BAM
Bundesanstalt für Materialforschung und -prüfung

Sicherheit in Technik und Chemie

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RELACRE

CHALLENGES AND IMPACT OF THE ISO/IEC 17025 REVISION

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Overview

- International Standardization on general aspects of conformity assessment -
  Standard development in ISO CASCO
- Revision of ISO / IEC 17025 - Aims and main focus, timeline
- The impact of ISO 9001
- ISO / IEC 17025 in the context of other CASCO standards - The Common Elements
- Structure and process approach
- New clauses and important technical changes
- Summary and outlook

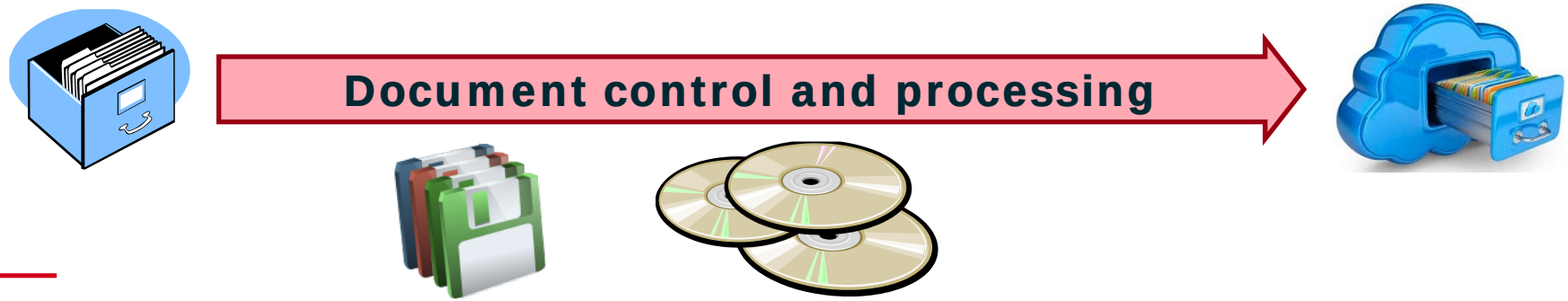
Standards for conformity assessment - The ISO CASCO Toolbox

ISO 9001:2015 - Impact on the ISO CASCO Toolbox

- **New structure:** High Level Structure and new terminology (e. g. products -> products and services)
- **Reinforcing the process-based approach:** Processes related to product quality and customer satisfaction more strongly emphasized
- **Strengthening the responsibility of leadership**
  - responsibility for effectiveness of the QMS
  - No obligation to formally appoint a quality manager, instead obligation to employ, instruct and support appropriate persons
- **Promoting the risk-based approach:** especially in the context of planning
  - Risk analysis and emergency planning as well as consideration/use of opportunities arising
- **Documented information**
  - Classic Quality Manual no further explicitly required
  - Sufficient flexibility in handling the documentation (electronic, paper-based, etc.)

ISO / IEC 17025 - Historical development

- Section 5 “Technical requirements” unchanged since 1999
- Have laboratories, testing and calibration laboratories changed?



Graphics: H. Schorn (I^2PS)

