

REMCO

ISO's Committee on

Reference Materials



Introduction to REMCO 2005-08-24

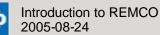
REMCO – ISO Committee on Reference Materials

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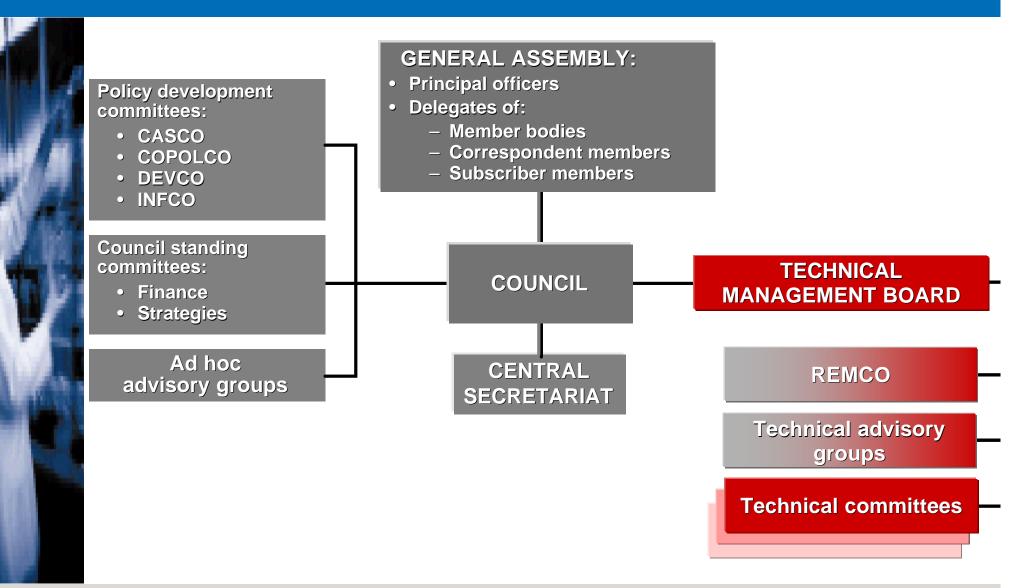
- About REMCO (background)
- What are reference materials?
- Partners
- Work Programme
- Committee structure

About REMCO (background)

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REMCO



Introduction to REMCO 2005-08-24



ISO Committee on Reference Materials

ToR to ...

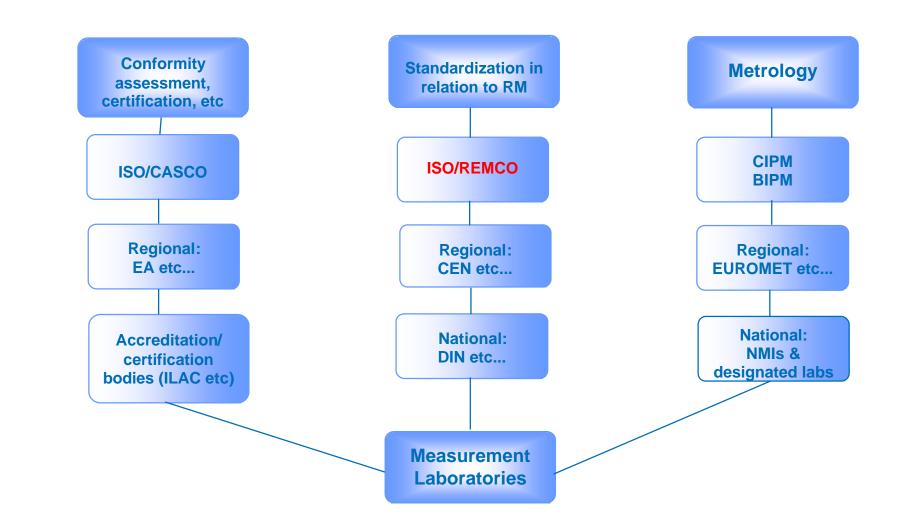
- ... carry out and encourage a broad international effort for the harmonization and promotion of certified reference materials, their production and their application
- ... be the global centre of excellence in relation to issues relating to reference materials



Origins & Future

- Established 1975
- Roots are in chemical analysis
- Recently established close cooperation with the 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 ...





