Accred Qual Assur (2017) 22:381–387
DOI 10.1007/s00769-017-1285-5

INTERNATIONAL BODIES

The new International Standard ISO 17034: general requirements for the competence of reference material producers

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Received: 12 June 2017 / Accepted: 9 August 2017 / Published online: 26 September 2017

Abstract The International Organization for Standardization (ISO) has published ISO 17034:2016 on the general requirements for the competence of reference material producers (RMPs). Previously, these requirements were addressed in ISO Guide 34:2009, originally developed by the ISO Committee on Reference Materials (ISO/REMCO). The need for an International Standard was triggered as several accreditation bodies could not accredit to a guide, at all, while in other countries ISO Guide 34 could only serve as accreditation standard in combination with ISO/IEC 17025. For the transformation into a conformity assessment standard of the ISO/IEC 17000 series, the ISO Committee on Conformity assessment (ISO/CASCO) and ISO/REMCO joined forces. A Joint Working Group, formed by experts and stakeholders from both committees, finalised the transformation within 2 years. During the transformation, the structure of ISO 17034 has been aligned with other ISO/IEC 17000 series standards and the content of ISO 17034 has been harmonised with the recent editions of other relevant ISO Guides. Requirements for the production of reference materials (RMs) were elaborated on more clearly in the new standard, specifying the requirements for (non-certified) reference materials and the additional requirements for certified reference materials. The new International Standard ISO 17034:2016 supersedes ISO Guide 34:2009.

Keywords Reference material producer (RMP) · Reference material (RM) · Certified reference material (CRM) · Conformity assessment · Accreditation · ISO Guide 34

Introduction

Previously minimum requirements for the production of reference materials (RMs) were contained in ISO Guide 34:2009 [1]. This document was developed by the International Organization for Standardization (ISO) Committee on Reference Materials (ISO/REMCO) and has been used by accreditation bodies for the third-party assessment of reference material producers (RMPs). The fact that the document was issued as a guide rather than a standard is based on ISO internal rules: ISO/REMCO is not allowed to issue standards, hence a guide, that was largely indistinguishable from a standard, was published [2]. The official status as guide, however, hindered its international harmonised acceptance and in some countries the application for third-party assessment without combining it with another International Standard. Therefore, ISO/REMCO decided in 2014 to transform ISO Guide 34 also formally into a standard and approached the Technical Management Board of ISO (ISO/TMB) with this request. Following the advice of ISO/TMB, a Joint Working Group was formed between the ISO Committee on Conformity assessment (ISO/CASCO) and ISO/REMCO with the ambitious goal to complete the transformation within 2 years.

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Need for transforming ISO Guide 34

With the publication of the third edition of ISO Guide 34:2009, the technical competence required for the production of RMs were either assessed against ISO Guide 34:2009 alone or in conjunction with ISO/IEC 17025:2005 [3], specifying the general requirements for the competence of testing and calibration laboratories. The application of different rules hindered harmonisation, and the International Laboratory Accreditation Cooperation (ILAC) noted an increasing need to transform the existing guidance for RMPs into a standard of the ISO/IEC 17000 series (Note: The majority of conformity assessment standards are joint publications from ISO and the International Electrotechnical Commission (IEC). However, there are some CASCO publications that are published by ISO only, e.g. the here-discussed ISO 17034:2016). This transformation would allow accreditation bodies, who could not accredit to ISO Guide 34:2009 alone so far, to satisfy the increasing need for accreditation of RMPs. At the same time, it would further facilitate the combined use of ISO 17034 and other standards of the ISO/IEC 17000 series, relevant for RMPs. This concerns specifically ISO/IEC 17025, but also ISO/IEC 17043 [4], specifying general requirements for proficiency testing (PT) providers. The alignment with the latter was seen as a positive side effect as many RMPs are involved in PT activities.