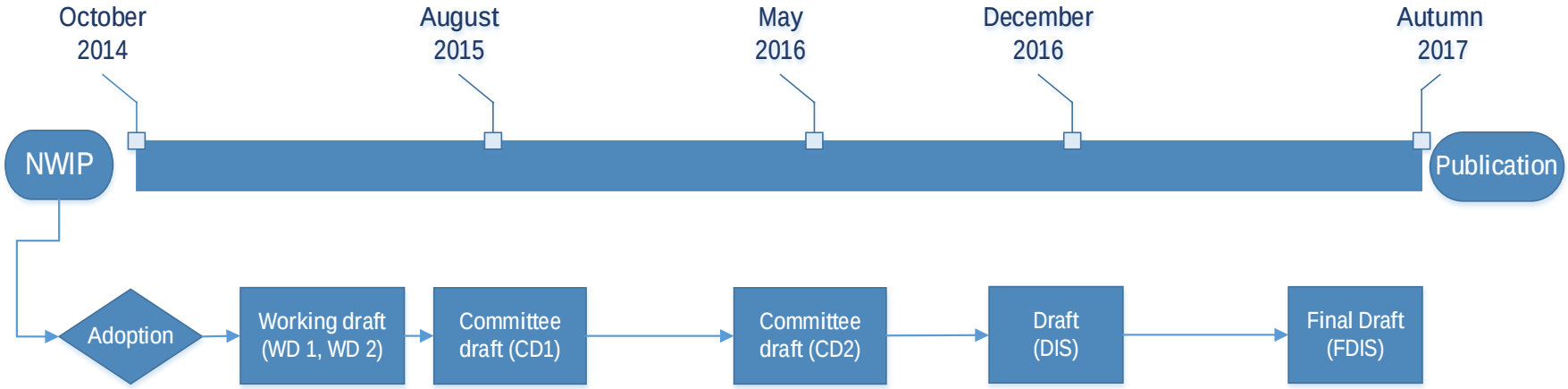
ISO / IEC 17025 - The New work item proposal

- Last review in 2010; text of the standard obsolete
- Further development of standardization on conformity assessment (structure, management requirements, etc.)

Proposal on revision :

- Submitted in summer 2014 (ILAC and SABS)
- Survey among ILAC members revealed the following result: 84% approval (DAkkS: rejection)
- Foundation of ISO CASCO WG 44
- Convenors: Warren Merkel (ILAC), Steve Sydney (SABS) , Heribert Schorn (IEC)
- ~140 experts reported
- high percentage from emerging and developing countries

