



ISO/REMCO activities and future work

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ISO/REMCO

Seminar on accreditation of PT providers and
RM producers

Rio de Janeiro, 5-6 June 2008

REMCO

ISO Committee on Reference Materials

ToR to ...

- ... carry out and encourage a broad international effort for the harmonization and promotion of certified reference materials, their production and their application
- ... be the global centre of excellence in relation to issues relating to reference materials

REMCO Stakeholders and clients

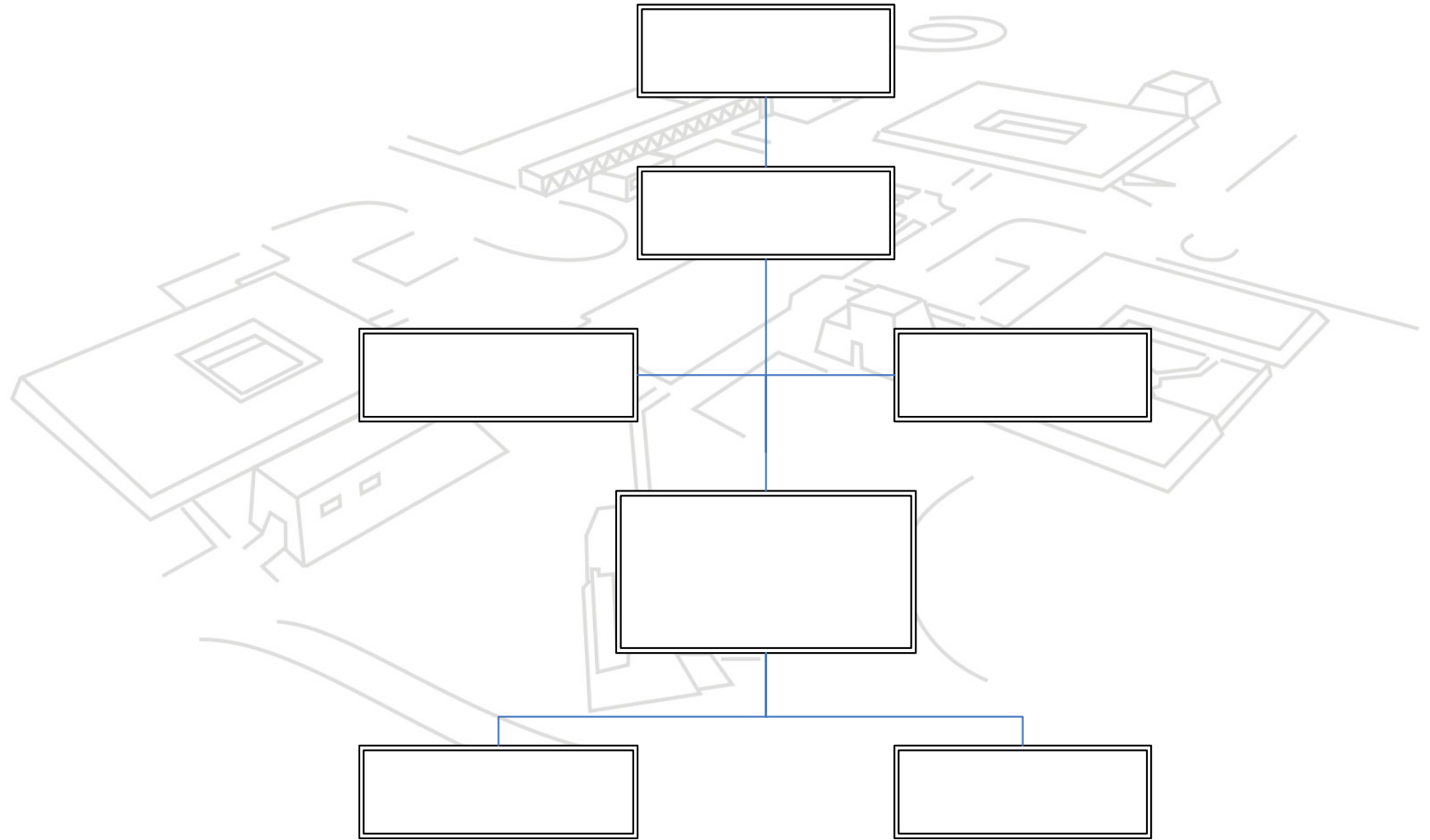
Stakeholders

- Standardisation bodies
- Metrology institutes
- International and regional liaison partners

