Lecturer introduction

Lecturer, affiliation

Dr. Bojan Acko, assistant professor

University of Maribor
Faculty of Mechanical Engineering
SI-2000 Maribor, Smetanova 17
Slovenia

Laboratory for Production Measurement

http://www.ltm.fs.uni-mb.si/

Lecturer introduction

Education

- 1986 - Diploma at FS MB
- 1990 - Master of Science at FS MB
- 1997 - Doctor of Science at FS MB

- 1991 – 1992: Postmaster study at Virginia Tech, VA USA
- 1994 – 2006: 6 international and national courses on accreditation
- 1999: special education in legal metrology at NMi Delft, NL

Lecturer introduction

Professional record

- 1986 – 1989: young researcher
- 1989 – 1998: assistant
- 1998 - ..: assistant professor

- 1996 – 2001: quality manager of an accredited calibration laboratory - LTM
- 2001 - ..: head of LTM

Lecturer introduction

Education activity

Graduate and postgraduate study

- Metrology
- Production measurements
- Quality management
- Standardisation and quality
- Co-ordinate measuring systems
- Metrology and measurements in tool production

Lecturer introduction

Other activities

- **External lead and technical assessor for Slovenian Accreditation (SA)** - from 1997 (more than 50 assessments performed)
- **Member of Expert Metrology Council at SA** – from 2000
- **Member of Accreditation Committee at SA** – from 2006
- **Representative of Slovenia in Euromet TCL** – from 1998
- **Member of SIST/TC UGA – Conformity assessment** – from 2001
- **Member of SIST/TC STM - Statistical methods** – from 2001

Lecturer introduction

Experience in assignments related to European Research

- Partner in PRAQIII programme (Regional Programme on QA) – Intercomparison of Length Measurements of Gauge blocks, 1998
- Partner in the 5th EU framework project INITIATION (Interpretation and implementation of the standard ISO 17025 by national metrology institutes in Europe), 2001-2002
- Cooperation in 10 Euromet projects (co-ordinator for Slovenia)
- Partner in Copernicus project Model Based Quality Control for Precision Gearings and Couplings, 2002 - 2003
- Key expert for accreditation in EU EAR project in SCG, 2004 - 2006
- Metrology expert in EU CARDS project i Albania; 2005 - 2007
- Tempus project PoMaCoM

Laboratory introduction

Accreditation

- International Accreditation: RvA The Netherlands
- National Accreditation

SLOVENSKA AKREDITACIJA SIST EN ISO/IEC 17025 LK-003

SLOVENSKA AKREDITACIJA SIST EN ISO/IEC 17020/C K-027

RvA CALIBRATION RvA K 112

National Metrology Laboratory for quantity Length

- Associated laboratory of the National Metrology Institute
- Holder of the national standard for LENGTH

MIRS

Nominated Conformity Assessment Body in Legal Metrology

- Inspection and verification of length measuring instruments used for legal metrology purposes

Calibration, documentation and laboratory management

Contents

- Quality of a measurement result
- Definition of calibration and traceability
- Role and importance of calibration
- Principles of calibration
- Traceability to national and international standards of measurement
- Metrology system in an enterprise
- Accreditation and ISO/IEC 17025
- Quality system in a calibration laboratory

Course introduction

Literature

- B. Ačko: Course materials
- Fluke: Calibration: Philosophy and Practice, 1994
- C.W. Kenedy. Inspection and gaging, 1987
- F.T. Farago, M.A. Curtis: Handbook of Dimensional Measurements, 1994.
- EN/ISO/IEC 17025-2000: General requirements ..
- EN ISO 10012: 2003 "Measurement management systems …
- EA-2/03 EAL Interlaboratory Comparisons
- EA-2/07 EAL Strategy to Achieve Comparability of Results in Calibration and Testing
- EA-4/02 Expression of the Uncertainty of Measurement in Calibration
- EA-4/07 Traceability of Measuring and Test Equipment to National Stand.
- ILAC-G2 Traceability of Measurements
- ILAC-G2 Guidance for Accreditation to ISO/IEC 17025

Course introduction

Seminar work

- Written report on chosen topic; discussion

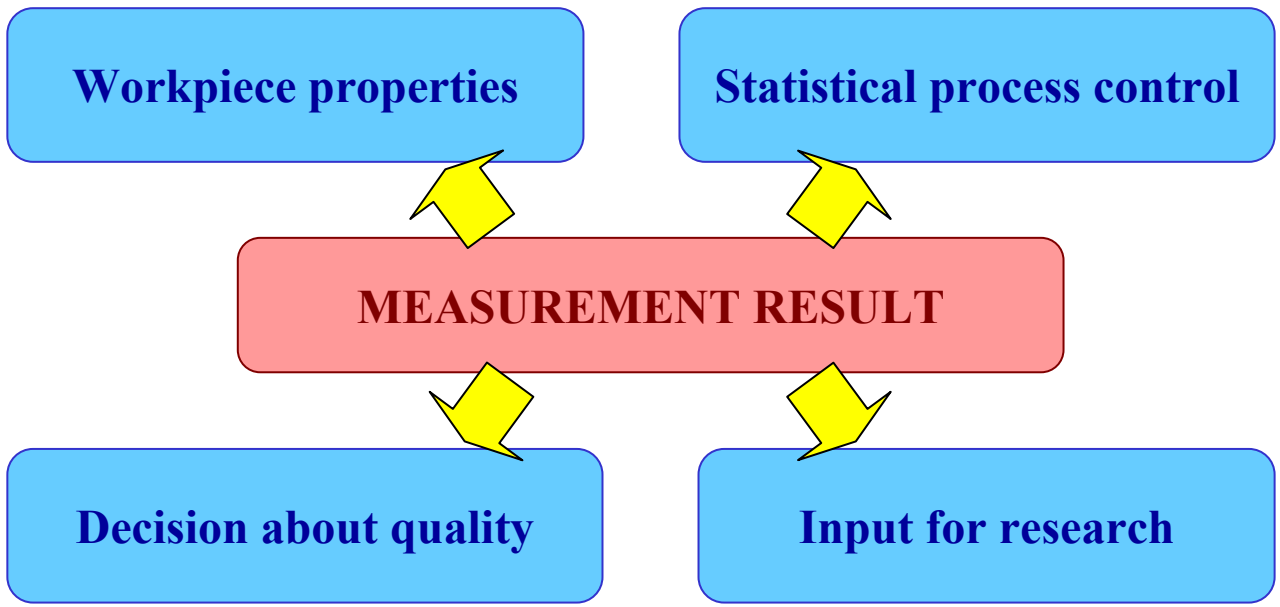
Exam

- Written exam – 5 questions

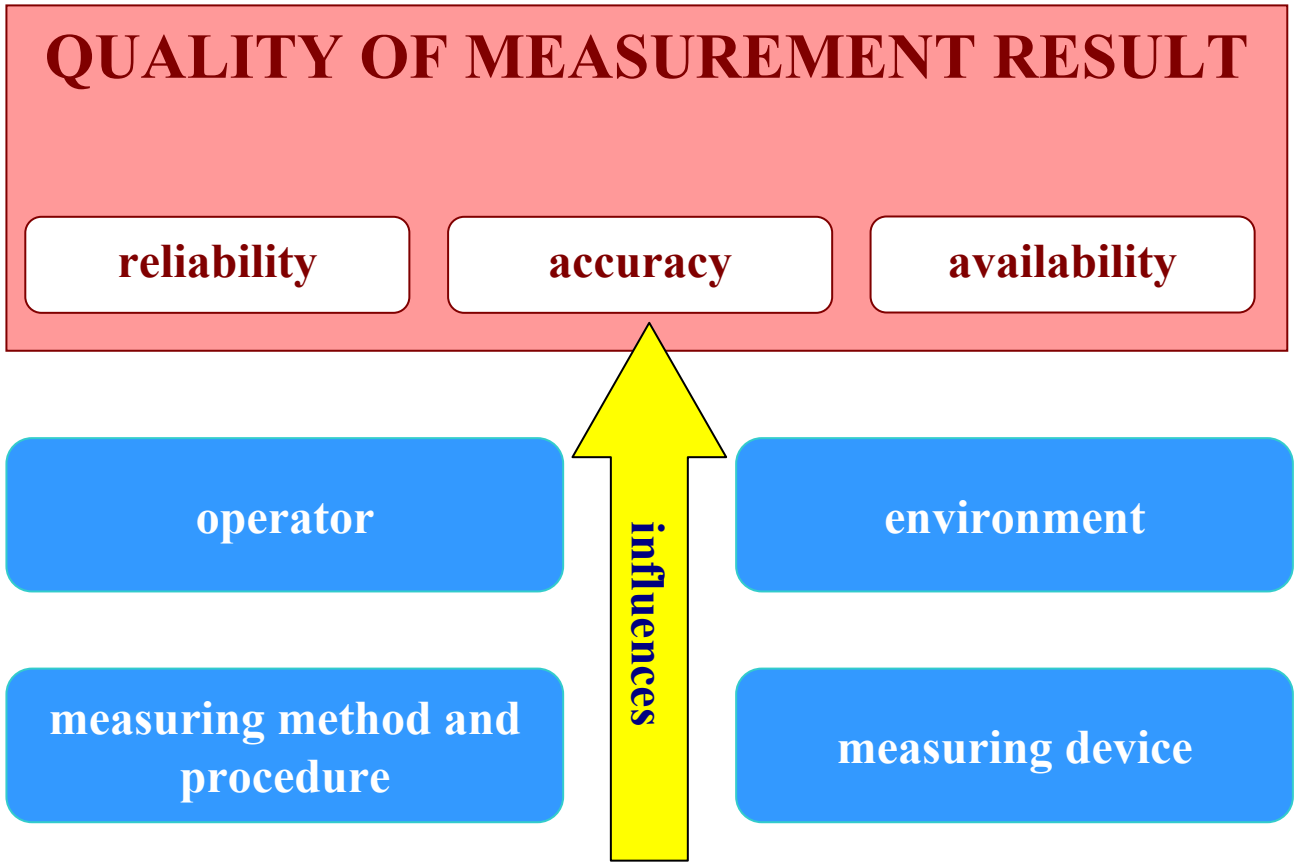
  Oral exam

Quality of measurement result

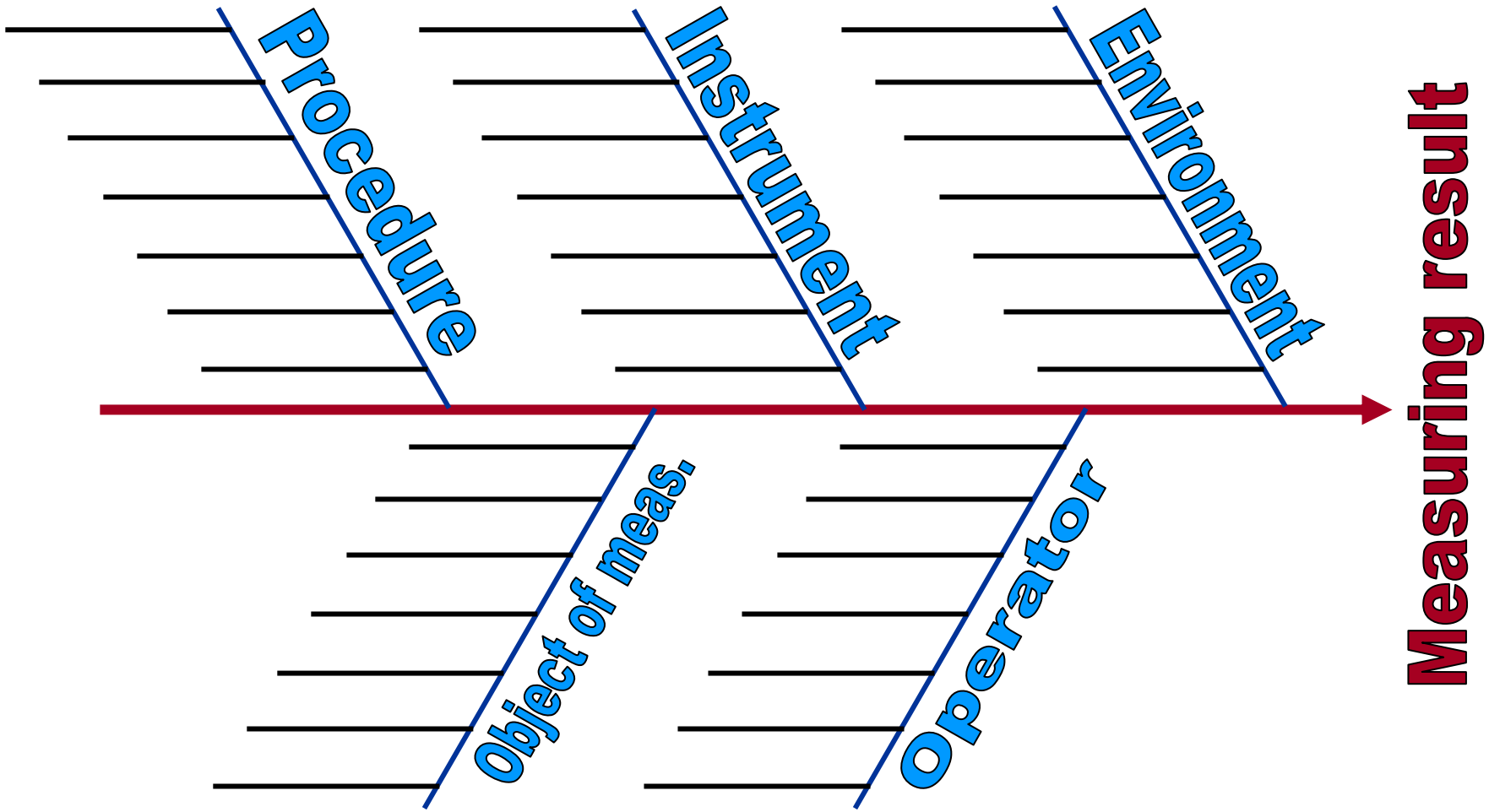
IMPORTANCE OF MEASUREMENT RESULT



Quality of measurement result



Quality of measurement result



Quality of measurement result

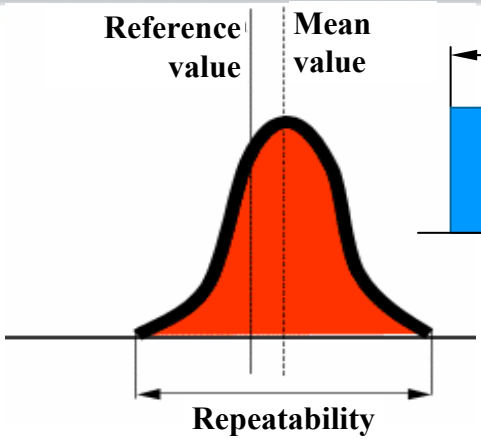
Measuring procedure

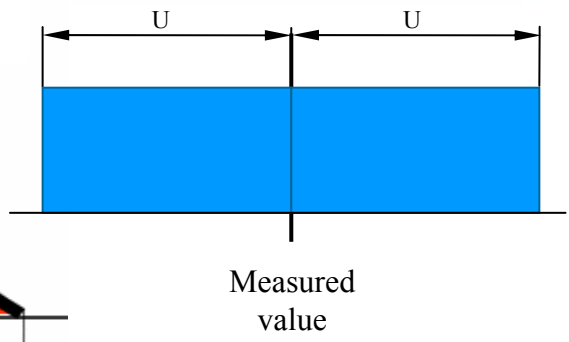
- Number of measurements
- Measurement time
- Method selection
- Selection of a reference / standard of measurement
- Selection of measurement instrument(s)
- Number of operators
- Filter (for results)

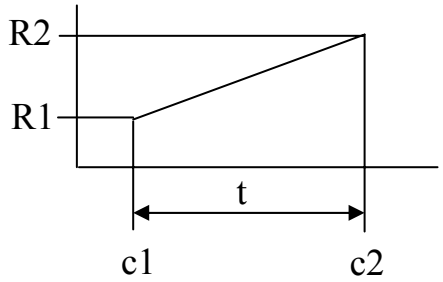
Quality of measurement result

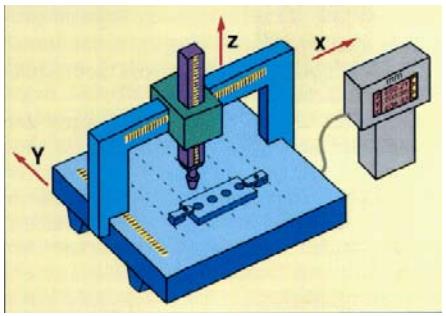
Measuring instrument

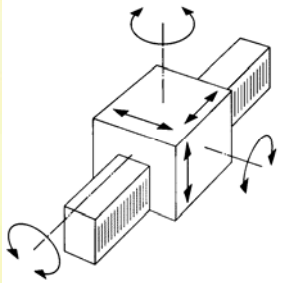
- Repeatability (scattering)
- Calibration uncertainty
- Time from the last calibration
- Materialization of measuring axes
- Temperature
- Measuring and evaluating software

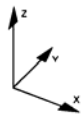












Quality of measurement result

Environment

- Temperature
- Humidity
- Vibrations
- Air pressure
- Dirt
- Magnetism
- Gravitation
- Radiation / light

Quality of measurement result

Measuring object

- Temperature
- Surface
- Material
- Dimensions / mass
- Dirt
- Form deviations
- Position in the measuring space
- Vibrations

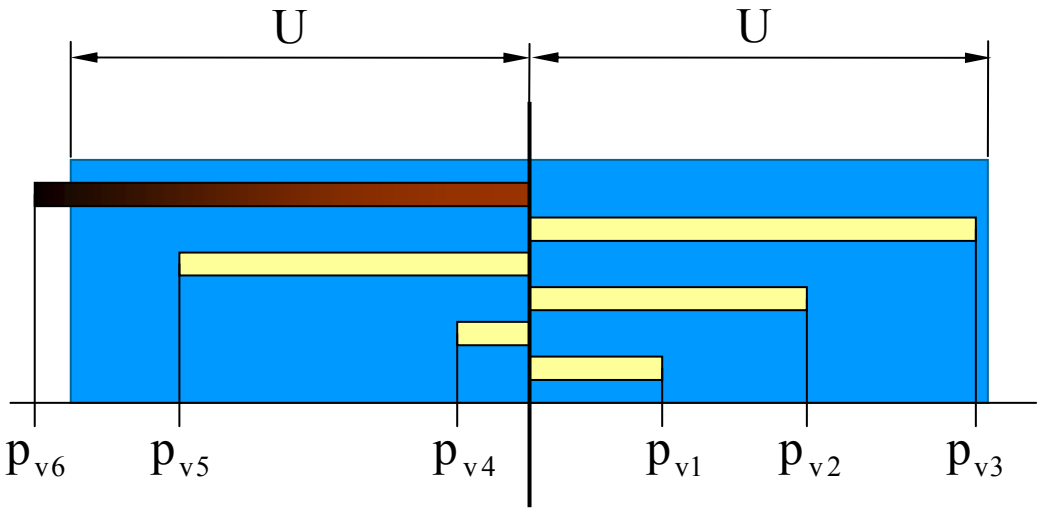
Quality of measurement result

Operator

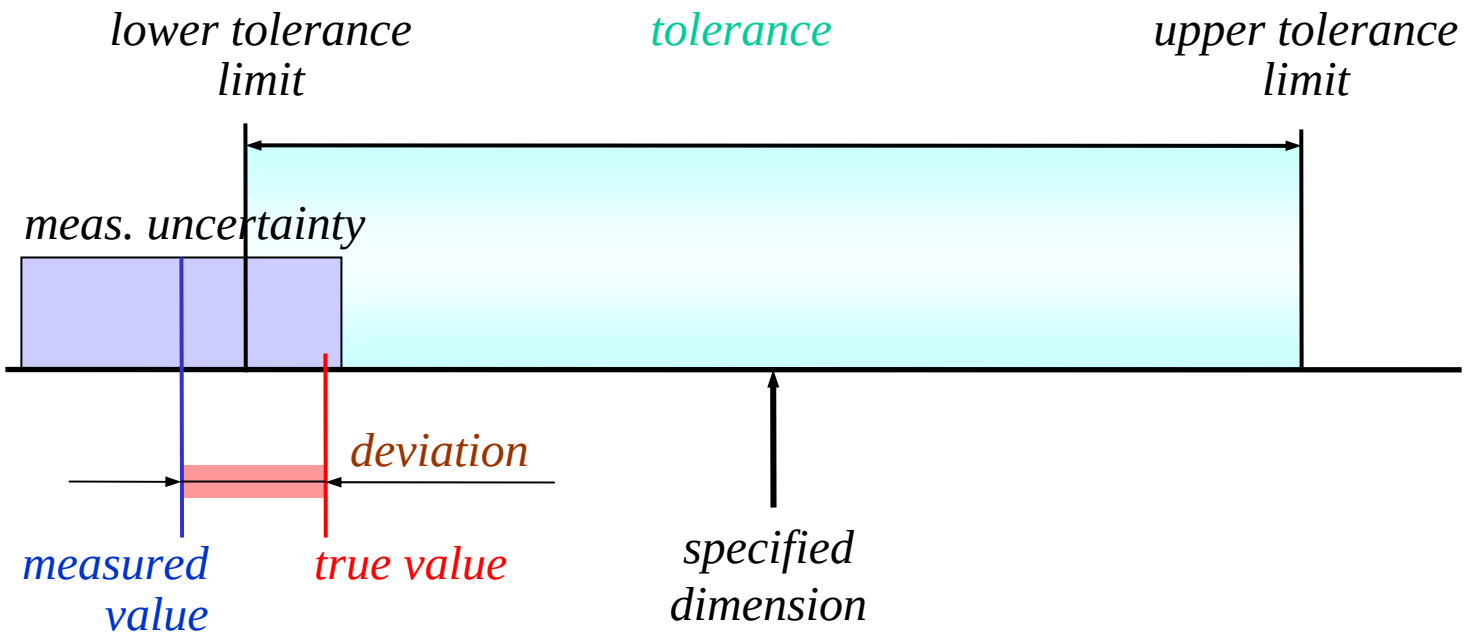
- Measuring force
- Experiences
- Selection of instrument(s)
- Education
- Parallax
- Care
- Manipulation

Quality of measurement result

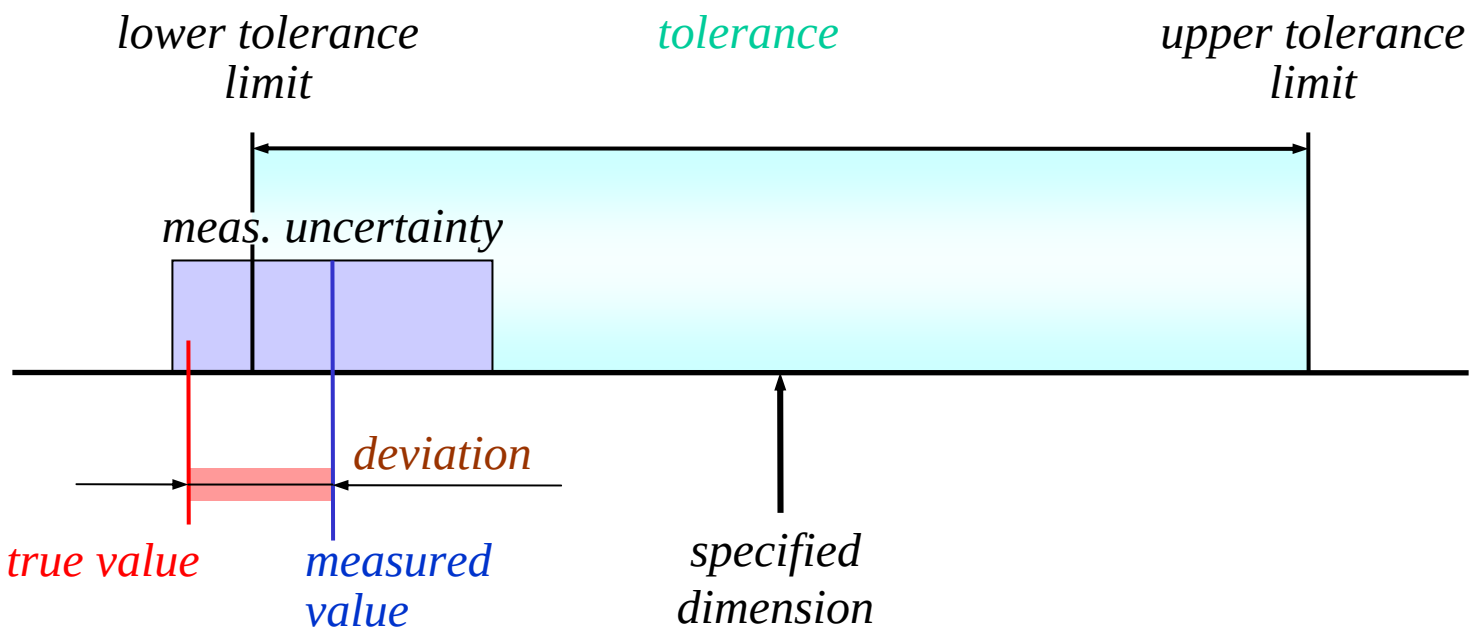
- **Unceratinty of measurement can be simply expressed as an interval around the measured value, in which would with certain probability (usually 95 %) lie the true value of the measured quantity (which is not known)**