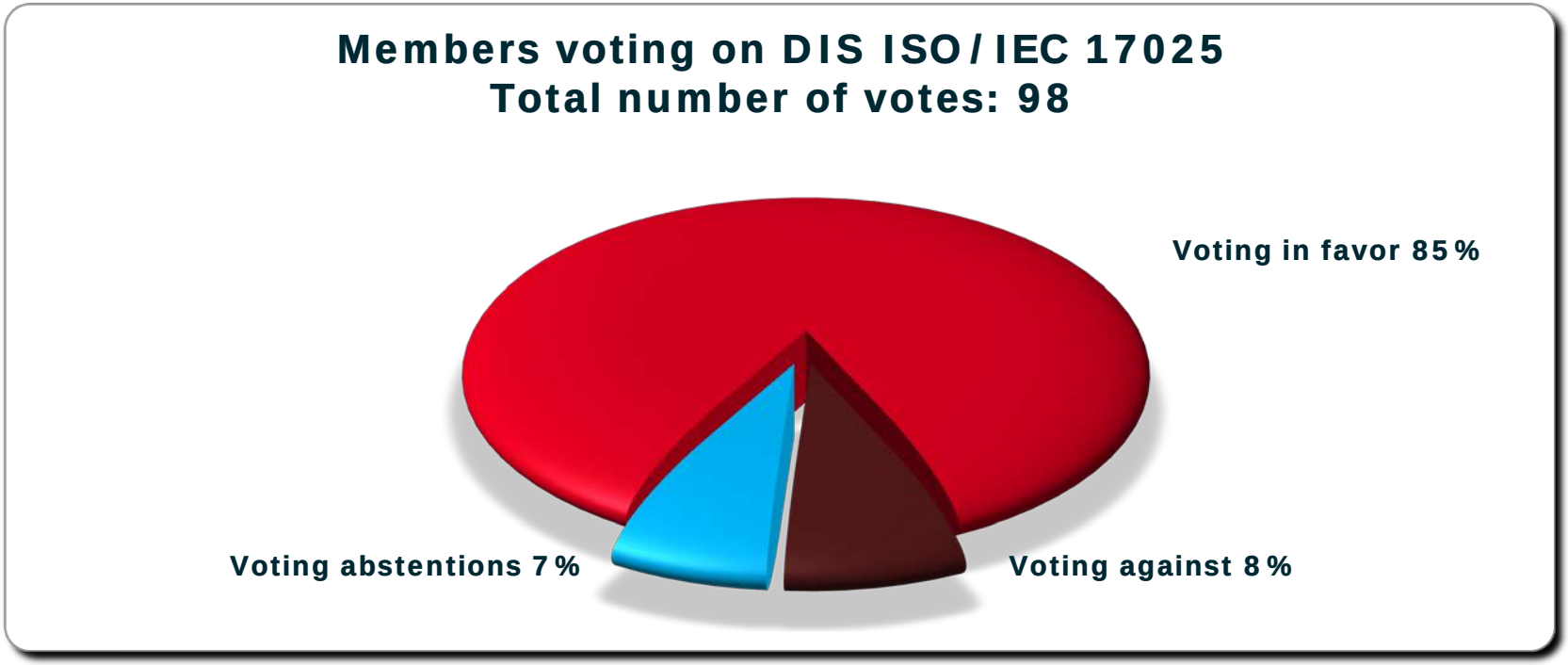
ISO / IEC 17025 – Timeline of Revision



- Commenting on the Draft International Standard (DIS) completed internationally
- Total time of the revision: 36 months
- FDIS is basically optional

Vote on ISO / IEC DIS 17025 and further action

- 98 countries (O- and P-Members) participated
- Proceeding to the next stage (DIS→ (FDIS) → IS)
- Voting results:



- More than 1800 comments will be discussed in July 2017

Impact of the new ISO 9001 on ISO / IEC 17025

- **Process-based approach and structure**
  - Separation of the requirements for structure, resources and testing or calibration process
  - split of the processes in core processes and supporting processes

    → difficult to handle and therefore not included

- **Risk-based thinking and acting**
  - In principle, nothing new
  - More flexibility in the process requirements and in the extent of documentation
  - Consider risks and opportunities

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The Common Elements

- Former ISO/PAS documents 17001-17005 written on an understandig of some common elements:
  - **impartiality,**
  - **confidentiality,**
  - **complaints and appeals,**
  - **use of management systems**
- intended for use by ISO/CASCO WGs in the development of ISO/CASCO standards
- **two categories of requirements:**
  - obligatory text: element has to be addressed, without modification, except for substitution of more specific terms
  - recommended text: working groups (WGs) may use if they wished to have a greater degree of specification on the particular topic
  - general, structural and resource requirements

Requirements for management systems (MS)

- ISO/CASCO working groups shall not write MS requirements that contradict these established requirements where they exist (e. g. ISO 9001, ISO 14001)
- MS is an internal mechanism to assure consistent fulfilment of requirements
- Bodies that choose to have a QMS that fulfils all of the requirements of ISO 9001 shall gain benefit from this fulfilment (no conflicts!)

Options A und B

Option A: minimum MS requirements shall be addressed in the standard

Option B: MS, in accordance with ISO 9001 that is capable of supporting/demonstrating the consistent fulfilment of the requirements of clauses 4 to 7 of ISO/IEC 17025

Implementation of COMMON ELEMENTS

Results of discussion in the working group:

- **No types of independency** A, B, C (such as for inspection bodies)
- More emphasis on the importance of impartiality
- **Appeals:**
  have no relevance in the daily laboratory work → deletion
- **Management system requirements:**