Clients

- ISO committees (horizontal advisory function)
- Users of reference materials (e.g analytical laboratories)
- Producers of reference materials
- Accreditation bodies (in particular for RM producers)

Committee Structure



ISO/REMCO Publications	User	Producer
Guide 30 – Terms and Definitions (1992) (under revision)		
Guide 31 – Contents of Certificates (2000)		
Guide 32 – Calibration Using RMs (1997)		
Guide 33 – Uses of CRMs (2000) (under revision)		
Guide 34 – Requirements for the Competence of Producers (2000)(Amd 2003)		
Guide 35 – General and statistical principles for certification (2006)		
Associated informative publications, e.g planned “Guide to the use and interrelationships of REMCO Guides”		

ISO Guide 30

- Vocabulary of terms and definitions in relation to reference materials
- Present edition (1992) pretty outdated
- More recent definitions in ISO Guides 33-35

ISO Guide 31

- Contents of certificates, labels, reports
- Document not written in view of accreditation
- Document contains a minimum set of requirements → suitable for accreditation

Minimum information on certificate (1)

- the properties of interest;
- their values;
- their uncertainties;
- a statement concerning metrological traceability of the property values

Minimum information on certificate (2)

- general particulars of the certifying body assuming responsibility a description of the material
- its intended use
- expiry date (period of validity) of the certificate
- instructions for use
- appropriate storage conditions

ISO Guide 32

- Describes use of CRMs in calibration



ISO Guide 33

- Describes uses of CRMs
 - Quality control
 - Method validation (bias assessment)
 - Conventional scales


ISO Guide 34

- Describes quality management system of a RM producer
- Requirements for demonstrating competence
- Document also used for accreditation purposes
- For measurements, reference is made to ISO/IEC 17025

ISO Guide 35

- Describes certification of reference materials
 - Project design and development
 - Material preparation
 - Homogeneity testing
 - Stability testing
 - Characterisation
 - Evaluation of measurement uncertainty
 - Certification and recertification

Homogeneity testing

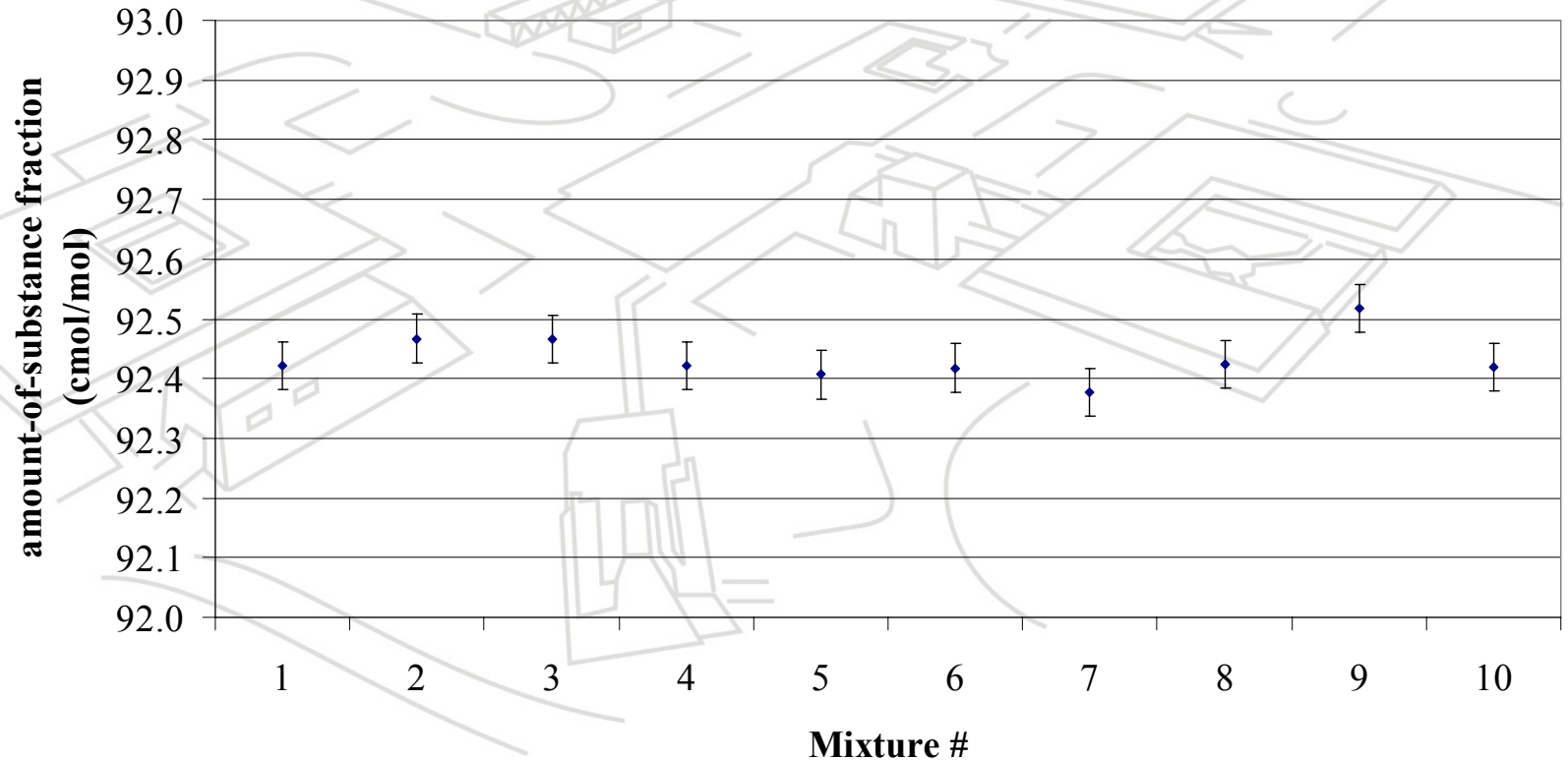
- On all parameters to be certified (with some exceptions)
 - Using a well repeatable method
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Homogeneity testing