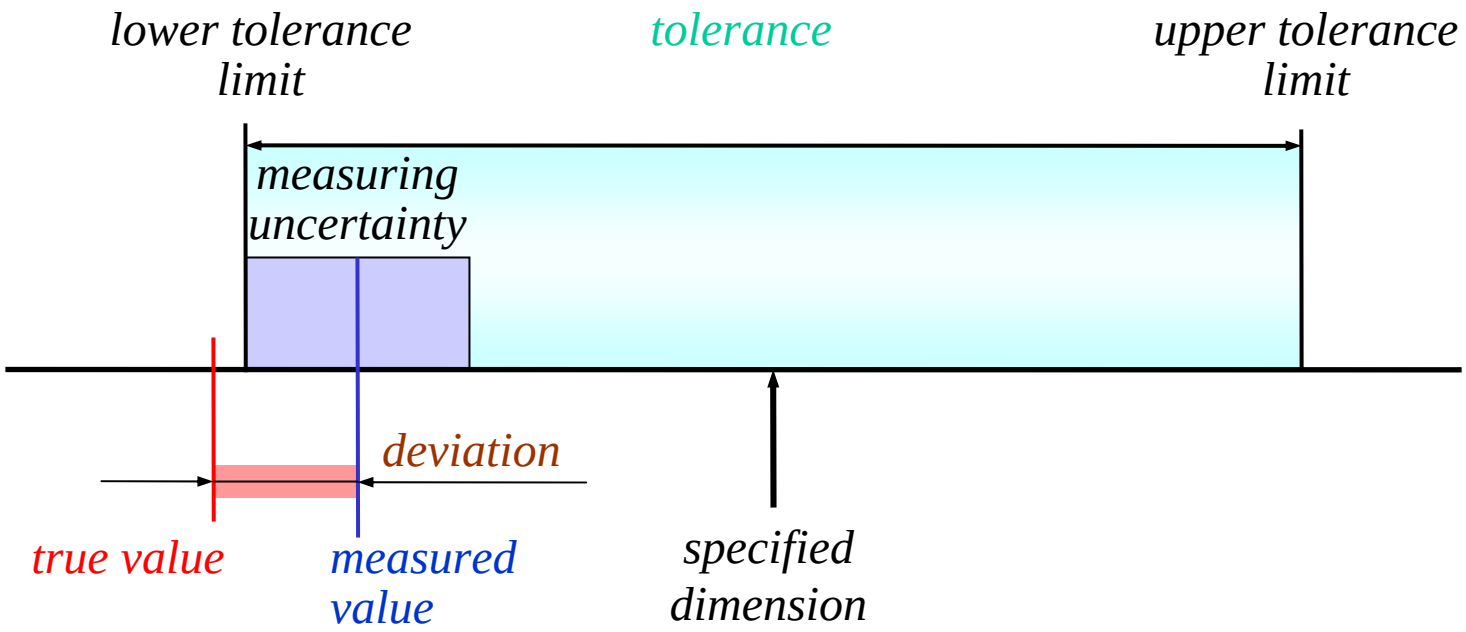
Quality of measurement result



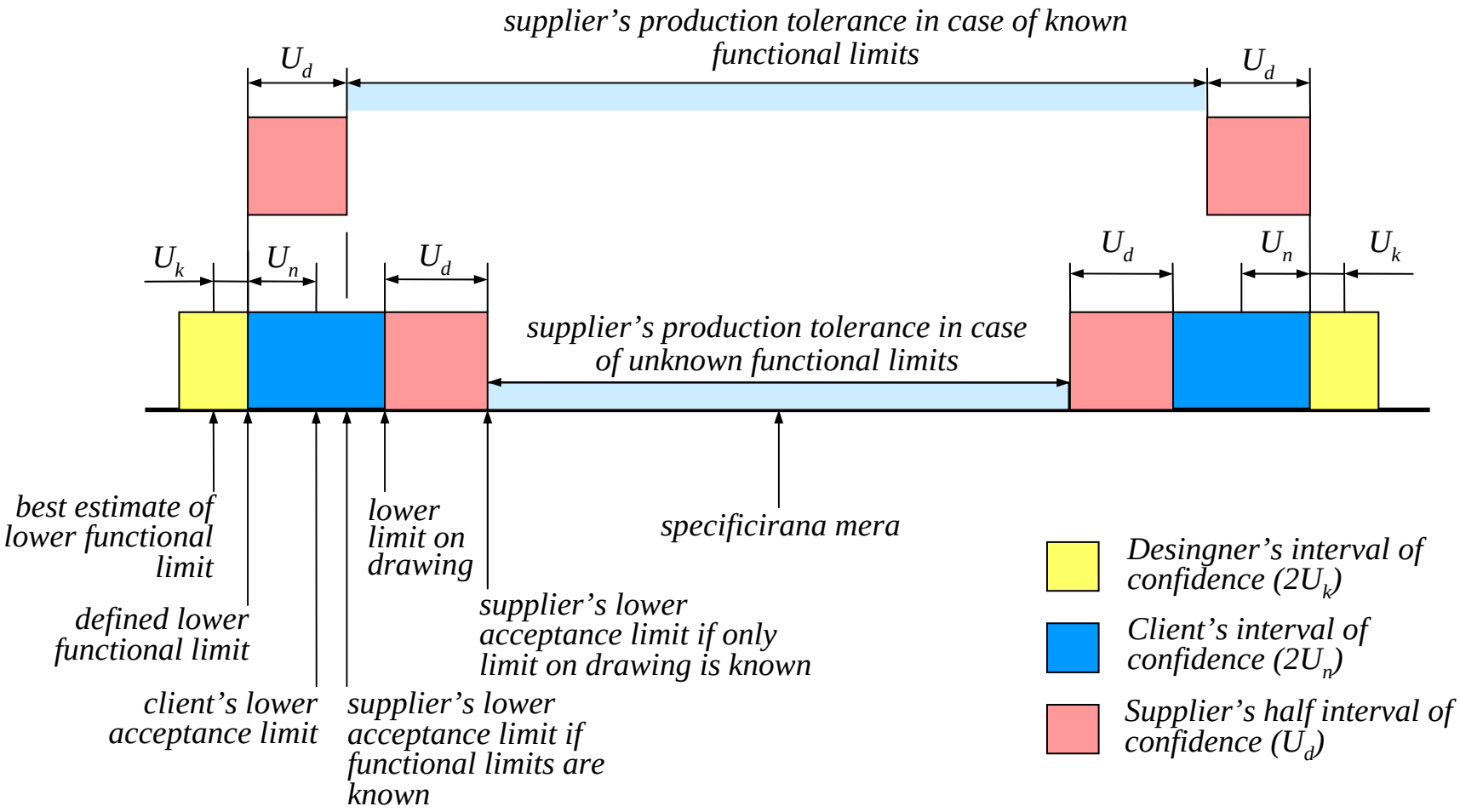
Quality of measurement result



Quality of measurement result



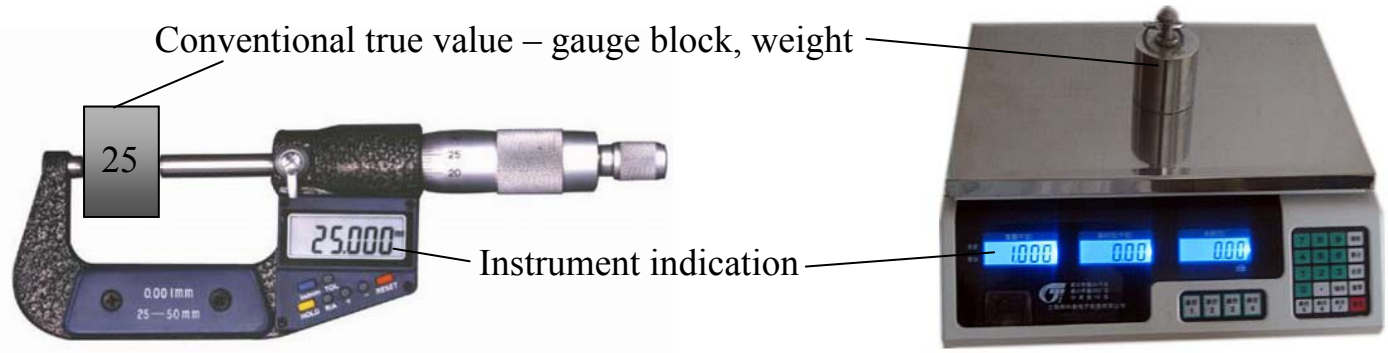
Quality of measurement result



Definition of calibration and traceability

What is calibration?

- *Definition according to VIM: Calibration is a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or system and the corresponding values realised by standards*
- **Establishing relation between the instrument indication and the true value of a measuring object, which is realized by a standard of measurement or by an instrument of higher accuracy**



Definition of calibration and traceability

Standard of measurement (VIM): material measure, measuring instrument, reference material or measuring system intended to define, realize, conserve or reproduce a unit or one or more values of a quantity to serve as a reference.

- **The whole measuring range of the instrument shall be covered by calibration**
- **Number of calibration points is chosen in accordance with the measuring range and the precision level of the instrument**
- **Periodical establishment of metrological properties of a measuring instrument / standard**
- **Calibration result is reported in a document "Calibration certificate" or "calibration report"**

Definition of calibration and traceability

What is verification?

Verification is conformity assessment of a measurement instrument with national or international regulation

Difference between calibration and verification

Calibration

Industrial metrology – free market

(reliable monitoring of product quality)

Verification

Legal metrology - regulated by a state or a region

(customer protection, health, environment)

Definition of calibration and traceability

Calibration

Product: **calibration certificate**
(metrological data: deviations, …)
label
(for indicating the calibration status)

Verification

Product: **conformity attestation**
(statement of conformity with regulations)
label
(for legal monitoring purposes)

Definition of calibration and traceability

Traceability is a property of the result of a measurement or a value of the standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties

(the unbroken chain of comparisons is called a traceability chain)

Role and importance of calibration

Why to calibrate?

- To get an information about the measurement instrument status
- To get information about deviations and accuracy

!

- To fulfil internal quality system requirements
- To fulfil external requirements (clients, certification bodies, accreditation bodies…)

Why is (in many cases) calibration not performed?

- Lack of basic metrology knowledge
- Company management doesn't assign proper finances for this activity
- Lack of finances
- No external requirements (clients, certification bodies, accreditation bodies…)

Principles of calibration

What shall be taken into account when calibrating?

- Important for defining calibration intervals and points

- Type and design properties of the instrument to be calibrated
- Frequency of use
- Working conditions
- Costs

Who can calibrate?

- Company (owner of instruments) – in-house calibrations
- Calibration laboratories (offering services on market)
- National laboratory (nominated by state authorities)

Principles of calibration

How to establish in-house calibration system?

- Availability of reference and working standards
- Proper traceability of standards used for calibration (calibration in appropriate institutions)
- Availability and training of calibration personnel
- Availability of premises assuring proper environmental conditions
- Availability of validated calibration procedures, including evaluation of measuring uncertainty
- Availability of operating quality management system

Principles of calibration

How to evaluate potential calibration laboratories?

- **Accreditation (accreditation scope shall be considered!)**
  - national
  - international –MLA signatories
- **National laboratories (published CMCs shall be considered!)**
  - home country
  - Europe
  - other regions
- **Audit (own facilities are necessary!)**
  - conformity assessment (with our own requirements or e.g. ISO/IEC 17025

Principles of calibration

National metrology institutes

Germany

United Kingdom

The Netherlands

France

Austria

Slovenia

USA

……..

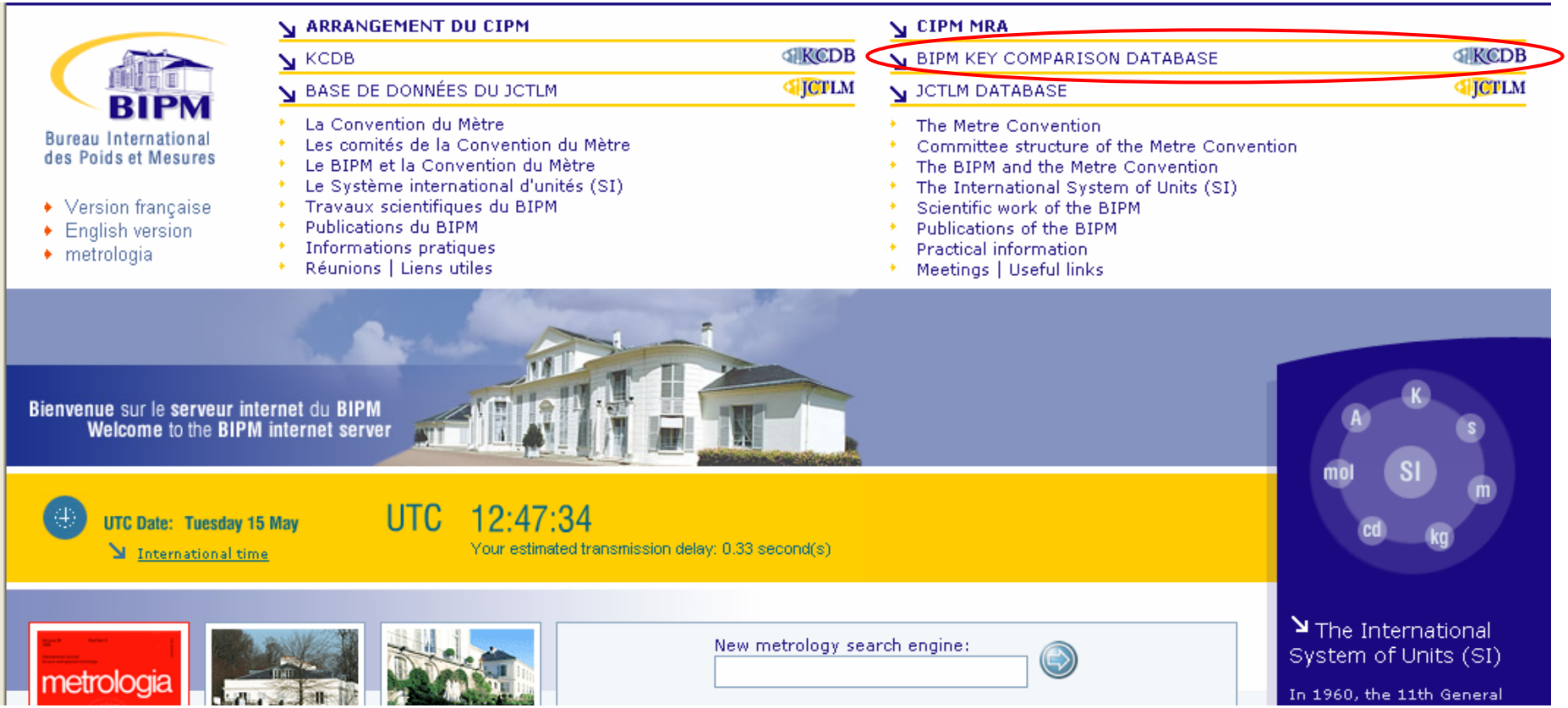
- National Metrology Institutes maintain primary standards that realise the SI units directly from their definition based upon the fundamental physical principles.
- The standards are compared at key comparisons arranged by BIPM or Euromet.
- If an NMI does not have a primary standard it should provide a national reference standard traceable directly to another NMI´s primary standard.

Principles of calibration

CMC – calibration and measurement capability

LTM-sample

- **Published on BIPM web site**



Principles of calibration

Important backgrounds for calibration

- Internal calibrations shall be introduced whenever possible (especially for simple and frequent measuring instruments)
- Calibration laboratories shall be chosen by checking their quality res. competence
- Recalibration intervals shall be defined very carefully
- Calibration points shall be defined very carefully
- Calibration results shall be checked and analysed

Principles of calibration

Recalibration intervals

Re-calibration intervals shall be established based on experience, metrological knowledge, instrument history, advises… Indicators are:

- **Which accuracy is required in measurements?**
- **How often is the standard/instrument used? (Is it exposed to wear?)**
- **How stable is the standard/instrument (history of calibration results)?**
- **Environment where the standard /instrument is used?**
- **How is the standard /instrument stored?**
- **Has the standard /instrument been subject to overload or mishandling? (calibrate immediately!)**
- **Are work and reference standards /instruments compared frequently (intermediate controls)?**

Principles of calibration

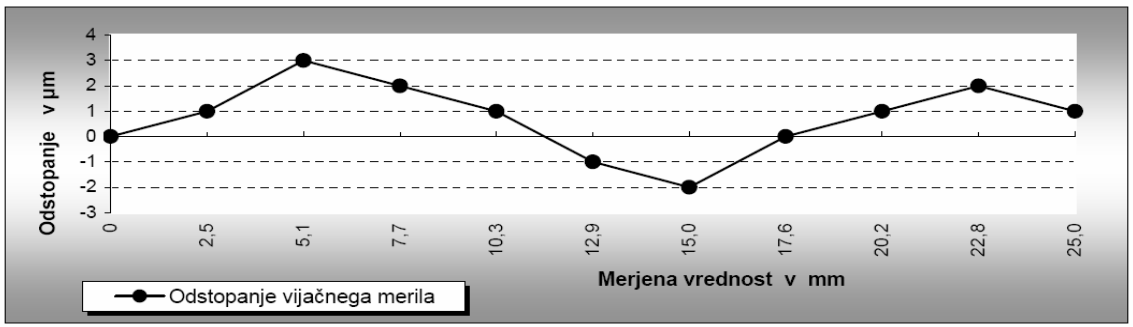
Selection of calibration points

Number and position of calibration points on a measuring instrument are chosen according to:

- **Measuring range**
- **Accuracy of instrument**
- **Measurements, for which the instrument will be used (allowed maximum uncertainty, measuring range)**

Merilni rezultat
Measurement result

Nazivna vrednost (Ln) v mm	0	2,5	5,1	7,7	10,3	12,9	15	17,6	20,2	22,8	25
Odstopanje (o) v µm	0	1	3	2	1	-1	-2	0	1	2	1



Principles of calibration

Contents of a calibration report (certificate)

- Title “Calibration report (certificate)
- Name and address of the performer of calibration (lab, company)
- Unique report (certificate) number
- Dates of calibration and issuing the report (certificate)
- Page number and total number of pages on each page
- Identification of the client
- Data of the instrument that was calibrated
- Environmental conditions (if important for the measuring result)
- Identification of the calibration method
- General statement about traceability of the measurement
- Way of expressing uncertainty of measurement
- Calibration result (results of all performed measurements)

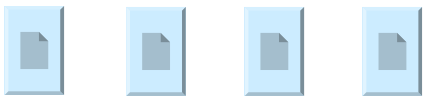
Principles of calibration

Contents of a calibration report - continued

- Signature of the calibration performer (not obligatory)
- Signature of the person who approved the report and stamp
- Uncertainty of measurement
- Standards and instruments used for calibration (not obligatory)

Additional possible contents of a calibration report

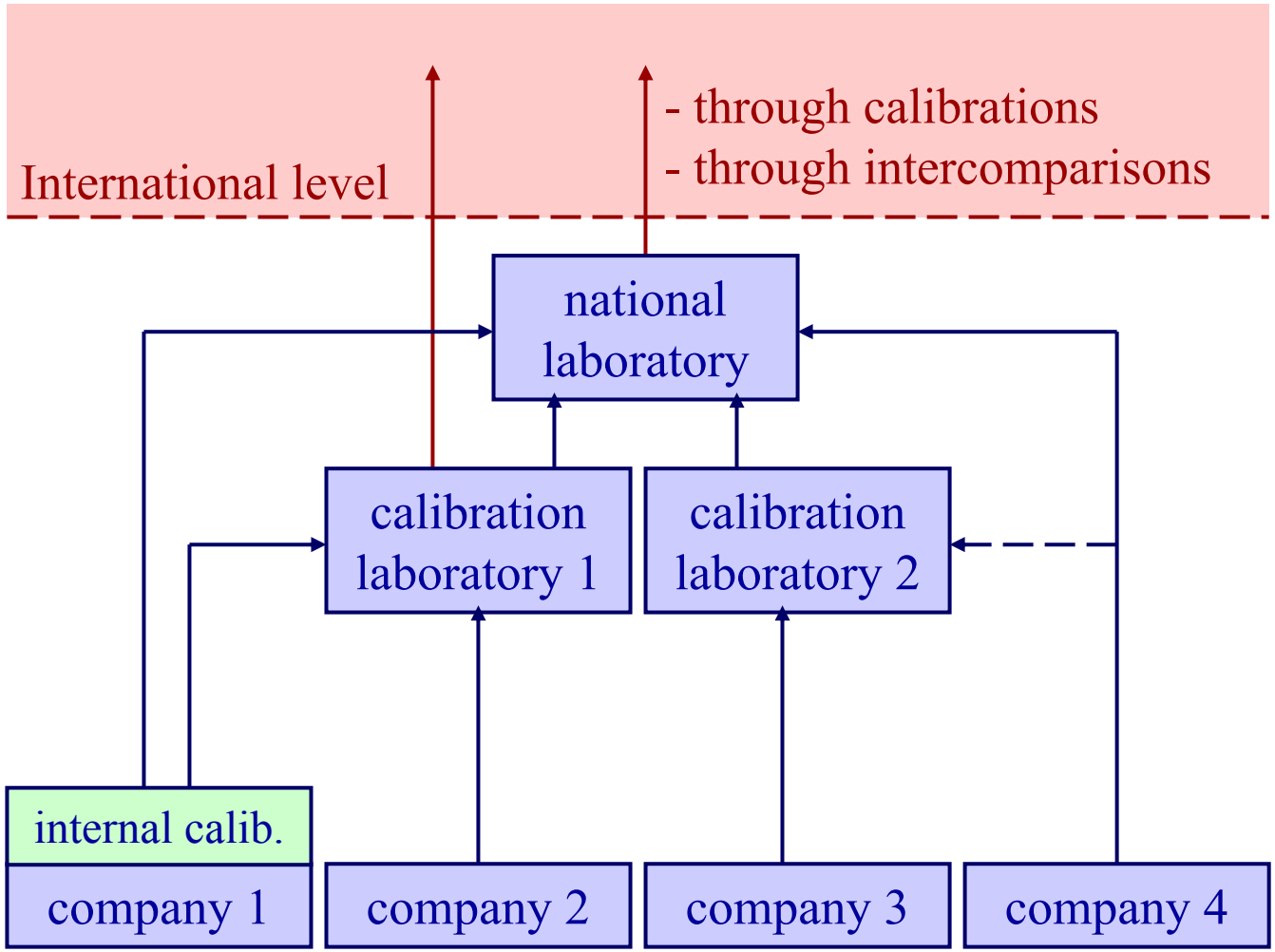
- Remarks (e.g. detected damages on the calibrated instrument)
- Date of the next calibration (but only as an information, not as suggestion or recommendation; it should be avoided if possible!)
- Explanation of the results (deviation or correction)



Traceability to national and international standards

Traceability

Unbroken chain of calibrations



Traceability to national and international standards

$$U_{k4}$$

$$\wedge$$

$$U_{k3} = \sqrt{U_{k4}^2 + U_{kp3}^2}$$

$$\wedge$$

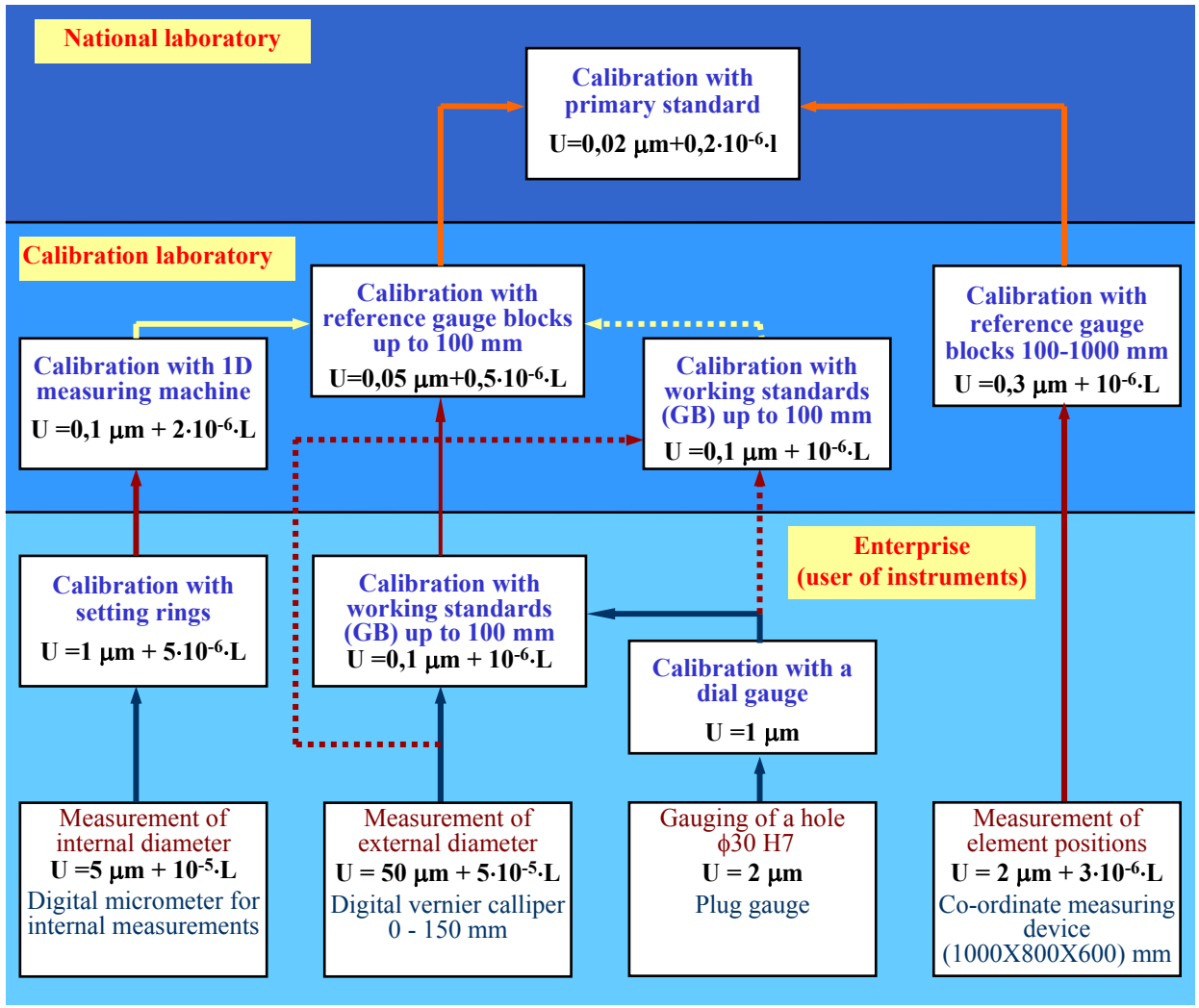
$$U_{k2} = \sqrt{U_{k3}^2 + U_{kp2}^2}$$

$$\wedge$$

$$U_{k1} = \sqrt{U_{k2}^2 + U_{kp1}^2}$$

$$\wedge$$

$$U_m = \sqrt{U_{k1}^2 + U_{mp}^2}$$



Interlaboratory comparisons (intercomparisons)

What is an intercomparison?