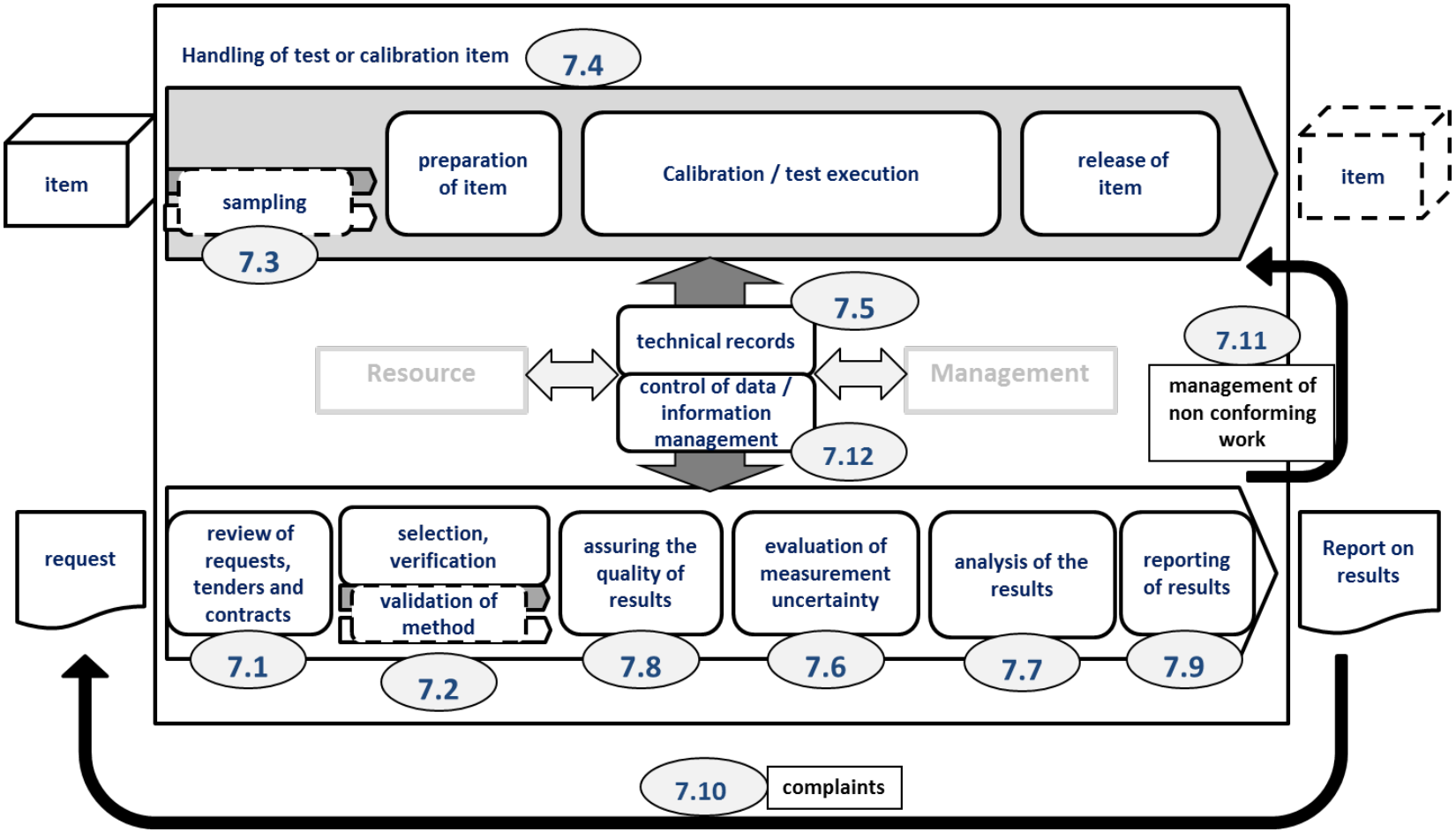
➡ Keep connection to the latest ISO 9001

➡ Consider principles of ISO 9001

➡ Options A and B have to be integrated

The new structure

The Process Approach



The Scope

- Basic requirements for the competence of all organizations that carry out **laboratory activities**
- Laboratory activities are :
  - tests
  - calibrations
  - sampling associated with subsequent calibration or testing
- Activities using standardized and non-standardized methods (in-house methods)
- Applicable to all forms of organizations, without distinction in terms of the organizational independence
- Independent of the size of the company
- Difference to ISO 9001: **technical competence requirements!**

Terms and Definitions – Changes

New Terms / Definitions:

- Laboratory
- Intralaboratory comparison
- Decision rule
- Impartiality

Obsolete Terms:

- Quality manager
- Technical manager
- Accomodation -> Facility
- Preventive actions -> risk and opportunities

Definition of Impartiality

impartiality
presence of objectivity

Note 1 to entry:
Objectivity is understood to mean that conflicts of interest do not exist, or are resolved so as not to adversely influence the activities of the laboratory.