In the European Union (EU), legislation sets out the requirements for accreditation and market surveillance and Regulation (EC) No 765/2008 demands that accreditation has to be based on international harmonised standards. Accreditation towards a guide was therefore only accepted during a transition period and would not be possible in the long term.

Since 2008 a new structure is used for the conformity assessment standards (standards of the ISO/IEC 17000 series) handled by ISO/CASCO. Furthermore, the revision of ISO/IEC 17025:2005 was planned. Ensuring the alignment of the standards focusing on the competence of RMPs and the competence of testing and calibration laboratories was considered to be of further added value.

ISO Guide 34:2009 was originally developed by ISO/REMCO together with a number of additional guidance documents. The transformation created the possibility to align and consolidate the content of ISO Guide 34 with the other REMCO Guides which were recently revised and where revision was close to completion, respectively. This concerned specifically: ISO Guide 30:2015 (about terms and definitions) [5], ISO Guide 31:2015 (about the content of certificates, labels and accompanying documentation) [6], and ISO Guide 35:2017 (about characterisation and assessment of homogeneity and stability) [7].

Transformation process

The ISO/REMCO decision to transform ISO Guide 34 into an International Standard was laid down in a resolution during the 37th REMCO meeting in July 2014. Following the advice of ISO/TMB, ISO/REMCO approached ISO/CASCO for the transformation process.

Within ISO/REMCO, an *ad hoc* group 'AHG3—Transformation of ISO Guide 34:2009 into an ISO Standard' was created to foster the technical exchange on the revision of the existing guidance document between REMCO and CASCO.

ISO/CASCO and ISO/REMCO created a Joint Working Group 'JWG43—Revision of ISO Guide 34:2009: General requirements for the competence of reference material producers' and experts from the conformity assessment community, international accreditation bodies and RMPs active in various analytical fields were invited to join.

During the 1st JWG43 meeting in December 2014, key aspects listed by ISO/REMCO AHG3 were implemented. The core requirements for reference material production were listed to make ISO 17034 the only reference for the required competence of RMPs, while further guidance, technical details and examples for implementation remained in the related ISO Guides 30, 31 and 35. Different requirements for the production of non-certified RMs and certified reference materials (CRMs) were more explicitly outlined, and the generic competence for the production of RMs elaborated in a clear way.

The new common structure for the ISO conformity assessment standards (ISO/IEC 17000 series) and its new sequence (general requirements, structural requirements, resource requirements (including human resources), process requirements (including operational functions) and management system requirements) were implemented.

The outcome of the first meeting was a text which additionally clarified the positions of the future ISO 17034 and ISO/IEC 17025 and their relationship to each other. The revised text was then submitted to the Committee Draft stage (ISO CD 17034) for a 3 months enquiry amongst CASCO and REMCO members who submitted 1042 comments.

During the 2nd JWG43 meeting in July 2015, these comments were scrutinised and the resulting document moved forward as Draft International Standard. ISO DIS 17034 was approved with 96 % positive votes in ISO/CASCO and 1573 comments were collected.

During the 3rd JWG43 meeting in April 2016, a clearer distinction between certified property values and other assigned property values (e.g. 'indicative values' or 'information values') was introduced and an informative Annex with a table summarising the specific requirements

for RMs and CRMs was added. At the end of the 3rd JWG43 meeting, the group decided to proceed to the Final Draft International Standard (FDIS) stage and ISO FDIS 17034 was later approved with 100 % positive votes.

The transformation of ISO Guide 34:2009 into ISO 17034:2016 [8] was completed within 2 years, and the new standard was published in November 2016, superseding ISO Guide 34:2009 (Fig. 1).

Major changes in the new International Standard ISO 17034:2016

In the following paragraphs, more details are given on the changes introduced in the various clauses during the transformation process from ISO Guide 34:2009 into ISO 17034:2016.