Two or more parties (laboratories) measure the same measurand (distance, diameter, mass, resistance, temperature, …) and compare their results.

Why to perform an intercomparison?

To get information on comparability of measurement results.

Who are typical participants?

National metrology laboratories / institutes

Accredited calibration laboratories

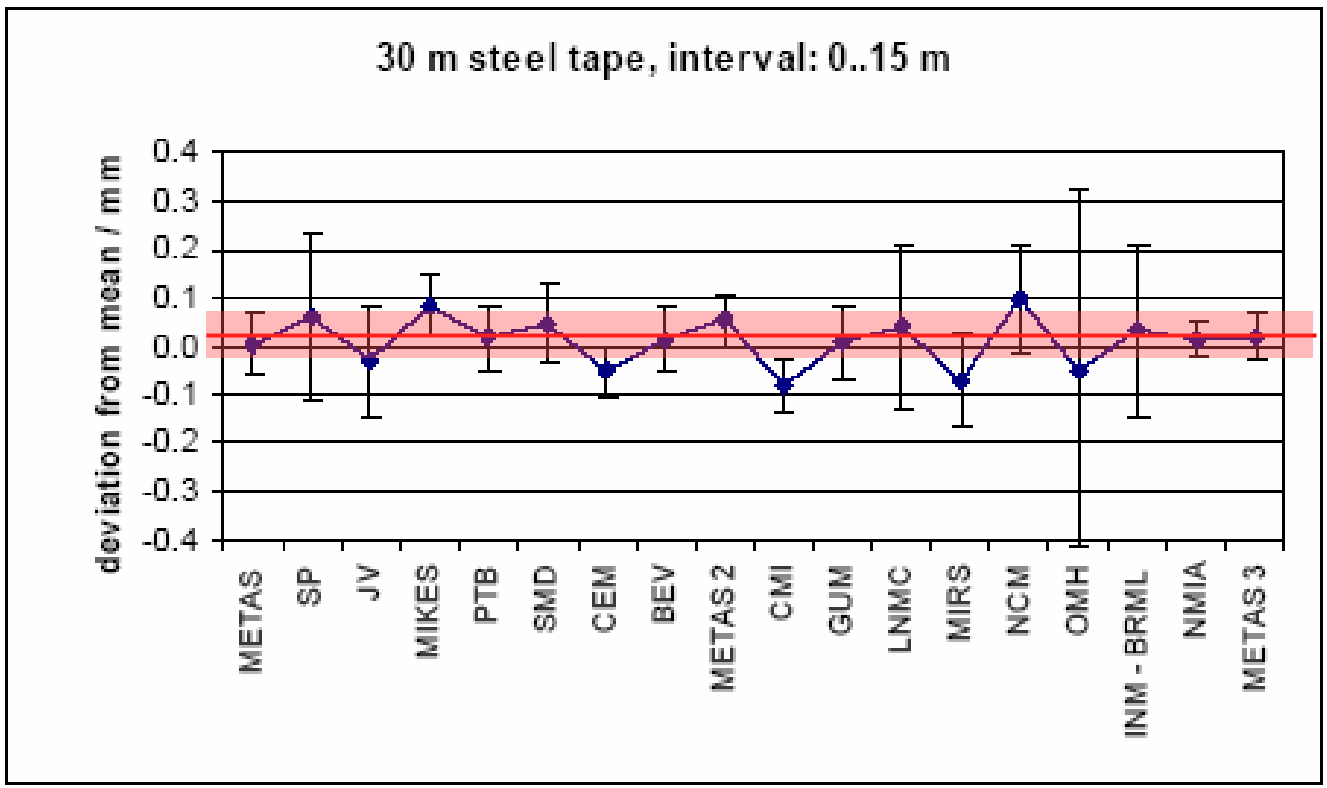
Interlaboratory comparisons (intercomparisons)

What should be considered?

- **Measurement / calibration in each participant laboratory is performed under typical conditions for this laboratory**
- **Measurement uncertainty shall be evaluated and stated with the results**
- **A pilot laboratory responsible for organising the comparison and for evaluating the results is normally appointed** (not in case of bilateral intercomparison)
- **Acceptance criteria shall be defined**

Interlaboratory comparisons (intercomparisons)

Interpretation of results



Acceptance value (EA):

$$E_n = \frac{x_{lab} - x_{ref}}{\sqrt{(U^2_{lab} - U^2_{ref})}}$$

$$E_n < 1$$

$$x_{ref} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

$$u_{ref} = u(x_{ref}) = \sqrt{\frac{\sum u^2(x_i)}{n}}$$

MRA and BIPM key and supplementary comparisons

Mutual Recognition

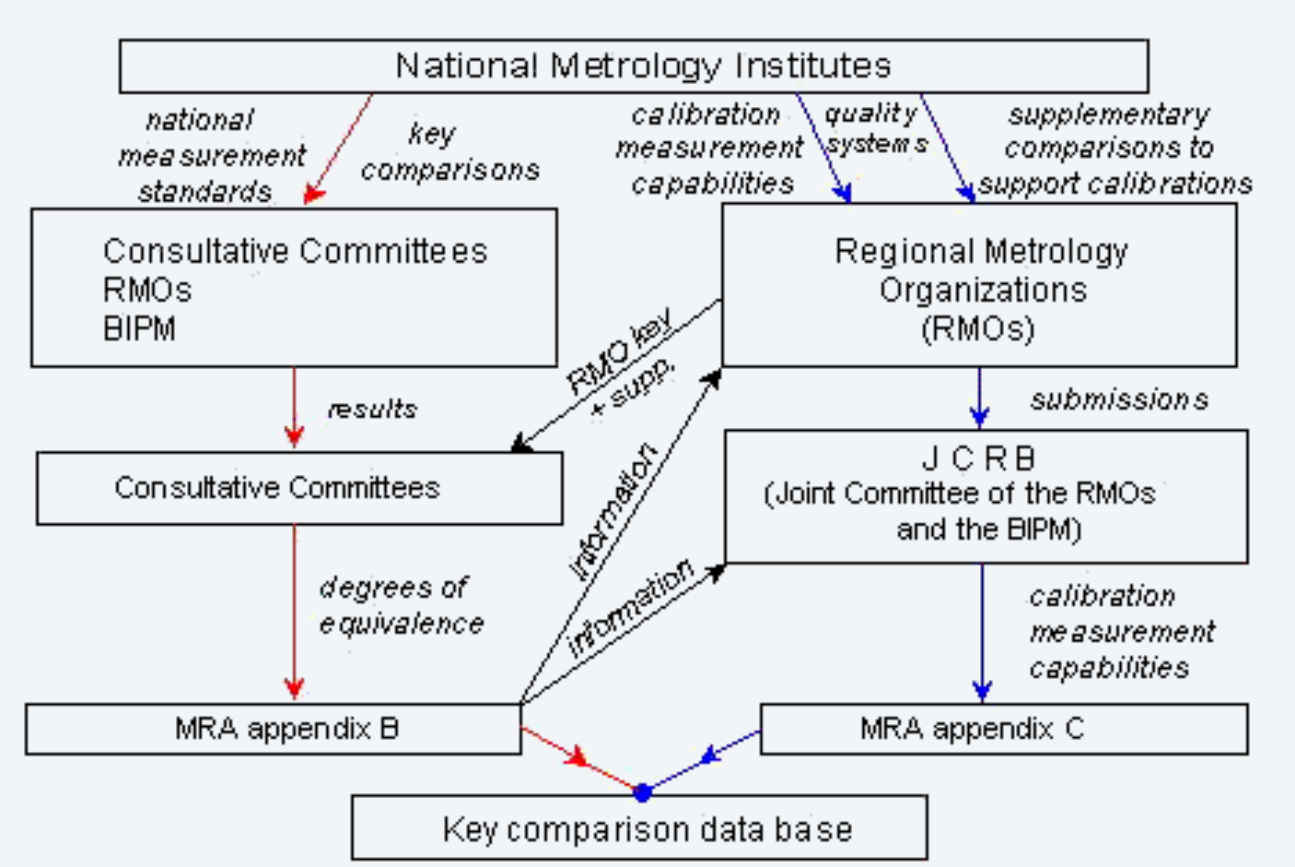
The CIPM MRA (Mutual Recognition Arrangement of the International Committee of Weights and Measures) creates a framework within which participating national metrology laboratories can establish the degrees of equivalence of their national measurement standards as well as the mutual recognition of their calibration and measurement certificates.

The CIPM MRA is open to Member States of the Metre Convention and Associates of the General Conference on Weights and Measures.

The objectives of the CIPM MRA are:

- To provide international recognition of, and to improve the realization of national standards.
- To provide confidence in, and knowledge of the measurement capabilities of participating laboratories for all users, including the regulatory and accreditation communities.
- To provide the technical basis for acceptance between countries of measurements used to support the trade of goods and services - "equivalent" certificates issued in the framework of the MRA, which can be accepted worldwide.
- To reduce Technical Barriers to Trade arising from lack of traceability and equivalence.

MRA and BIPM key and supplementary comparisons



MRA and BIPM key and supplementary comparisons

Participants in the CIPM MRA:

- Declare the uncertainties associated with their calibration and measurement capabilities (CMCs) used in day to day services and have these validated by international experts.
- Participate in 'key comparisons' organized by the CIPM's Consultative Committees or by Regional Metrology Organizations, chosen to characterize activities and calibration services in a particular technical area (some results are seen in the accompanying figures), and to provide evidence to backup CMCs.
- Install a quality management system.

Measurement Services Covered:

- Acoustics, Ultrasound and Vibration;
- Chemical standards (amount of substance);
- Electricity and Magnetism;
- Ionizing radiation;
- Length;
- Mass (e.g. mass standards, force, pressure, density, hardness, viscosity and fluid flow);
- Photometry and Radiometry;
- Thermometry;
- Time and Frequency.

MRA and BIPM key and supplementary comparisons

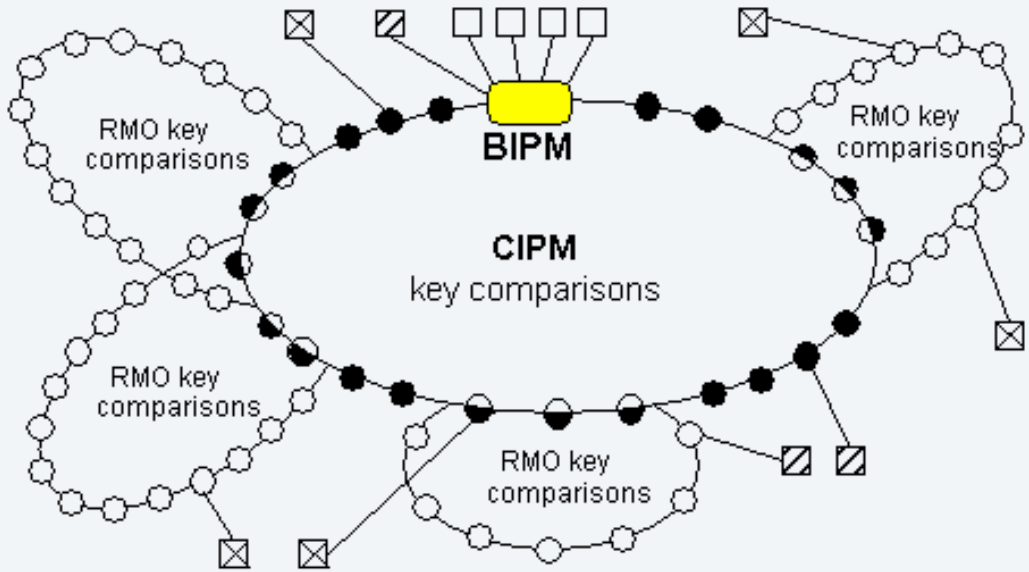
The principal output of the CIPM MRA is the BIPM key comparison database (KCDB), which is maintained at the BIPM as part of its role to ensure worldwide conformity of measurements and their traceability to the SI.

The BIPM KCDB provides a searchable database of:

- Results of international (key) comparisons of national standards.
- Internationally reviewed and recognized capabilities associated with uncertainties of measurement services.

"Under the MRA, all participating institutes recognize the validity of each other's calibration and measurement certificates for the quantities, ranges and measurement uncertainties specified in Appendix C of the KCDB."

MRA and BIPM key and supplementary comparisons



- National metrology institute (NMI) participating in CIPM key comparisons
- NMI participating in CIPM key comparisons and in regional metrology organization (RMO) key comparisons
- NMI participating in RMO key comparisons
- NMI participating in ongoing BIPM key comparisons
- NMI participating in a bilateral key comparison
- International organization signatory to the MRA

Metrology system in an enterprise

Operation and responsibility

- Quality department, directly supported by the executive management

Planning

- Systematic planning in parallel to production system planning, in accordance with the quality demands of the enterprise
- Involvement into enterprise investment plans based on the quality costs (quality assurance costs: costs of improper quality)
- All quality system elements shall be covered

Metrology system elements

- Personnel
- Equipment
- Metrology rooms assuring proper measuring conditions
- Measurement methods and procedures
- Cost management
- Quality system documentation
- Records

Metrology system in an enterprise

Personnel

- Selection (knowledge, experiences, psychophysical qualities, skills, concentration)
- Training for specific tasks
- Systematic monitoring
- Periodical training
- Authorisation and responsibilities
- Stimulation and motivation

Measuring equipment

- Selection (purpose, measuring range, accuracy, level of automation, economical parameters)
- Labeling (unique recognition, status)
- Proper use (instructions, authorisation, responsibilities)
- Maintenance
- Metrological checks and calibration
- Storage

Metrology system in an enterprise

Premises

- Selection (regarding the metrology supervision needs – machine, workshop, measuring room, laboratory)
- Determining necessary conditions (cleanness, temperature, humidity, …)
- Installations (electricity, air condition, computer network, ….)
- Maintenance
- Monitoring conditions (e.g. temperature measurements)
- Protection of special rooms (equipment storage, rooms with special conditions, rooms for records, rooms for special equipment, …)

Measurement methods and procedures

- Selection (regarding the type of measurement, necessary accuracy, result form, frequency of measurements, necessary measurement speed)
- Creation or acquisition of procedures (e.g. standard procedure)
- Distribution on working places
- Education of users
- Principles for creation: easy use, clearness, unambiguously defined measurement records, accommodation to users

Metrology system in an enterprise

Cost management

Quality assurance costs

- Quality planning
- Quality department management
- Monitoring competence for quality
- Auditing suppliers
- Inspection planning
- Quality audits
- Quality improvements
- Performing quality inspection
- Equipment costs (purchasing, calibration, maintenance)
- Documentation, …

Costs of improper quality

- Scrap
- Additional treatment and repairs
- Sorting
- Repeated check of repaired parts
- Detecting faults causes
- Value reduction
- Warranties
- Market share decrease, …

Metrology system in an enterprise

Records

- Standard quality system element
- In accordance with system procedures for creation, filing, …
- Simple, unambiguous, clear
- Short and to the point
- Possibly on the pre-prepared forms or templates
- Transparent

Accreditation

What is accreditation?

- Accreditation is **official recognition of competence** of a conformity assessment body **for performing specific activities**. Basic condition for accreditation is **active quality system**
- Conformity assessment bodies are **testing and calibration laboratories, certification bodies** and **inspection bodies**
- Accreditation is performed by **bodies that are nominated by state authorities**

Accreditation

Why to become an accredited laboratory?

- Accreditation is a signal to customers that the laboratory has competence and quality in its services
- Accreditation is mandatory in certain sectors (defined by authorities, regulations, …)
- Certificates issued by accredited laboratories can be recognised across borders (not only by other Accreditation Bodies but also customers and regulatory authorities)

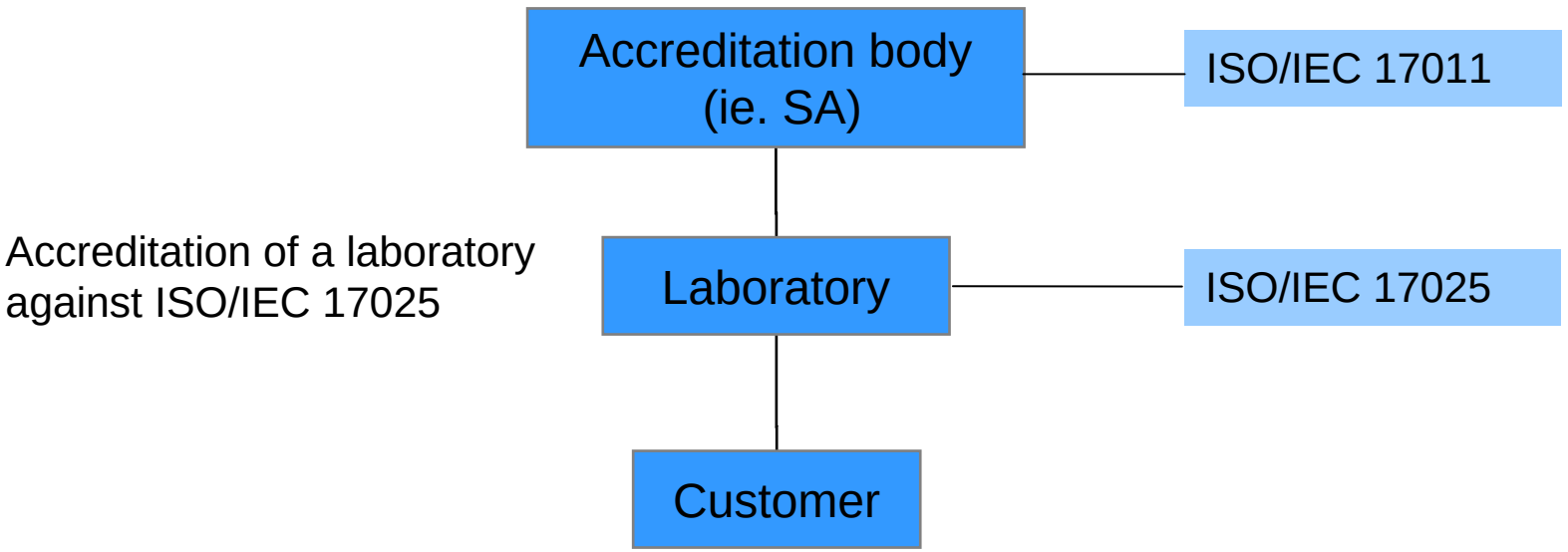
Accreditation

Laboratories can be accredited for:

- Environmental testing
- Food testing
- Mechanical and electrical testing
- Calibration
- Health sector (also ISO 15189)

Accreditation of laboratories is performed in accordance with ISO/IEC 17025

Accreditation of a laboratory

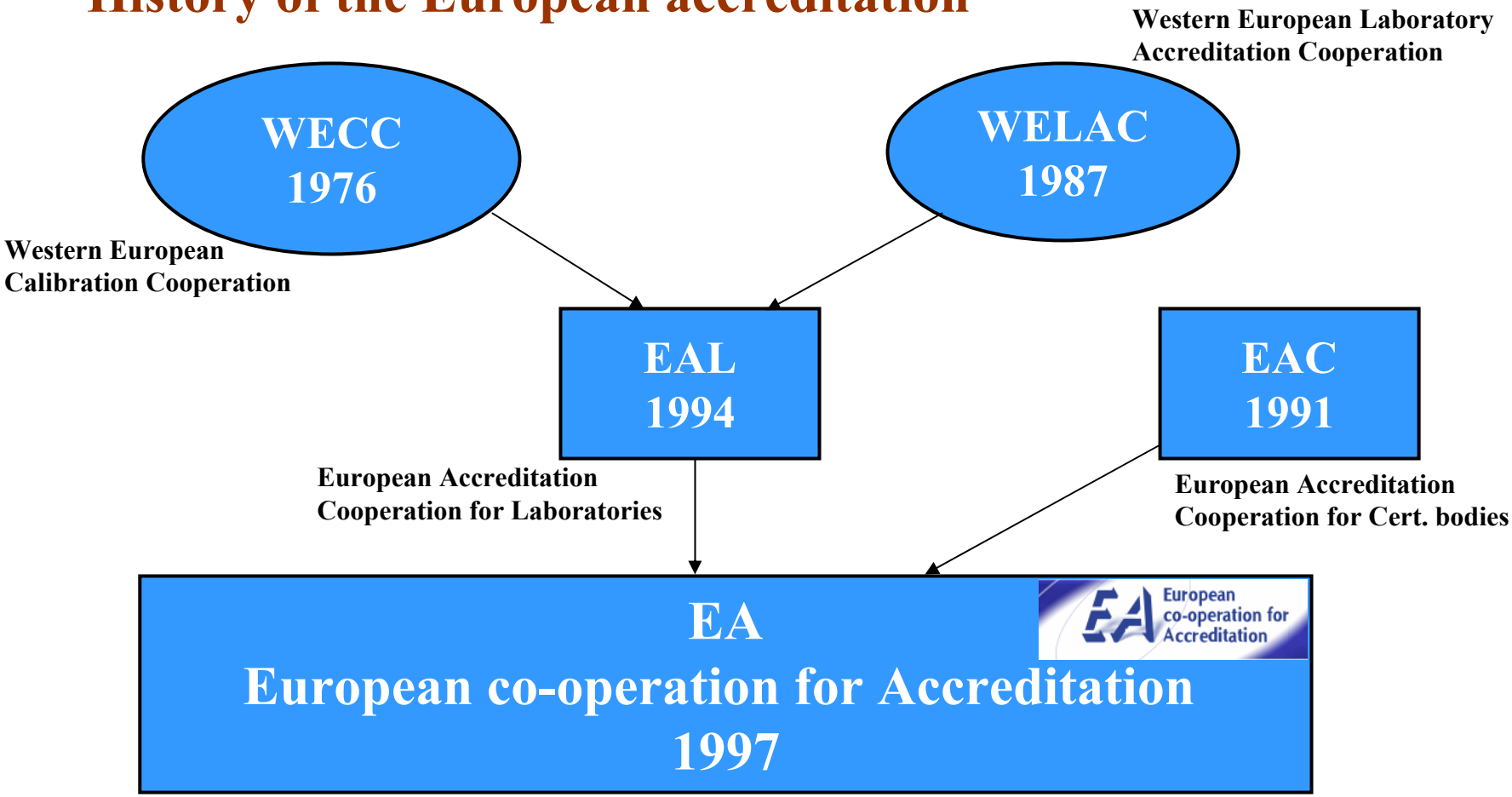


Accreditation in Europe

EA (European Accreditation) aims:

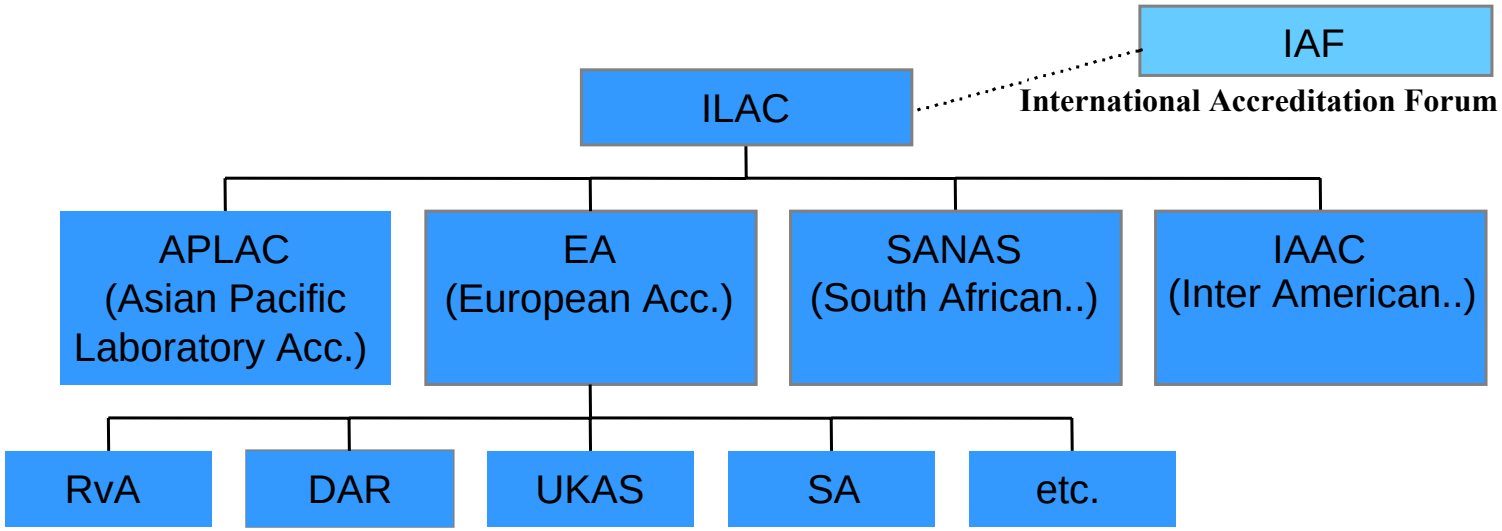
- **to promote accreditation as a service for European trade and industry by facilitating cross border trade.**
- **to exchange technical knowledge between accreditation bodies and other relevant organisations (i.e. EU and ISO).**
- **to support the mutual recognition of test and calibration certificates. EA has an MLA (*Multi Lateral Agreement*) for calibration and testing that is maintained by peer evaluation of the accreditation bodies who has joined the MLA.**

History of the European accreditation



The whole world: ILAC
The International Laboratory Accreditation Cooperation

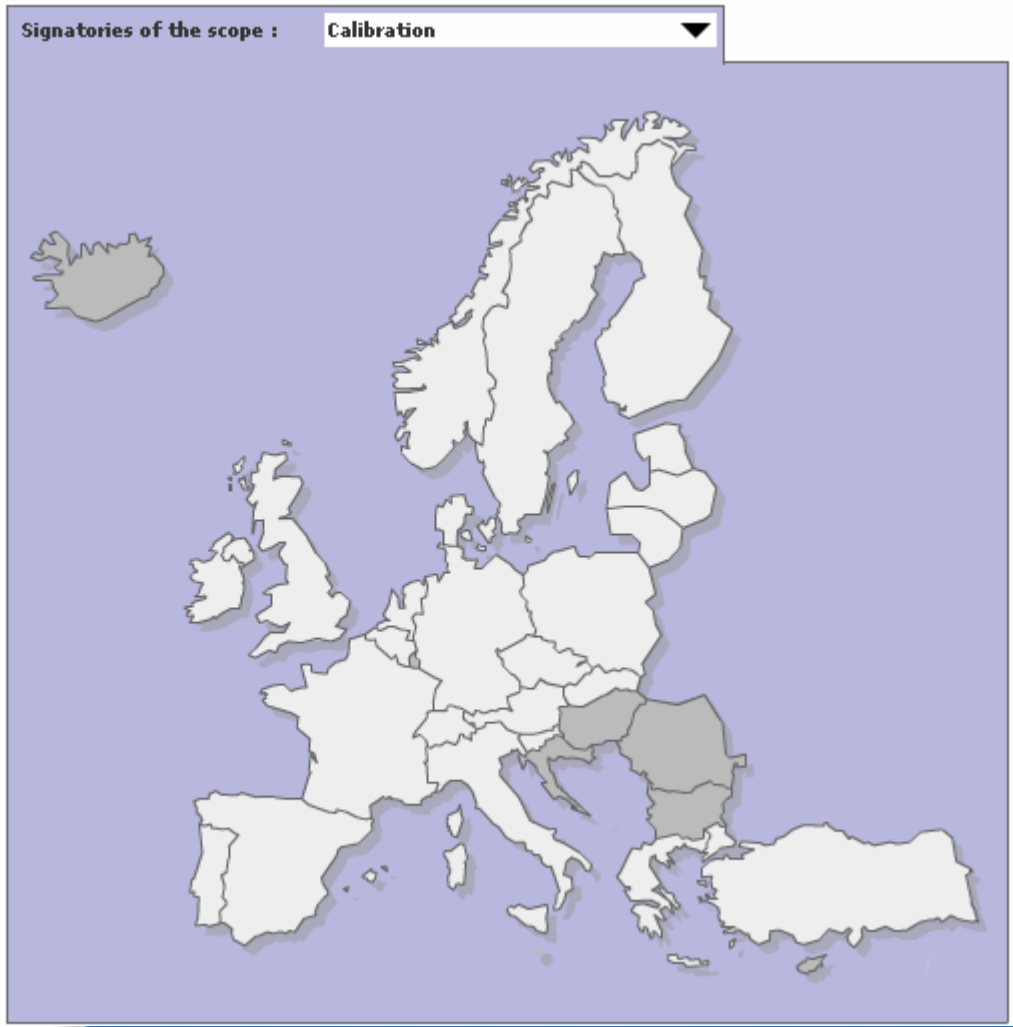
International Laboratory Accreditation Cooperation



Accreditation

MLA for calibration

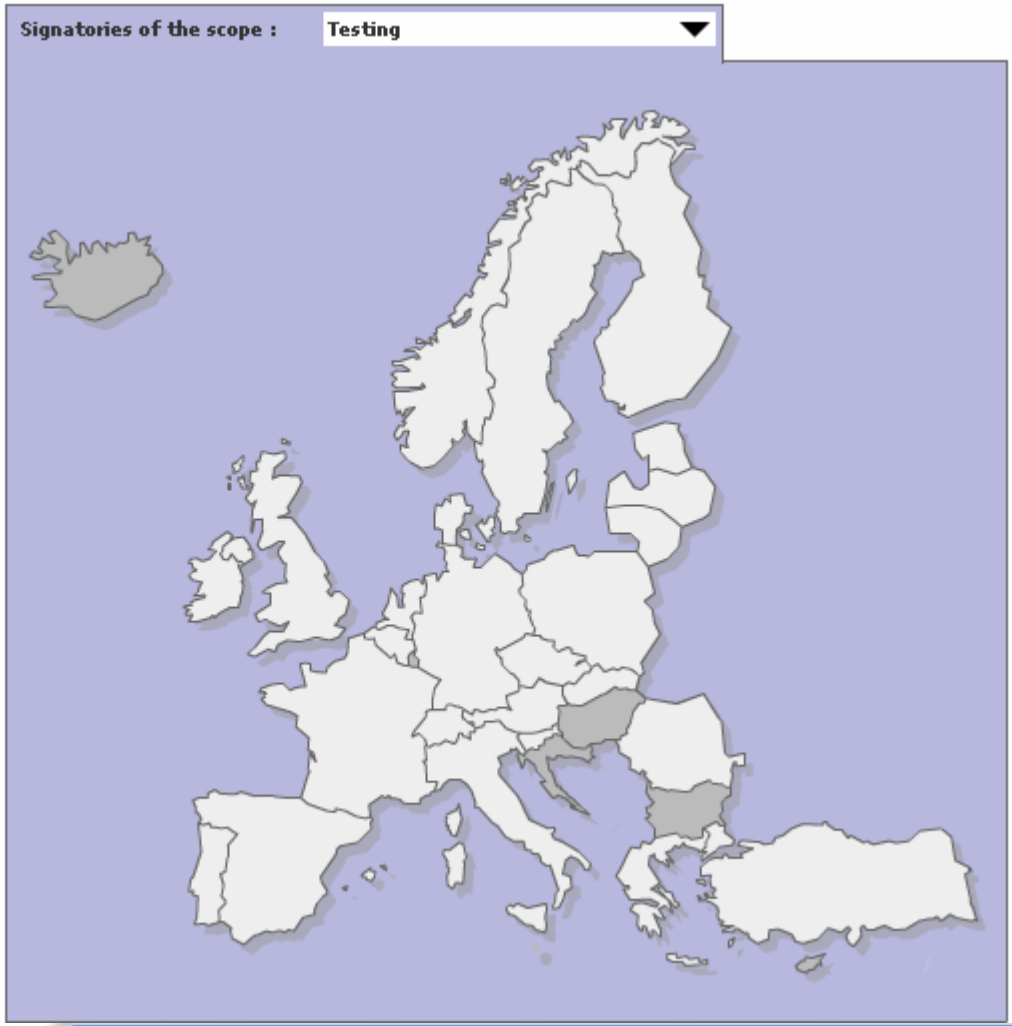
Calibration
Nata (Australia)
Bmwa (Austria)
Belac (Belgium)
Inmetro (Brazil)
Hkas (China)
Cai (Czech Republic)
Danak (Denmark)
Eak (Estonia)
Finas (Finland)
Cofrac (France)
Dkd (Germany)
Esyd (Greece)
Inab (Ireland)
Israc (Israel)
Sit (Italy)
Latak (Latvia)
La (Lithuania)
Rva (Netherlands)
Ianz (New Zealand)
Na (Norway)
Pca (Poland)
Ipac (Portugal)
Sac/spring (Singapore)
Snas (Slovakia)
Sa (Slovenia)
Sanas (South Africa)
Enac (Spain)
Swedac (Sweden)
Sas (Switzerland)
Turkak (Turkey)
Ukas (United Kingdom)
A2la (Usa)



Accreditation

MLA for testing

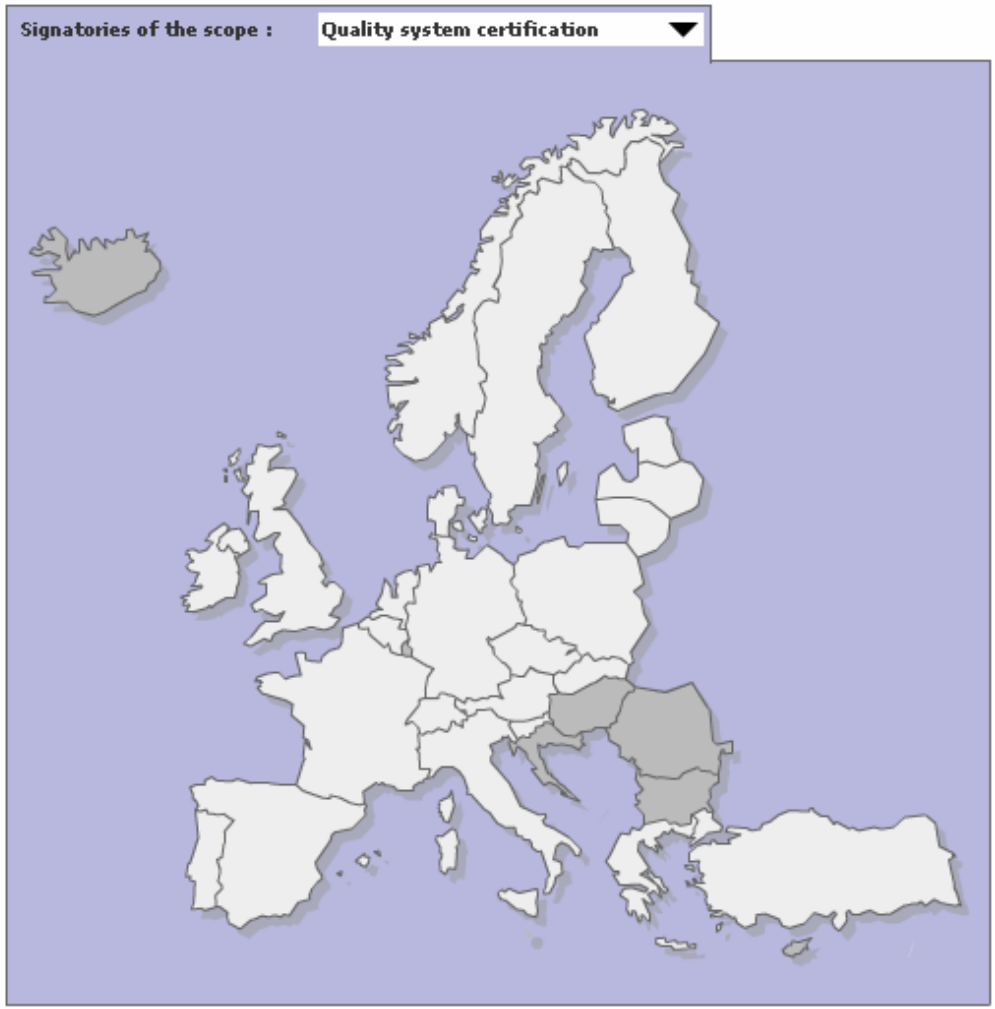
Testing
Nata (Australia)
Bmwa (Austria)
Belac (Belgium)
Inmetro (Brazil)
Hkas (China)
Cai (Czech Republic)
Danak (Denmark)
Eak (Estonia)
Finas (Finland)
Cofrac (France)
Dach (Germany)
Dap (Germany)
Datech (Germany)
Esyd (Greece)
Inab (Ireland)
Israc (Israel)
Sinal (Italy)
Latak (Latvia)
La (Lithuania)
Rva (Netherlands)
Ianz (New Zealand)
Na (Norway)
Pca (Poland)
Ipac (Portugal)
Renar (Romania)
Sac/spring (Singapore)
Snas (Slovakia)
Sa (Slovenia)
Sanas (South Africa)
Enac (Spain)
Swedac (Sweden)
Sas (Switzerland)
Turkak (Turkey)
Ukas (United Kingdom)
A2la (Usa)



Accreditation

MLA for QMS

Quality system certification
Bmwa (Austria)
Belac (Belgium)
Cai (Czech Republic)
Danak (Denmark)
Eak (Estonia)
Finas (Finland)
Cofrac (France)
Tga (Germany)
Esyd (Greece)
Inab (Ireland)
Sincert (Italy)
Latak (Latvia)
La (Lithuania)
Rva (Netherlands)
Na (Norway)
Pca (Poland)
Ipac (Portugal)
Snas (Slovakia)
Sa (Slovenia)
Enac (Spain)
Swedac (Sweden)
Sas (Switzerland)
Turkak (Turkey)
Ukas (United Kingdom)



Accreditation

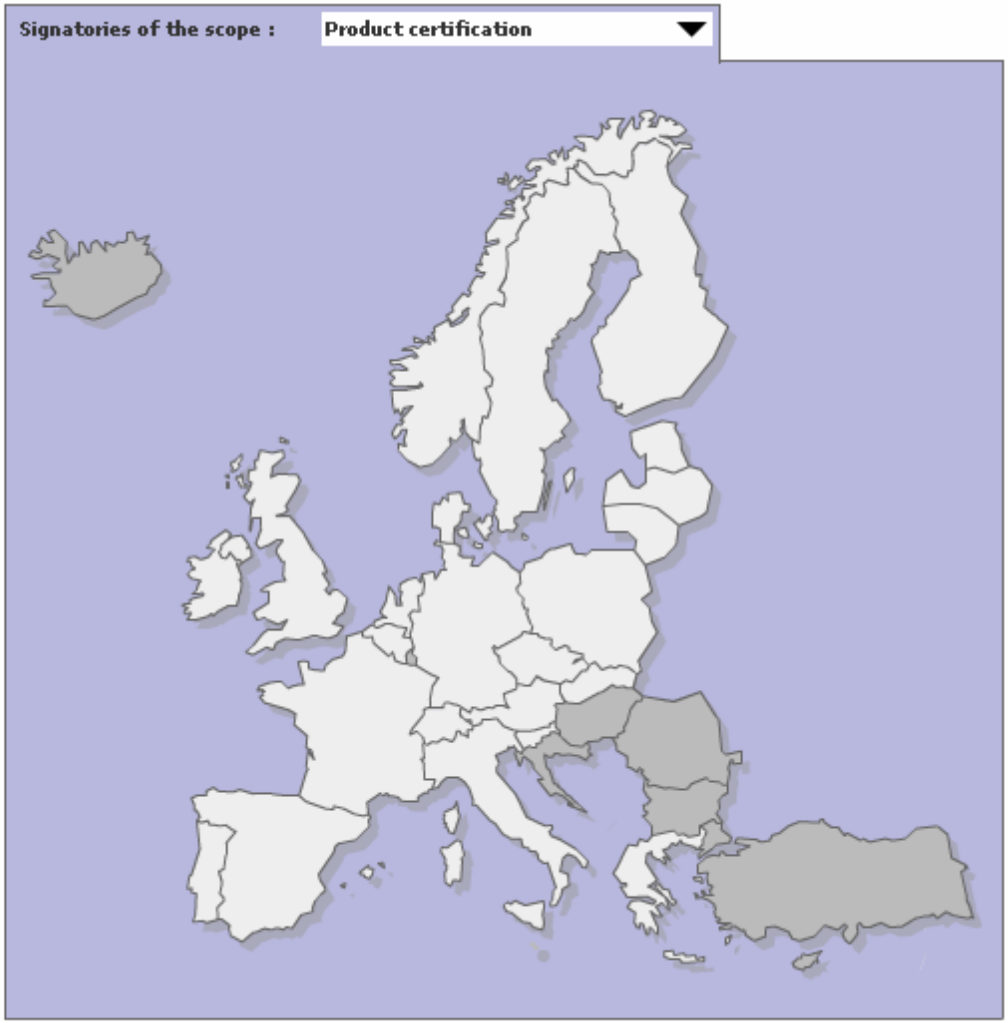
MLA for EMS

EMS certification
Jas-anz (Australia - New Zealand)
Bmwa (Austria)
Belac (Belgium)
Cai (Czech Republic)
Danak (Denmark)
Eak (Estonia)
Finas (Finland)
Cofrac (France)
Tga (Germany)
Esyd (Greece)
Inab (Ireland)
Sincert (Italy)
La (Lithuania)
Rva (Netherlands)
Na (Norway)
Pca (Poland)
Ipac (Portugal)
Snas (Slovakia)
Sa (Slovenia)
Sanas (South Africa)
Enac (Spain)
Swedac (Sweden)
Sas (Switzerland)
Ukas (United Kingdom)

Accreditation

MLA for product certification

Product certification
Jas-anz (Australia - New Zealand)
Bmwa (Austria)
Belac (Belgium)
Cai (Czech Republic)
Danak (Denmark)
Eak (Estonia)
Finas (Finland)
Cofrac (France)
Dap (Germany)
Datech (Germany)
Esyd (Greece)
Inab (Ireland)
Sincert (Italy)
Latak (Latvia)
La (Lithuania)
Rva (Netherlands)
Na (Norway)
Pca (Poland)
Ipac (Portugal)
Snas (Slovakia)
Sa (Slovenia)
Enac (Spain)
Swedac (Sweden)
Sas (Switzerland)
Ukas (United Kingdom)



Accreditation

MLA for certification of persons

Certification of persons
Bmwa (Austria)
Belac (Belgium)
Cai (Czech Republic)
Danak (Denmark)
Eak (Estonia)
Finas (Finland)
Cofrac (France)
Tga (Germany)
Esyd (Greece)
Sincert (Italy)
Latak (Latvia)
La (Lithuania)
Rva (Netherlands)
Na (Norway)
Pca (Poland)
Ipac (Portugal)
Snas (Slovakia)
Enac (Spain)
Swedac (Sweden)
Sas (Switzerland)
Ukas (United Kingdom)

Accreditation

MLA for inspection

Inspection
Belac (Belgium)
Cai (Czech Republic)
Danak (Denmark)
Eak (Estonia)
Finas (Finland)
Cofrac (France)
Dap (Germany)
Datech (Germany)
Esyd (Greece)
Inab (Ireland)
Sincert (Italy)
Latak (Latvia)
La (Lithuania)
Rva (Netherlands)
Ianz (New Zealand)
Na (Norway)
Pca (Poland)
Ipac (Portugal)
Snas (Slovakia)
Sa (Slovenia)
Sanas (South Africa)
Enac (Spain)
Swedac (Sweden)
Sas (Switzerland)
Turkak (Turkey)
Ukas (United Kingdom)

Accreditation and certification

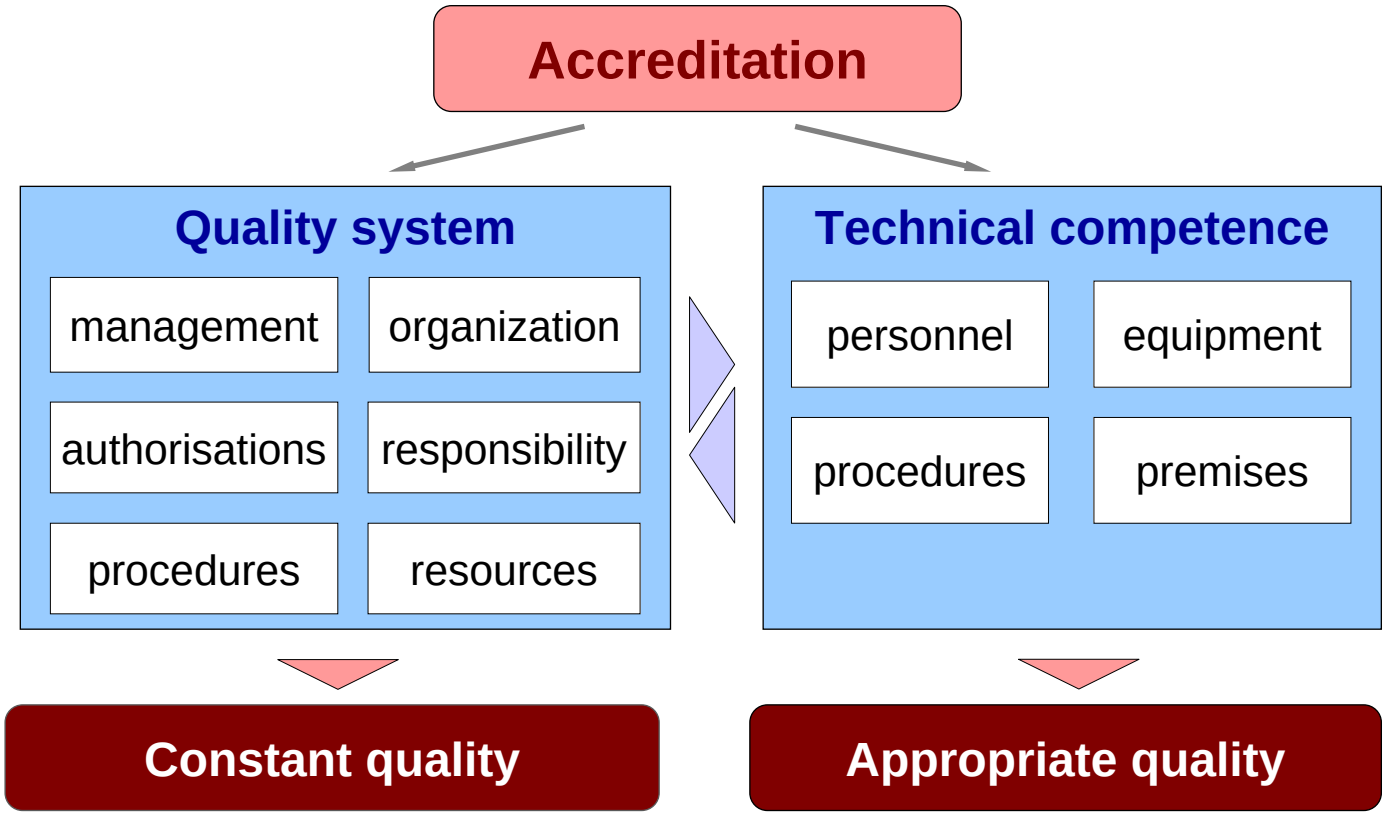
Accreditation:

- In Latin *accredere* means: To give confidence
- Third party recognition of competence

Certification:

- In Latin *certifiere* means: Testify, confirm
- Third party assessment that a product, a system or a person conforms with specified requirements.