- “within-bottle” → minimum sample intake
- “between-bottle”
 - batch homogeneity
 - quality control
 - determination of remaining heterogeneity among samples

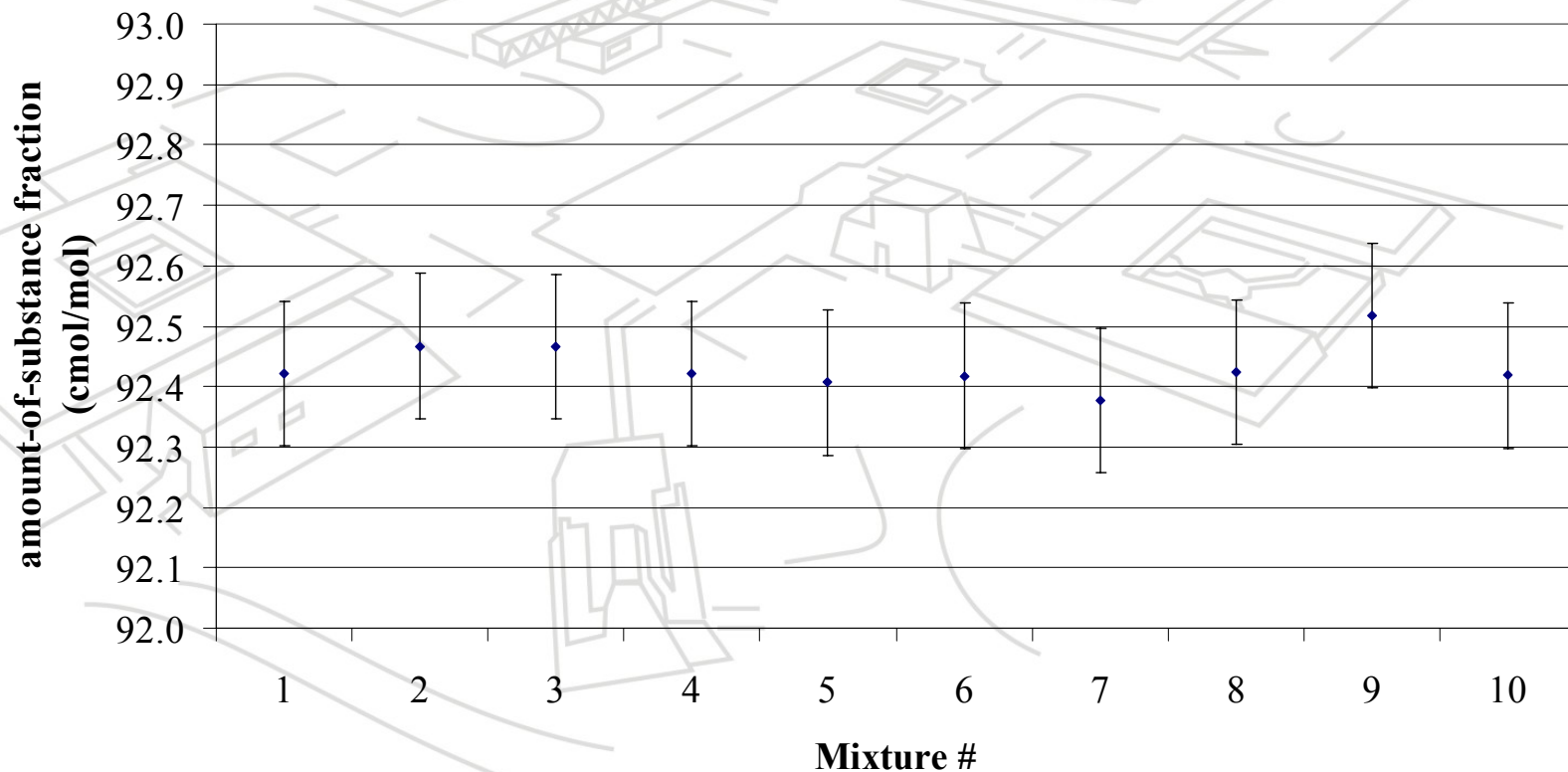
Homogeneity data of methane fraction in natural gas

