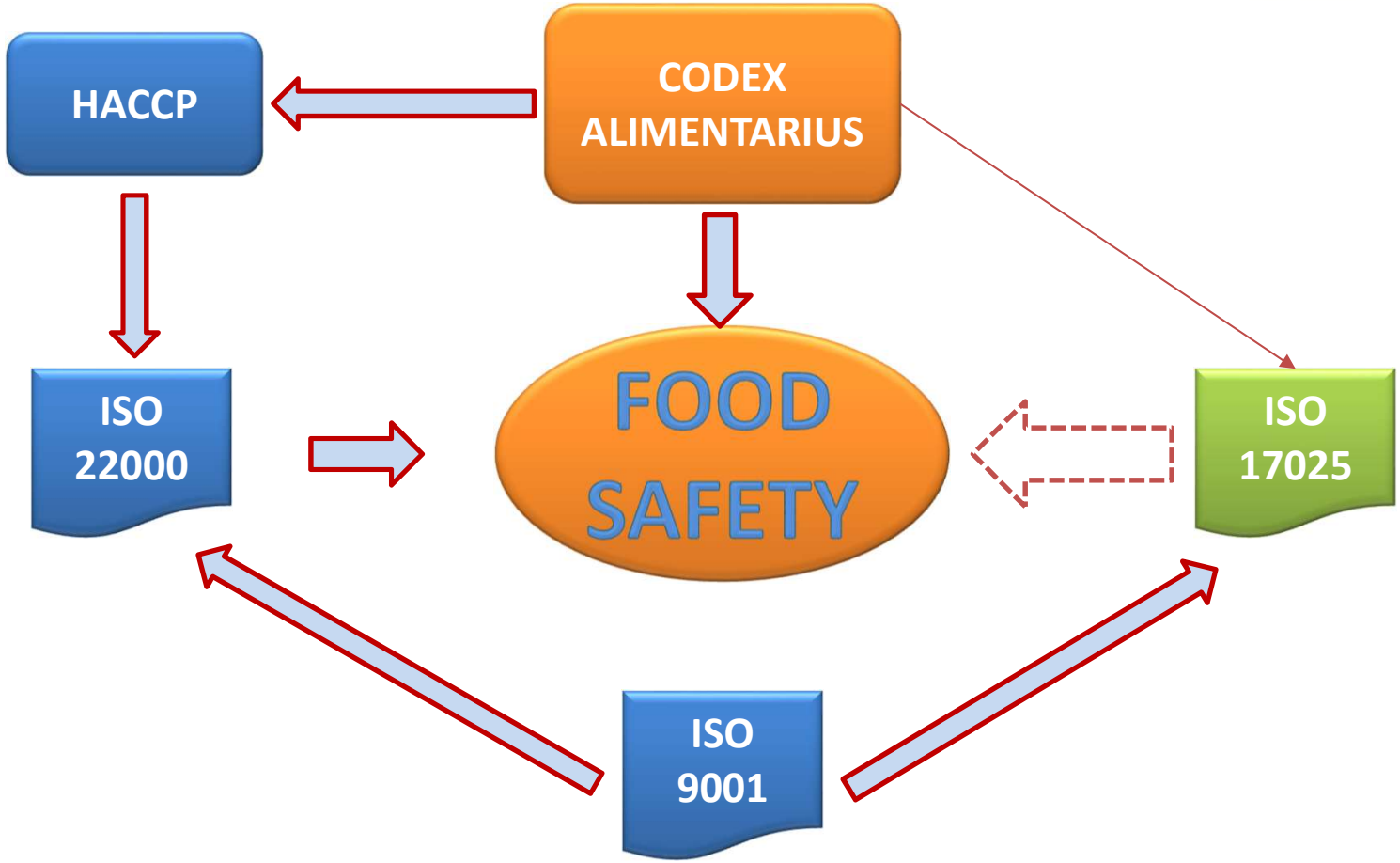
Independent, non-governmental international organization with a membership of 162 national standards bodies.

Standard - provides rules, guidelines or characteristics for activities or for their results, aimed at achieving the optimum degree of order in a given context

Certification and accreditation milestones

- 1946 - Foundation of International Standards Organization (ISO)
- 1951 - Publication of the first standard (ISO/R 1:1951)
- 1960 - ISO publishes the standard ISO 31 on quantities and units
- 1987 – ISO 9000 family (Quality Management Standards)
- 1996 – ISO 14000 family (Environmental Management Standards)
- 2000 – ISO 17025 General requirements for the competence of testing and calibration laboratories
- 2005 – ISO 22000 family (Food Safety Management Standard)

Quality in Food Safety



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Certification vs Accreditation

- **Certification**

  Recognition of an effective quality management system meeting the requirements of the ISO 9000 series

- **Accreditation**

  Recognition of the technical competence of an organization to properly perform specific types of testing, inspection, calibration, and other related activities.

Accreditation Bodies

- ILAC is the international organization for accreditation bodies involved in the accreditation of conformity assessment bodies including calibration laboratories and testing laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO 15189) and inspection bodies (using ISO/IEC 17020).

Accreditation Bodies

Regional Accreditation Bodies

Inter American Accreditation Cooperation

Asia Pacific Laboratory Accreditation Cooperation

European co-operation for Accreditation

European co-operation for Accreditation

36 full members and 13 associate members

ALBANIA – DPA
AUSTRIA – AA
BELGIUM – BELAC
BULGARIA – BAS
CYPRUS – CYS-CYSAB
CZECH REPUBLIC – CAI
DENMARK – DANAK
ESTONIA – EAK
FINLAND – FINAS
FRANCE – COFRAC
GERMANY – DAkkS
GREECE – ESYD
HUNGARY – NAH
ICELAND – ISAC
IRELAND – INAB
ITALY – ACCREDIA
LATVIA – LATAK
LITHUANIA – LA
LUXEMBURG – OLAS
MALTA - NAB-Malta
MONTENEGRO – ATCG
NORWAY – NA
POLAND – PCA
PORTUGAL – IPAC
REPUBLIC OF CROATIA – HAA
ROMANIA – RENAR
SERBIA – ATS
SLOVAKIA – SNAS
SLOVENIA – SA
SPAIN – ENAC
SWEDEN – SWEDAC
SWITZERLAND – SAS
MACEDONIA – IARM
NETHERLANDS – RVA
TURKEY – TURKAK
UNITED KINGDOM - UKAS