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About REMCO (background)

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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.
- 3. ISO Guide 31 gives guidance on the contents of certificates.



About REMCO (background)

• What are reference materials?

Partners

- Work Programme
- Committee structure

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)

AOAC	(formerly) Association of Official Analytical Chemists
BIPM	Bureau International des Poids et Mesures
CCQM	Committee for Amount of Substance
CITAC	Co-operation on International Traceability in Analytical Chemistry
WASPaLM	World Association of Societies of Pathology & Laboratory Medicine
ECCLS	European Council for Clinical and Laboratory Standards
EURACHEM	Network of organizations concerned with analytical chemistry in Europe
IAEA	International Atomic Energy Agency
IFCC	International Federation of Clinical Chemistry
IAG	International Association of Geoanalysts
ILAC	International Laboratory Accreditation Cooperation
IRMM	Institute for Reference Materials and Measurements
IUPAC	International Union of Pure and Applied Chemistry
OIML	International Organization of Legal Metrology
PDG	Pharmacopoeia Discussion Group
WHO	World Health Organization



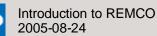
Sector involvement

(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,...)

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"

	ISO/REMCO Publication	User	Producer
P	Guide 30 – Terms and Definitions (1992)		
	Guide 31 – Contents of Certificates (2000)		
	Guide 32 – Calibration Using RMs (1997)		
1	Guide 33 – Uses of CRMs (2000)		
1	Guide 34 – Requirements for the Competence of Producers (2000)(Amd 2003)		
	Guide 35 – Certification- General and Statistical Principles (1989) (New edition due 2005)		
	Guide (new) – Quality control materials (new project)		
	Associated informative publications, e.g planned "Guide to the use and interrelationships of REMCO Guides"		



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)



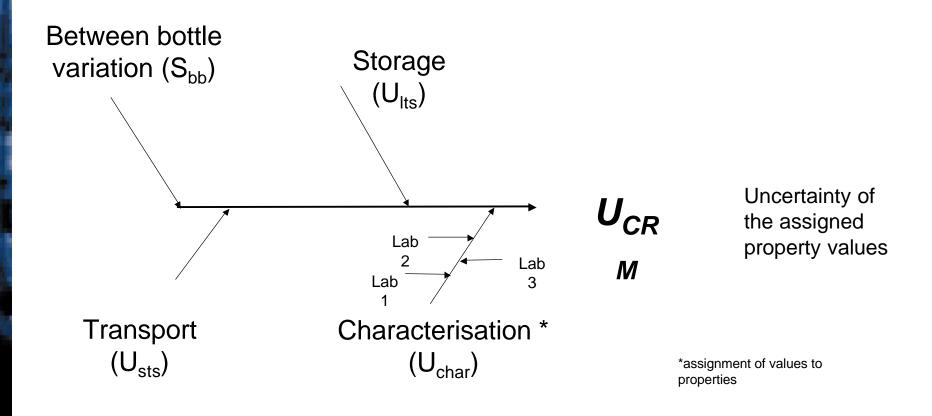
ISO Publications - Status

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ISO/REMCO Publication	Status	
Guide 30 – Terms and Definitions (1992)	Revision in hand	
Guide 31 – Contents of Certificates (2000)	Under systematic review	
Guide 32 – Calibration Using RMs (1997)	Under systematic review	
Guide 33 – Uses of CRMs (2000)	Revision foreseen First draft May 2006	
Guide 34 – Requirements for the Competence of Producers (2000)(Amd 2003)	Under systematic review	
Guide 35 – Certification- General and Statistical Principles (1989)	New edition due 2005	
Guide (new) – Quality control materials (new project)	First draft May 2006	
TRs on (i) transportation issues and (ii) categorization	Under development (text end-2006)	