Accreditation



Accreditation

Standards, guidelines, laws etc.

- **ISO/IEC 17011: Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies (the last issue in 2004)**
- **ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories (the last issue in 2005)**
- ISO/IEC 17020: General criteria for the operation of various types of bodies performing inspection (the last issue in 1998)
- ISO/IEC 17021: Conformity assessment - Requirements for bodies providing audit and certification of management systems (the last issue in 2006)
- ISO/IEC 17024: Conformity assessment - General requirements for bodies operating certification of persons (the last issue in 2003)
- ISO/IEC 17040: Conformity assessment - General requirements for peer assessment of conformity assessment bodies and accreditation bodies (the last issue in 2005)

Accreditation

Standards, guidelines, laws etc.

- EN 45011: General criteria for certification bodies operating product certification systems (the last issue in 2005)
- **Guidelines by EA and ILAC**
- **Requirements put on accredited laboratories by regulatory authorities**

EA documents/guidelines

Categorisation In addition, EA Guidance documents have been categorised. The 4 categories (see below) give an indication on how to apply the document.

1. EA MLA procedure documents

EA MLA procedure documents are the documents that lay down the requirements for the operation of the MLA

2. EA MLA support documents

EA MLA support documents are documents of a horizontal nature that support the application of the standards used for accreditation. These documents must be implemented by EA member accreditation bodies for use in their accreditation systems. Their implementation will be assessed as part of the EA MLA peer evaluation process.

3. EA MLA Sector specific documents

EA Sector specific documents are documents of a sector specific nature that support the implementation of the standards used for accreditation in specific sector applications. These documents must be implemented by EA member accreditation bodies that provide accreditation in the sectors in question for use in their accreditation systems. Their implementation will be assessed as part of the EA MLA peer evaluation process.

4. Technical documents

Technical documents are documents that provide technical or scientific guidance that defines recommended examples how to fulfil the criteria.

EA documents/guidelines

- General
  - Publicity and Information Documents Series 1
  - Procedural and Policy Documents Series 2
- Application documents
- International
- Advisory and Specific calibration documents

EA documents/guidelines

- General
- Application documents
  - Application documents for Accreditation Bodies Series 3
  - Application documents for Laboratories Series 4
  - Application documents for Inspection Bodies Series 5
  - Application documents for Certification of Products Series 6
  - Application documents for Certification of Management System Series 7
  - Application documents for Certification of Persons Series 8
  - Application documents for Attestation Bodies Series 9
- International
- Advisory and Specific calibration documents

Accreditation

EA documents/guidelines

- General
- Application documents
- International
  - ILAC

    In application of EA-2/12 -The development and Approval of EA Documents and the adoption of ILAC/IAF documents - "EA does not hold a separate vote on ILAC/IAF approved documents. Once a document is approved in either of these two bodies, EA is normally obliged to accept the result. However EA reserves the right in exceptional circumstances not to accept the result where such a document is found to be in conflict with the principles or policies of the European Council or European Commission." EA does not maintain a separate list of ILAC, IAF and joint ILAC-IAF endorsed document.

    To download ILAC documents, please click here: www.ilac.org
  - IAF

    In application of EA-2/12 -The development and Approval of EA Documents and the adoption of ILAC/IAF documents - "EA does not hold a separate vote on ILAC/IAF approved documents. Once a document is approved in either of these two bodies, EA is normally obliged to accept the result. However EA reserves the right in exceptional circumstances not to accept the result where such a document is found to be in conflict with the principles or policies of the European Council or European Commission." EA does not maintain a separate list of ILAC, IAF and joint ILAC-IAF endorsed document.

    To download IAF documents, please click here: www.iaf.nu
  - Joint ILAC-IAF

    In application of EA-2/12 -The development and Approval of EA Documents and the adoption of ILAC/IAF documents - "EA does not hold a separate vote on ILAC/IAF approved documents. Once a document is approved in either of these two bodies, EA is normally obliged to accept the result. However EA reserves the right in exceptional circumstances not to accept the result where such a document is found to be in conflict with the principles or policies of the European Council or European Commission." EA does not maintain a separate list of ILAC, IAF and joint ILAC-IAF endorsed document.

    To download ILAC or IAF documents, please click here: www.ilac.org; www.iaf.nu
- Advisory and Specific calibration documents

EA documents/guidelines

- General
- Application documents
- International
- Advisory and Specific calibration documents
  - Advisory documents
  - Specific calibration documents

The specific calibration documents of the EA series no 10 have been transferred to Euromet which accepted to manage them in the future as agreed under the EA/Euromet MoU.They are available at: www.euromet.org

EA documents/guidelines

CEC – Coordinating European Council

OMCL-Official Medicines Control Laboratories

EWDTS – European Workplace Drug Testing S.

- General
- Application documents
- International
- Advisory and Specific calibration documents
  - Advisory documents

All category 4 (advisory) documents) are adopted at the committees level. They shall not necessarily be approved by the General Assembly. You can also find advisory documents in series 2 to 9 above.

- CEC_EA_LC_ISO17025_interpretation [download, "PDF" , 145 Ko]
  Subject : ISO/IEC 17025 interpretation document for CEC test methods
- EWDTS Guidelines EA-LC [download, "PDF" , 628 Ko]
  Subject : European Laboratory Guidelines for Legally Defensible Workplace Drug Testing
- OMCL 05 47 [download, "PDF" , 291 Ko]
  Subject : Validation of Analytical Procedures
- OMCL 05 48 [download, "PDF" , 370 Ko]
  Subject : Scope of Accreditation of official Medecines Laboratories
- OMCL 05 49 [download, "PDF" , 292 Ko]
  Subject : Uncertainty of measurement part 1
- Citac Eurachem Guide (6 june 02) [download, "PDF" , 1215 Ko]
  Subject : CITAC EURACHEM Guide to Quality and analytical Chemistry

Specific calibration documents

The specific calibration documents of the EA series no 10 have been transferred to Euromet which accepted to manage them in the future as agreed under the EA/Euromet MoU.They are available at: www.euromet.org

EA documents/guidelines

- Publicity and Information Documents Series 1
  - **EA Articles of Association** [download, "PDF" , 147 Ko]
    Subject : EA Articles of Association
  - **EA-1/01** rev 30th April 2007 [download, "PDF" , 347 Ko]
    Subject : List of EA Publications
  - **EA-1/05** rev 26th April 07 [download, "PDF" , 344 Ko]
    Subject : Contact Persons of EA Full & Contracts of Co-operation & observers
  - **EA 1/06** (rev04) [download, "PDF" , 139 Ko]
    Subject : EA Multilateral Agreement
  - **EA-1/08** rev 19 [download, "PDF" , 288 Ko]
    Subject : EA Multi and Bilateral Agreement Signatories

Accreditation

EA documents/guidelines

- Procedural and Policy Documents Series 2
  - **EA 2/01** (rev01) [download, "PDF" , 146 Ko]
    Subject : EA Rules of Procedures
  - **EA 2/01 S1** (rev01) [download, "PDF" , 151 Ko]
    Subject : Criteria for Membership
  - **EA 2/01 S3** (rev02) [download, "PDF" , 263 Ko]
    Subject : EA Supplement 3 to EA-2/01, EA Rules of Procedures - EA Procedure for the investigation and resolution of Complaints & Appeals
  - **EA 2/01 S4** (rev00) [download, "PDF" , 168 Ko]
    Subject : EA Supplement 4 to EA-2/01, EA Rules of Procedure - Proxy Procedure
  - **EA 2/01 S5** (rev01) [download, "PDF" , 25 Ko]
    Subject : EA Supplement 5 to EA-2/01, EA Rules of Procedures - Levying of Membership Fees
  - **EA 2/02** (rev02) Category 1 [download, "PDF" , 176 Ko]
    Subject : EA Policy and Procedures for the Multilateral Agreement

EA documents/guidelines

- Procedural and Policy Documents Series 2
  - **EA 2/04** (rev01) [download, "PDF" , 208 Ko]
    Subject : Procedure for the Preparation of EA Publications
  - **EA 2/05** (rev02) Category 2 [download, "PDF" , 60 Ko]
    Subject : The scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing (with Eurolab, Eurachem)
  - **EA 2/09** (rev00) Category 4 [download, "PDF" , 174 Ko]
    Subject : EA Policy on the Accreditation of Providers of Proficiency Testing Schemes
  - **EA 2/10** (rev00) Category 2 [download, "PDF" , 32 Ko]
    Subject : EA Policy for Participation in National and International Proficiency Testing Activities
  - **EA 2/11** rev01 [download, "PDF" , 214 Ko]
    Subject : EA Policy for Sector Schemes
  - **EA 2/12** (rev02) [download, "PDF" , 298 Ko]
    Subject : Procedure for development and approval of EA Guidance Documents and the adoption of ILAC/IAF Guidance Documents
  - **EA 2/12 (Appendix A)** [download, "DOC" , 22 Ko]
    Subject : Proposal for the preparation of EA Guidance Documents

Accreditation

EA documents/guidelines

Application documents for Accreditation Bodies Series 3

- **EA 3/01** (rev01) Category 2 [download, "PDF" , 252 Ko]
  Subject : EA Conditions for thr use of Accreditation Marks
- **EA 3/03** (rev00) Category 2
  Withdrawn - EAC-EAL General requirements for Bodies Providing Accreditation of Inspection Bodies
- **EA 3/04** (rev01) Category 4 [download, "PDF" , 100 Ko]
  Subject : Use of Proficiency Testing as a Tool for Accreditation in Testing
- **EA 3/05** (rev01) [download, "PDF" , 53 Ko]
  Subject : Guidelines for Training Courses for assessors used by laboratory accreditation schemes
- **EA 3/06** (rev01) [download, "PDF" , 46 Ko]
  Subject : Guidelines for Selection of Participants to Courses for the training of assessors involved in assessments of laboratories applying for accreditation
- **EA 3/07** (rev01) [download, "PDF" , 47 Ko]
  Subject : Programme for Course for Tutors for assessor training
- **EA 3/08** (rev03) Category 2 [download, "PDF" , 235 Ko]
  Subject : EA Guidelines on the Application of EN 45010
- **EA 3/09** (rev00) Category 2 [download, "PDF" , 195 Ko]
  Subject : Surveillance and Reassessment of accredited orgaisations
- **EA 3/10** (rev00) Category 2
  Withdrawn - EA Guidance on the Application of ISO/IEC TR 17010

EA documents/guidelines

Application documents for Laboratories Series 4

- **EA 4/02** (rev00) Category 2 [download, "PDF" , 1835 Ko]
  Subject : Expressions of the Uncertainty of Measurements in Calibration
- **EA 4/07** (rev01) Category 2 [download, "PDF" , 229 Ko]
  Subject : Traceability of Measuring and Test Equipment to National Standards
- **EA 4/09** (rev01) Category 4 [download, "PDF" , 169 Ko]
  Subject : Accreditation for Sensory Testing Laboratories
- **EA 4/10** (rev02) Category 4 [download, "PDF" , 124 Ko]
  Subject : Accreditation for Laboratories Performing Microbiological Testing
- **EA 4/14** (rev00) Category 4 [download, "PDF" , 315 Ko]
  Subject : Selection and Use of Reference Materials
- **EA 4/15** (rev00) Category 4 [download, "PDF" , 182 Ko]
  Subject : Accreditation for Bodies Performing non-Destructive Testing
- **EA 4/16** (rev00) Category 2 [download, "PDF" , 315 Ko]
  Subject : Guidelines on the expression of uncertainty in quantitative testing

EA documents/guidelines

- Application documents for Inspection Bodies Series 5
  - **EA 5/01** (rev03) Category 2
    Withdrawn - EA Guidance on the Application of EN 45004 - Replaced by ILAC/IAF A4: Guidance on the Application of ISO/IEC 17020. Please download the document at www.ilac.org or at www.iaf.nu
    In application of 2/12 by which EA automatically endorses an ILAC, IAF or ILAC/IAF document unless it contradicts the European and EA principles for accreditation, the Communications and Publications Committee recommended to the EA GA that EA stops publishing and maintaining a separate list of such ILAC, IAF and ILAC/IAF EA endorsed documents. As a result, it was proposed to create a link to the web pages of ILAC and IAF. This was accepted by the GA in Riga in June 2006 and implemented immediately.
  - **EA 5/02** (rev00) Category 4 [download, "PDF" , 448 Ko]
    Subject : EA Guidance on the Application of EN 45004 (ISO/IEC 17020) in recurrent inspection of motor vehicles

EA documents/guidelines

- Application documents for Certification of Products Series 6
  - **EA 6/01** (rev00) Category 2
    Withdrawn - Guidelines on the Application of EN 45011. Replaced by IAF GD 5:2006: Guidance on the Application of Guide 65: 1996. You can download the document on the IAF website: www.iaf.nu
    In application of 2/12 by which EA automatically endorses an ILAC, IAF or ILAC/IAF document unless it contradicts the European and EA principles for accreditation, the Communications and Publications Committee recommended to the EA GA that EA stops publishing and maintaining a separate list of such ILAC, IAF and ILAC/IAF EA endorsed documents. As a result, it was proposed to create a link to the web pages of ILAC and IAF. This was accepted by the GA in Riga in June 2006 and implemented immediately.
  - **EA 6/02** (rev00) Category 2 [download, "PDF" , 91 Ko]
    Subject : Guidelines on the use of EN 45011 and EN 45012 for certification to EN 729
  - **EA 6/03 rev01** category 3 [download, "PDF" , 655 Ko]
    Subject : EA Guidance for Recognition of Verification Bodies under EU ETS Directive

EA documents/guidelines

Application documents for Certification of Management System Series 7

- **EA 7/01** (rev02) Category 2
  EA Guidelines on the Application of EN 45012.
  Withdrawn and replaced by IAF GD 2: 2005: Guidance on the Application of Guide 62: 1996. Please download the document on the IAF website: www.iaf.nu
  In application of 2/12 by which EA automatically endorses an ILAC, IAF or ILAC/IAF document unless it contradicts the European and EA principles for accreditation, the Communications and Publications Committee recommended to the EA GA that EA stops publishing and maintaining a separate list of such ILAC, IAF and ILAC/IAF EA endorsed documents. As a result, it was proposed to create a link to the web pages of ILAC and IAF. This was accepted by the GA in Riga in June 2006 and implemented immediately.
- **EA-7/02** Category 2 EA Guidelines for the Accreditation of Certification Bodies for Environmental Management Systems
  Withdrawn and replaced by IAF GD 6 : 2006 Guidance on the Application of ISO/IEC Guide 66 : 1999. You can download the document on the IAF website: www.iaf.nu
- **EA 7/03** (rev00) Category 4 [download, "PDF" , 685 Ko]
  Subject : Guidelines for the Accreditaton of bodies operating certificaton/registration of information Security Management Systems
- **EA-7/04** rev01 Category 2 [download, "PDF" , 267 Ko]
  Subject : Legal Compliance as a part of Accredited ISO 14001: 2004 Certification

EA documents/guidelines

Application documents for Certification of Persons Series 8

EA 8/01 (rev01) Category 2 IAF/EA Guidance on the Application of ISO/IEC 17024:2003

Withdrawn and replaced by IAF GD 24: 2004 Guidance on the Application of ISO/IEC 17024:2003. Please download the document on the IAF website: www.iaf.nu

Application documents for Attestation Bodies Series 9

EA 9/01 [download, "DOC" , 114 Ko]

Subject : EAC Guidelines on the Application of EN 45503, European Attestation Standard for the Assessment of Contract Award Procedures of Entities Operating in the Water, Energy, Transport and Telecommunication Sectors

ILAC documents/guidelines

Publications

- **Brochures** - In addition to English, several of these documents, promoting laboratory accreditation, are available in Chinese, Japanese, Russian, French, Spanish and Hindi.
- **Information Series (I Series)** - Information documents providing background or reference information on a range of topics.
- **Guidance Series (G Series)** - For laboratories and accreditation bodies. These guidance documents may provide information on the interpretation of accreditation criteria for specific applications.
- **Procedural Series (P Series)** - Procedural and policy publications for ILAC's operation, which form part of the criteria for ILAC MRA evaluations.
- **Secretariat Series (S Series)** - Publications of the Secretariat, including lists of members of committees, list of publications, etc.
- **ILAC-IAF Joint Publications (A Series)** - Publications jointly prepared by ILAC and IAF.

ILAC documents/guidelines

Brochures

The HTML versions of the brochures listed below are available in English.

- Why use an accredited laboratory?
- Why become an accredited lab
- How does using an accredited lab benefit government and regulators
- The advantages of being an accredited laboratory
- Laboratory Accreditation or ISO 9001 Certification?

ILAC documents/guidelines

Information Series

- **ILAC I1:1994 Legal Liability in Testing**
  This document provides information to technically-trained persons working in the testing area about the general approaches to legal liability issues and how they may apply to testing laboratories, accreditation bodies and certification bodies.

- **ILAC I2:1994 Testing, Quality Assurance, Certification and Accreditation**
  This document is currently under review.

- **ILAC I3:1996 The Role of Testing and Accreditation in International Trade**
  This document has been withdrawn.

- **ILAC I4:1996 Guidance Documents for the Preparation of Laboratory Quality Manuals**
  This document has been withdrawn.

ILAC documents/guidelines

Guidance Series

Please note that Spanish translations of ILAC Guidance documents G-17 and G-21 can be found on the IAAC website at http://www.iaac.org.mx/Spanish/Index.html

- **ILAC G3:1994 Guidelines for Training Courses for Assessors**
  These guidelines have been prepared to assist laboratory accreditation bodies to set up training courses that are in line with international practice and which will enable them to generate the lead assessors and technical assessors that they need.

- **ILAC G7:1996 Accreditation Requirements and Operating Criteria for Horseracing Laboratories**
  The purpose of this document is to provide: Part A: A compilation of test-method-related requirements for horseracing laboratories that accreditation bodies have submitted. Part B: Recommendations for establishing the presence of prohibited substances that have been agreed within the horseracing industry. Part C: The performance specification for horseracing laboratories that has been adopted by the International Federation of Horseracing Authorities.

- **ILAC G8:1996 Guidelines on Assessment and Reporting of Compliance with Specification**
  The guidelines give rules for supplier and client concerning the assessment and reporting of compliance or non-compliance for a single unit of product using an agreed test method. Legal requirements supersede any agreement.

ILAC documents/guidelines

Guidance Series

- **ILAC G9:2005 Guidelines for the Selection and Use of Reference Materials**
  These guidelines aim at establishing the framework by which laboratories seeking accreditation, and technical assessors, will be able to propose and evaluate the CRMs relevant to their specific needs.

- **ILAC G10:1996 Harmonised Procedures for Surveillance & Reassessment of Accredited Laboratories**
  These guidelines provide a procedure for a harmonised approach to conducting surveillance and reassessment of accredited laboratories.

- **ILAC G11:07/2006 ILAC Guidelines on Qualifications & Competence of Assessors and Technical Experts**
  This document interprets and amplifies ISO/IEC 17011 requirements for an adequate procedure for qualifying and monitoring the performance of assessors and describes criteria for lead assessors and technical assessors.

- **ILAC G12:2000 Guidelines for the Requirements for the Competence of Reference Materials Producers**
  These Guidelines have been developed for evaluation of the competence of reference materials producers with a view to the eventual establishment of internationally accepted criteria.

ILAC documents/guidelines

Guidance Series

- **ILAC G13:2000 Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes**
  This document is for providers of proficiency testing schemes who wish to demonstrate their competence by formal compliance with a set of internationally-acceptable requirements for the planning and implementation of proficiency testing schemes.

- **ILAC G17:2002 Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025**
  This document describes how the concept of uncertainty of measurement should be introduced taking into account present state of the art understanding. It is realised that during the course of the implementation of ISO/IEC 17025, suitable sector-specific guidance will be needed. However, the harmonisation of the application of the principles of uncertainty of measurement in testing between different disciplines, industry sectors and economies should remain the main goal.

- **ILAC G18:2002 The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing**
  The purpose of this publication is to provide information on how to define the scope of accreditation and to identify some criteria and ways of assessing the scope in order to provide practical guidance for an effective and harmonised application of the relevant international Standards. The major parts concern the implementation of the state of practice of describing the scope for laboratories accredited to modify methods or design new methods as foreseen in ISO/IEC 17025, § 1.6, 5.4.3 and 5.4.4.

ILAC documents/guidelines

Guidance Series

- **ILAC G19:2002 Guidelines for Forensic Science Laboratories**
  This document is intended to provide guidance for laboratories involved in forensic analysis and examination by providing application of ISO/IEC 17025.

- **ILAC G20:2002 Guidelines on Grading of Non-conformities**
  This document outlines one approach to grading non-conformities, from more to less serious, through linking the seriousness of the nonconformity with the actions that the accreditation body may need to take. Some examples of the various gradings are listed.

- **ILAC G21:2002 Cross Frontier Accreditation - Principles for Avoiding Duplication**
  The ILAC General Assembly 2001 endorsed the guidance document "Cross-frontier accreditation- principles for avoiding duplication" as a code of good practice for ILAC member bodies (ILAC Decision GA 5.19). This publication is compatible with the relevant WTO/TBT requirements and takes into account other views in a pragmatic, logical, sensible and constructive way.

ILAC documents/guidelines

Guidance Series

- **ILAC G22:2004 Use of Proficiency Testing as a Tool for Accreditation in Testing**
  The objective of this document is to ensure a consistent good practice for Accreditation Bodies and laboratories in the cost-effective use of proficiency testing in accreditation.

- **ILAC G23:2004 ILAC Evaluator Training Courses**
  The guidelines give outlines for a training course for MRA evaluators and another training course for MRA lead evaluators. The way in which ILAC regions advise each other of their evaluator training courses is also detailed.

ILAC documents/guidelines

Procedural Series

- **ILAC P1:2003 ILAC Mutual Recognition Arrangement (Arrangement): Requirements for Evaluation of Accreditation Bodies By ILAC-recognised Regional Cooperations**
  This document provides the ILAC Arrangement Council with criteria for evaluating the procedures used by Cooperations in their Mutual Recognition Arrangement evaluation process.

- **ILAC P2:2003 ILAC Mutual Recognition Arrangement (Arrangement): Procedures for Evaluation of Regional Cooperation Bodies for Purpose of Recognition**
  This document provides the ILAC Arrangement Council with a procedure for evaluating Cooperation for the purpose of Recognition.

- **ILAC P3:2003 ILAC Mutual Recognition Arrangement (Arrangement): Procedures for Evaluation of Unaffiliated Bodies for Purpose of Recognition**
  To provide the ILAC Arrangement Council with a procedure for evaluating bodies not currently affiliated to an ILAC-recognised Cooperation for the purpose of Recognition.

- **ILAC P4:2003 ILAC Mutual Recognition Arrangement (Arrangement): Policy Statement**
  This document provides details on the objectives, foundation, management, procedures and decisions associated with the ILAC MRA.

ILAC documents/guidelines

Procedural Series

- **ILAC P5:04/2007 ILAC Mutual Recognition Arrangement (Arrangement)**
  This document describes the elements of a Mutual Recognition Arrangement (hereinafter referred to as the Arrangement) for testing and calibration laboratory accreditation

- **ILAC P6:2003 Application for Full Member Status**
  This form is for use by ILAC Associate Members wishing to apply for ILAC Full Member status. An electronic version of this form is available from ILAC by emailing the ILAC secretariat

- **ILAC P7:2003 ILAC Mutual Recognition Arrangement (Arrangement): Key Performance Indicators (KPIs)**
  This document has been replaced by **IAF/ILAC A3:2005 IAF/ILAC MRAs: Key Performance Indicators**

- **ILAC P8:07/2006 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories**
  The requirements and guidelines in this document have been developed to ensure a more uniform approach to the use of accreditation symbols and for the manner in which a laboratory may refer to its accreditation status and make claims to ILAC MRA. Since this document contains both requirements and guidelines, to avoid confusion, only those statements that include "shall" set requirements.