Note 2 to entry:
Other terms that are useful in conveying the element of impartiality are freedom from conflicts of interest, freedom from bias, freedom from prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment and balance.

[SOURCE: ISO/IEC 17021-1:2015, 3.2]

Impartiality

(Obligatory wording, adapted to laboratories)

- The laboratory shall not allow commercial, financial or other pressures to compromise impartiality

- Laboratory activities shall be structured and managed so as to safeguard impartiality

- all personnel of the laboratory, either internal or external, that could influence the conformity assessment activities, shall act impartially

➡ Mandatory text for CASCO standards

Resource Requirements - Externally Provided Products and Services

Basic idea:

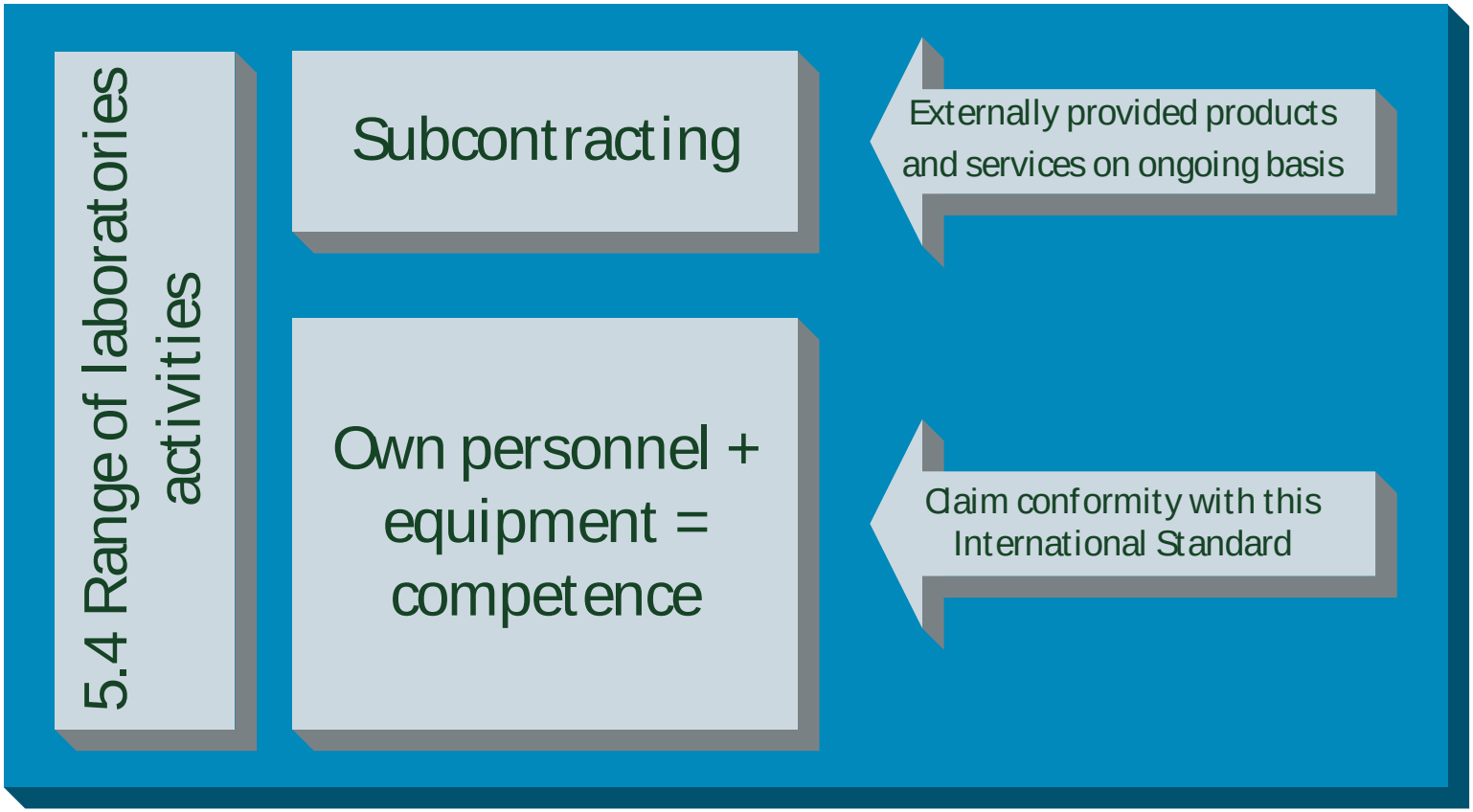
- Procurement and subcontracting are considered as externally provided services, in conformity with ISO 9001:2015
- No explicit reference to "subcontracting" anymore
- External testing and calibration services are basically treated like external services
- summarized in *one* section.