Ongoing issue: Education and awareness E.g. ensuring user understanding of (the limits of) CRM

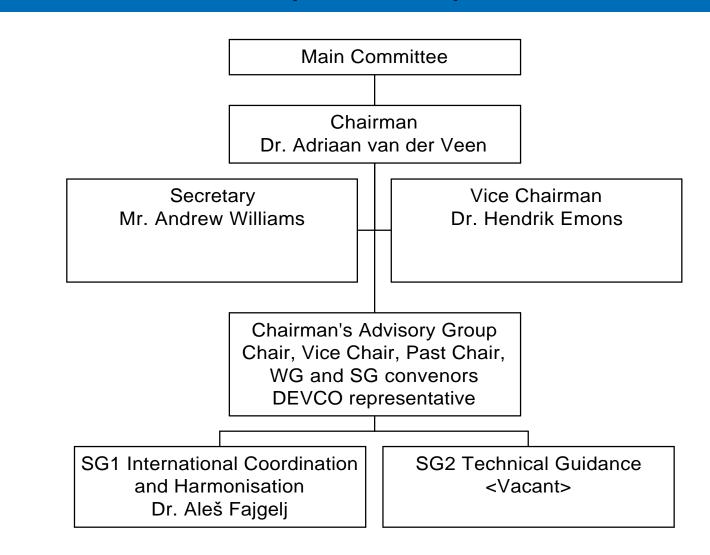
Need to ensure awareness of users that the properties of CRM can change, due to various factors, including the effects of sample division (includes homogeneity), storage, transport, ageing, etc.

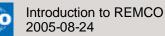


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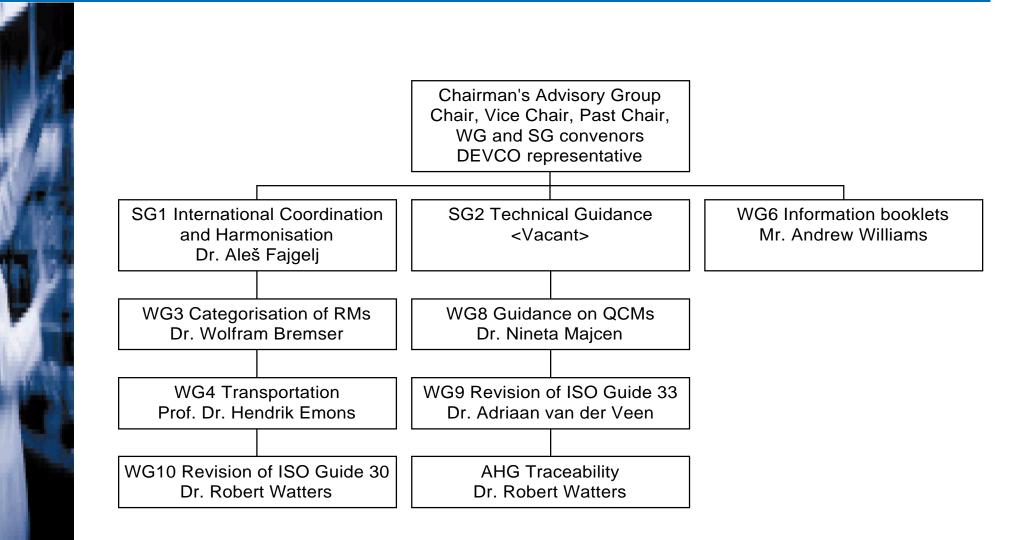
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Committee Structure (June 2005)





Working groups in ISO/REMCO (June 2005)



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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



WG9 – ISO Guide 33

- 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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