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Benefits of an accreditation system

- Provides confidence in results
- Acceptance of the public and industry
- Meets buyer's specifications or regulations
- National and international recognition
- Increase competitiveness and market share
- Guarantee of good laboratory practice
- Ensures better support in case of legal challenge
- Save money when you hit the first time

Accreditation in food Laboratories

- Food Chemistry
- Food Microbiology
- Food Rheology and other Physical Testing
- Food Toxicology
- Sensory Testing
- Molecular Biology

General considerations of EN ISO/IEC 17025

Adopted in Europe

International Electrotechnical Commission

EN ISO/IEC 17025:2005

International Standards Organization

Identification number

Year of the version

General considerations of EN ISO/IEC 17025

1978 **ISO/IEC Guide 25**

1982

1990 ← **EN 45001**

2000 **ISO/IEC 17025:1999**

← **ISO 9001:2000**

2005 **ISO/IEC 17025:2005**

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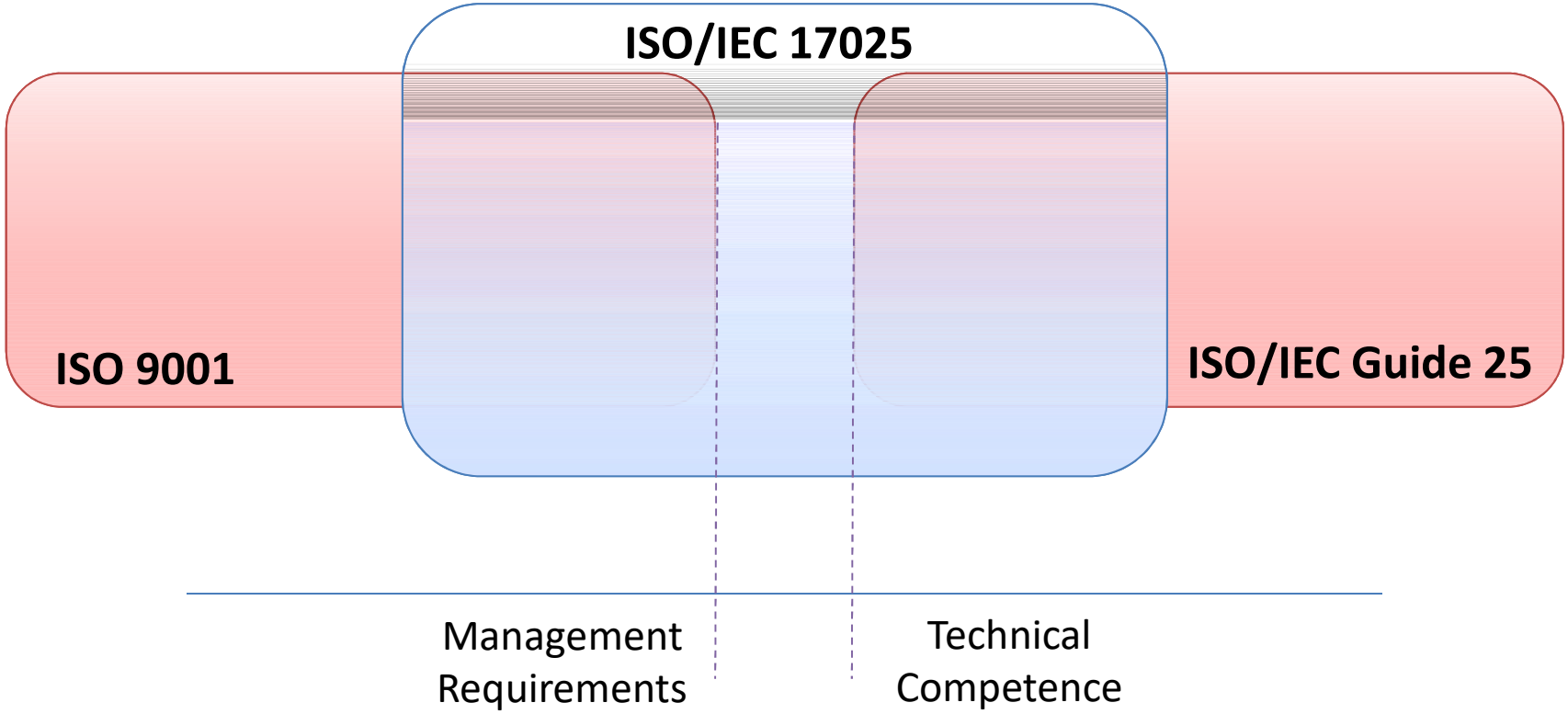
ISO 9001 vs ISO/IEC 17025



Content of EN ISO/IEC 17025


INTERNATIONAL STANDARD

ISO/IEC 17025

Second edition
2005-05-15

General requirements for the competence of testing and calibration laboratories

Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais

Reference number
ISO/IEC 17025:2005(E)

© ISO 2005

1. Scope
2. Normative References
3. Terms and Definitions
4. Management Requirements
5. Technical Requirements

- ANNEX A - Cross References to ISO 9001
- ANNEX B – Guidelines for Specific Fields

Management Requirements

4.1 Organization

Definition of the laboratory to be accredited (4.1.1)

- Laboratory with its own legal personality, composed of one or more technical units

or

- Laboratory integrated in an entity with its own legal personality.

The laboratory shall show that it meets the regulatory requirements applicable to its accredited area of activity and/or to accredit. (4.1.2)

- Applicable to conducting tests / calibrations and sampling.
- The evaluation of compliance with other legal requirements, such as contributory obligations or with Social Security does not fall within the scope of NP EN ISO/IEC 17025

4.1 Organization

The QMS shall be designed to cover all activities for which the laboratory is seeking accreditation, regardless of the location (4.1.3)

- Work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities shall be identified.

