CZECH ACCREDITATION INSTITUTE

Experience of the Accreditation Body with the Transition to ISO/IEC 17025:2017

Pavel Nosek

Content

- Czech Accreditation Institute (CAI)
- International cooperation (European Accreditation – EA)
- Harmonized standard ISO/IEC 17025:2017
- Statistical overview of transition in Czechia

Czech Accreditation Institute (CAI)

- National Accreditation Body of the Czech Republic in accordance to Regulation No 765/2008 of the European Parliament and of the Council
- Full member of European co-operation for Accreditation (EA), ILAC and IAF
- Signatory of EA Multilateral Agreement (MLA) for:

Calibration, **Testing**, Medical analyses, Certification of products, Certification of management systems certification, Certification of persons, GHG, Inspection bodies and Proficiency testing providers

Significance of Accreditation

- Accreditation means **official recognition** that accredited body (CAB) **is competent perform specified activities**
- Accreditation Certificate and Annex
- Competent in this context means that is impartial, independent, has implemented quality management system (QMS) and is **professionally qualified**

Accreditation in the area of chemistry is one of the historically most frequent and is well supported by regulators as well as by industry in voluntary sector.

OSVĚDČENÍ O AKREDITACI

International Co-operation

- CAI as an EA member is a part of EA Laboratory Committee (LC)
- The EA LC is the floor where is possible to share knowlage and discuss any harmonization problems
- Other tasks of the EA LC:
  - Cooperation with stakeholders (Eurachem, Eurolab, ENFSI, EGOLF, …), sharing information with them
  - Contribution to EA documents
- CAI as a part of EA appreciate Eurachem effort especially at the field of Proficiency Testing

Revised harmonized standard ISO/IEC 17025:2017

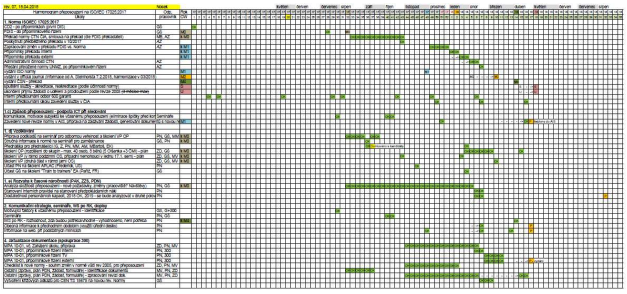
Expectations vs. Results

Revised harmonized standard ISO/IEC 17025:2017

- History and Goals for Revision
- Structural Changes
- Risk Based Approach
- Process Approach
- Option A&B
- Other changes

History of ISO/IEC 17025:2017 revision

- ISO decided that standard will be revised in October 2014 (WG ISO CASCO no 44)
- Four drafts and more then 6900 comments
- Standard **ISO/IEC 17025:2017 published 29th of November 2017**
- Czech version of standard ČSN EN ISO/IEC 17025:2018 published 1st of April 2018 and effective from 1st of May
- Harmonisation to Regulation (EC) No 765/2008 was done on 9th of March 2018
- After this date **AB's in EA could started to offer service according to "new 17025"**
- Original due date for the transition due to COVID-19 postponed on 01/06/2021



Goals for Revision of ISO/IEC 17025:2017

- New structure – harmonization with other 17000 standards and framework standards (ISO 9001), options A & B
- Generalization of requirements - simplification of the text of the standard through implementation of Risk Based Approach
- Introduction of process approach in laboratories
- Modernization – requirements on IT (data integrity, validation and verification of SWs, control of documentation by electronic means…) included
- Basic rules on Reporting statements of conformity

New Structure of ISO/IEC 17025:2017

Old structure with two main chapters:

4 for management system requirements

5 for technical requirement

The new one is very similar to ISO 9001

chapters:

4. **General requirements**
5. **Structural requiremnts**
6. **Resource requirements**
7. **Process requirements**
8. **Management system requirements**

Results:

- Positive – much more clear for users of other 17000 standards and no problems for all the others

Risk Based Approach in ISO/IEC 17025:2017

Introduction of ISO/IEC 17025:

This document requires the laboratory **to plan and implement actions to address risks and opportunities**. Addressing both risks and opportunities establishes a basis for **increasing the effectiveness** of the management system, achieving improved results and preventing negative effects. **The laboratory is responsible for deciding which risks and opportunities need to be addressed.**

Risk Based Approach in ISO/IEC 17025:2017

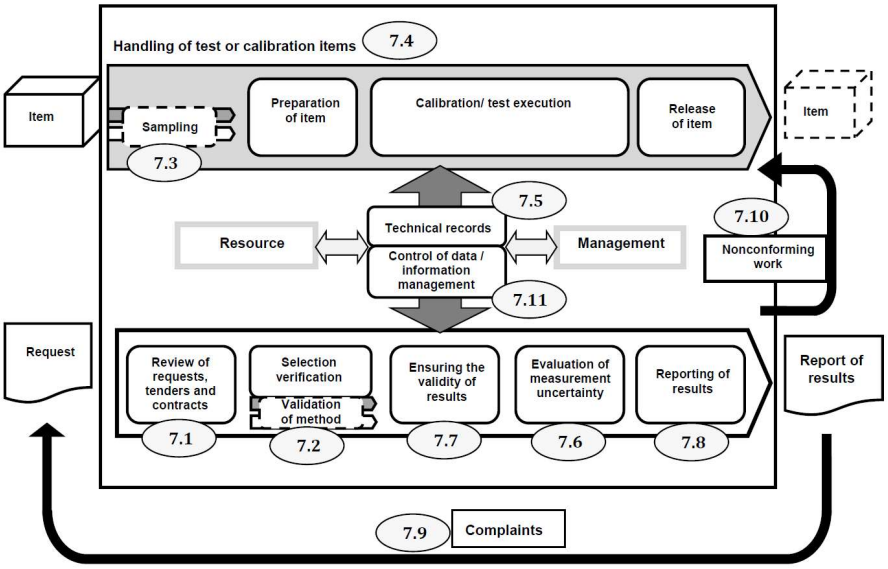
Results:

- Most of laboratories prepared acceptable system for dealing with risks
- Mostly on minimalistic level, just for the key parts of the standard
- Requirements of standard fullfilled but:

Overally little bit **missed opportunity** to modernize the management system, to put it on higher level

Process Approach in ISO/IEC 17025:2017

- Previous revision „criterial“ – specific requirements not linked to testing process
- Actually clearly directed according to main laboratory process “Testing”
- Appendix B shows basic process model of laboratory



Process Approach in ISO/IEC 17025:2017

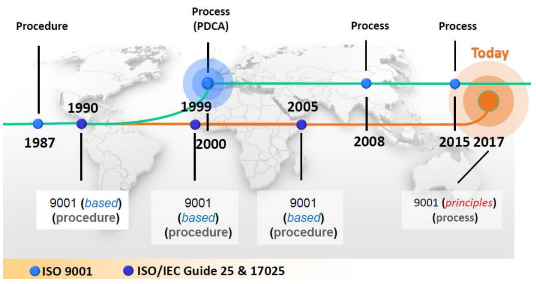
- Overally - **Processes in laboratories implemented**
- Mainly on basic level – often „just rearrangement“ of already described parts into right proces order
- The main process (chapter 7) is usually well defined – described in Quality manual (QM)
- New ways of description (e.g. Flow charts) rarely used
- Other processes mentioned just briefly – mostly in QM

- **Laboratories use the process approach in the very simplest way they need**

Option A & B in ISO/IEC 17025:2017

Old standard (2005):

- operate a quality management system, meets the principles of ISO 9001
- Annex A - nominal cross-references
- Covers technical competence requirements not covered by ISO 9001



New standard (2017):

- **Operate generally in accordance with the principles of ISO 9001**
- Introduces Option A&B - already known from other standards 17000
- Option A – direct implementation of whole ISO/IEC 17025
- Option B – offers to use a management system already implemented according to ISO 9001
  - **All requirements of ISO/IEC 17025 must be always fulfilled**

