REMCO

ISO’s Committee on Reference Materials
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- What are reference materials?
- Partners
- Work Programme
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About REMCO (background)

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Introduction to REMCO

REMCO – ISO Committee on Reference Materials

**REMCO**

**CENTRAL SECRETARIAT**

**GENERAL ASSEMBLY:**
- Principal officers
- Delegates of:
  - Member bodies
  - Correspondent members
  - Subscriber members

**COUNCIL**

**TECHNICAL MANAGEMENT BOARD**

**REMCO**

**Technical advisory groups**

**Technical committees**

**Policy development committees:**
- CASCO
- COPOLCO
- DEVCO
- INFCO

**Council standing committees:**
- Finance
- Strategies

**Ad hoc advisory groups**

**COUNCIL**

**TECHNICAL MANAGEMENT BOARD**

**REMCO**

**Technical advisory groups**

**Technical committees**
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
Established 1975
Roots are in chemical analysis
Recently established close cooperation with the pharmacopoeias (pharmaceuticals)
Health sector represented via WHO, WASPaLM et al (needs to be further developed)
New sectors (e.g. Geoanalysts) starting to participate
Establishment of central role of REMCO and relevance in all fields, including association with workshops etc. on RM
Reinforcement of links to CASCO
Various approaches to outreach, including association with workshops etc. on RM
Our place ...

Conformity assessment, certification, etc
ISO/CASCO
Regional: EA etc...
Accreditation/certification bodies (ILAC etc)

Standardization in relation to RM
ISO/REMCO
Regional: CEN etc...
National: DIN etc...

Metrology
CIPM
BIPM
Regional: EUROMET etc...
National: NMIs & designated labs

Measurement Laboratories
About REMCO (background)

What are reference materials?

Partners

Work Programme

Committee structure
New definitions

- Greater clarity was needed in the understanding of what ‘reference material’ meant.
- Was becoming urgent with the accelerated evolution of all practices associated with use, production, certification, claims of conformity etc.
- Improved definitions were established by REMCO in 2005.
- Will be used as a basis for focussing and enhancing REMCO’s family of publications and informative materials.
- Will be promoted as widely as possible, including in the context of the revision of VIM (International Vocabulary of basic and general terms in Metrology).
Reference Materials (RM)

Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

Notes:

1. RM is a generic term.
2. Properties can be quantitative or qualitative, e.g., identity of substances or species.
3. Uses may include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.
4. An RM can only be used for a single purpose in a given measurement.
Certified Reference Materials (CRM)

RM characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that states the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

Notes:

1. The concept of value includes qualitative attributes such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities.

2. Metrologically valid procedures for the production and certification of reference materials are given in, among others, ISO Guides 34 and 35.

- About REMCO (background)
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- **Partners**
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REMCO stakeholders and clients

Stakeholders
- Standardisation bodies
- Metrology institutions
- 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)
REMCO membership
(28 ‘Participating’ members in 2004)

- Australia (SAA)
- Belarus (BEST)
- Brazil (ABNT)
- Canada (SCC)
- China (CSBT)
- Czech Rep. (COSMT)
- Ecuador (INEN)
- France (AFNOR)
- Germany (DIN)
- Hungary (MSZT)
- India (BIS)
- Indonesia (DSN)
- Iran, Islamic Rep. of (ISIRI)
- Italy (UNI)
- Japan (ISC)
- Kenya (KEBS)
- Korea, Rep. of (KATS)
- Netherlands (NNI)
- Russian Federation (GOST R)
- Slovakia (UNMS)
- Slovenia (SMIS)
- South Africa (SABS)
- Spain (AENOR)
- Sweden (SIS)
- Switzerland (SNV)
- Thailand (TISI)
- United Kingdom (BSI)
- USA (ANSI)

+ plus 38 ‘Observer’- members

Blue = developing country or emerging economy
(approx.50% of P+O members)
REMCO liaison members

