Creation of and first meeting of the new ISO technical committee for reference materials (ISO/TC 334)

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Abstract. On 14 December 2020, the ISO Technical Management Board (TMB) took the decision to transform ISO/REMCO, the ISO Committee for Reference Materials, and to create a new technical committee (ISO/TC 334). The main reason for this decision was to facilitate the transformation of the ISO/REMCO Guides, developed for the production and use of reference materials, into other ISO deliverables, most probably international standards. The inaugural meeting of the committee took place on 8 and 9 September 2021 and the resolutions from the first meeting was approved at a subsequent meeting on 16 November 2021. The most important decisions that were taken during this meeting included the approval of the title and scope of work of the committee and the plan of action for the transformation of the ISO/REMCO Guides into international ISO standards.

1. Introduction and background
ISO/REMCO was the Committee for Reference Materials of the International Organisation for Standardisation (ISO) that carried out and encouraged a broad international effort for the harmonisation and promotion of the production and use of reference materials. It aimed to be the global centre of excellence with respect to issues relating to reference materials. Since the 1970s, ISO/REMCO has developed internationally harmonised guidance for the production and use of reference materials and published a suite of five ISO/REMCO Guides.

In February 2019, the ISO Committee on Consumer Policy (COPOLCO) raised concerns with the ISO Technical Management Board (TMB) about the purpose and intended use of ISO Guides. ISO TMB then instructed ISO/Central Secretariat (CS) to review all the existing ISO Guides and propose a course of action for the future of each Guide. The course of action could either include a specific plan to promote the Guide to the ISO technical committee community or to transform the Guide into other ISO deliverables, such as an international standard or technical report. During the review performed by ISO/CS, it was found that the Guides developed by ISO/REMCO did not meet the criteria of a Guide.
The definition of a Guide as published in the ISO/IEC Directive Part 2 [1] state that they should function as guidance documents to assist the development of ISO documents, principally standards, i.e., ISO Guides are written to support the work of standards writers. Contrary to this definition, the ISO/REMCO Guides, were developed as general technical guidance documents in the specific field of the production and use of reference materials to be used by producers and users of reference materials. Therefore, the ISO/REMCO Guides do not conform to the ISO definition of a Guide.

ISO TMB then decided in February 2020, that it will be more appropriate for ISO/REMCO to become an ISO technical committee. As a technical committee, ISO/REMCO could review the scope and purpose of the ISO/REMCO Guides and decide to transform the Guides into other ISO deliverables, including international standards. On 14 December 2020, ISO TMB approved the creation of the new technical committee, ISO/TC 334, Reference materials. ISO TMB approved the disbandment of ISO/REMCO on 15 February 2021 and allocated REMCO’s published documents and current projects to ISO/TC 334.

This change is a very beneficial change for the committee in all aspects of the activities of the committee. ISO/TC 334 will be able to develop international standards, which has been on the wish list of the committee since 2002. The committee will now be able to decide to transform some, or all, of the guidance documents that it has developed over the years into international standards and will also be able to develop new guidance documents as international standards. As international standards the guidance documents developed for the production and use of reference materials will now have the standing of internationally harmonised documents that can be adopted as part of regulations, as it is the requirement for the European Union (EU) and other countries, such as Japan.

On this point, it is important to note that international standards as per the definition of the ISO/IEC Directives Part 2 [1] are not required to only consist of requirements, which is the usual perception of a ‘standard’. There are a number of published international standards that consist of only recommendations, e.g., ISO 26000:2010 [2] (this example is also mentioned in clause 11.5.2 of the ISO/IEC Directives, Part 2) and ISO 24156-1:2014 [3]. ISO/TC 334 will therefore be able to continue to develop its documents either as a mixture of requirements and recommendations or solely as recommendations.

2. Program of work of ISO/TC 334

2.1. Existing guidance for the production and use of reference materials

ISO/REMCO developed and maintained a coherent series of five generic Guides focused on users and producers of reference materials:

- ISO Guide 30:2015 - Reference Materials – Selected terms and definitions [4]
- ISO Guide 31:2015 - Reference materials - Contents of certificates, labels and accompanying documentation [5]
- ISO Guide 33:2015 – Reference materials – Good practice in using reference materials [6]
- ISO Guide 35:2017 - Reference materials - Guidance for characterisation and assessment of homogeneity and stability [7]
- ISO Guide 80:2014 – Guidance on the in-house preparation of quality control materials (QCMs) [8]
ISO 17034 [9], the international standard that was developed for the conformity assessment of the competence of reference material producers forms the core of the guidance documents that was developed by ISO/REMCO (see Fig. 1). The standard is based on ISO Guide 34 [10] that was initially developed by ISO/REMCO and then transformed into the international standard through a joint working group with ISO/CASCO, the ISO Committee for Conformity Assessment.