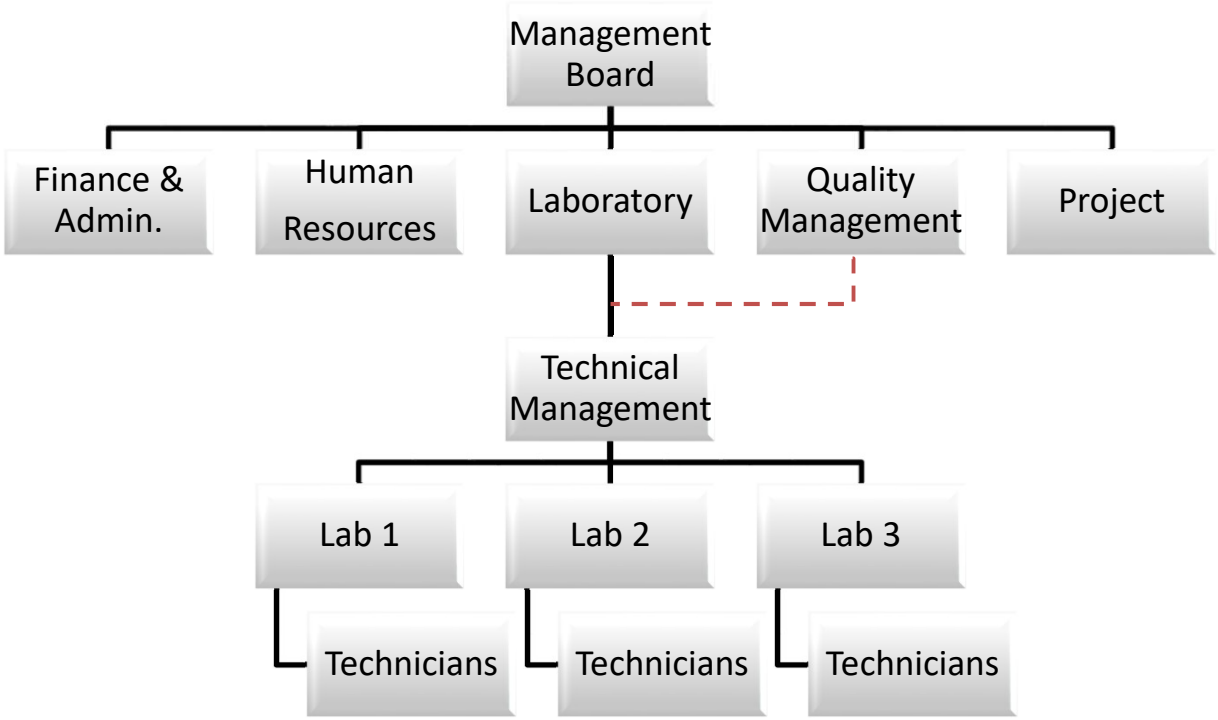
4.1 Organization

Conflicts of interest, independence and confidentiality (4.1.4 and 4.1.5)

- If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.
- Written arrangements should be in place to manage pressures and ensure there is no undue pressure on laboratory staff.
- There should be a policy statement in the QA manual and procedure(s) to protect the client's proprietary information and rights

4.1 Organization

Organization Chart (4.1.5)



4.1 Organization

Key Posts (4.1.5)

- **Technical Management**

  There is not necessarily one technical laboratory manager, but the laboratorial management structure must be defined.

- **Quality Manager**

  The Laboratory shall appoint a member of staff as quality manager

Deputies

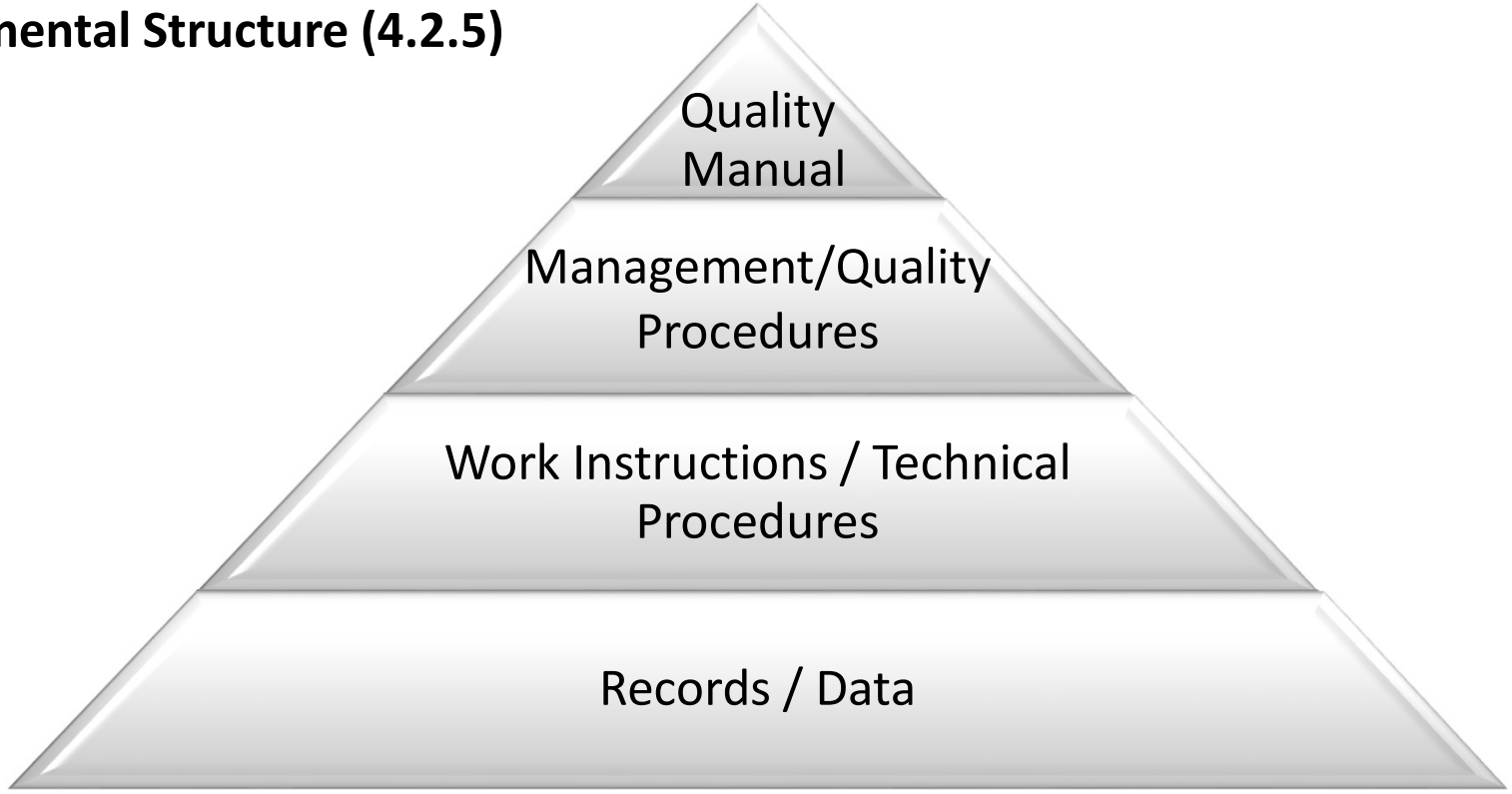
4.1 Organization

Communication (4.1.5)

Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system

4.2 Management System

Documental Structure (4.2.5)



4.2 Management System

The laboratory shall document:

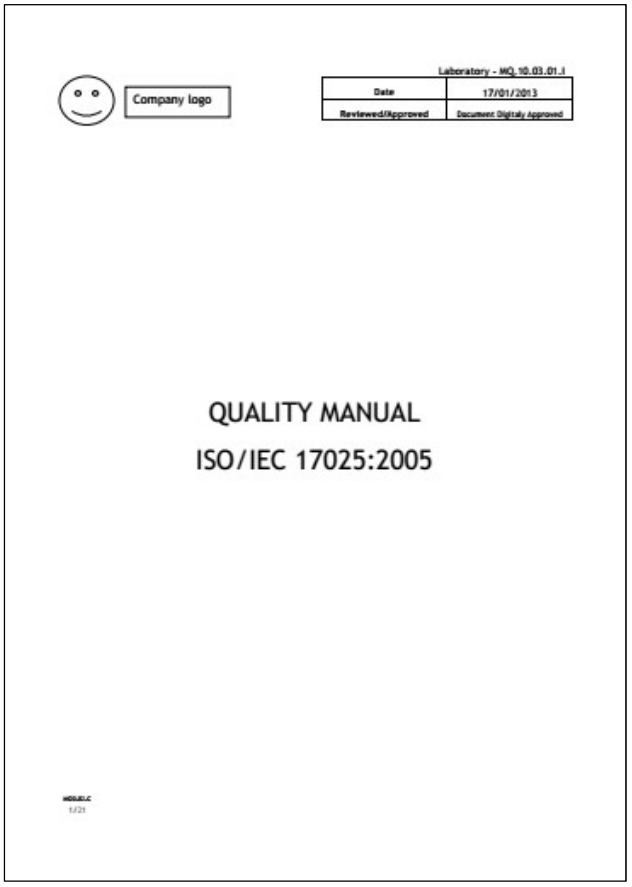
- policies
- systems
- programmes
- procedures and instructions

to assure the quality of the test and/or calibration results.

All documents shall :

- be written in an accessible language and understood by the user
- demonstrate compliance with the requirements of ISO/IEC 17025.

4.2 Management System


Company logo

Laboratory - MQ.10.03.01.I

Date	17/01/2013
Reviewed/Approved	Document Digitaly Approved

QUALITY MANUAL

ISO/IEC 17025:2005

- MQS Structure
- Quality Policy
- Quality Objectives
- Supporting Procedures

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4.2 Management System

Quality Policy Statement (4.2.2)

a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;

b) the management’s statement of the laboratory's standard of service;

c) the purpose of the management system related to quality;

d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work;

e) the laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system

4.2 Management System

Supporting Procedures (4.2.5)

-Management or Quality Procedures

-Technical Procedures

-Work Instructions

4.2 Management System

Supporting Procedures (4.2.5)

- clear and unambiguous identification of the document (on all the pages that constitute it);
- evidence of their validation and updating;
- the purpose and scope of the activity described in the procedure;
- contain Who (responsible) does What (action), How (procedure) and When (conditions);
- applicable materials, equipment and documentation;
- activity control and recording mode.

4.2 Management System

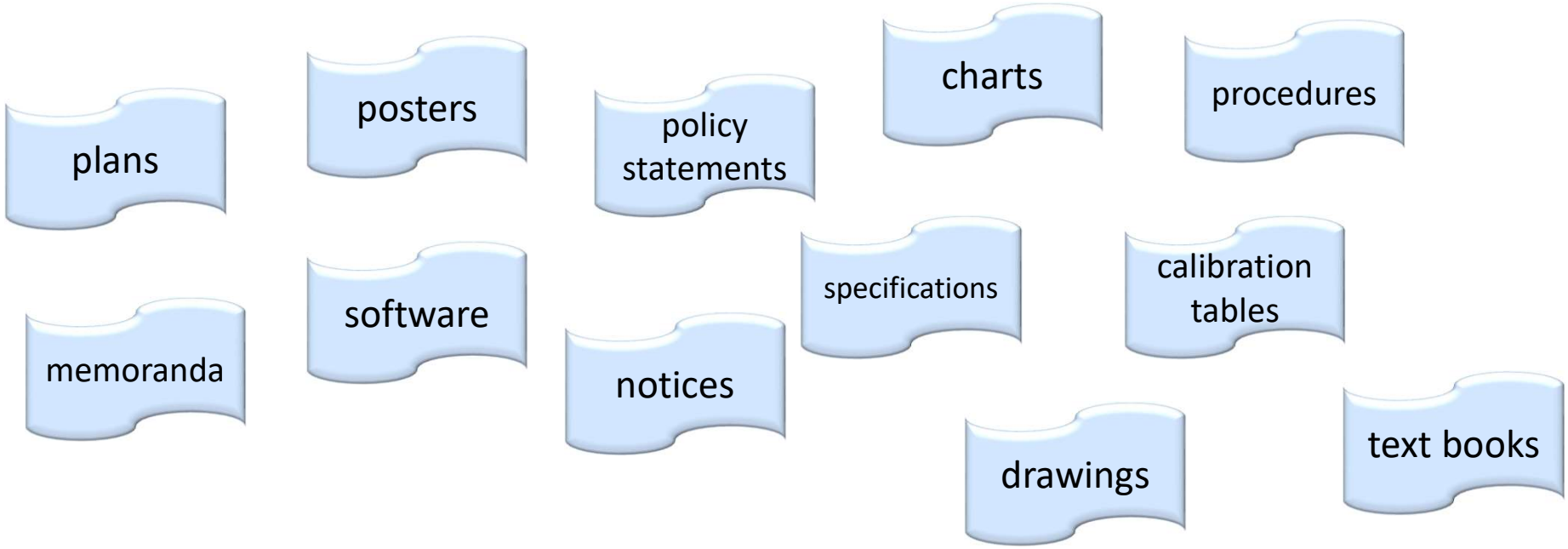
Top Management Shall:

4.2.3 provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness;

4.2.4 communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements;

4.2.7 ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented .

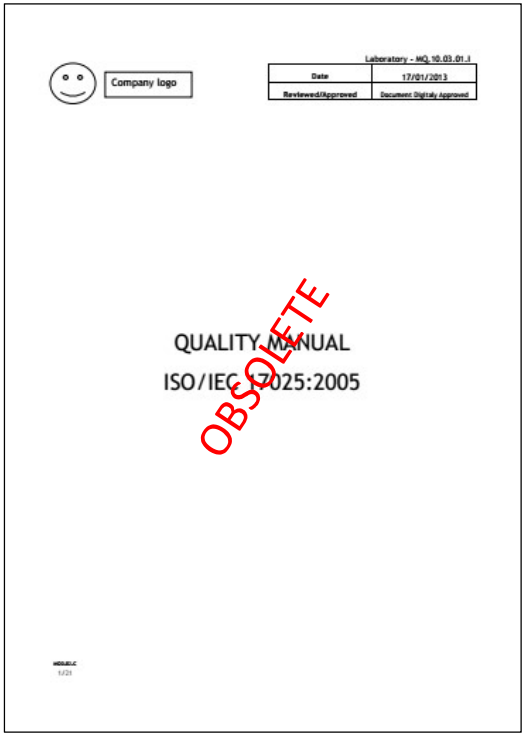
4.3 Document Control

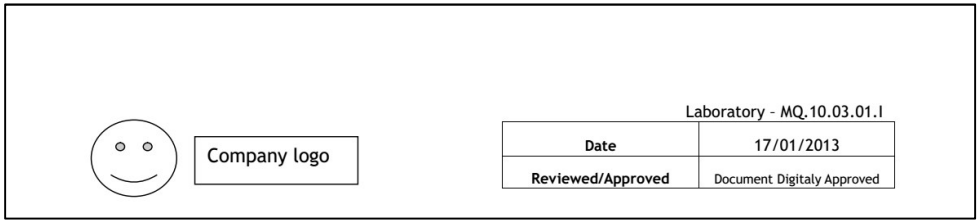


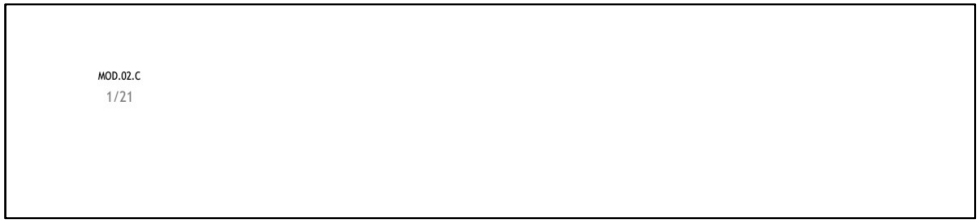
These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.

4.3 Document Control

Document approval and issue (4.3.2)







4.3 Document Control

Document changes (4.3.3)

- Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise.
- The altered or new text shall be identified in the document or the appropriate attachments.

~~The removed text may be struck-out~~ and the new one can be highlighted

4.4 Review of requests, tenders and contracts

The policies and procedures should ensure that:

a) the requirements, including the methods to be used, are adequately defined, documented and understood

b) the laboratory has the capability and resources to meet the requirements;

c) the appropriate test and/or calibration method is selected and is capable of meeting the customers‘ requirements

Records of
- Meetings
- Phone calls
- E-mails
- Faxes

→

- Deadlines for delivery of results
- Prices
- Responsibilities for sample collection
- Etc…

4.5 Subcontracting of tests and calibrations

Subcontracting → **Accredited Laboratories**

Customer must be informed, preferably in writing, and accept the conditions.

4.6 Purchasing services and supplies

Relevant Supplies:

- Consumables
- Standards
- Certified Reference Material
- Measuring and testing equipment
- Reagents

Relevant Services:

- Subcontracting
- Calibration
- Maintenance
- Training
- Internal audits
- Interlaboratory comparisons

Must be inspected and approved before use

Suppliers Evaluation → List of approved suppliers

4.7 Service to the customer

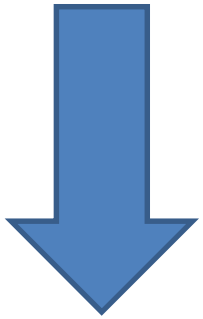
The Laboratory must provide:

- all of the information that client needs
- access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the customer

Customer's Feedback

4.8 Complaints

Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory



Requirement (4.11)

4.9 Control of nonconforming testing and/or calibration work

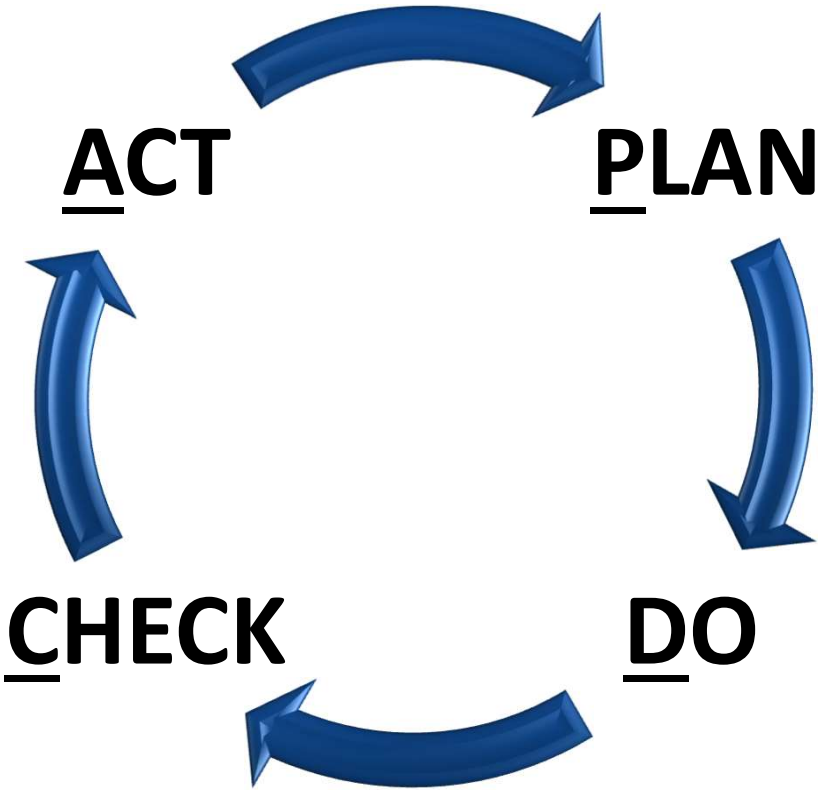
Correction **VS** **Corrective Action** → **Req. (4.11)**

Test Repetition

Training, supervision or disqualification of the operator, acquisition, calibration or maintenance of Equipment, etc.

