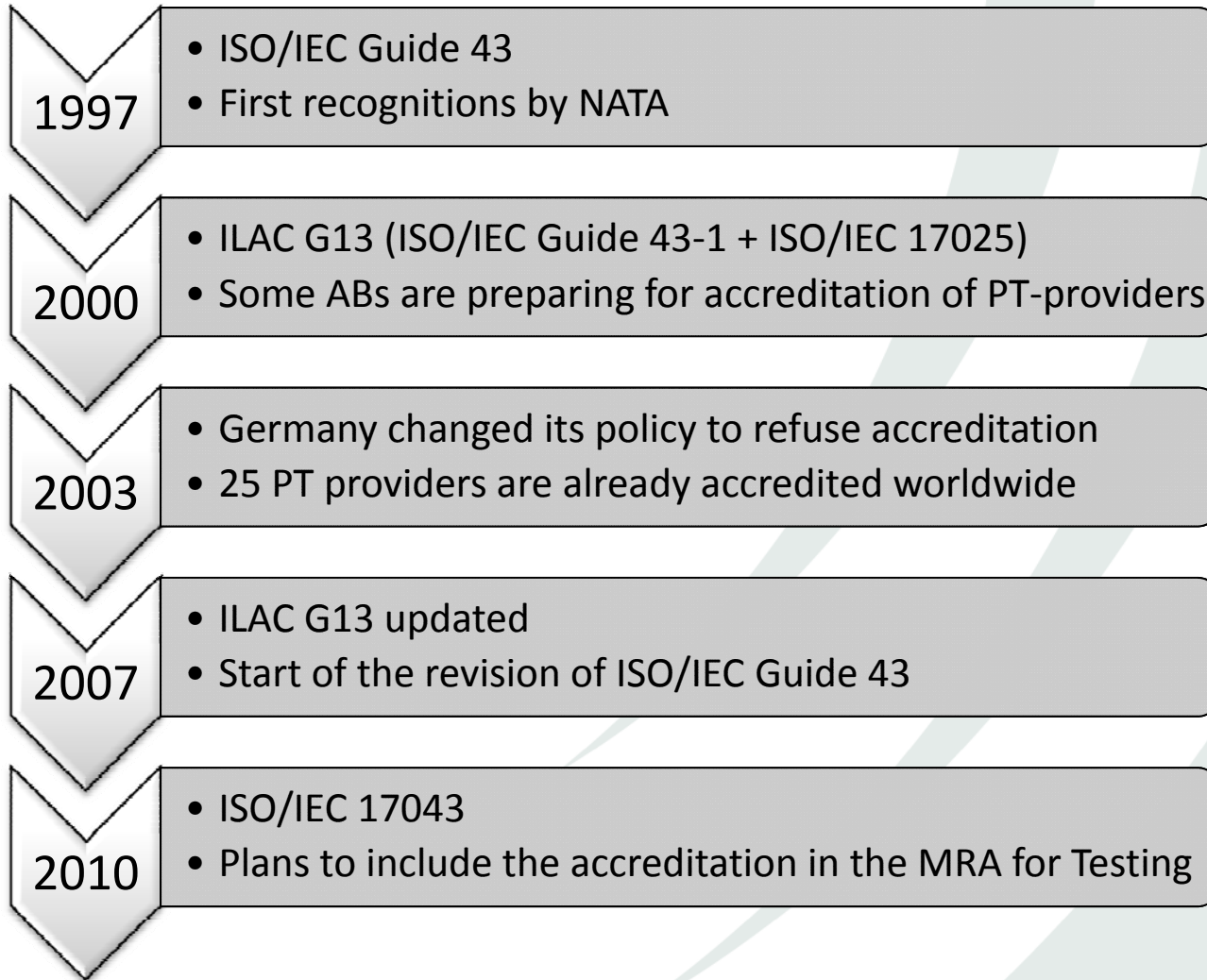# Accrediting PT/EQA providers to ISO/IEC 17043

7th Workshop on Proficiency Testing in Analytical Chemistry, Microbiology and Laboratory Medicine
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Historical Development of Accreditation of PT-Providers

1997
- ISO/IEC Guide 43
- First recognitions by NATA

2000
- ILAC G13 (ISO/IEC Guide 43-1 + ISO/IEC 17025)
- Some ABs are preparing for accreditation of PT-providers

2003
- Germany changed its policy to refuse accreditation
- 25 PT providers are already accredited worldwide