Trade and industry, quality of life and human health, product and process safety, the enforcement of environmental requirements and many pieces of legislation are dependent on measurement and testing results. Many of these activities are border-crossing, and it is important that there is a known, proven, and accepted equivalence, when measurement results are generated at different locations and at different points in time. This comparability can often be best established through certified reference materials (CRMs) with established metrological traceability.

Reference materials are fundamental to ensuring confidence in measurement results. Users of reference materials:

- calibrate equipment or a method,
- validate a measurement method,
- carry out performance control of their methods and staff, and
- ensure comparability of measurement results between laboratories.
ISO/REMCO Guides provide procedures for maximising the benefit of the use of reference materials in these applications.

The ever-increasing need for new reference materials, in existing and new fields of measurement and testing, continues to lead to the emergence of new producers and new challenges to existing producers of reference materials. The production of a new reference material requires in-depth knowledge of metrology, material handling and preparation and estimation of measurement uncertainty. Additionally, knowledge is also required on the targeted property, the measurement methods involved, and the associated problems with defining the quantity intended to be measured (the measurand) to be value assigned for a particular material. ISO/REMCO Guides are a source of this understanding and knowledge. Equally important is that these Guides lay out the “generic characteristics” of reference materials.

The impact of the production and use of reference materials on the development of ISO standards by ISO/TCs is considerable. Many International Standards describe a measurement, calibration, or testing procedure and one of the key tools for implementing the procedure and controlling its performance are reference materials. Newly developed standards may require new reference materials, which might also present new problems with respect to the design and execution of such a reference material project. On a generic level, ISO/REMCO provided, mainly through its Guides, advice to experts working in a particular field to develop high-quality reference materials.

2.2. First meeting of ISO/TC 334

The first meeting of ISO/TC 334 was held on 8 and 9 September 2021. The most important decisions that were taken during the first meeting included the approval of the title of the committee to be ISO/TC 334 – Reference materials with the scope to develop standards in the competent production and use of reference materials, including the concepts, terms and definitions related to reference materials. Discussions on the way forward to meet the mandate from the ISO TMB to transform the ISO/REMCO Guides into other ISO deliverables lead to the extension of the meeting to 16 November for the finalisation and approval of the resolutions.

It was decided to transform the ISO/REMCO Guides into international ISO standards without technical change through a draft international standard (DIS) enquiry stage. The structure of ISO/TC 334 was expanded with the establishment of new working groups to facilitate the new work item proposals for the transformation of the existing ISO/REMCO Guides.

The liaison relationships that ISO/REMCO previously had with other ISO/TCs, and several external organisations have been re-established in the new committee. This strong horizontal function of ISO/REMCO to advise other technical committees on issues related to reference materials will continue as part of the work of the new committee. It is hoped that the recognition that the ISO/REMCO Guides will gain when they become standards will also highlight the importance of reference materials in the field of the establishment of metrological traceability for chemical as well as biological measurements and other fields of testing.
3. Conclusions
On 14 December 2020, ISO TMB took the decision to transform ISO/REMCO and to create a new technical committee for reference materials (TC 334). The main reason for this decision was to facilitate the transformation of the ISO/REMCO Guides into other ISO deliverables, most probably international standards. The first meeting of ISO/TC 334 took place on 8 and 9 September 2021 and the resolutions of the meeting were finalised and approved at a subsequent meeting on 16 November 2021.

The most important decisions that were taken during the first meeting included the approval of the title of the committee to be ISO/TC 334 – Reference materials with the scope to develop standards in the competent production and use of reference materials, including the concepts, terms and definitions related to reference materials. It was also decided to transform the ISO/REMCO Guides into international ISO standards without technical change through a draft international standard (DIS) enquiry stage. The structure of ISO/TC 334 was expanded to facilitate the transformation of the Guides through the use of the traditional working group structure of the committee. The liaison relationships that ISO/REMCO previously had with other ISO/TCs, and several external organisations have been re-established in the new committee. This strong horizontal function of ISO/REMCO to advise other technical committees on issues related to reference materials will continue as part of the work of ISO/TC 334.

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[10] ISO Guide 34:2009 General requirements for the competence of reference material producers International Organization for Standardization (ISO) (Geneva, Switzerland) pp. 34.