4.10 Improvement

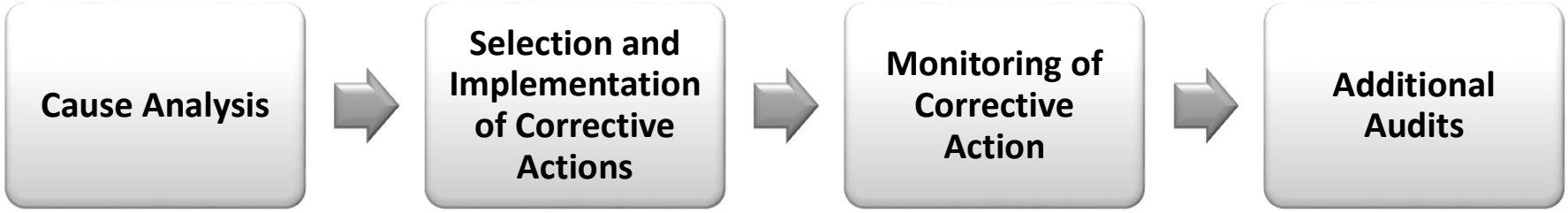
PDCA Cycle



4.10 Improvement

***PDCA Cycle**

4.11 Corrective action



4.12 Preventive action

Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

4.13 Control of Records

Laboratory shall have procedures for:

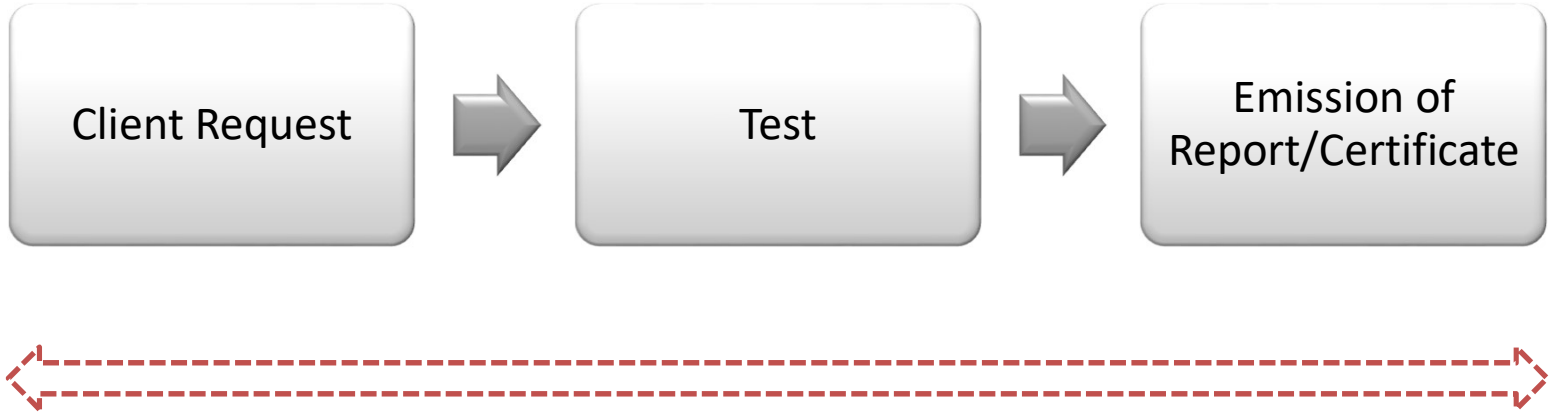
- Identification
- Collection
- Indexing
- Access
- Filing
- Storage
- Maintenance
- Disposal

Quality and Technical records

4.13 Control of Records

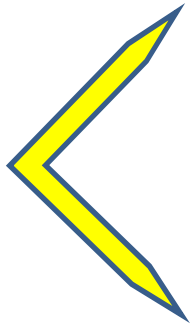
Technical Records

Shall include sufficient information to establish an audit trail



4.14 Internal Audits

Cycle for internal auditing (1 year)



Completed once and cover all of the requirements of ISO/IEC 17025

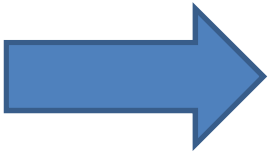
Several audits on different areas or aspects of ISO/IEC 17025

All ISO/IEC 17025 requirements and all technical areas covered or to be covered by accreditation must be audited in an internal audit cycle.

4.15 Management reviews

Inputs

- Audit Reports
- Feedback from customers
- Audit and review program
- Quality control checks
- Nonconformities
- Complaints
- Preventive actions
- Results form interlaboratory trials



