MEETING REPORTS



Progress with the work program of ISO/REMCO during 2020

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Received: 17 September 2020 / Accepted: 4 March 2021 / Published online: 22 March 2021 © The Author(s), under exclusive licence to Springer-Verlag GmbH Germany, part of Springer Nature 2021

Abstract

The 43rd meeting of the Reference Material Committee of ISO, ISO/REMCO, that was scheduled to take place in Milan, Italy, from 30 June to 3 July 2020 with Accredia, the Italian accreditation body and INRIM, the Italian Metrology Institute as the hosts, was cancelled due to the COVID-19 pandemic. This report shares the details of the important decision that was taken by the ISO Technical Management Board (TMB) in December 2020 to transform ISO/REMCO into an ISO technical committee, ISO/TC 334, *Reference materials*. The background that led to the decision is provided as well as the implications of the decision for the future of the development of guidance for the production and use of reference materials. The report also gives an update on the progress with the work program of the committee during the past year and the strategy for the future work of the committee.

Keywords ISO/REMCO · Work program · Reference materials · Guidance documents

Introduction

The 43rd meeting of the Reference Material Committee of ISO, ISO/REMCO, was scheduled to take place in Milan, Italy, from 30 June to 3 July 2020, to be hosted by Accredia, the Italian accreditation body and INRIM, the Italian Metrology Institute. However, the meeting was cancelled due to the COVID-19 pandemic. Since March 2020, the committee has, and continues to progress the technical work program virtually as required by ISO, using on-line meetings, etc. ISO/REMCO now has a membership of 71 members of the International Organization for Standardization (ISO) and liaisons with 16 international organisations

and multiple ISO-internal committees (9 'to' and 24 'from' ISO/REMCO).

This report gives an update on the progress with the work program of the committee and the strategy for the future work of the committee. Furthermore, it also explains the details of the important decision that was taken by the ISO Technical Management Board (TMB) in December 2020 to transform ISO/REMCO into an ISO technical committee, ISO/TC 334, *Reference materials*. The background that led to the decision is provided as well as the implications for the future of the development of guidance for the production and use of reference materials.

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ISO TMB decides to create a new technical committee (TC 334), Reference Materials

In February 2019, the ISO Committee on Consumer Policy (COPOLCO) raised concerns with ISO TMB about the purpose, intended use and audience of ISO Guides. At that time ISO TMB instructed ISO/Central Secretariat (CS) to review all the existing ISO Guides and propose a course of action for the future of each Guide, such as 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 during 2019, it was found



that the Guides developed by ISO/REMCO do not meet the criteria as per the definition of a Guide as published in the ISO/IEC Directive Part 2 [1], i.e. they should function as guidance documents to assist the development of ISO documents, principally standards. The ISO/REMCO Guides, written as general technical assistance in the specific field of the production and use of reference materials, therefore, do not conform to this specific ISO definition.

ISO TMB then decided in February 2020 that it will be more appropriate for ISO/REMCO to become a technical committee. As a technical committee, ISO/REMCO could review the scope and purpose of the REMCO Guides and decide to transform the Guides into other ISO deliverables, including international standards. ISO TMB then requested ISO/REMCO to work with its secretariat to develop a proposal for the transformation of the committee into a technical committee. On 14 December 2020, ISO TMB approved the creation of the new 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, *Reference materials*.

This change is a very beneficial change for the committee in all aspects. Finally, ISO/REMCO 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).

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.

Currently, two committee internal ballots (CIBs) are underway in the new ISO/TC 334: the first to create a mirror of the working group structure of ISO/REMCO in ISO/TC 334 and the second to re-establish the liaison relationships that ISO/REMCO previously had with other ISO/TCs and several external organisations. 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 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. The first meeting of the ISO/TC 334 is planned for some time around May 2021. This meeting will focus on the finalisation of the terms of reference and the scope of work of the new committee. The review of the scope of work will include the decisions that will need to be made on how to transform the existing REMCO Guides as well as the Guides under development.

Progress with the technical work program of ISO/REMCO

Guidance on the production of qualitative reference materials and the assignment of nominal properties

The working draft of ISO Guide 85 "Guidance for the production of reference materials having one or more assigned qualitative property values" is planned to be completed by the end of 2021. So far good progress has been made with the drafting of the important clauses on characterisation, the evaluation of the uncertainty of measurement of a qualitative property value and the establishment of the traceability of a qualitative property value. Currently, the characterisation-clause looks at providing guidance at the hand of the examples of DNA sequencing and protein identification in a matrix material. During a recent web meeting of the working group, who is drafting the Guide, some in-depth discussions on these topics were held. Some of the gaps in the current version of the draft Guide that were identified were also discussed during the working group meeting. A few of the working group members volunteered to draft text on the assessment of the homogeneity and stability of qualitative reference materials. The meeting also emphasised the importance of the close working relationship between this working group and the working group responsible for terminology of reference materials.

Guidance on the production of high purity reference materials

The first draft of ISO Guide 86 "Guidance for pure reference materials for small organic molecules" is progressing well with most of the work performed in a small drafting group which was completed by April 2020. The first draft has been sent to all the working group members and the comments collected until August 2020. All the comments received will now be reviewed by the convenor and the drafting group for the update of the draft. Final discussions of the technical



issues that the working group members raised during the commenting phase will be held during web meetings of the working group. The plan is to have the working draft of ISO Guide 86 ready by the end of 2020 so that the committee draft ballot can be completed, the comments reviewed, and the text updated for discussion of the technical issues at the next annual meeting of ISO/REMCO.

The working draft of ISO Guide 87 "Guidance for 'pure' reference materials for metals and metalloids" is planned to be completed by the end of 2020. The membership of the working group is still being established, and experts who are interested and active in the field and would like to become involved with the development of ISO Guide 87 is welcome to contact the ISO/REMCO secretariat or Dr Zoltan Mester from NRC in Canada who is the convenor of the working group.

A new approved work item

Three of the published guidance documents of ISO/REMCO underwent systematic review during 2019, i.e. ISO Guide 30 "Reference materials—Selected terms and definitions" [4], ISO Guide 33 "Reference materials—Good practice in using reference materials" [5] and ISO Guide 80 "Guidance for the in-house preparation of quality control materials (QCMs)" [6]. The committee members re-affirmed ISO Guide 33 and ISO Guide 80. Since an amendment ballot for ISO Guide 30 to revise the definitions of reference material and certified reference material was approved by the ISO/REMCO members and by ISO TMB in 2019, a new committee internal ballot was launched early in 2020 to stop with the amendment of ISO Guide 30 and instead revise the complete 2015 edition of ISO Guide 30. This new ballot was also approved by the REMCO members. In the meantime, ISO TMB has also approved the new work item proposal to revise the complete ISO Guide 30.

In a continued effort to attempt to align the definitions of reference material and certified reference material in the International Vocabulary for Metrology (VIM) [7] and ISO Guide 30 [4], REMCO has joined a focus group established by JCGM WG2 responsible for drafting the fourth edition

of the VIM. During the first meeting of the focus group, good progress has been made to discuss and establish a common understanding of the concepts of measurement, reference material, certified reference material, metrological approaches, which often result in misunderstandings and misinterpretations of terms between the two groups. It is envisaged that although there is still a difference in the use of the concept of measurement between the two groups, the definitions of reference material and certified reference material will be much better aligned between ISO Guide 30 [4] and the draft of the fourth edition of the VIM [7] that is expected to be available for public comment by the end of 2020.

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