- REMCO benefits from exceptionally positive relationships with its liaison members
- Liaison members of REMCO have an extremely important role across industry, laboratories, etc. by ensuring
  - Consistency, compatibility & interworking across projects (including in the areas of certification, accreditation, conformity assessment etc.)
  - Awareness of REMCO’s portfolio of ISO Guides
  - Understanding, acceptance & application of ISO Guides
  - The relevance & currency of content
## REMCO liaison members
(sample from liaison membership of 22)

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>AOAC</td>
<td>(formerly) Association of Official Analytical Chemists</td>
</tr>
<tr>
<td>BIPM</td>
<td>Bureau International des Poids et Mesures</td>
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<tr>
<td>CCQM</td>
<td>Committee for Amount of Substance</td>
</tr>
<tr>
<td>CITAC</td>
<td>Co-operation on International Traceability in Analytical Chemistry</td>
</tr>
<tr>
<td>WASPaLM</td>
<td>World Association of Societies of Pathology &amp; Laboratory Medicine</td>
</tr>
<tr>
<td>ECCLS</td>
<td>European Council for Clinical and Laboratory Standards</td>
</tr>
<tr>
<td>EURACHEM</td>
<td>Network of organizations concerned with analytical chemistry in Europe</td>
</tr>
<tr>
<td>IAEA</td>
<td>International Atomic Energy Agency</td>
</tr>
<tr>
<td>IFCC</td>
<td>International Federation of Clinical Chemistry</td>
</tr>
<tr>
<td>IAG</td>
<td>International Association of Geoanalysts</td>
</tr>
<tr>
<td>ILAC</td>
<td>International Laboratory Accreditation Cooperation</td>
</tr>
<tr>
<td>IRMM</td>
<td>Institute for Reference Materials and Measurements</td>
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<td>IUPAC</td>
<td>International Union of Pure and Applied Chemistry</td>
</tr>
<tr>
<td>OIML</td>
<td>International Organization of Legal Metrology</td>
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<tr>
<td>PDG</td>
<td>Pharmacopoeia Discussion Group</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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Sector involvement
(With examples amongst membership of ISO/REMCO)

- Chemical analysis (IUPAC, CITAC)
- Pharmaceuticals (PDG)
- Health (WHO, IFCC, ECCLS)
- Geoanalysis (IAG)
- Metrology & Legal Metrology (OIML, BIPM, CCQM, IRMM)
- Environment (IAEA,…)
- Bioanalysis (CCQM, IRMM,…)
- Food (AOAC, IRMM,…)

Introduction to REMCO
2005-08-24
REMCO – ISO Committee on Reference Materials
About REMCO (background)
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REMCO’s Deliverables

- Normative
  - Guides
  - Technical Reports
- Non-normative
  - Booklets
  - Contributions to conferences, workshops, journals etc.
REMCO’s “Pocket Knife”

<table>
<thead>
<tr>
<th>ISO/REMCO Publication</th>
<th>User</th>
<th>Producer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guide 30 – Terms and Definitions (1992)</td>
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<tr>
<td>Guide (new) – Quality control materials (new project)</td>
<td></td>
<td></td>
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<tr>
<td>Associated informative publications, e.g planned “Guide to the use and interrelationships of REMCO Guides”</td>
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Current study topics …

What IS a reference material. Includes

- Establishment of base definitions for Reference Material (RM) and Certified RM in revision of VIM (REMCO has focused its contribution on ensuring, through wide consultation, the adequacy of these two definitions)

- Development of guidance on ‘quality control materials’

Traceability and RM
(new Ad-Hoc Group established in 2004)
A longstanding topic, with growing relevance with the growth in global MRA etc.