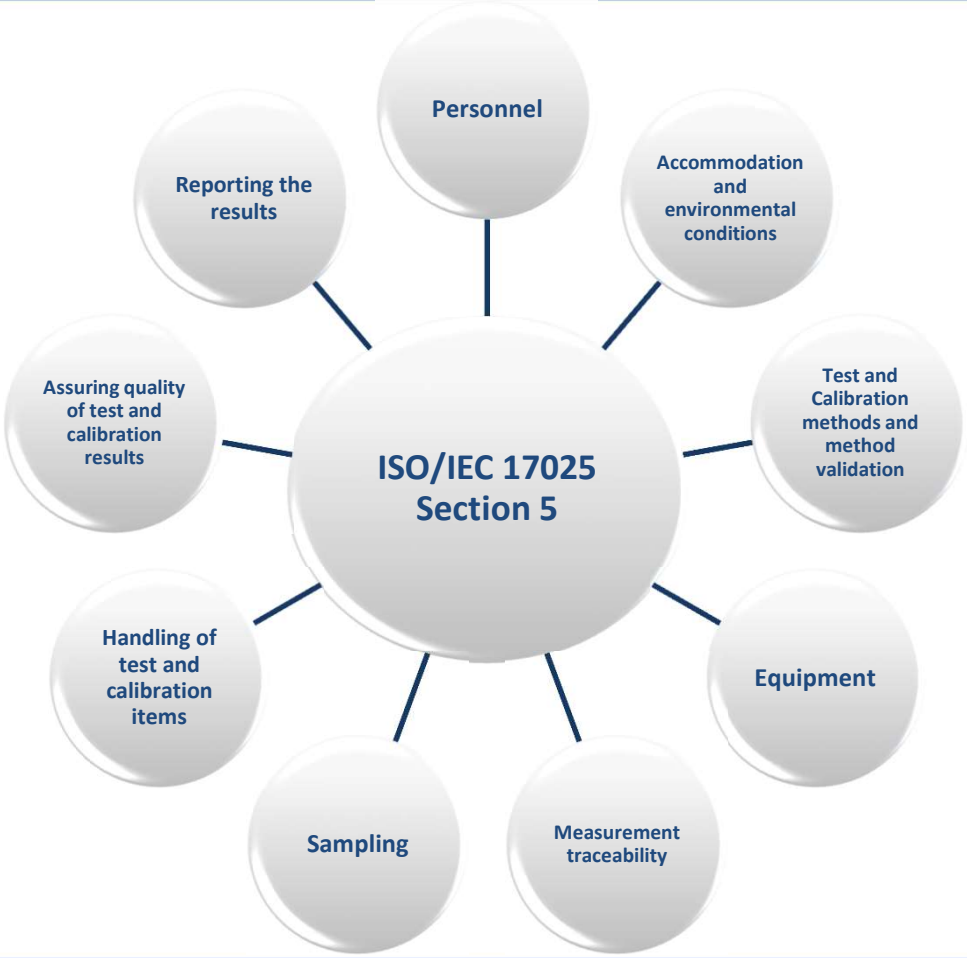
Outputs

- Audit and review program
- New quality objectives
- Preventive actions
- Interlaboratory trials program

Recommended Procedures

- Documents and records control;
- Review of requests, tenders and contracts;
- Purchasing services and supplies;
- Customer satisfaction assessment;
- Complains;
- Control of nonconforming work;
- Corrective, preventive and improvement actions;
- Internal audits.

Technical Requirements



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5.2 Personnel

- Assurance of competence
- Personnel training programme
- Personnel under contract
- Job descriptions

5.3 Accommodation and environmental conditions

- **Types of facilities:**

  Permanent installations

  Temporary facilities

  Mobile facilities

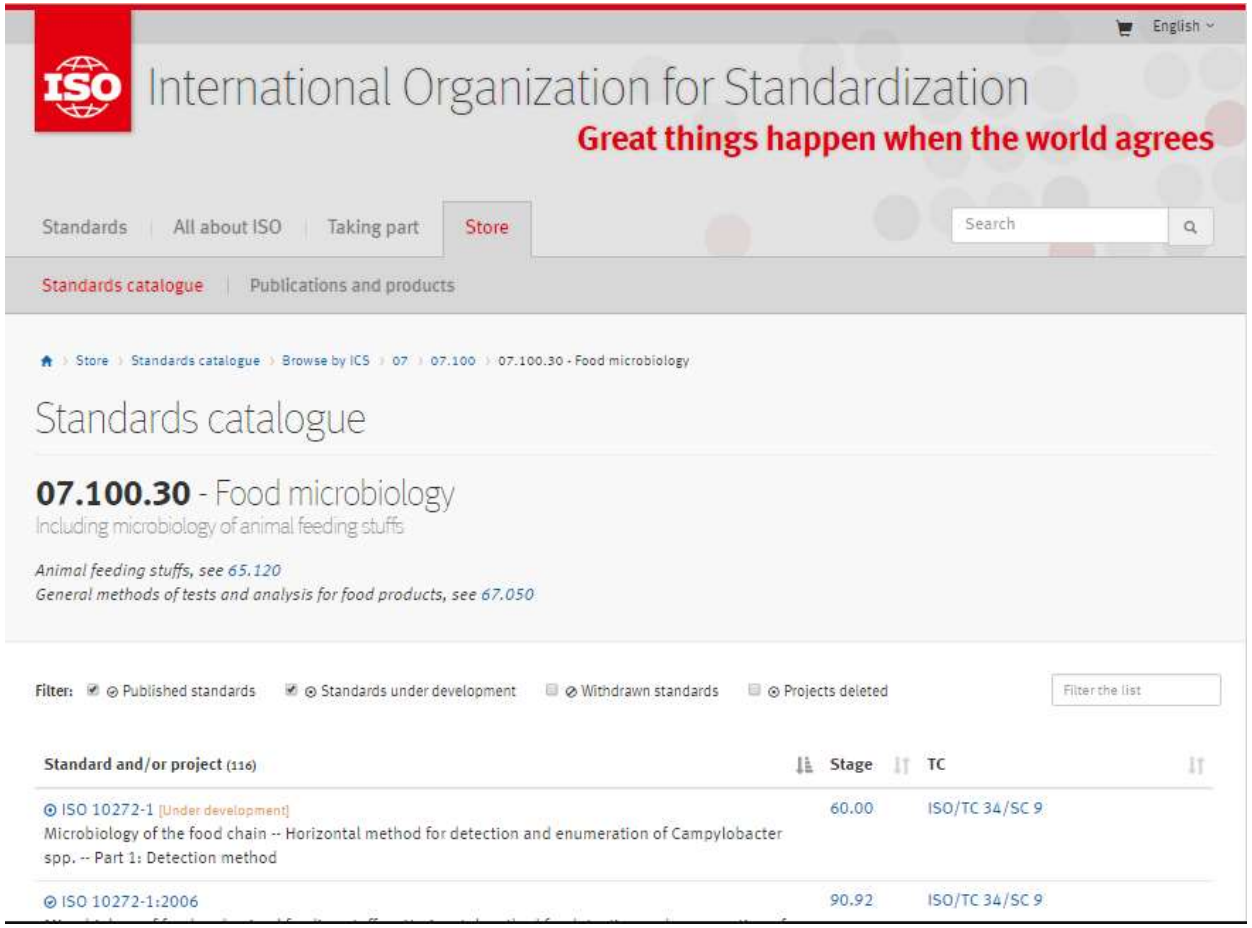
  Customer or customer-defined facilities

5.4 Test and calibration methods and method validation

Test Method

- **Standard Method**
- **In-house methods**
  - **Based on Standards**
  - **Non- standard method**