Therefore:

→ Requirements also for control of the ext. provider and communication to the customer (acceptance criteria are to be communicated to the customer)

→ Definition of criteria for reviewing external products and services is needed

Range of laboratory activities



Metrological traceability (I)

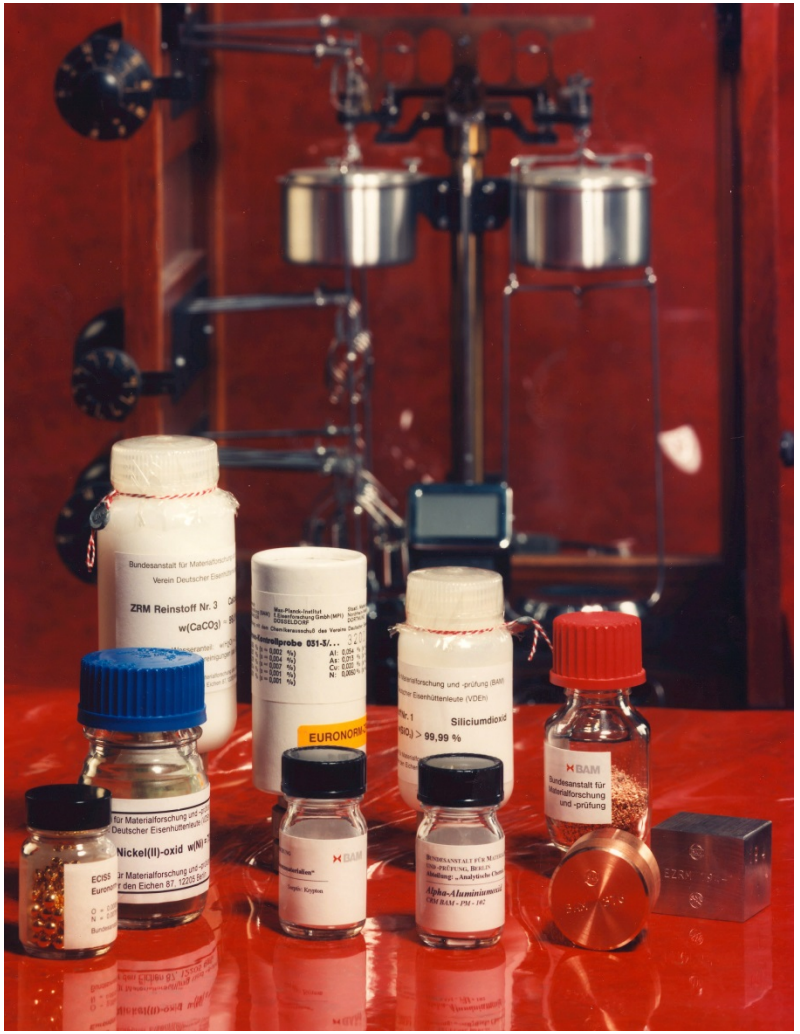
- Text held deliberately shorter than previously
- If technically possible → traceability to SI System through comparative measurement or use of certified RM
- If technically not possible → traceability to another suitable reference (certified RM, reference methods, consensus-based standards etc.)
- Provision of calibrations through competent actors
- Explanations in an informative Annex A