Homogeneity data methane



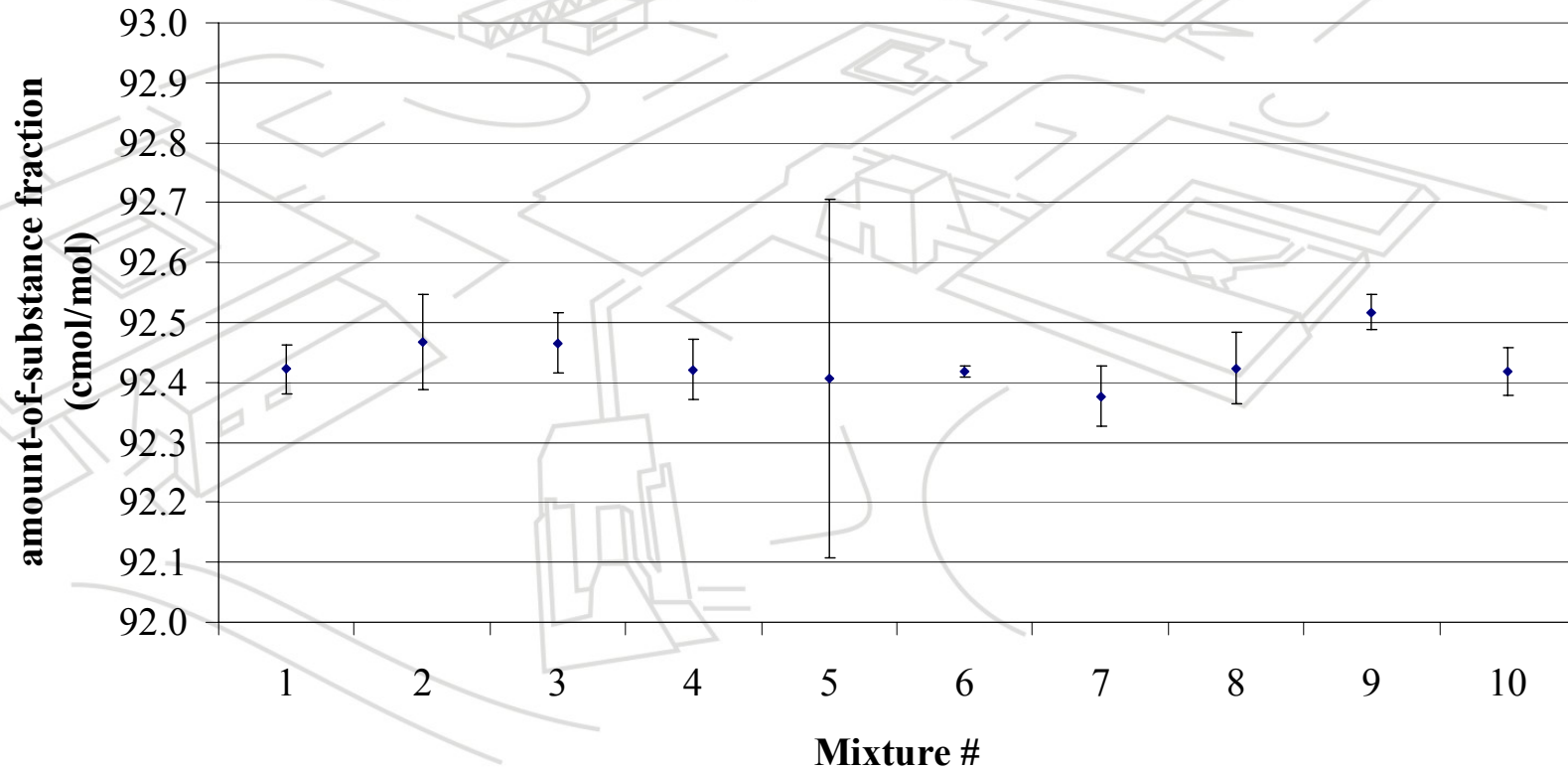
Example of poor repeatability

Homogeneity data methane

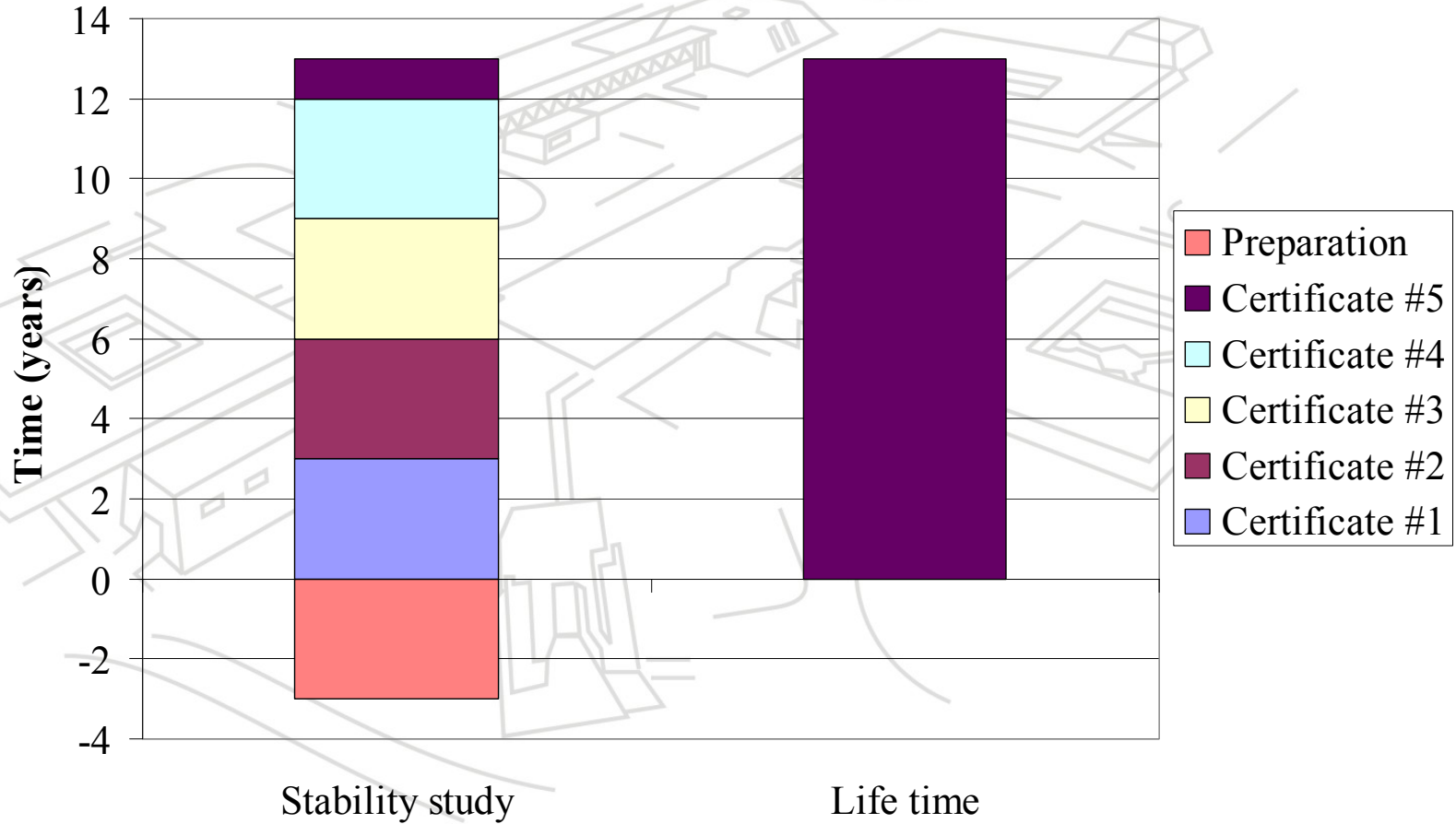


Example of insufficient statistical control

Homogeneity data methane



Stability studies and life time

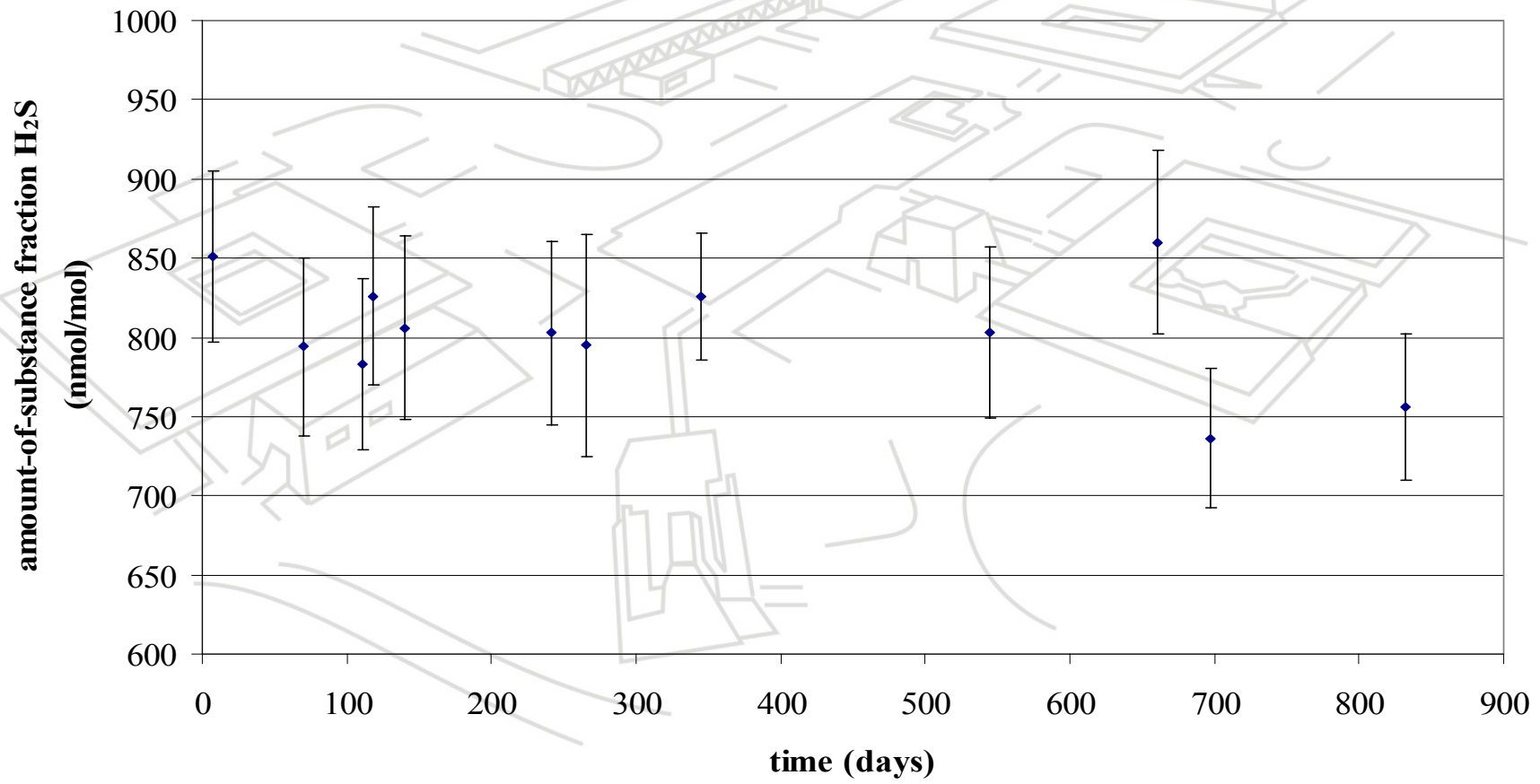


Stability of reference materials

- Two types
 - long-term stability (at the shelves of the producer/reseller)
 - short-term stability (during transport)
- Ideally, transport conditions/material should be established so that short-term stability effects do not exceed those of long-term stability

Long-term stability study

Stability study



Characterisation approaches

- Property values from
 - Preparation of the CRM (synthetic materials, dilutions)
 - Single measurement method
 - Multiple measurement methods
- Collaborative studies
 - Multiple methods
 - Method-specific approach

Collaborative study

- Preferably 10 – 15 laboratories
 - Allows scrutinising of data