2007
- ILAC G13 updated
- Start of the revision of ISO/IEC Guide 43

2010
- ISO/IEC 17043
- Plans to include the accreditation in the MRA for Testing

Before 2010

ISO/IEC 17025 + ILAC G13 + ISO/IEC Guide 43

ILAC G13 + ISO/IEC Guide 43 one of them or both

ILAC G13 + ISO/IEC 17025

ISO/IEC 17020 + ILAC G13 + ISO/IEC Guide 43

Self-made procedures

Since 2010

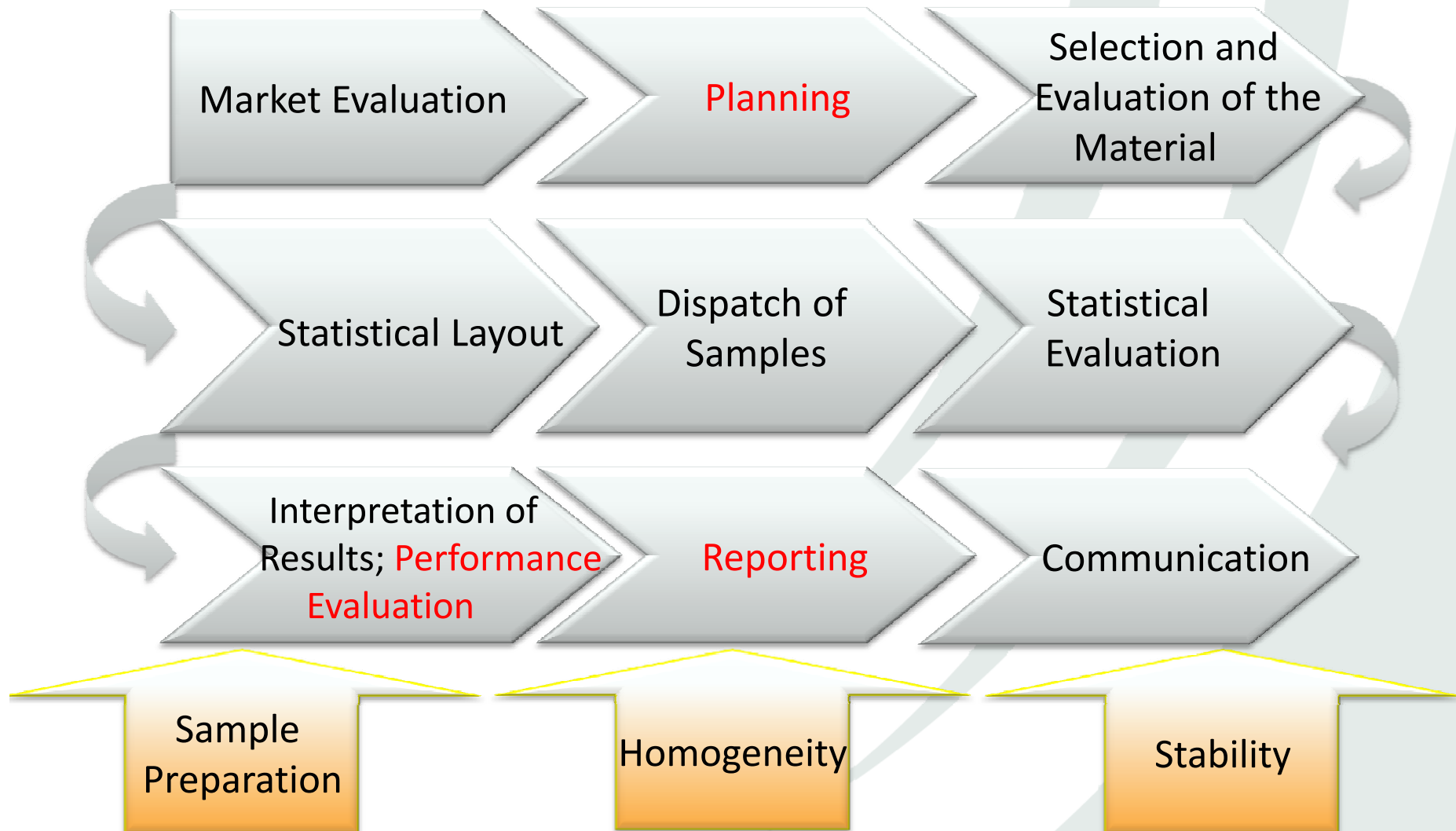Harmonisation of Implementation of ISO/IEC 17043

Current Situation in Germany

✓ 10 PT providers accredited

 ✓ 1 Mechanical

 ✓ 2 Food

 ✓ 1 Olfactometry

 ✓ 3 Medical

 ✓ 3 Environmental

All of them are assessed to ISO/IEC 17043 but for some the procedure has been not finished.

On-site assessment

✓ Initial assessment

   ✓ 3 assessors: System and technical assessor plus statistician

   ✓ All together: 5.1 Organisation, 4.2 Personnel, 4.4.1 Planning

✓ Transition assessment (combined with surveillance)

   ✓ 2 assessors: System and technical assessor

Providing Proficiency Tests
How does it work?