ILAC documents/guidelines

Procedural Series

- **ILAC P9:2005 ILAC Policy for Participation in National and International Proficiency Testing Activities**
  This document is based on existing regional cooperation documents – ie "EA Policy for Participation in National and International Proficiency Testing Activities – EA-2/10, August 2001" and "Summary of APLAC Proficiency Testing Requirements – APLAC: 2000".

- **ILAC P10:2002 ILAC Policy on Traceability of Measurement Results**
  This document provides a policy on traceability of measurement results which is intended to be implemented by ILAC members and to encourage the development of supporting bodies such as CIPM/BIPM. Unless otherwise noted in the text for some clauses, this policy is effective as of 1 January 2003.

ILAC documents/guidelines

Procedural Series

- **ILAC P11:2004 Monitoring Performance of ILAC Evaluators**
  This document sets out the procedure for monitoring the performance of ILAC evaluators and reporting on that performance to the Chair of the ILAC AMC. It also outlines the procedure to be followed when dealing with complaints and appeals against ILAC AMC actions in relation to evaluator performance.

- **ILAC P12:2005 Harmonisation of ILAC Work with the Regions**
  This document provides information on the steps involved in harmonising work between ILAC and regional accreditation cooperations, as well as criteria for adopting new ILAC work items.

- **ILAC Mutual Recognition Arrangement (Arrangement): Terms of Reference and Composition of the Arrangement Management Committee**
  This document details the terms of reference and composition of the ILAC Arrangement Management Committee.

ILAC documents/guidelines

Secretariat Series

- **ILAC S1:2003 Guidelines for the Proposal, Drafting, Approval and Publication of ILAC Documents**
  This document provides guidance on the proposal, drafting, approval, submission, format, style and classification of all types of ILAC Documents that will be distributed as official ILAC publications.

- **ILAC S2:2003 ILAC Rules**
  On 20 January 2003 ILAC was successfully incorporated and became an Association according to Dutch Law. These revised Articles of Association and Bylaws (ie ILAC Rules) were implemented from that date.

- **ILAC S3:2004 ILAC Strategic and Business Plan**
  This Plan describes proposed business development strategies to support, enhance, and expand domestic and regional confidence in accreditation created by ILAC members. These activities include outreach to the wider community to enhance global acceptance of the ILAC Arrangement.

- **ILAC S5:2005 ILAC Procedure for Disputes, Complaints and Appeals**
  This procedure outlines the ILAC secretariat's process to handle disputes, complaints and appeals.

ILAC documents/guidelines

ILAC-IAF Joint Publications

- **IAF/ILAC A1:2006 IAF/ILAC MRAs: Evaluation of a Regional Group**
  This document provides ILAC and IAF with requirements or criteria for evaluating Regional Groups for the purpose of recognition.

- **IAF/ILAC A2:2006 IAF/ILAC MRAs: Evaluation of a Single Accreditation Body**
  This document provides ILAC and IAF with general requirements for evaluating single Accreditation Bodies for the purpose of qualifying them to sign applicable multi-lateral mutual recognition Arrangement(s).

- **IAF/ILAC A3:2006 IAF/ILAC MRAs: Key Performance Indicators**
  This document provides a tool in the evaluation process: (1) to allow an evaluated accreditation body (AB) to present information about how it addresses thirteen topics important to its performance; (2) to focus the evaluation agenda on important topics; and (3) to provide a framework to present this information in an evaluation report. The effective date for application of this document is the date of publication.

- **IAF/ILAC A4:2004 Guidance on the Application of ISO/IEC 17020**
  This guidance will form the basis of mutual recognition arrangements between accreditation bodies, and is considered necessary for the consistent application of ISO/IEC 17020.

Accreditation

Accreditation of a laboratory *(before the visit to the lab)*

- **Laboratory receives information from AB**
- **Laboratory applies for accreditation**
- **AB:**
  - Appoints a Lead Assessor (LA) for the assessment of the applicant
  - LA appoints one or more Technical Assessors (TA).

- **Documentation that is reviewed by AB:**
  - CV for personnel
  - Methods
  - Uncertainty budgets
  - Range and (for calibration) Best Measurement Capability (BMC)
  - Equipment
  - Quality Manual

Accreditation

Tools used during assessment

- Summary of data that has been passed to AB before the assessment
- Agenda for the assessment
- Accreditation criteria relevant for the assessment
- Lists of Methods and/or BMC
- Checklists
- Observation sheets
- Nonconformity report forms
- Report template

Accreditation of laboratories
(visit to the lab)

- **Pre-evaluation visit**
- **Assessment**
  - *Review of the quality system and its implementation*
  - *Review of the technical competence (personnel, equipment, procedures, premises)*
  - *Assessment of proficiency testing or bilateral comparisons with other accredited laboratories*
  - *Demonstration of competence to laboratory personnel*
  - *Nonconformity reports are presented to the lab*
  - *Agreement/decision on deadlines for implementation of corrective actions.*

Reporting

- **Reporting is performed in the report template and must be accompanied by:**
  - Summary of the scope of the accreditation
  - Annex from TA should be provided whenever necessary
  - Summary of nonconformities that has been written
- **The report shall address specific issues as claimed in ISO 17011.**

Accreditation of a laboratory
(after the visit to the lab)

- Implementation of corrective actions is assessed by AB
- LA issues a statement whether granting accreditation to the AB
- AB approves (or disapproves) the statement
- AB grants accreditation
- Certificate of accreditation is passed to the lab

Accreditation

Accreditation of a laboratory
(after the accreditation is granted)

- Accreditation is granted for a maximum of 5 years
- After 1 year the first surveillance visit is made
- Surveillance is less comprehensive as initial accreditation.
- Reaccreditation is carried out month before the accreditation expires (reassessment is necessary)

Scope of accreditation

In EA-2/05 *The Scope of accreditation and consideration of methods and criteria for the assessment of scopes in testing* the scope is defined as:

- Formal precise statement of the activities which the lab is accredited for (e.g. electrical, chemical, microbiological, mechanical)
- A combination of information (scope parameters) concerning the test field
- The type of test (describing the measurement principle)
- The object tested and
- The methods and procedures for the test

Scope of accreditation

Scope in testing and calibration field is normally identified in terms of:

- **Quantities to be measured** (sometimes also instruments to be calibrated or test items)
- **Range**
- **Uncertainties** (not always applicable in testing)
- **Methods** (standard, non-standard, not always applicable in calibration)

Scope is usually presented in the attachment to the accreditation certificate (with detailed information of the testing/calibration field)

Scope of accreditation – examples of scopes

Examples from scopes presented to the public can be found at most homepages of accreditation bodies. Examples from SA is given in the following slides.

Scope of accreditation – examples of scopes

SLOVENSKA AKREDITACIJA

Priloga k akreditacijski listini št. / *Annex to the Accreditation Certificate No.*	LK-003
Datum izdaje / *Issued on*	26. februar 2007
Velja do / *Valid until*	30. november 2010
Zamenjuje izdajo z dne / *Replaces Annex dated*	8. september 2005

3.2 Podrobni opis obsega akreditacije / *Detailed scope of accreditation*

Tabela 1- Kalibracije v laboratoriju / *In-lab calibrations*

Merjena veličina *(Measured quantity & field)*		Območje *(Range)*	Najboljša merilna zmogljivost / *BMC (k=2)**	Opombe *(Notes)*
4.	**DIMENZIONALNE VELIČINE** *Dimensional Quantities*			
4.1	**Dolžina** *Length*			*L* – merjena dolžina / *measured length*
4.1.2	**Merila dolžine** *Length gauges*			
	Mejna vzporedna dolžinska merila - merilne kladice (jeklene) / *Gauge blocks (steel)*	(0,5 do/*to* 100) mm (100 do/*to* 1000) mm	$U = \sqrt{(35\ nm)^2 + (0{,}5 \cdot 10^{-6} \cdot L)^2}$ 0,1 µm + 1 · 10^{-6} · *L*	

Accreditation

Scope of accreditation – examples of scopes

	Merjena veličina *(Measured quantity & field)*	Območje *(Range)*	Najboljša merilna zmogljivost / *BMC (k=2)**	Opombe *(Notes)*
	Merilne urice / *Dial gauges*	(0 do/*to* 50) mm	0,9 µm + 4,5 · 10^{-6} · *L*	
	Naprave za kalibracijo merilnih uric / *Dial gauge testers*	(0 do/*to* 50) mm	0,1 µm + 2,5 · 10^{-6} · *L*	
	Induktivna tipala / *Inductive probes*	(0 do/*to* 4) mm	0,03 µm	
4.1.3	**Črtna merila** *Ruler/displacement*			
	Toga črtna merila / *Rulers*	(0 do/*to* 150) mm (0 do/*to* 3000) mm	0,12 µm + 2,4 · 10^{-6} · *L* 1,5 µm + 1,5 · 10^{-6} · *L*	
	Tračna merila / *Tape measures*	(0 do/*to* 200) m	10 µm + 7 · 10^{-6} · *L*	
4.1.4	**Instrumenti za merjenje dolžine** *Length measuring instruments*			
	Dvotočkovna vijačna merila (zunanja in notranja) / *2 point micrometers (external and internal)*	(0 do/*to* 1000) mm	1,5 µm + 4 · 10^{-6} · *L*	
	Pomična merila / *Vernier calliper gauges*	(0 do/*to* 1000) mm	7,0 µm + 7 · 10^{-6} · *L*	

Scope of accreditation – examples of scopes

3.2 Podrobni opis obsega akreditacije / *Detailed scope of accreditation*

Tabela 1 - kalibracije v laboratoriju, nominalna temperatura med kalibriranjem: 23 °C / *In-lab calibrations, the nominal ambient temperature: 23 °C*

Merjena veličina in območje *(Measured quantity, range)*	Frekvenca *(Frequency)*	Najboljša merilna zmogljivost / *BMC (k=2)**	Opombe *(Remarks)*
1	**ELEKTRIŠKE VELIČINE** / *Electrical Quantities*		
1.1	**ENOSMERNE IN NF VELIČINE** / *DC/LF Quantities*		
1.1.1	**Napetost** / *Voltage*		
1.1.1.1	**Enosmerna napetost** / *DC voltage*		
	1 / 1,018 / 100 V	$1{,}0 \cdot 10^{-6} \cdot U$	Merjenje / *Measuring*
	10 V	$7{,}0 \cdot 10^{-7} \cdot U$	
	1 kV	$2{,}0 \cdot 10^{-6} \cdot U$	
	0 µV do/*to* 10 µV	$1{,}5 \cdot 10^{-2} \cdot U + 0{,}05$ µV	
	10 µV do/*to* 100 µV	$1{,}5 \cdot 10^{-3} \cdot U + 0{,}01$ µV	
	100 µV do/*to* 1 mV	$1{,}5 \cdot 10^{-4} \cdot U + 0{,}01$ µV	
	1 mV do/*to* 10 mV	$1{,}5 \cdot 10^{-5} \cdot U + 0{,}01$ µV	
	10 mV do/*to* 100 mV	$5{,}0 \cdot 10^{-6} \cdot U + 0{,}01$ µV	
	0 µV do/*to* 10 µV	$7{,}0 \cdot 10^{-3} \cdot U + 0{,}01$ µV	Generiranje / *Generating*
	10 µV do/*to* 100 µV	$7{,}0 \cdot 10^{-4} \cdot U + 0{,}01$ µV	
	100 µV do/*to* 1 mV	$7{,}0 \cdot 10^{-5} \cdot U + 0{,}01$ µV	
	1 mV do/*to* 10 mV	$1{,}0 \cdot 10^{-5} \cdot U + 0{,}01$ µV	
	10 mV do/*to* 100 mV	$5{,}0 \cdot 10^{-6} \cdot U + 0{,}01$ µV	
	100 mV do/*to* 1 V	$3{,}0 \cdot 10^{-6} \cdot U$	Merjenje in generiranje / *Measuring and generating*
	1 V do/*to* 100 V	$2{,}0 \cdot 10^{-6} \cdot U$	
	100 V do/*to* 1000 V	$5{,}0 \cdot 10^{-6} \cdot U$	

Accreditation

Scope of accreditation – examples of scopes

Merjena veličina *(Measured quantity & field)*	Območje *(Range)*	Najboljša merilna zmogljivost */ BMC (k=2)**	Opombe *(Notes)*
10.	**TEMPERATURA, VLAGA IN TERMOFIZIKALNE LASTNOSTI** */ Temperature, humidity and thermo-physical properties*		
10.1	**Uporovni termometri** */ Resistance thermometers*		
	Kalibracija v fiksnih točkah */ Fix point calibration*		
	Trojna točka argona */ Triple point of Argon*	-189,3442 °C	0,8 mK
	Trojna točka živega srebra */ Triple point of Mercury*	-38,8344 °C	0,6 mK
	Trojna točka vode */ Triple point of Water*	0,01 °C	0,3 mK
	Tališče galija */ Melting point of Gallium*	29,7646 °C	0,4 mK
	Strdišče indija */ Freezing point of Indium*	156,5985 °C	1,2 mK
	Strdišče kositra */ Freezing point of Tin*	231,928 °C	1,0 mK
	Strdišče cinka */ Freezing point of Zinc*	419,527 °C	1,5 mK
	Strdišče aluminija */ Freezing point of Aluminium*	660,323 °C	3,0 mK
	Strdišče srebra */ Freezing point of Silver*	961,78 °C	15 mK

Scope of accreditation – examples of scopes

Tabela 1- Kalibracije v laboratoriju / *In-lab calibrations*

Merjena veličina *(Measured quantity & field)*		Območje *(Range)*	Najboljša merilna zmogljivost */ BMC (k=2)**	Opombe *(Notes)*
5.	**MEHANSKE VELIČINE** */ Mechanical Quantities*			
5.2	**Masa** */ Mass*			
	Etalonske uteži */ Standard weights*			
		1 mg 2 mg 5 mg 10 mg 20 mg 50 mg 100 mg 200 mg 500 mg	0,0006 mg 0,0006 mg 0,0006 mg 0,0008 mg 0,0010 mg 0,0012 mg 0,0015 mg 0,0020 mg 0,0025 mg	Za razred uteži E1 / *for weights of class E1*
		1 g 2 g 5 g 10 g 20 g 50 g 100 g 200 g 500 g 1 kg 2 kg 5 kg 10 kg	0,003 mg 0,004 mg 0,005 mg 0,006 mg 0,008 mg 0,010 mg 0,015 mg 0,030 mg 0,075 mg 0,15 mg 0,30 mg 0,75 mg 1,5 mg	Za razred uteži E1 / *for weights of class E1* (Pogoj za kalibracijo uteži je predhodno kalibriranje volumna uteži; Laboratorij ne izvaja kalibracij volumna */ Calibration of mass is possible only after the volume calibration of weight. Laboratory does not perform volume calibration)*

Accreditation

Scope of accreditation – examples of scopes

Tabela 1 - preskušanje v laboratoriju
Table 1 - Testing in the laboratory

Področje preskušanja (klasifikacija po A45): Opis (šifra)
Field of testing (classification according to SA document A45): Description (code)
Kemija (2.04) - goriva in maziva (nafta in derivati, kemični proizvodi in topila)
Chemistry (2.04) - fuels and lubricants (petroleum and derivatives chemical products and dissolvents)

Št. No.	**Oznaka standarda** ali nestandardne preskusne metode *Reference to standard or non-standard testing method*	**Naslov standarda** ali nestandardne preskusne metode in morebitne navezave na druge standarde ali metode *Title of standard or non-standard testing method and eventual relations to other standards or methods*	**Območje** preskušanja; **Negotovost** rezultata preskušanja (kjer je to pomembno) *Range of testing; Uncertainty of the result of testing (where relevant)*	**Materiali; proizvodi** *Materials; products*
1.	ASTM D 4420: 1994	Test Method for Determination of Aromatics in Finished Gasoline by Gas Chromatography *Določevanje vsebnosti benzena in drugih aromatov v bencinih s plinsko kromatografijo*		motorni bencini
2.	EN ISO 3405: 2000 SIST EN ISO 3405: 2000	Petroleum products - Determination of distillation characteristics Naftni proizvodi - Določanje destilacijskih lastnosti		goriva in naftna topila
3.	EN 116: 1997 SIST EN 116: 1998	Diesel and domestic heating fuels - Determination of cold filter plugging point *Dieselsko gorivo in kurilno olje za gospodinjstvo - Določevanje filtrirnosti*		dieselsko gorivo

Accreditation

Scope of accreditation – examples of scopes

Področje preskušanja (klasifikacija po A45): Opis (šifra) /
Field of testing (classification according to SA document A45: Description (code)

Mehanika (2.05) - Mehansko preskušanje kovin (v laboratoriju)

Mechanics (2.05) - Mechanical testing of metals (in laboratory)

Št. No.	**Oznaka standarda** ali nestandardne preskusne metode *Reference to standard or non-standard testing method*	**Naslov standarda** ali nestandardne preskusne metode in morebitne navezave na druge standarde ali metode *Title of standard or non-standard testing method and eventual relations to other standards or methods*	**Območje** preskušanja; **Negotovost** rezultata preskušanja (kjer je to pomembno) *Range of testing; Uncertainty of the result of testing (where relevant)*	**Materiali; proizvodi** *Materials; products*
1.	* SIST EN 1321:1998	Porušitveno preskušanje zvarnih spojev na kovinskih materialih – Makroskopske in mikroskopske preiskave zvarov *(Destructive testing on welds in metallic materials - Macroscopic and microscopic examination of welds)*	(0 do 1000) kratna povečava	kovine *(metals)*
2.	SIST EN 895:1996	Porušni preskus zvarnih spojev na kovinskih materialih - Prečni natezni preskus *(Destructive tests on welds in metallic materials - Transverse tensile test)*	(0 do 400) kN	kovine *(metals)*
3.	*SIST EN 875:1996	Porušitveno preskušanje zvarov na kovinskih materialih - Udarni preskus - Položaj preskušanca, smer zareze in vrednotenje *(Destructive testing on welds in metallic materials - Impact tests -Test specimen location, notch orientation and examination)*	(0 do 300) J	kovine *(metals)*
4.	*SIST EN 10045-1:2000	Kovinski materiali - Udarni preskus po Charpyju - 1.del: Preskusna metoda *(Metallic materials - Charpy impact test - Part 1: Test method)*	(0 do 300) J	kovine *(metals)*
5.	SIST EN ISO 7438:2000	Kovinski materiali - Upogibni preskus *(Metallic materials - Bend test)*	(0 do 180) °	kovine *(metals)*

Accreditation

Scope of accreditation – examples of scopes

Področje preskušanja (klasifikacija po A45): Opis (šifra)
Field of testing (classification according to SA document A45): Description (code)
Biologija, mikrobiologija, biokemija (2.02): kmetijski pridelki in živilski proizvodi (mleko in mlečni izdelki, meso in mesni izdelki)
Biology, microbiology, biochemistry (2.02): Agricultural and Food Products (milk and milk products, meat and meat products)

Št. No.	**Oznaka standarda** ali nestandardne preskusne metode ***Reference** to standard or non-standard testing method*	**Naslov standarda** ali nestandardne preskusne metode in morebitne navezave na druge standarde ali metode ***Title** of standard or non-standard testing method and eventual relations to other standards or methods*	**Območje** preskušanja; **Negotovost** rezultata preskušanja (kjer je to pomembno) ***Range** of testing; **Uncertainty** of the result of testing (where relevant)*	**Materiali; proizvodi** ***Materials; products***
1.	ISO 6888-1: 1999 (E)	Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) - Part 1: Technique using Baird-Parker agar medium *Preiskava na koagulaza pozitivne stafilokoke* SOP 203	100/gr	meso in mesni izdelki *meat and meat products*
2.	ISO 6888-2:1999	Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) - Part 2: Technique using rabbit plasma fibrinogen agar medium *Preiskava na koagulaza pozitivne stafilokoke* SOP 204	LOD 10 cfu/g	mleko in mlečni izdelki *milk and milk products* meso in mesni izdelki *meat and meat products*

Scope of accreditation – examples of scopes

3.2.1 Laboratorij za radiološke merilne sisteme in meritve radioaktivnosti

Tabela 1 /*Table 1*

Tip obsega*: obseg z delno fleksibilnostjo (možnost uvajanja manjših sprememb metode) / *partially flexible scope (possibility of implementig minor modifications of the method)*
Mesto izvajanja: v laboratoriju / *in the laboratory*
Področje preskušanja glede na vrsto preskušanja: radiokemija, sevanje (alfa, beta, gama spektrometrija) *Iradiochemistry, radiation (alfa, beta, gamma spectrometry)*
Področje preskušanja glede na vrsto preskušanca:-

Št. No.	**Oznaka standarda** ali nestandardne preskusne metode *Reference to standard or non-standard testing method*	**Naslov standarda** ali nestandardne preskusne metode in morebitne navezave na druge standarde ali metode *Title of standard or non-standard testing method and eventual relations to other standards or methods*	**Območje** preskušanja; **Negotovost** rezultata preskušanja (kjer je to pomembno) *Range of testing; Uncertainty of the result of testing (where relevant)*	**Materiali; proizvodi** *Materials; products*
1.	LMR-DN-10 Interna metoda *In-house method*	Meritve aktivnosti sevalcev gama in rentgenskih žarkov v homogenih cilindričnih vzorcih z visokoločljivostno spektrometrijo gama *Measurements of activities of gamma-ray and x-ray emitters in cylindrical homogenous samples with high-resolution gamma-ray spectrometry*	Območje emisij iz vzorca *Range of emissions from the sample*: $(0{,}5 \cdot 10^{-2}$ do/*to* $0{,}5 \cdot 10^{5})$ s^{-1} Območje energij *Energy range*: (5 do/*to* 3000) keV	trdni in tekoči materiali *solid and liquid materials*

Accreditation

Scope of accreditation – examples of scopes

Področje preskušanja (klasifikacija po A45): Opis (šifra)
Field of testing (classification according to SA document A45): Description (code)
Kemija (2.04) – kemična analiza
Chemistry (2.04) – chemical analysis

Št. No.	**Oznaka standarda** ali nestandardne preskusne metode *Reference to standard or non-standard testing method*	**Naslov standarda** ali nestandardne preskusne metode in morebitne navezave na druge standarde ali metode *Title of standard or non-standard testing method and eventual relations to other standards or methods*	**Območje** preskušanja; **Negotovost** rezultata preskušanja (kjer je to pomembno) *Range of testing; Uncertainty of the result of testing (where relevant)*	**Materiali; proizvodi** ***Materials; products***
1.	DIN 38404-C4	Deutsche Einheitsverfahren zur Wasser-, Abwasser- und Schlammuntersuchung Physikalische und physikalisch-chemische Kenngrößen (Gruppe C); Bestimmung der Temperatur (C4) *Temperatura*		pitna voda podtalnica odpadna voda
2.	SIST EN 27888	Determination of electrical conductivity *Določanje električne prevodnosti*	1- 1500 µS/cm	pitna voda podtalnica odpadna voda
3.	SIST ISO 10523	Water quality – Determination of pH *Kakovost vode - Določanje pH*		pitna voda podtalnica odpadna voda

Accreditation

Scope of accreditation – examples of scopes

Področje preskušanja (klasifikacija po A45): Opis (šifra) *Field of testing (classification according to SA document A45): Description (code)* Gradbeništvo (2.12) - agregati *Building (2.12): aggregates*				
Št. No.	**Oznaka standarda** ali nestandardne preskusne metode ***Reference** to standard or non-standard testing method*	**Naslov standarda** ali nestandardne preskusne metode in morebitne navezave na druge standarde ali metode ***Title** of standard or non-standard testing method and eventual relations to other standards or methods*	**Območje** preskušanja; **Negotovost** rezultata preskušanja (kjer je to pomembno) ***Range** of testing; **Uncertainty** of the result of testing (where relevant)*	**Materiali; proizvodi** ***Materials; products***
1.	DIN 18 127	Baugrund. Versuche und Versuchsgeräte. Proctorversuch *Soil; testing procedures and testing equipment; Proctor-test*	Samo za premer valja 100 in 150 mm	Zemljine Kamnine Tampon stabilizirani materiali
2.	SIST EN 1097-5	Preskusi mehanskih in fizikalnih lastnosti agregatov – 5. del: Določevanje vode s sušenjem v prezračevanem sušilniku *Test of mechanical and physical propeties of aggregates – Part 5: Determination of the water content by drying in a ventilated oven*	samo do velikosti zrn 63 mm	Kameni agregat Zemljine Tamponi
3.	SIST EN 932-2 razen točk 7 in 9	Preskusi splošnih lastnosti agregatov – 2. del: Metode zmanjševanja *Test for general properties of aggregates – Part 2: Methods for reducing laboratory samples*		kameni agregat, nasipni materiali, tampon, stabilizirani materiali, zemljine

Suspension of accreditation

Reasons for suspension:

- **Failure of quality system or failure of equipment**
- **Use of unauthorized persons**
- **Unsatisfactory participation in proficiency testing**
- **Changes in organisation or absence of key personnel**
- **Non conformities in services offered by lab which has serious implications for other clients of the lab**
- **Serious complaints from customers of the CAB**
- **Lack of payment for accreditation services offers to CAB by AB**

ISO/IEC 17025 chapter 4 - management requirements

- Organization - 4.1.
- Quality system - 4.2
- Document control - 4.3
- Subcontracting of tests and calibrations - 4.5
- Purchasing services and supplies - 4.6
- Service to the client/complaints - 4.7- 4.8
- Control of nonconforming work and corrective and preventive actions - 4.9 - 4.11
- Control of records - 4.12

ISO/IEC 17025 chapter 5 – technical requirements

- **Competence of personnel. Training and authorization of personnel - 5.2**
- **Environmental conditions for the laboratory (noise, filth, temperature) - 5.3**
- **Testing and calibration methods and their validation - 5.4**
  - Estimation of uncertainty
  - Control of data
- **Equipment and traceability - 5.5-5.6**
- **Sampling - 5.7**
- **Assuring quality of test and calibration results - 5.9**
- **Reporting the results - 5.10**

4.1 Organization

4.1.1 Entity that can be held legally responsible

4.1.2 Lab must meet the requirements of this standard and requirements from regulatory authorities and AB

4.1.4 If lab is a part of a bigger organization responsibilities of key personnel must be defined to prevent conflicts of interests. This is particular important for third party labs

4.1.5 Specific requirements to lab:

b) Free from any undue internal or external commercial, financial and other pressures and influences that might influence the quality of the work

4.1 Organization

4.1.5 Specific requirements - continued:

c) - g) Confidentiality, responsibility and authorization, supervision of personnel.

h) Have technical management with overall responsibility of technical functions and provision of resources (to achieve the required quality).

i) Appoint a quality manager (one person) with reference to the highest level of management.

j) Appoint deputies for key managerial personnel.