 - Allows use of outlier tests
- If better control, number of labs can be smaller
- Metrological traceability
 - Assessment of calibrations (including collaborators!)
 - Control over measurement methods (validation of results!)
- Agreement between results is necessary, but not sufficient (!)

Development of ISO Guides

- Drafting of a new Guide on the preparation of QCMs (WG8)
- Revision of ISO Guide 33 (WG9)
- Revision of ISO Guide 30 (WG10)
- Revision of ISO Guide 34 (WG11)
- Drafting of an introductory guide (WG12)

Other activities

- Orientation on CRMs for qualitative measurement, for e.g.,
 - Chemical weapons convention
 - Colour measurement in the manufacturing and process industry
 - Fraud detection (e.g., origin of food products)
 - Drug testing (e.g., in traffic and sport)

Qualitative measurement

- Approx. 95% of the testing in industry, law enforcement, etc. is *qualitative*
- Decisions are taken with respect to compliance/non-compliance
- Measurements have a tremendous impact on economy
- CRMs do exist
- Guidance on “good practice” is lacking

Revisison ISO Guide 30

- Amendment of ISO Guide 30 unanimously accepted to replace definitions RM and CRM
- Document further revised in view of
 - International Vocabulary in Metrology (VIM)
 - Description of, e.g., qualitative measurement

Development of ISO Guide 80

- Draft document addresses “in-house” preparation of RMs
- Distinction made between
 - Characterised RMs
 - Uncharacterised RMs (for precision determination/control)

Uncharacterised RMs (1)

- Use for
 - Precision control
 - Proficiency testing with a consensus value
 - Method validation
(determination of repeatability/reproducibility)
- Necessary information
 - (batch) homogeneity
 - Stability

Uncharacterised RMs (2)

- **Stability**
 - Often done by 'monitoring' (= comparison against a standard with established stability)
 - Often responsibility of the *user*
 - Producer needs however to establish material with sufficient stability

Revision ISO Guide 33

- Covers also calibration (formerly contained in ISO Guide 32)
- Addresses applications of
 - Characterised RMs
 - Uncharacterised RMs
- Includes selection of (C)RMs
 - Based in part on existing papers of 4E-RM and ILAC

Mainstream applications

- Calibration
 - Method validation
 - Quality control
 - Maintenance of conventional scales
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Revision of ISO Guide 34

- Limited revision is undertaken
 - No new requirements
 - Re-statement of existing requirements for clarification purposes
 - Inflow of experience from users of ISO Guide 34:2000
- 2nd and final vote in autumn 2008

Development of ISO Guide 79

- Introductory guide to RMs/CRMs
- Contents
 - Outline of basic concepts and requirements
 - Cross-reference to other guides
- No new requirements
- Target audience
 - Laboratory staff
 - Decision takers, legislators, regulators, standards developers

Report published

- **“Report of the 30th meeting of ISO/REMCO”,
Accred. Qual Assur. 13 (2008), pp. 53-55**