DAkkS
Deutsche
Akkreditierungsstelle

Market Evaluation → Planning → Selection and Evaluation of the Material

Statistical Layout → Dispatch of Samples → Statistical Evaluation

Interpretation of Results; Performance Evaluation → Reporting → Communication

Sample Preparation

Homogeneity

Stability

Assessing the competence

✓ Planning (4.4)

The PT plan is not a formality

✓ Performance evaluation (4.7.2)

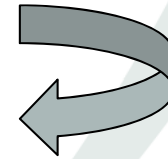$$z = \frac{\left(x_{lab} - x_{assigned} \right)}{\sigma}$$

✓ Authorisation of the report (4.8)
✓ Evaluation of subcontractors (5.5)

Contents of ISO/IEC 17043

Introduction

1. Scope

2. Normative references

3. Terms and definitions

4. Technical Requirements

5. Management requirements

Annex A Types of proficiency testing schemes

Annex B Statistical methods for proficiency testing

Annex C Selection and use of proficiency testing

Additional Documents in DAkkS

✓ **Rules for the Accreditation of Providers**
Harmonisation of the assessments

✓ **Rules for the Accreditation of EQAS Organisations according to Directive 98/79/EG**
Additional requirements for EQAS Organisations operating PT in the regulated area.

4.2 Personnel

✓ **Requirement for the technical management**

  ✓ Scientific university study (or equivalent)

  ✓ 3 years work experience (2 of them in a CAB)

  ✓ Experience in quality management

✓ **External personnel – Minimum content of contracts**

  ✓ Job description

  ✓ Time frame

  ✓ Embedding in the Quality management system

  ✓ Confidentiality.....

4.3 Equipment, accommodation and environment

4.3.6 "Proficiency testing providers shall ensure that performance characteristics of laboratory methods and equipment used to confirm the content, homogeneity and stability of proficiency testing items are appropriately validated and maintained."

- ✓ Accreditation of the relevant testing methods or
- ✓ on-site assessment by the technical assessor

4.4 Design of proficiency testing schemes

4.4.1.3 "The proficiency testing provider shall document a plan before commencement of the proficiency testing scheme that addresses the objectives, purpose and basic design of the proficiency testing scheme…. "

✓ In the initial assessment the PT provider has to show that the requirements of the standard are applied in recent PTs for each area to be accredited.

✓ In the surveillance audits the provider has to provide documented plans.

4.4. Design of proficiency testing schemes

4.4.1.4 "The proficiency testing provider shall have access to the necessary technical expertise …… This may be achieved, if necessary, by establishing an advisory group."

✓ Documented procedure for the advisory group

    ✓ Description of tasks (according to 4.4.5.1)

    ✓ Selection criteria for members

    ✓ List of members with technical experience

    ✓ Meeting protocols

4.7.1 Data analysis and records

4.7.1.1 "All data processing equipment and software shall be validated in accordance with procedures before being brought into use."

✓ Common used commercial equipment and software

   ✓ Entrance check with test data sets

✓ Homebrew (self made) software (e. g. Excel sheets)

   ✓ Various checks with data sets to check all functions of the software

4.9 Communication with participants

4.9.5 "If the proficiency testing provider issues statements of participation or performance, they shall contain sufficient information to not be misleading."

- ✓ Minimum requirements for Certificates
  - ✓ Subject of the PT and analysed parameters
  - ✓ Identification of the participant with Code number
  - ✓ Identification of the PT and reference to the final report
  - ✓ Results of the participant….

- ✓ Statement of successful or not successful participation
  - ✓ Criteria for successful participation has to be stated

5.4 Review of requests, tenders and contracts

2 Scenarios:

- ✓ Routine Proficiency Test which runs regularly
  - ✓ No contract review is required
  - ✓ Covered by 4.9 "Communication…"

- ✓ Special proficiency test for a certain client (e. g. Industry)
  - ✓ Application of clause 5.4

5.5 Subcontracting services

✓ Requirements

    ✓ Contract with the subcontractor (minimum content defined)

    ✓ For testing or calibration service accreditation is sufficient

    ✓ Without accreditation the PT provider has to make an on site audit which shows the validity of the tests or calibrations

    ✓ Self declarations are not accepted. There must be objective evidence about the fulfilment of the requirements of ISO/IEC 17043

Special requirements for EQAS Organisations

According to § 11 of the EU Directive 98/79/EG (IVD) are required by national legislation to announce problems with IVDs in EQAS to the responsible national authority.

✓ In addition fulfil the requirements of EN 14136
✓ DAkkS rule on EQAS Organisation

Scope of the Certificate

Testing field	Matrix/ Product	Measurand/ Parameter	PT- Programm
Mechanical Testing (Tensil test)	Metall	ISO 6805-1	Name of the PT programm
Residue Analysis	Fruites	Pesticides	Name of the PT programm

Summary

➢ ISO/IEC 17043 is well applicable for the accreditation of PT providers

➢ To have a harmonised approach for the assessment of PT providers some additional rules are necessary.

➢ To find out if a PT provider is competent the discussion on clause 4.4.1 and 4.7.2 give a good impression.

Interpretation of a standard
What does it depend on?

➢ Translation of the standard

➢ Experience of the AB

➢ Experience and training of the assessor

➢ PT provider in the country

➢ ....

Harmonisation can only be successful by open minded exchange of experience on an international level.

Thank you for your attention

Questions?