



International Union of Pure and Applied Chemistry

A member of the International Council of Scientific Unions

Analytical Chemistry Division (V): Interdivisional Working Party on Harmonization of Quality Assurance Schemes for Analytical Laboratories

Vienna, 2000-05-31

To:
IUPAC Secretariat
Dr. John Jost
Executive Director

Subject: **Report on participation at the 23rd ISO REMCO meeting, 15-17 May 2000, Geneva, Switzerland**

The Committee on Reference Materials (REMCO) of the International Organisation for Standardisation (ISO) was established in 1975. The aim of the committee is to carry out and encourage a broad international effort for the harmonisation and promotion of certified reference materials, their production and applications. The objectives of ISO REMCO are:

- To establish definitions, categories, levels and classification of reference materials for use by ISO.
- To determine the structure of related forms of reference materials.
- To formulate criteria for choosing sources for mention in ISO documents (including legal aspects).
- To prepare guidelines for technical committees for making reference to reference materials in ISO documents.
- To propose as far as necessary, action to be taken on reference materials required for ISO work.
- To deal with matters within the competence of the Committee, in relation with other organisations and to advise the Technical Board on action to be taken.

ISO REMCO has so far been structured in six task groups: Hierarchy, Calibration, Promotion, Accreditation, Sampling, and Transportation and distribution of reference materials.

There is a traditionally strong co-operation between ISO REMCO and IUPAC, especially IUPAC Interdivisional Working Party for Harmonisation of Quality Assurance Schemes for Analytical Laboratories. As a successor to Dr. Arthur Head in the position of IUPAC – ISO REMCO liaison person, I attended the ISO REMCO 2000 annual meeting. 23rd ISO REMCO meeting took place in ISO Headquarters in Geneva, Switzerland between 15 and 17 May 2000. Conclusions of this meeting are described in 20 resolutions.¹ The most important are:

- Business plan/strategic review of REMCO: ISO REMCO should be the highest body dealing with technical and ‘political’ issues related to certified reference materials, i.e. classification, regulation, certification principles, preparation of guides, etc. In the last years also other organisations have entered this field, e.g. EURACHEM, ILAC². This has resulted in some discrepancies in guidance documents issued by various organisations in duplication of work. To improve the situation, a strategic plan was prepared and introduced to the members.

¹ Please note that at the time when this report was prepared, the resolutions were still under final approval. They are listed only by the topic. The accompanying text reflects only author’s opinion.

² International Laboratory Accreditation Co-operation, Secretariat in Sydney, Australia

Chairman: Dr. A. FAJGELJ
International Atomic Energy Agency
Agency's Laboratories Seibersdorf
A-2444 Seibersdorf, Austria
Tel: +43 (1) 2600 28233 (or 28200)
Fax: +43 (1) 2600 28222
EMAIL: A. Fajgelj@iaea.org

- New organisational structure: Number of Task Groups was reduced from six to three and renamed to Subcommittees: 1. International Co-ordination and Harmonisation, 2. Technical guidance, 3. Classification and Education). Seven new working groups (WG) were formed: 1. Revision ISO Guide 35, 2. Inclusion GUM in ISO Guides, 3. Categories of CRMs, 4. Transportation, 5. Pharmacopeia, Information Booklets, 6. Revision of VIM. I was nominated chairman of the WG on categorisation of RMs.
- Publication of ISO Guide 31 and ISO Guide 33: ISO Guide 31 ‘Contents of certificates of reference materials’ and ISO Guide 33 ‘Uses of certified reference materials’ were accepted and will be published within a few months. Final versions can be obtained from ISO Central Secretariat. Unfortunately, the publication of both above-mentioned guides delayed for almost two years from the initial plan. This means that a new revision, needed to bring them in accordance with the latest version of ISO Guide 34 and a new ISO Guide 35 will be required soon.
- Publication of ISO Guide 34: ISO Guide 34 ‘Quality system requirements for reference materials producers’ was just published. Although originally planned that there will only be one such document has ILAC published similar guide as ILAC Guide 12. A difference in classification of reference materials exists and should be resolved between both organisations.
- Consistency between ISO Guides and GUM: The ISO Guide on ‘Expression of uncertainty in measurement’ (Geneva 1995) has in the last few years influenced almost all fields in analytical chemistry. Requirement of the standard ISO 17025, that the analytical results need to be reported together with their associated measurement uncertainty, has strongly been taken also by ISO REMCO in preparation of the new Guide 35 ‘Certification of reference materials – General and statistical principles’. This is understandable as RMs are often applied in field laboratories for quantification of combined uncertainty or separate sources of measurement uncertainty. At the moment is revision of the Guide 35 around 50 % accomplished. Its publication is not to be expected before summer next year. ISO Guide 35 is also a basis for future classification of RM. However, the principles of the new guide are clear and they will, to a certain extent, influence all reference materials producers dealing with matrix RMs. These principles include:
 - a) Characterisation of the candidate material through large international laboratory comparisons, which normally results in a consensus value is not any more foreseen to be appropriate. Small number of laboratories is preferred, however, all participants have to demonstrate traceability of the results obtained and report their measurement uncertainty.
 - b) When a number of laboratories participate, as described above, the results should be treated in the same way as if they were produced by a single laboratory. Statistics applied for combination of these results and their uncertainties does not break a traceability chain when each laboratory separately reported traceable results. At the same time can a small number of participants better communicate in clarification of eventual discrepancies and the entire certification project can be processed faster. Only statistically based exclusion of outliers is not allowed. In large world-wide intercomparisons it is almost impossible to achieve and to control the above mentioned requirements.
 - c) In preparation of the revised ISO Guide 35 no difference will be made between ‘primary’ methods of measurement and ‘other’ methods. There is a common requirement that methods applied for CRM characterisation are ‘fit for purpose’ and that the measurement uncertainty is as small as reasonably achievable. This decision was partially based on the latest developments at the Consultative Committee for the Amount of Substance (CCQM) at BIPM, Paris. CCQM has realised that methods of analysis cannot be declared as traceable as methods *per se*. A combination: analyte, measurand, matrix, technique is important. For various analytical techniques was the ability to produce results that are ‘fit for purpose’ already demonstrated, although not declared as ‘primary’.³
- Similarities and differences of materials used in measurement processes: Several different types of materials are used in a measurement processes, e.g. CRMs, RMs, proficiency testing materials, internal quality control samples, calibration standards, etc. A clear distinction between them, based on the quality requirements for these materials and their intended use has to be made. The first draft of the paper on this topic is expected for September 2000. As this topic relates also to the chemical terminology, a strong co-operation with IUPAC is foreseen. The result of the IUPAC project 501/9/97, a ‘Compilation and Clarification of Quality Assurance Related Nomenclature’, the ‘Alphabetical index of defined terms and where they can be found’, prepared by Mr. David Holcombe and published in three parts in the Journal Accreditation and Quality Assurance will

³ For more details see a report on participation at CCQM (BIPM) meeting 2000, prepared by A. Fajgelj.

serve as a starting point. (For details see *Accred Qual Assur* **4**, No. 12, pp. 525-530 (1999); **5**, No. 2, pp. 77-82 (2000) and **5**, No. 4, pp. 159-164 (2000).

The next two ISO REMCO meetings are planned to take place at NIST, Washington (USA), 21 to 23 May 2001 in conjunction with the 100th anniversary of NIST and in Ljubljana, Slovenia in May 2002 respectively.

Dr. Aleš Fajgelj