5.4 Test and calibration methods and method validation



English

International Organization for Standardization

Great things happen when the world agrees

Standards | All about ISO | Taking part | Store

Search

Standards catalogue | Publications and products

Store › Standards catalogue › Browse by ICS › 07 › 07.100 › 07.100.30 - Food microbiology

Standards catalogue

07.100.30 - Food microbiology

Including microbiology of animal feeding stuffs

Animal feeding stuffs, see 65.120
General methods of tests and analysis for food products, see 67.050

Filter: Published standards | Standards under development | Withdrawn standards | Projects deleted

Filter the list

Standard and/or project (116)	Stage	TC
ISO 10272-1 [Under development] Microbiology of the food chain -- Horizontal method for detection and enumeration of Campylobacter spp. -- Part 1: Detection method	60.00	ISO/TC 34/SC 9
ISO 10272-1:2006	90.92	ISO/TC 34/SC 9

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5.4 Test and calibration methods and method validation

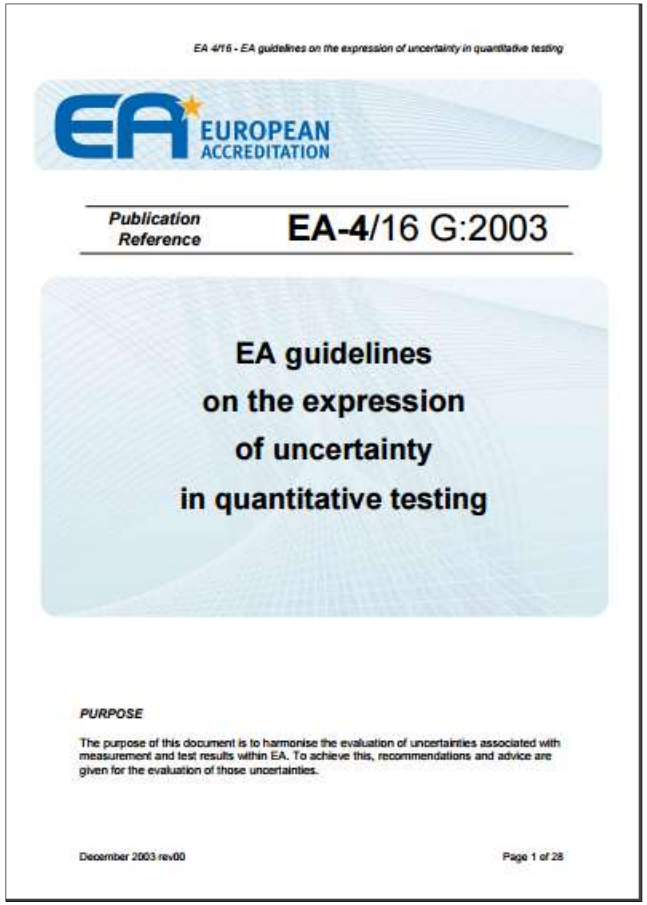
Validation of methods

- Calibration using reference standards or reference materials;
- Comparison of results achieved with other methods;
- Interlaboratory comparisons;
- Systematic assessment of the factors influencing the result;
- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

5.4 Test and calibration methods and method validation

Estimation of uncertainty of measurement

Result of the evaluation aimed at characterizing the range within which the true value of a measure and is estimated to lie, generally with a given likelihood.


EA 4/16 - EA guidelines on the expression of uncertainty in quantitative testing

EUROPEAN ACCREDITATION

Publication Reference EA-4/16 G:2003

EA guidelines on the expression of uncertainty in quantitative testing

PURPOSE

The purpose of this document is to harmonise the evaluation of uncertainties associated with measurement and test results within EA. To achieve this, recommendations and advice are given for the evaluation of those uncertainties.

December 2003 rev00 Page 1 of 28

5.4 Test and calibration methods and method validation

Control of data

Software

- Commercial off-the-shelf software
- Developed by the laboratory

Data protection

5.5 Equipment

- All equipment shall be checked or calibrated before being placed into service
- Equipment shall be operated by authorized personnel.
- Each item of equipment shall be identified

5.5 Equipment

- Records shall be maintained :

- Identity;
- Manufacturer's name, type identification, and serial number or other unique identification;
- Checks that equipment complies with the specification
- Current location, where appropriate;
- Manufacturer's instructions

5.5 Equipment

- Records shall be maintained :

- Dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
- Maintenance plan, where appropriate, and maintenance carried out to date;
- Any damage, malfunction, modification or repair to the equipment.

5.5 Equipment

- The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment
- Any equipment that is not suitable for use shall be marked and removed from service
- All equipment shall have an indication of its calibration status.

5.6 Measurement traceability

Calibration Program

- have a significant influence on the results of the tests
- calibration is required standards or specifications

Accredited Calibration Laboratories

5.7 Sampling

The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration.

This clause applies only to laboratories whose work involves the extraction of samples as part of the testing program

Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole

5.8 Handling of test and calibration items

- Procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items
- Identification of items
- Records of abnormalities
- Preservation of samples

5.9 Assuring the quality of test and calibration results

- **Quality control procedures**
  - use of certified reference materials
  - participation in interlaboratory comparison
  - replicate tests or calibrations
  - retesting or recalibration
  - correlation of results

5.10 Reporting the results

The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported:

accurately

clearly

unambiguously

objectively

5.10 Reporting the results

Test report or calibration certificate shall include:

- a title (e.g. “Test Report” or “Calibration Certificate”);
- the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;
- unique identification of the test report or calibration certificate
- the name and address of the customer;
- identification of the method used;
- a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;

5.10 Reporting the results

Test report or calibration certificate shall include:

- the date of receipt of the test or calibration item(s)
- reference to the sampling plan and procedures used by the laboratory or other bodies;
- the test or calibration results with, where appropriate, the units of measurement;
- he name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;
- where relevant, a statement to the effect that the results relate only to the items tested or calibrated

New version of ISO/IEC 17025

DRAFT INTERNATIONAL STANDARD
ISO/IEC DIS 17025

ISO/CASCO | Secretariat: ISO
Voting begins on: 2016-12-29 | Voting terminates on: 2017-03-22

General requirements for the competence of testing and calibration laboratories

Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais

ICS: 03.120.20

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/IEC DIS 17025:2016(E)

Contents

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"Political nationalism will most probably prevail for as long as we live. Economic nationalism is about to disappear. And technical nationalism has disappeared!"

Olle Sturen, ISO Secretary General (1969)