Ongoing clarification of relationships with accreditation of CRM producers
Consolidated opinion being established, with opinion favouring the joint (complementary) application of ISO Guide 34 & ISO 17025
Current study topics … (contd)

- Extensions & clarifications of principles and guidelines (with a view to ensuring relevance to an enlarged user base)
- Categorization of reference materials (feasibility study; related to facilitating the identification of RM by users – closely linked to, for example, electronic retrieval of information on RM)
- Transportation & storage (includes aspects of regulations addressing cross-border movements, together with how to ensure the ongoing integrity of RM during transport and storage)
Work programme – Current (2005)

- Revision of
  - ISO Guide 35 (WG1)

- Activities on
  - Categorisation (WG3)
  - Transport and customs issues (WG4)
  - Booklets (WG6)
Work programme 2006-2008

- Revision of
  - ISO Guide 30 (WG10)
  - ISO Guide 33 (WG9)

- Preparation of
  - ISO Guide XX on QCMs (WG8)

- Upcoming/envisaged/needed(?)
  - Systematic review of REMCO Guides
  - Work with Pharmacopoeias
Work programme 2006-2008

- Systematic review of ISO Guides 30, 31, 32, 33, and 34
- Revision of
  - ISO Guide 30 (WG10)
  - ISO Guide 33 (WG9)
- Preparation of
  - ISO Guide XX on QCMs (WG8)
  - ISO TR on a categorisation scheme (WG3)
- Getting contact to World Customs Organisation (WG4)
## ISO Publications - Status

<table>
<thead>
<tr>
<th>ISO/REMCO Publication</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guide (new) – Quality control materials (new project)</td>
<td>First draft May 2006</td>
</tr>
<tr>
<td>TRs on (i) transportation issues and (ii) categorization</td>
<td>Under development (text end-2006)</td>
</tr>
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</table>
Ongoing issue: Education and awareness
E.g. ensuring user understanding of (the limits of) CRM

Need to ensure awareness of users that the properties of CRM can change, due to various factors, including the effects of sample division (includes homogeneity), storage, transport, ageing, etc.

Between bottle variation ($S_{bb}$)

Storage ($U_{lts}$)

Transport ($U_{sts}$)

Characterisation * ($U_{char}$)

Uncertainty of the assigned property values

*assignment of values to properties
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Committee Structure
(June 2005)

Main Committee

Chairman
Dr. Adriaan van der Veen

Secretary
Mr. Andrew Williams

Vice Chairman
Dr. Hendrik Emons

Chairman's Advisory Group
Chair, Vice Chair, Past Chair, WG and SG convenors
DEVCO representative

SG1 International Coordination
and Harmonisation
Dr. Aleš Fajgelj

SG2 Technical Guidance
<Vacant>
Working groups in ISO/REMCO
(June 2005)

Chairman's Advisory Group
Chair, Vice Chair, Past Chair,
WG and SG convenors
DEVCO representative

SG1 International Coordination
and Harmonisation
Dr. Aleš Fajgelj

SG2 Technical Guidance
<Vacant>

WG3 Categorisation of RMs
Dr. Wolfram Bremser

WG4 Transportation
Prof. Dr. Hendrik Emons

WG6 Information booklets
Mr. Andrew Williams

WG8 Guidance on QCMs
Dr. Nineta Majcen

WG9 Revision of ISO Guide 33
Dr. Adriaan van der Veen

AHG Traceability
Dr. Robert Watters

WG10 Revision of ISO Guide 30
Dr. Robert Watters
WG3 – Categorisation

- ISO TR on Categorisation scheme (key words) of RMs by 2006
- Report to be finalised in 2007(?)
- Publication in *Accreditation and Quality Assurance*
WG4 – Transportation and customs

- Improvement of arrangements with WCO/WTO for export/import of CRMs
- Results of WG4 to be compiled in an ISO TR (by 2006)
WG6 – Information booklet

- To be revised
- Going to print as soon as possible
- Text to appear also on ISO/REMCO website
WG8 – Guide on QCMs

- First complete draft of Guide until end of 2005
- Guide ready for ballot in 2007
Review of ISO Guide 33 to be amended according to results of systematic review

First revised Guide available until next meeting (May 2006)

Guide ready for ballot in 2008
WG10 – ISO Guide 30

- Review of ISO Guide 30 to be amended according to results of systematic review
- First revised Guide available until next meeting (May 2006)
- Guide ready for ballot in 2008
More Information

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