4.2 Quality system

4.2.1 Lab shall establish, maintain and implement a QS that suits its activities and the lab must:

Document policy, systems, programs, procedures and instructions.

The QS must be communicated to, available to, understood and implemented by all personnel.

4.2 Quality system

4.2.2 In the quality manual (QM) policies and objectives must be defined (commitment for management and quality of services) plus

d) a requirement that personnel familiarizes and implement the policies and procedures in their work.

4.2.3 QM must refer to supporting procedures.

4.2.4 QM must define roles and responsibilities for the technical management and the quality manager.

4.3 Document control

4.3.1 Procedure for control of all documents (regulations, standards, test/calibrations methods, software, instructions, …) that are a part of the QS.

4.3.2 All documents must be approved by authorized personnel and there shall be a master list, that identifies current revision status shall be readily available.

4.3.2.2 Availability on all location and periodically reviews. Removal of invalid documents and eventually preservation of these (properly marked!!!).

4.3.2.3 Unique identification of documents.

4.3 Document control

4.3.3 Changes shall be reviewed and approved by the same function that originally approved them if possible.

4.3.3.2 If possible changes in the text shall be identified in the document(s).

4.3.2.2 If hand pending is accepted, a procedure must be established for it (who, how).

4.3.3.4 There shall be procedures for how changes in electronically maintained documents are made.

4.4 Review of requests, tenders and contracts

4.4.1 Policy and procedure for review shall ensure that:

a) Requirements are adequately defined, documented and understood

b) Lab has capability and resources to meet the requirements

c) The requirements of the client are met by using appropriate methods

4.4.2-3 Records of reviews are kept also for subcontracting

4.4.4 Information to client if deviations from contract occur. In this case reviews of contract must be repeated and any amendments to the contract shall be communicated to all affected personnel

4.5 Subcontracting tests and calibrations

If a lab makes use of subcontracting (only on a part of its services or in case of temporary incapacity), it must ensure:

- Qualified subcontractors – accredited laboratories are recognized immediately (for relevant accredited services)
- The client must be informed in written form about use of subcontractors
- Lab is responsible for subcontractors unless the client or regulators specify, which subcontractor is to be used
- The lab must maintain a register and records in compliance with 17025 for its subcontractors

4.6 Purchasing services and supplies

4.6.1 Policy and procedures for selection and purchasing of services, that can affect the quality of tests and calibrations

4.6.2 Consumable materials (reagents, contact oil, strain gages, …..) are not to be used until they have been inspected; records of the inspection must be maintained

4.6.4 Suppliers of critical consumables and services (ie. Calibrations) shall be evaluated and the results shall be recorded. A list of approved suppliers shall be maintained

4.7 Service to the client

Cooperation with the client shall be defined. It includes the possibility for the client to monitor the work, under condition that confidentiality to other clients is ensured.

4.8 Complaints

Policy and procedures for complaints.

Complaints shall be recorded together with investigations and corrective actions.

4.9 Control of nonconforming testing and/or calibration work

Lab shall have a policy and procedures that ensure:

- **Responsibilities and authorities for handling nonconforming work are designated (halting of work)**
- **Evaluation of significance is assured. Can the work be accepted?**
- **Corrective actions are taken**
- **Client is notified**
- **Responsibility for authorizing resumption of work is defined**

4.10 Corrective actions

4.10.1 Lab shall establish policy and procedures that ensure responsibility and authorization for implementing corrective actions

4.10.2 Initially there shall be an investigation. What is the cause of the problem?

4.10.3 Selection of corrective action. Extent depends on size of the problem and risk for reappearance

4.10.4 Effectiveness of corrective actions is monitored

4.10.5 Additional audits initiated if necessary (in case of non-compliance of work with QS or 17025)

4.11 Preventive actions

- Preventive action is a proactive process, that is not caused by problems, complaints etc. Preventive actions can be initiated by trends, proficiency testing etc.
- Necessary improvements and potential sources for nonconformities must be identified
- There shall be a procedure for preventive actions

4.12 Control of records

Quality records:

- Tenders
- Contracts
- Subcontracts
- Suppliers of consumables and services
- Complaints
- Internal audits
- Management review.

4.12 Control of records

Technical records:

- Copies of certificates and test reports issued by lab (5 years)
- Original observations
- Derived data, names of those, who were responsible for the sampling and testing and for checking the results
- Equipment and software including calibration data and/or verification information

4.12 Control of records

4.12.1 Procedures for records must include:
What (identification)?
How (collecting, indexing, maintaining)?
Where (archiving)?
How long (secure preservation, safe disposal)?

4.12.2.3 Mistakes in record must not be wiped out or otherwise made illegible. Correct values must be entered alongside and marked with initials of the person doing the correction!

Similar precautions must be taken for electronic records to avoid loss or change of original data!

4.13 Internal audits

- There shall be a predetermined schedule and procedure for internal audits (periodically)
- All activities shall be covered
- Audit shall be carried out by trained and independent personnel
- When findings cast doubt on the effectiveness of the work corrective actions shall be taken
- Results from internal audit shall be recorded

4.14 Management review

- There shall be a schedule and procedure for the management review (at least annually)
  - Suitability of policies and procedures
  - Reports from managerial and supervisory personnel
  - Results from internal audits
  - Corrective and preventive actions
  - Assessments by external bodies
  - Results from proficiency testing
  - Changes in volume and type of work
  - Client feedback
  - Complaints
  - Resources, training etc.
- Results from management review shall be recorded

5.2 Personnel – general requirements

4.1.5 Lab must have managerial and technical personnel with authority and resources needed to carry out their duties, have technical management and a quality manager and deputies for key managerial personnel.

5.2.1 Lab management shall ensure competence to:

- operate specific equipment
- perform test/calibration
- evaluate results
- sign reports/certificates
- to issue opinions and interpretations

5.2 Personnel – general requirements

5.2.1 (continued)

Qualification shall be based on appropriate:

- **education**
- **training**
- **experience**
- **demonstrated skills**

Staff under training can only work under direct supervision

5.2.3 Management shall define goals of training etc. and there shall be a policy and procedure for training.

5.2 Personnel – employment

Staff shall be employed by or work under contract with the lab. All staff no matter how shall follow the QS (5.2.3).

The lab shall maintain current job descriptions for (5.2.4):

- managerial persons
- technical staff
- key support personnel (administrative staff)

Job descriptions should describe at least:

- what tests to carry out
- evaluation of results
- reporting opinions and interpretations
- modification, evaluation and validation of new methods
- expertise and experience required
- qualifications and training programmes
- managerial duties

5.2 Personnel – special requirements

- Regulations might imply specific qualifications
- In NDT personnel certification may be required
- For personnel responsible for opinions and interpretations knowledge of regulations, standards and manufacturing technology is obligatory

5.2 Personnel – records

5.2.5 Lab shall maintain records on:

- Authorizations (to specific kinds of work and to sign reports)
- Competence
- Educational and professional qualifications (CV)
- Training

Date on which authorizations and/or competence is confirmed shall be included.

5.3 Accommodation and environmental conditions

5.3.1 **Lab shall ensure that environmental conditions in the lab (or on site) does not affect results of tests/calibrations.**

Documentation for technical requirements is needed.

5.3.5 **There must be appropriate housekeeping and special procedures if needed.**

5.3 Accommodation and environmental conditions

5.3.2 Lab shall

- **monitor**
- **control**
- **record**

environmental conditions when they influence the quality of results.

Examples of environmental parameters:

- Temperature, pressure, humidity
- Sound and vibration
- Dust
- Radiation, EMC, electric supply
- Biological sterility

5.3 Accommodation and environmental conditions

CAUTION!!

When environmental conditions are jeopardizing the results, tests or calibrations shall be stopped. (Some personnel shall be authorized to stop activities)!

5.3 Accommodation and environmental conditions

5.3.3 Effective separation between incompatible activities shall be ensured and cross-contamination shall be prevented

5.3.4 Access to lab and test facilities shall be controlled

5.3.1 Special care shall be taken for work on site

5.4 Test and calibration methods and method validation - - Selection of methods

The lab shall use methods that:

- **Meet the needs of the client**
- **Are (preferably) published as national or international standards or by reputable organizations (eventually in texts, scientific magazines,…)**
- **Are developed by the lab (own methods - needs separate validation)**
- **The lab has demonstrated ability to perform a test/calibration.**

The lab shall contact client:

- **To inform about the chosen method**
- **If it is necessary to use non-standard methods**
- **If a method is inappropriate or out of date**

5.4 Test and calibration methods and method validation - - Development of non-standard methods

To be able to develop methods by its own, the lab must:

- **Plan the development activity**
- **Have qualified personnel with adequate resources for the development**

Plans for the development shall include:

- **Identification and scope of the method**
- **Parameters, equipment and reference materials/standards required**
- **Environmental requirements**
- **Description of the procedure including, checks to be performed on test item before start up, check of equipment, recording of results and safety measures.**
- **Estimation of uncertainty and criteria for approval/rejection.**

5.4 Test and calibration methods and method validation - - Validation of methods

Methods that need validation:

- **Own methods**
- **Non-standard methods**
- **Standard methods used outside intended scope**
- **Modified methods**

5.4 Test and calibration methods and method validation - - Validation of methods

Methods used for validation:

- **Calibration or testing using reference standards or reference materials**
- **Comparison with results obtained with other methods**
- **Interlaboratory comparisons**
- **Assessment of factors influencing the results**
- **Assessment of uncertainties based on scientific understanding of theoretical principles and practical experience.**

5.4 Test and calibration methods and method validation - - Validation of methods

Results of the validation shall be recorded and shall include:

- **All relevant data**
- **A statement whether the method fits the intended use**
- **Range and accuracy (uncertainty) of results/parameters**
- **Detection limit, selectivity, linearity, repeatability, reproducibility, robustness against external influence and cross-sensitivity from the matrix of the sample/test object.**

Validation is always a balance of cost, risks and technical possibilities

5.4 Test and calibration methods and method validation - - Validation of methods

There are sector specific guidance in EA documents:

- **EA-4/05 (EAL-G4) ”Accreditation for Chemical Laboratories”**
- **EA-4/10 (EAL-G18) ”Accreditation for Microbiological Testing”**

5.4 Test and calibration methods and method validation - - Uncertainty of measurement

- If we perform any measurements we have to know how precise we are. The process is called estimation of uncertainty of measurements
- A calibration or testing laboratory shall be capable (covered by proper procedures) to perform estimation of uncertainty of measurements
- In some cases (depending if the nature of test method allows) testing laboratories can at least attempt to identify all the components (the most influential) of uncertainty and make reasonable estimation of measuring uncertainty
- In the case of calibration laboratories we usually speak about best measuring capability (expressed as uncertainty)

5.4 Test and calibration methods and method validation - - Control of data

All calculations and data transfer shall be adequately checked in a systematic manner

When computer or automated systems are used for acquisition, processing, recording, reporting, storage or retrieval of test/calibration results (data), the laboratory shall ensure that:

- **computer software developed by the user is documented and validated before use**
- **procedures for protecting data are established and implemented**
- **computers and automated systems are regularly maintained**

5.5 Equipment

- Laboratory shall have all equipment which is necessary to perform sampling, testing and calibration procedures according to the documented procedures
- Equipment used for testing/calibration shall be capable to achieve required accuracy and shall comply with specifications relevant to tests/calibrations performed
- Before the equipment is put into service it shall be calibrated or checked to verify that it meets foreseen specifications
- Equipment shall be used by authorised/trained staff and up-to date instructions for use and maintenance of equipment shall be available for use by appropriate staff

5.5 Equipment

The records of equipment shall include:

- the identity of the item of equipment and its software
- the manufacturer's name, type identification, and serial number or other unique identification
- checks that equipment complies with the specification
- the current location, where appropriate
- the manufacturer's instructions, if available, or reference to their location;
- dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration
- the maintenance plan, where appropriate, and maintenance carried out
- any damage, malfunction, modification or repair to the equipment

5.5 Equipment

- Storage, safe handling, transport, use and planned maintenance of the equipment shall be covered by appropriate procedures
- Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service
- It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure

5.5 Equipment

- Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified
- All equipment under the control of the laboratory and need to be calibrated shall be labelled to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due. The recalibration period shall be established on such way that ensures the reliable measuring results
- If laboratory lends the equipment, it shall ensure that equipment is checked before returned to the service
- For the calibration equipment it is not wise to use it for testing.

5.6 Measurement traceability

Calibration laboratories

- Calibration laboratories shall establish such procedures for calibration of their equipment that laboratory can ensure that calibrations and measurements are traceable to the International System of Units (SI).
- A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement.

5.6 Measurement traceability

Testing laboratories

- The same requirements regarding the traceability of calibrations as for calibration laboratories apply also for testing laboratories.
- The only deviation from this principle is allowed when the contribution from the calibration results contributes little to the total uncertainty of test results.

5.6 Measurement traceability

Reference standards

Reference standards shall be calibrated on such way that traceability to relevant primary standards is established. Reference standards shall be used only for calibration purposes.

Reference materials

Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

5.7 Sampling

- Laboratory shall establish appropriate sampling procedures (substances, materials, or products for subsequent testing or calibration)
- Sampling plans shall be based on appropriate statistical methods
- Laboratory shall ensure the procedures for recording relevant data and operations related to sampling process

5.8 Handling of test and calibration items

Laboratory shall have procedures:

- **for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the client**
- **for unambiguous system for identification of all test/calibration items for recording any damage on test/calibration item**
- **and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation**

5.8 Assuring the quality of test and calibration results

Laboratory can improve the quality of it's work trough:

- **regular use of certified reference materials and/or internal quality control using secondary reference materials**
- **participation in interlaboratory comparison or proficiency-testing programs**
- **replicate tests or calibrations using the same or different methods;**
- **retesting or recalibration of retained items**
- **correlation of results for different characteristics of an item**

5.8 Reporting results

Laboratory shall report results of tests/calibrations:

- **accurately**
- **clearly**
- **unambiguously and objectively**
- **and in accordance with any specific instructions in the test or calibration methods**

The usual form of reporting results is testing report or calibration certificate

5.8 Reporting 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**
- **unique identification of the test report / calibration certificate (such as serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report / calibration cert. and a clear identification of the end of the test report / calibration certif.**
- **the name and address of the client**
- **identification of the method used**
- **a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated**

5.8 Reporting results

- the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration
- reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results
- the test or calibration results with, where appropriate, the units of measurement
- the 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

5.8 Reporting results

Additional information in test reports:

- deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions
- where relevant, a statement of compliance/non-compliance with requirements and/or specifications
- where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a client's instruction so requires, or when the uncertainty affects compliance to a specification limit;
- where appropriate and needed, opinions and interpretations (see 5.10.5);
- additional information which may be required by specific methods, clients or groups of clients.

5.8 Reporting results

Additional information in test reports including sampling:

- the date of sampling
- unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate)
- the location of sampling, including any diagrams, sketches or photos
- a reference to the sampling plan and procedures used
- details of any environmental conditions during sampling that may affect the interpretation of the test results
- any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned

5.8 Reporting results

Additional information on calibration certificates:

- the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results
- the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof
- evidence that the measurements are traceable

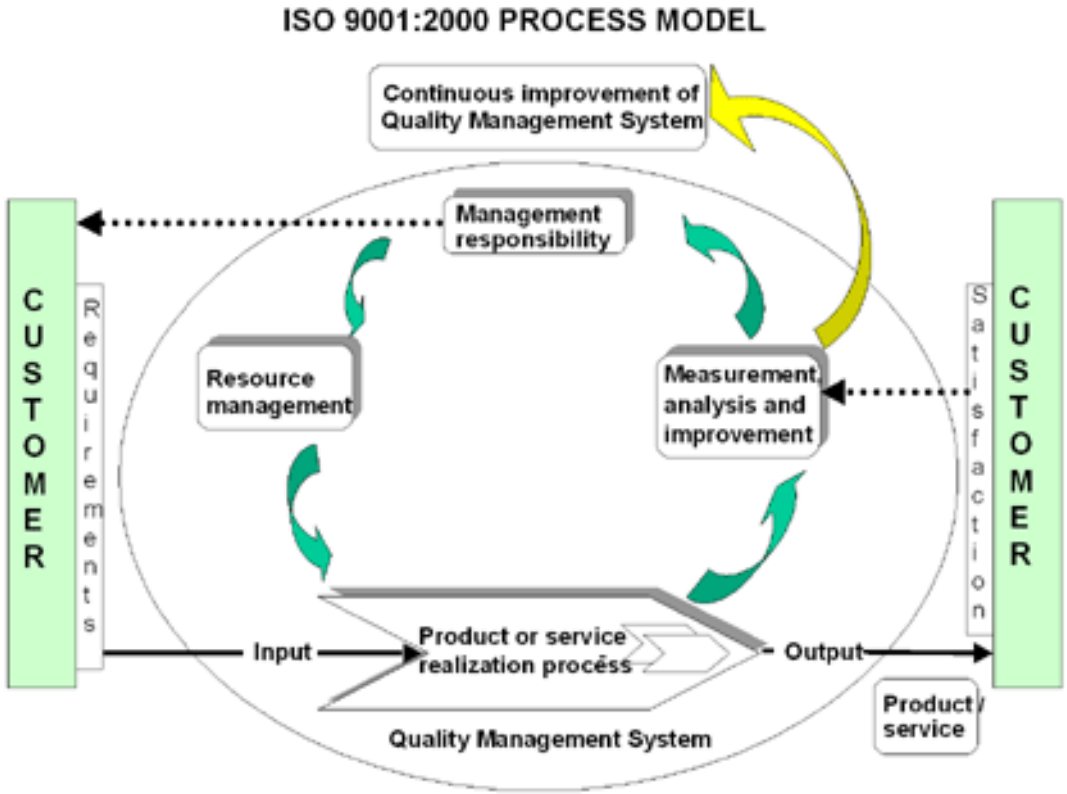
5.8 Reporting results

- Opinions and interpretations shall be clearly identified in test report and laboratory shall document (state) the basis for opinions and interpretations
- When the test report includes results from subcontractors, these results shall be clearly identified

Quality system in a laboratory

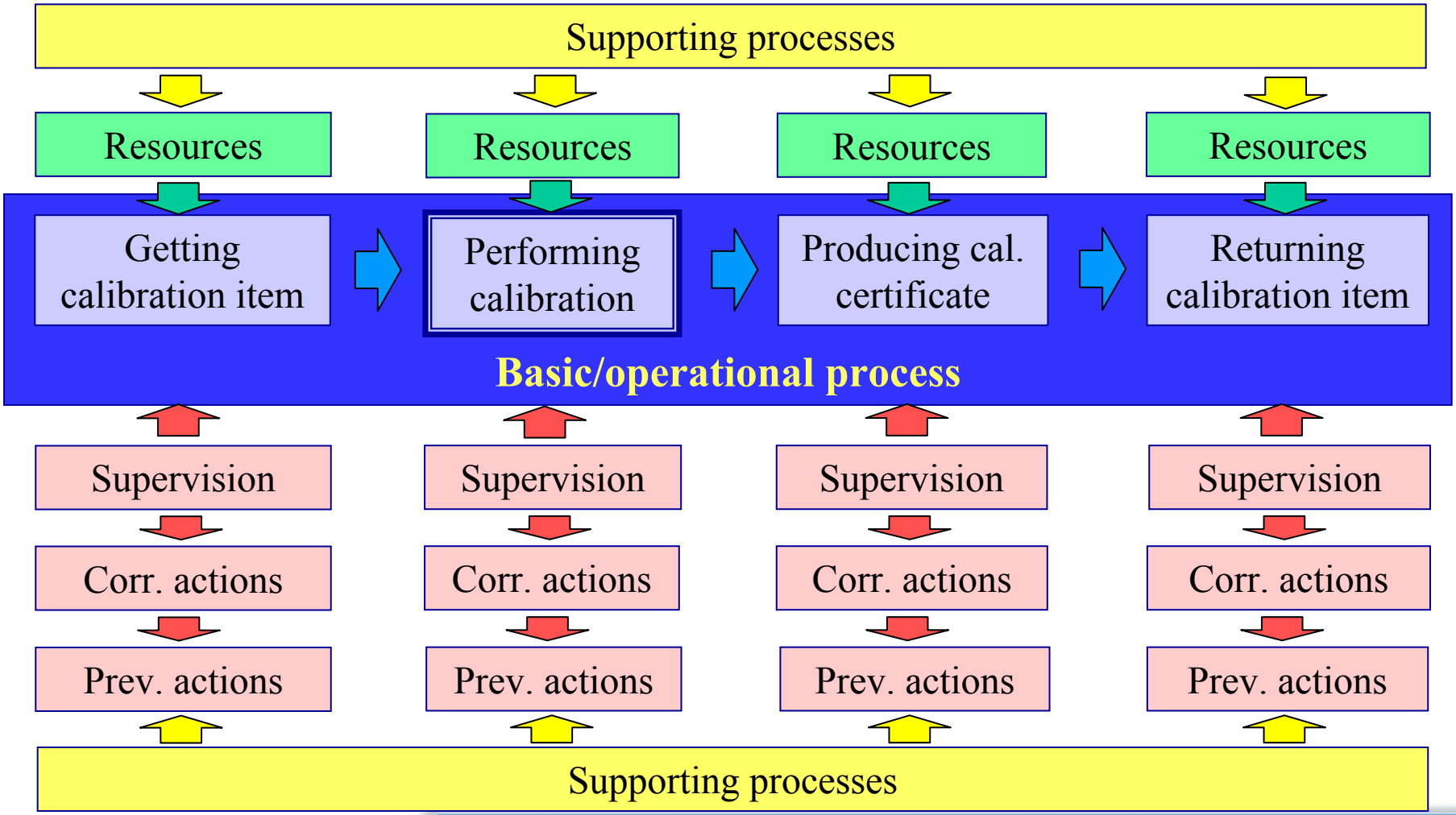
Process approach

Deming circle



Quality system in a laboratory

Process approach



Quality system in a laboratory

Process approach

Resources for performing calibration

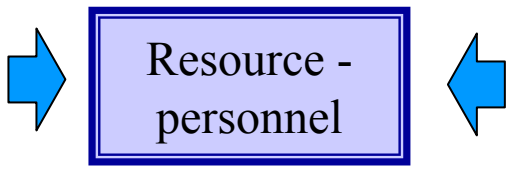
- Personnel
- Equipment (measuring instruments, auxiliary equipment)
- Reference standards/materials
- Premises
- Procedure
- External documents (standards, guidelines, …)
- Auxiliary means (computer, cleaning means, special cloths, paper, …)

Quality system in a laboratory

Process approach

Requirements (quality, standard):

- Qualification
- Supervision
- Training
- Authorisation
- Responsibilities



Processes:

- Selection process
- Supervision process
- Training process
- Management processes (dedicating responsibilities, ..)