Metrological traceability (II)

Main points of Discussion:

- Use of internal calibration
- Text in the new ISO/IEC 17025 is more flexible and risk based
- Not everything is traceable to SI with a reasonable effort
- Consensus-based standards or reference methods shall be accepted by an authoritative body

  Example: Laboratory Medicine (JCTLM)



Process Requirements - Fundamental considerations

- Greater involvement of the customer, especially in case of changes during the process and when including external bodies

- Validation is always used in the context of „Validation of methods“

- **Much discussed question:**

  Can sampling be considered as a stand alone activity or should sampling activities always be associated with testing or calibration)?

Sampling as a stand alone activity (I)

Problem:

- "External samplers" are often no "laboratories" (separation from laboratory activity)
- Applicability of ISO/IEC 17025 outside the laboratory is questioned
- No international harmonization in accreditations

Discussion results so far:

- Scope of the standard: laboratories

  connection to the process in the laboratory that produces the results is important

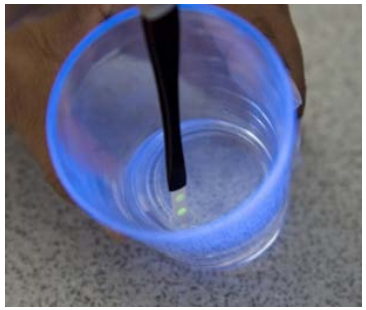
- Possibly separate standard for other organizations (special expertise)?

- Worldwide survey started in 2015 (as input for the working group)

Sampling as a stand alone activity (II)

Worldwide survey (09-11/2015):

- 80 countries and 8 organizations got involved
- Question: *"Should the revised ISO/IEC 17025 be explicitly applicable to organizations that perform sampling without the subsequent testing or calibration?"*
- Result: 41 x YES; 39 x NO



Justifications (excerpts):

Supported because :

- Sampling is essential for the whole testing and calibration process
- Applicability of ISO/IEC 17025 for sampling organizations needs to be improved
- ISO/IEC 17025 should be t h e standard for sampling

Rejected because :

- Sampling activity is not a conformity assessment
- Sampling is carried out also in connection with other conformity assessment activities (ISO/IEC 17020, ISO 17034, ISO/IEC 17065)
- Modification of the scope was no intention of the revision
- better an own standard

Requirements for sampling

- procedure shall address all factors to ensure the validity of results
- laboratory shall have a sampling plan and documented procedures for sampling
- Statement “analyzed as received”:

  → where the laboratory has not been responsible for the sampling stage

  → it shall be stated in the reports
- Record of relevant data:
  the laboratory shall detail all parameters
- Report shall include all information required to evaluate MU for subsequent testing or calibration

Statements of Conformity

- Laboratories often make statements on conformity of the results with certain specifications (compliance with limits, test passed (yes/no), etc.)
- Clear decision rules are to be communicated, documented and to be applied

Foto: © JrCasas

- When reported information associated with a calibration not includes measurement results and MU:

→ Addition of a statement required:
data is not intended to be used in support of the further dissemination of traceability (e. g. to calibrate another device)

Opinions and interpretations

- Opinions and interpretations shall be clearly identified
- Always keep reference to the result of the tested or calibrated item
- To be given only by authorized personnel (experience)
- Bases for the statements made have to be documented
- **Clear dissociation from assessments / evaluations in the context of inspections and product certifications has to be required**

Duck or rabbit?