Option A & B in ISO/IEC 17025:2017

- Most of laboratories is running system based on Option A
- Expected state as already known from ISO/IEC 17020 and ISO/IEC 17065
- Limited use of Option B
- 8.1.3 Option B
  - A **laboratory that has established** and maintains a management system, in accordance with the requirements of ISO 9001,
- ISO 9001 is not primarily intended for laboratories – there is no reason to implement it in laboratory
- To use a suitable parts of „**company**" management system based on ISO 9001 is it possible also simply with Option A – and this is what laboratories use

Other changes in ISO/IEC 17025:2017

- Impartiality – Risk identification on an on-going basis (identical to ISO/IEC 17020)
  - Generally much more emphasis on impartiality
- Documentation of Management System
  - Generally very low emphasis on documentation
  - Missing „Policies“
- Minimal changes in technical requirements
- Ensuring the validity of results
  - More options as intralaboratory comparism, …

- Mostly well established and maintained
  - Labs focus on impart. risks

- Without significant changes
  - Labs like to keep policies

- Decision rules, Uncertainity samplin, etc.

- Well accepted
  - Labs use or plan to use a new tools

Other changes in ISO/IEC 17025:2017

- Modernization – requirements on IT (data integrity, validation and verif. of SWs, control of documentation by electronic means…) included
- Basic rules on Reporting statements of conformity – decision rules
- Customers data in test reports
- Contributions to measurement uncertainty arising from sampling

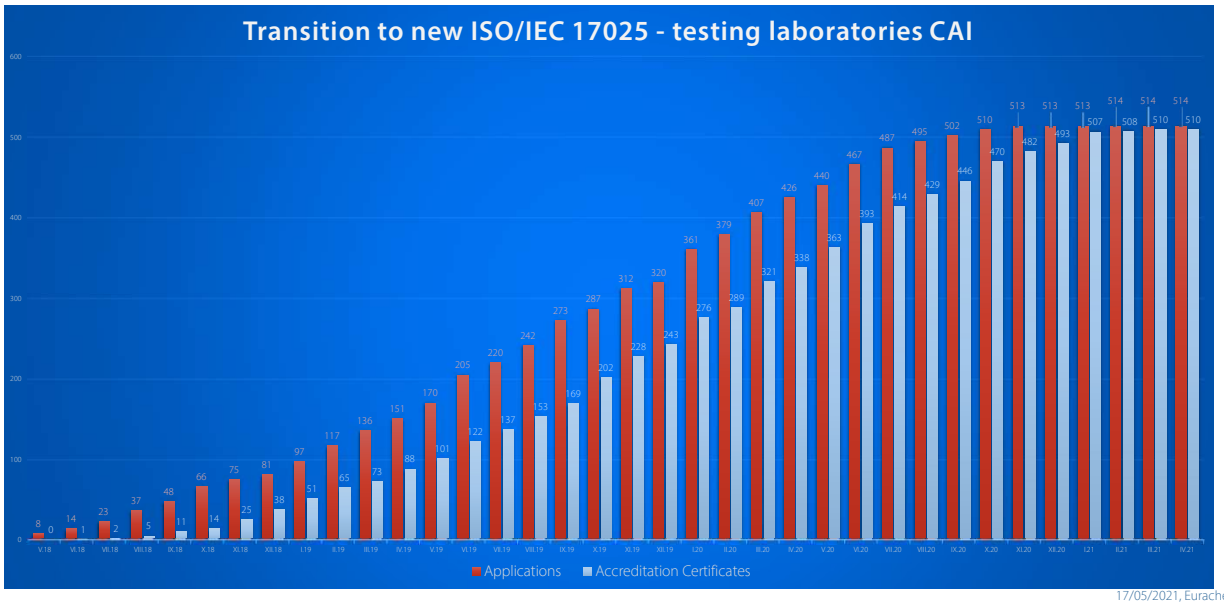
- Well accepted
  - Validation of older LIMS sometimes problematic

- More explanation needed
  - Risks associated to DR

- Simple requirement for laboratory protection
  - misunderstood

- CAI - opened approach
  - The ealuation of significance on laboratory

Statistical overview of transition in Czechia



Thank you for your attention

Pavel Nosek

CZECH ACCREDITATION INSTITUTE

www.cai.cz