Quality system in a laboratory

Introduction of a quality system

Determining quality policy
Responsibility: Top management

Determining organisation scheme
Responsibility: Top management

Assigning competences and responsibilities
Responsibility: Top management

Appointing quality manager
Responsibility: Top management

Appointing quality group
Responsibility: Quality manager

Quality system in a laboratory

Determining processes / activities
Responsibility: Quality manager, technical managers

Approving processes / activities
Responsibility: Top management

Assigning tasks for building quality system
Responsibility: Quality manager

Writing quality manual and supporting documentation
Responsibility: Quality manager

Approving quality system documents
Responsibility: Top management

Quality system in a laboratory

Acquainting all employees with the quality manual
Responsibility: Quality manager

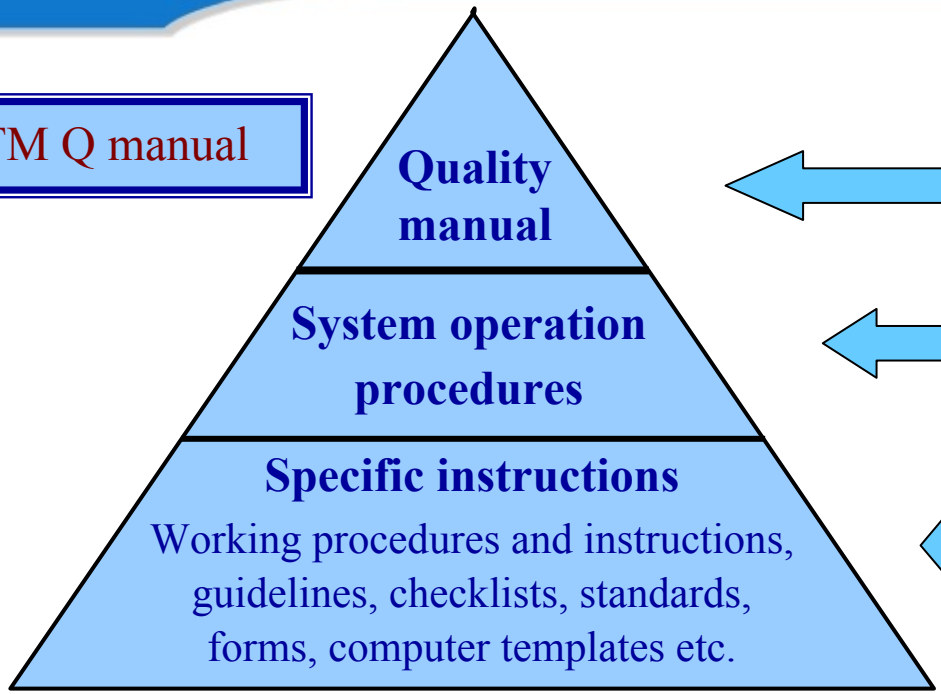
Quality system start
Responsibility: Top management

First quality system review (after approx. 6 months)
Responsibility: Top management

Corrective actions
Responsibility: Top management

Quality system operation and supervision
Responsibility: Quality manager

Quality system in a laboratory



Description of the entire system – policy, general principles

Definition of organisational flows related to quality

Detailed instructions and assistant forms and documents (for specific activity)

Documentation about technical competence

Records

Quality system in a laboratory

Purpose of the quality manual

- Introduction of the quality policy, procedures and organisation requirements
- Description and documentation of the quality system
- Improvement of the operation supervision and easier quality assurance
- Documentation of procedures for quality system monitoring (audits and management reviews)
- Assuring quality system continuity and requirements under changing conditions
- Education of personnel in the fields of quality system requirements and methods for fulfilling those requirements
- Promotion of the quality system for external purposes, like e.g. proving conformance with ISO 9001 requirements
- Prove of the quality system conformance with contractual quality requirements.

Quality system in a laboratory

Quality manual contents

- Information of revisions and issues
- Title and field of use
- Table of contents
- Introduction with presentation of the laboratory and the manual
- Quality policy and goals
- Description of organisation, competences and legal entity of the laboratory
- Description of the quality system elements and reference to documents with procedures for quality system operation
- Procedures (or reference to procedures) for quality system supervision (audits, management reviews, ..)
- Chapter with definitions and acronyms if applicable
- List of supporting documents and chapters to which the manual is refering

Quality system in a laboratory

Calibration procedure contents (sample)

- INTRODUCTION
- MEASURING EQUIPMENT
- RECEIPT
- CLEANING
- THERMAL STABILISATION
- CALIBRATION
  - Visual inspection
  - Functional check
  - Measurement of deviations
- EVALUATION OF MEASURING RESULTS
- DOCUMENTATION
- PROTECTION
- UNCERTAINTY
- TRACEABILITY
- LITERATURE

Vernier calliper

Mathematical model of measurement

Measurement result (calibrated deviation) is expressed by the equation:

$$e = \ell_i \cdot (1+\alpha_m \cdot \theta_m) - \ell_e \cdot (1+\alpha_e \cdot \theta_e) + d_F$$

where:

- e - deviation (calibration result) at 20 °C
- ℓ_i - indicated value on the vernier calliper
- α_m - linear thermal expansion coefficient of the vernier calliper
- θ_m - temperature deviation of the calliper from 20 °C
- ℓ_e - calibrated gauge block length at 20°C
- α_e - linear thermal expansion coefficient of the gauge block
- θ_e - temperature deviation of the gauge block from 20°C
- d_F - difference of deformation due to measuring force in calibration and in measurement (assumed to be 0)

Vernier calliper

If new quantities are introduced (because temperatures of the instrument and of the gauge block are dependent):

$$\delta\theta = \theta_m - \theta_e$$

$$\delta\alpha = \alpha_m - \alpha_e$$

the equation gets the following form:

$$e = \ell_i \cdot (1+\alpha_m \cdot \theta_e + \alpha_m \cdot \delta\theta) - \ell_e \cdot (1+\alpha_m \cdot \theta_e - \delta\alpha \cdot \theta_e) + d_F$$

Vernier calliper

Standard uncertainties of the input quantity estimates and combined standard uncertainty of measurement

The equation for calculating combined standard uncertainty (GUM) has in our case the following form:

$$u_c^2(e) = c_{\ell i}^2 u^2(\ell_i) + c_{\alpha m}^2 u^2(\alpha_m) + c_{\theta e}^2 u^2(\theta_e) + c_{\delta\theta}^2 u^2(\delta\theta) + c_{\ell e}^2 u^2(\ell_e) + + c_{\delta\alpha}^2 u^2(\delta\alpha) + c_{dF}^2 u^2(d_F)$$

where c_i are partial derivatives of function e:

$$c_{\ell i} = \partial L/\partial \ell_i = 1+\alpha_m\cdot\theta_e+\alpha_m\cdot\delta\theta \approx 1;\ \text{if } \theta_{emax} = \pm 1°C$$
$$c_{\alpha m} = \partial L/\partial \alpha_m = \theta_e\cdot(\ell_i - \ell_e) + l_i\cdot\delta\theta \approx \ell_i\cdot\delta\theta$$
$$c_{\theta e} = \partial f/\partial \theta_e = \alpha_m\cdot(\ell_i - \ell_e) + \ell_e\cdot\delta\alpha \approx \ell_e\cdot\delta\alpha$$
$$c_{\delta\theta} = \partial L/\partial \delta\theta = \alpha_m\cdot\ell_i$$
$$c_{\ell e} = \partial L/\partial \ell_e = -(1 + \alpha_m\cdot\theta_e + \delta\alpha\cdot\theta_e) \approx -1;\ \text{if } \theta_{emax} = \pm 1°C$$
$$c_{\delta\alpha} = \partial L/\partial \delta\alpha = -\ell_e\cdot\theta_e$$
$$c_{dF} = \partial L/\partial d_F = 1$$

Vernier calliper

Evaluation (estimation) of standard uncertainties of influence quantities for the equipment, procedure and conditions in the laboratory (LTM)

a) Uncertainty of reading $u(\ell_i)$

The biggest possible reading deviation for digital display is **±5 µm**, for nonius 0,02 mm is **±13 µm** (experiment), for nonius 0,05 is **±16 µm** (experiment), and for nonius 0,1 mm **±25 µm** (experiment). Uncertainties at assumed rectangular distribution are:

$u(l_i) = (5\mu m)/\sqrt{3} = 2{,}9\ \mu m$ **for digital display**

$u(l_i) = (13\mu m)/\sqrt{3} = 7{,}5\ \mu m$ **for nonius 0,02 mm**

$u(l_i) = (16\mu m)/\sqrt{3} = 9{,}5\ \mu m$ **for nonius 0,05 mm**

$u(l_i) = (25\mu m)/\sqrt{3} = 14{,}4\ \mu m$ **for nonius 0,1 mm**

Vernier calliper

b) Uncertainty of the thermal expansion coefficient $u(\alpha_m)$

Interval $\pm 1 \cdot 10^{-6}\ °C^{-1}$ is defined based on the data from a handbook.

Uncertainty at assumed rectangular distribution is:

$$u(\alpha_m) = (1 \cdot 10^{-6} °C^{-1}) / \sqrt{3} = 0{,}58\ °C^{-1}$$

c) Uncertainty of gauge block temperature deviation $u(\theta_e)$

The biggest temperature deviation in the room is **±1 °C**. Uncertainty at assumed normal distribution (**k = 2**) is:

$u(\theta_e) =$ **0,5 °C**

d) Uncertainty of temperature difference $u(\delta\theta)$

Assumed biggest temperature difference is **±1 °C**. Uncertainty at assumed normal distribution (**k = 2**) is:

$u(\delta\theta) = 1/2 =$ **0,5 °C**

Vernier calliper

e) Uncertainty of gauge block calibration $u(\ell_e)$

Calibration certificate states the following expanded uncertainty:

$U(\ell_e) = 0{,}1\ \mu m + 1 \cdot 10^{-6} \cdot \ell\ ;\ k = 2$

Standard uncertainty is then:

$u(\ell_e) = U(\ell_e)/2 = \mathbf{0{,}05\ \mu m + 0{,}5 \cdot 10^{-6} \cdot \ell}$

f) Uncertainty of the thermal expansion coefficient difference $u(\delta\alpha)$

Supposed limit is $\pm 2 \cdot 10^{-6}\ °C^{-1}$. Uncertainty at assumed rectangular distribution is:

$$u(\delta\alpha) = (2 \cdot 10^{-6}\ °C^{-1}) / \sqrt{3} = 1{,}2 \cdot 10^{-6}\ °C^{-1}$$

Vernier calliper

g) Uncertainty of supposed difference of deformation due to measuring force $u(d_F)$

Supposed deformation difference is 0. In fact, the forces in calibration and in measurement are not equal. Therefore we suppose (based on experience) possible difference of maximum 3 μm. Uncertainty at assumed rectangular distribution is:

$$u(d_F) = 3\mu m / \sqrt{3} = 1{,}73 \ \mu m$$

Examples of calculating uncertainty in calibration

Vernier calliper

Uncertainty budget

Standard uncertainties of the input value estimates on the lower meas. range limit (1 mm)

Veličina X_i	Ocenjena vrednost	Standardna negotovost	Porazdelitev	Koeficient občutljivosti	Prispevek negotovosti
l_i	1 mm	2,9 µm - digitalno 0,01 mm 7,5 µm - nonij 0,02 mm 9,5 µm - nonij 0,05 mm 14,4 µm - nonij 0,1 mm	pravokotna	1	2,9 µm 7,5 µm 9,5 µm 14,4 µm
α_m	11.10^{-6}°C^{-1}	$0,58.10^{-6}$°C^{-1}	pravokotna	10^3 µm°C	zanemarljivo
θ_e	0°C	0,5°C	normalna	0,002 µm°C^{-1}	zanemarljivo
$\delta\theta$	0°C	0,5°C	normalna	0,001 µm°C^{-1}	zanemarljivo
l_e	1 mm	0,05 µm	normalna	1	zanemarljivo
$\delta\alpha$	0 °C^{-1}	$1,2.10^{-6}$°C^{-1}	pravokotna	-10^3 µm°C	zanemarljivo
d_F	0	1,73 µm	pravokotna	1	1,73 µm
				Skupno:	3,4 µm 7,7 µm 9,7 µm 14,5 µm

Examples of calculating uncertainty in calibration

Vernier calliper

Standard uncertainties of the input value estimates on the upper meas. range limit (150 mm)

Veličina X_i	Ocenjena vrednost	Standardna negotovost	Porazdelitev	Koeficient občutljivosti	Prispevek negotovosti
l_i	150 mm	2,9 µm - digitalno 0,01 mm 7,5 µm - nonij 0,02 mm 9,5 µm - nonij 0,05 mm 14,4 µm - nonij 0,1 mm	pravokotna	1	2,9 µm 7,5 µm 9,5 µm 14,4 µm
α_m	$11 \cdot 10^{-6} °C^{-1}$	$0,58 \cdot 10^{-6} °C^{-1}$	pravokotna	10^6 µm°C	0,18 µm
θ_e	0°C	0,5°C	normalna	0,3 µm°C^{-1}	0,15 µm
$\delta\theta$	0°C	0,5°C	normalna	1,65 µm°C^{-1}	0,8 µm
l_e	150 mm	0,55 µm	normalna	1	0,55 µm
$\delta\alpha$	0 °C^{-1}	$1,2 \cdot 10^{-6} °C^{-1}$	pravokotna	$-1,5 \cdot 10^5$ µm°C	0,18 µm
d_F	0	1,73 µm	pravokotna	1	1,73 µm
				Skupno:	3,6 µm 7,8 µm 9,7 µm 14,6 µm

Examples of calculating uncertainty in calibration

Vernier calliper

Linearized standard uncertainties for the whole measuring range, based on the values for the lower and upper measuring range limits, are:

$u = 3{,}4\ \mu m + 1{,}4 \cdot 10^{-6} \cdot \ell$ (for digital display)

$u = 7{,}7\ \mu m + 1{,}3 \cdot 10^{-6} \cdot \ell$ (for nonius 0,02 mm)

$u = 9{,}7\ \mu m + 1{,}3 \cdot 10^{-6} \cdot \ell$ (for nonius 0,05 mm)

$u = 14{,}5\ \mu m + 1{,}3 \cdot 10^{-6} \cdot \ell$ (for nonius 0,1 mm)

Vernier calliper

Expanded uncertainty of measurement

Coverage factor k=2 is used in accordance with EA 4/02. Expanded uncertainty (rounded up) is:

$U = 7\ \mu m + 3 \cdot 10^{-6} \cdot \ell$ (for digital display)

$U = 15{,}5\ \mu m + 3 \cdot 10^{-6} \cdot \ell$ (for nonius 0,02 mm)

$U = 20\ \mu m + 3 \cdot 10^{-6} \cdot \ell$ (for nonius 0,05 mm)

$U = 29\ \mu m + 3 \cdot 10^{-6} \cdot \ell$ (for nonius 0,1 mm)

Dial gauge

Mathematical model of measurement

Measurement result (calibrated deviation) is expressed by the equation:

$$e = \ell_i \cdot (1+\alpha_m \cdot \theta_m) - \ell_e \cdot (1+\alpha_e \cdot \theta_e)$$

where:

- e - deviation (calibration result) at 20 °C
- ℓ_i - indicated value on the dial gauge
- α_m - linear thermal expansion coefficient of the dial gauge
- θ_m - temperature deviation of the dial gauge from 20 °C
- ℓ_e - indicated value on the calibration device
- α_e - linear thermal expansion coefficient of the calibration device
- θ_e - temperature deviation of the calibration device from 20°C

Dial gauge

If new quantities are introduced (because temperatures of the instrument and of the dial gauge are dependent):

$$\delta\theta = \theta_m - \theta_e$$

$$\delta\alpha = \alpha_m - \alpha_e$$

the equation gets the following form:

$$e = \ell_i \cdot (1+\alpha_m \cdot \theta_e + \alpha_m \cdot \delta\theta) - \ell_e \cdot (1+\alpha_m \cdot \theta_e - \delta\alpha \cdot \theta_e)$$

Dial gauge

Standard uncertainties of the input quantity estimates and combined standard uncertainty of measurement

The equation for calculating combined standard uncertainty (GUM) has in our case the following form:

$$u_c^2(e) = c_{\ell i}^2 u^2(\ell_i) + c_{\alpha m}^2 u^2(\alpha_m) + c_{\theta e}^2 u^2(\theta_e) + c_{\delta\theta}^2 u^2(\delta\theta) + c_{\ell e}^2 u^2(\ell_e) + c_{\delta\alpha}^2 u^2(\delta\alpha)$$

where ci are partial derivatives of function e:

$$c_{\ell i} = \partial L/\partial \ell_i = 1+\alpha_m\cdot\theta_e+\alpha_m\cdot\delta\theta \approx 1;\ \text{če je } \theta_{emax} = \pm 1°C$$

$$c_{\alpha m} = \partial L/\partial \alpha_m = \theta_e\cdot(\ell_i - \ell_e) + l_i\cdot\delta\theta \approx \ell_i\cdot\delta\theta$$

$$c_{\theta e} = \partial f/\partial \theta_e = \alpha_m\cdot(\ell_i - \ell_e) + \ell_e\cdot\delta\alpha \approx \ell_e\cdot\delta\alpha$$

$$c_{\delta\theta} = \partial L/\partial \delta\theta = \alpha_m\cdot\ell_i$$

$$c_{\ell e} = \partial L/\partial \ell_e = -(1 + \alpha_m\cdot\theta_e + \delta\alpha\cdot\theta_e) \approx -1;\ \text{če je } \theta_{emax} = \pm 1°C$$

$$c_{\delta\alpha} = \partial L/\partial \delta\alpha = -\ell_e\cdot\theta_e$$

Dial gauge

Evaluation (estimation) of standard uncertainties of influence quantities for the equipment, procedure and conditions in the laboratory (LTM)

a) Uncertainty of dial gauge reading $u(\ell_i)$

The biggest possible reading deviation for digital display with resolution 0,01 mm is **±5 µm**, for digital display with resolution 0,001 mm is **±0,5 µm**, and for conventional scale **±2 µm**. Uncertainties at assumed rectangular distribution are:

$u(l_i) = (5\mu m)/\sqrt{3} = 2{,}9\ \mu m$ **for digital display with resolution 0,001 mm**

$u(l_i) = (0{,}5\ \mu m)/\sqrt{3} = 0{,}29\ \mu m$ **for digital display with resolution 0,001 mm**

$u(l_i) = (2\ \mu m)/\sqrt{3} = 1{,}15\ \mu m$ **for conventional scale**

Dial gauge

b) Uncertainty of the thermal expansion coefficient $u(\alpha_m)$

Interval $\pm 1 \cdot 10^{-6}\ °C^{-1}$ is defined based on the data from a handbook.

Uncertainty at assumed rectangular distribution is:

$$u(\alpha_m) = (1 \cdot 10^{-6} °C^{-1}) / \sqrt{3} = 0{,}58\ °C^{-1}$$

c) Uncertainty of calibration instrument temperature deviation $u(\theta_e)$

The biggest temperature deviation in the room is **±1 °C**. Uncertainty at assumed normal distribution (**k = 2**) is:

$$u(\theta_e) = \mathbf{0{,}5\ °C}$$

d) Uncertainty of temperature difference $u(\delta\theta)$

Assumed biggest temperature difference is **±0,2 °C**. Uncertainty at assumed normal distribution (**k = 2**) is:

$$u(\delta\theta) = 1/2 = \mathbf{0{,}1\ °C}$$

Dial gauge

b) Negotovost linearne temperaturne razteznosti $u(\alpha_m)$

Interval $\pm 1 \cdot 10^{-6}\ °C^{-1}$ je definiran na osnovi podatkov iz priročnika.

Predpostavimo pravokotno porazdelitev, zato velja:

$$u(\alpha_m) = (1 \cdot 10^{-6} °C^{-1}) / \sqrt{3} = 0{,}58\ °C^{-1}$$

c) Negotovost temperature $u(\theta_e)$

Največji odstopek temperature v prostoru je **±1 °C**. Predpostavimo normalno porazdelitev in nivo zaupanja **k = 2**, zato velja:

$$u(\theta_e) = \mathbf{0{,}5\ °C}$$

d) Negotovost temperaturne razlike $u(\delta\theta)$

Predpostavimo največjo temperaturno razliko **±0,2 °C**. Predpostavimo normalno porazdelitev in nivo zaupanja k = 2, zato velja:

$$u(\delta\theta) = 0{,}2/2 = \mathbf{0{,}1\ °C}$$

Dial gauge

e) Uncertainty of the calibration instrument indication u(ℓ$_e$)

Calibration certificate states the following expanded uncertainty:

$U(\ell_e) = \mathbf{0{,}6\ \mu m + 2{,}5 \cdot 10^{-6} \cdot \ell}$; $k = 2$

Standard uncertainty is then:

$u(\ell_e) = \mathbf{U(\ell_e)/2 = 0{,}3\ \mu m + 1{,}25 \cdot 10^{-6} \cdot \ell}$

f) Uncertainty of the thermal expansion coefficient difference u(δα)

Supposed limit is $\pm 2 \cdot 10^{-6}\ °C^{-1}$. Uncertainty at assumed rectangular distribution is:

$$u(\delta\alpha) = (2 \cdot 10^{-6}\ °C^{-1}) / \sqrt{3} = 1{,}2 \cdot 10^{-6}\ °C^{-1}$$

Dial gauge

Uncertainty budget

Standard uncertainties of the input value estimates on the lower measuring range limit

Veličina X_i	Ocenjena vrednost	Standardna negotovost	Porazdelitev	Koeficient občutljivosti	Prispevek negotovosti
l_i	0,001 mm	0,29 µm - digitalno 0,001 mm 2,9 µm - digitalno 0,01 mm 1,15 µm – klasična (kazalec)	pravokotna	1	0,29 µm 2,9 µm 1,15 µm
α_m	$11 \cdot 10^{-6} °C^{-1}$	$0,58 \cdot 10^{-6} °C^{-1}$	pravokotna	0,2 µm°C	zanemarljivo
θ_e	0°C	0,5°C	normalna	$2 \cdot 10^{-6}$ µm°C^{-1}	zanemarljivo
$\delta\theta$	0°C	0,1°C	normalna	$11 \cdot 10^{-6}$ µm°C^{-1}	zanemarljivo
l_e	0,001 mm	0,3 µm	normalna	1	0,3 µm
$\delta\alpha$	0 °C^{-1}	$1,2 \cdot 10^{-6} °C^{-1}$	pravokotna	1 µm°C	zanemarljivo
				Skupno:	0,417 µm 2,915 µm 1,188 µm

Examples of calculating uncertainty in calibration

Dial gauge

Standard uncertainties of the input value estimates on the upper measuring range limit

Veličina X_i	Ocenjena vrednost	Standardna negotovost	Porazdelitev	Koeficient občutljivosti	Prispevek negotovosti
l_i	10 mm	0,29 µm - digitalno 0,001 mm 2,9 µm - digitalno 0,01 mm 1,15 µm – klasična (kazalec)	pravokotna	1	0,29 µm 2,9 µm 1,15 µm
α_m	$11 \cdot 10^{-6} °C^{-1}$	$0,58 \cdot 10^{-6} °C^{-1}$	pravokotna	$0,2 \cdot 10^{4}$ µm°C	zanemarljivo
θ_e	0°C	0,5°C	normalna	$2 \cdot 10^{-2}$ µm°C^{-1}	0,01 µm
$\delta\theta$	0°C	0,1°C	normalna	0,11 µm°C^{-1}	0,01 µm
l_e	10 mm	0,31 µm	normalna	1	0,31 µm
$\delta\alpha$	0 °C^{-1}	$1,2 \cdot 10^{-6} °C^{-1}$	pravokotna	-10^{4} µm°C	-0,01 µm
				Skupno:	0,425 µm 2,917 µm 1,191 µm

Examples of calculating uncertainty in calibration

Dial gauge

Linearized standard uncertainties for the whole measuring range, based on the values for the lower and upper measuring range limits, are:

$u = \mathbf{0{,}42\ \mu m + 2{,}1 \cdot 10^{-6} \cdot \ell}$ (for digital display with resolution 0,001 mm)

$u = \mathbf{2{,}91\ \mu m + 2{,}1 \cdot 10^{-6} \cdot \ell}$ (for digital display with resolution 0,01 mm)

$u = \mathbf{1{,}19\ \mu m + 2{,}1 \cdot 10^{-6} \cdot \ell}$ (for conventional scale)

Dial gauge

Expanded uncertainty of measurement

Coverage factor k=2 is used in accordance with EA 4/02. Expanded uncertainty (rounded up) is:

$U = 0{,}9\ \mu m + 4{,}5 \cdot 10^{-6} \cdot \ell$ (for digital display with resolution 0,001 mm)

$U = 6\ \mu m + 4{,}5 \cdot 10^{-6} \cdot \ell$ (for digital display with resolution 0,01 mm)

$U = 2{,}5\ \mu m + 4{,}5 \cdot 10^{-6} \cdot \ell$ (for conventional scale)