Quality assurance of the results

- Laboratory shall have procedures for regular monitoring of the effectiveness of QA measures

- Selection of surveillance measures:
  - Use of reference materials
  - Intermediate checks
  - Repetition of tests and calibrations
  - Internal comparisons
  - Blind tests

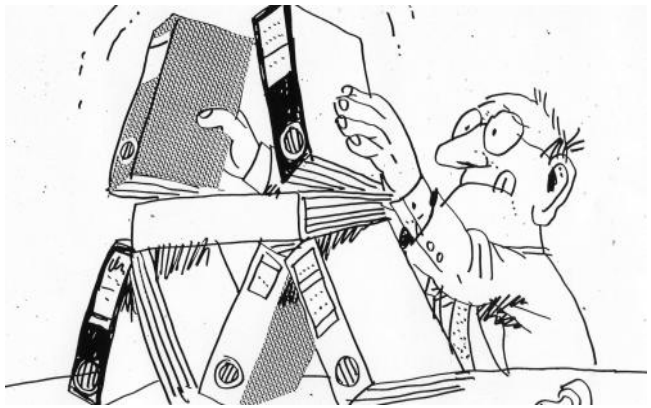
- Comparisons with other laboratories (e. g. PT and comparative tests): whenever available and suitable
- Results shall be analyzed to achieve improvements (interaction)

Reporting of results

- Content given by the customer shall be identified
- No "signature" required anymore (but an "identification" of a person authorising the report)
- Texts on "statement of conformity" now in this section together with "opinions and interpretations"

Documentation

- Determine necessary degree of documentation
- Stronger link to electronic data (data protection, monitoring changes, storage)
- Requirements for information management systems (interfaces, verification of functionality, etc.), target: data integrity
- Software changes:
  Modification of commercially available systems requires validation, authorization and documentation
- Technical records shall be maintained in a way which allows the repetition of laboratory activities



Management System Requirements

"Quality Management principles" are generally implemented:

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based decision making
- Relationship management

Minimum management system requirements of the laboratory (Option A):

- management system documentation
- control of management system documents
- control of records
- actions to address risks and opportunities
- improvement
- corrective action
- internal audits
- management review

Risk based approach

Options to Address:

- identifying and avoiding threats,
- taking risk in order to pursue an opportunity,
- eliminating the risk source,
- changing the likelihood or consequences,
- sharing the risk or retaining risk by informed decision

Consequences:

- „preventive measures“ no longer explicitly stated, because prevention is a core task of quality management and risk based approach
- No formalized risk management required
- Expression of measurement uncertainty as conceptual basis for dealing with the risk of a measurement result
- Accreditation: difficult to assess

Summary / Key points

- Scope: laboratory activities
- Laboratories that conform to this International Standard will also operate generally in accordance with the principles of ISO 9001
- Emphasis on "impartiality"
- Process orientation: Results of processes instead of process steps and how something needs to be done
- Emphasis on the competence of staff
- Risks and opportunities (no formal risk management!)
- IT: risk assessment, data integrity, data security, data protection, confidentiality, software and their validation
- "Decision rules" for passed/not passed {statement of conformity}

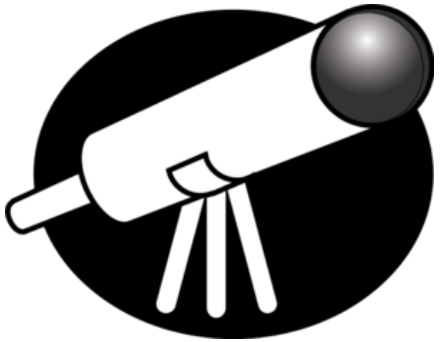
Outlook

Publication expected for autumn 2017

There is still some time left, but:

Substantial impact on many other standards:
more than 300 ISO standards reference to ISO/IEC 17025

- Transitional period for accredited laboratories is already determined by ILAC (3 years),
- Training will be needed
- Adaptation of many international (ILAC and EA) and national documents (accred. bodies) is to be expected
- Due to risk concepts, less "black and white" and more "grey" -> challenge for accreditors



Thank you
for your attention!