Introduction

The introduction clarifies that ISO 17034:2016 outlines the general requirements for producers of RMs and that it supersedes ISO Guide 34:2009. It informs that further guidance is given in the ISO Guides 31 and 35. The approaches outlined in the ISO Guides developed by ISO/REMCO meet the requirements of ISO 17034, but alternative ways may exist as well. Figure 2 illustrates the structure of ISO 17034 and its relationship to relevant ISO/REMCO Guides and other documents.

All parts of ISO/IEC 17025 relevant for measurement activities need to be applied. ISO 15189 [9] is mentioned as alternative for ISO/IEC 17025 for the medical sector. By this, the generic character of ISO/IEC 17025, listing requirements applicable for all laboratories, is emphasised.

Scope

ISO 17034:2016 specifies the general requirements for the competence of RMPs and is intended to be used as part of the general quality assurance procedures for the production of RMs. It covers the production of all types of RMs, including CRMs. A note in the scope clarifies that ISO 17034:2016 could also be used by regulatory authorities and accreditation bodies for assessing the competence of RMPs.

Normative references

ISO/IEC 17025 is the only normative reference for ISO 17034, while the ISO Guides received informative status during this transformation. As illustrated in Fig. 2, ISO 17034 is the standard for the competence of RMPs while

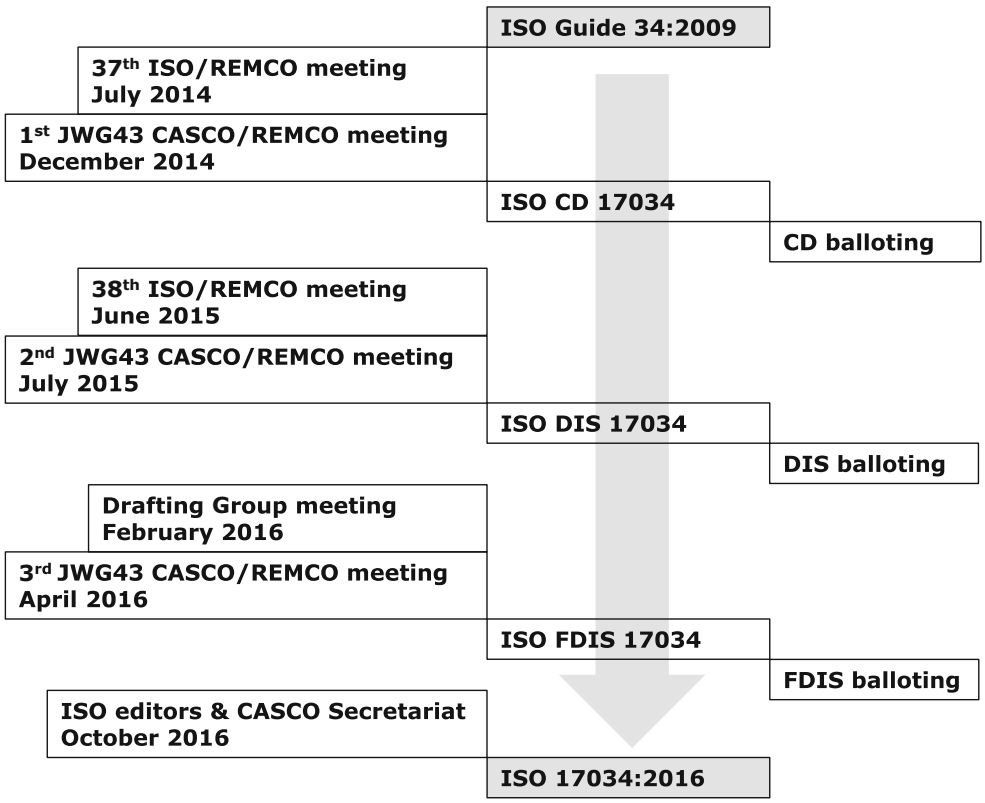

Fig. 1 Process of transforming ISO Guide 34:2009 into ISO 17034:2016

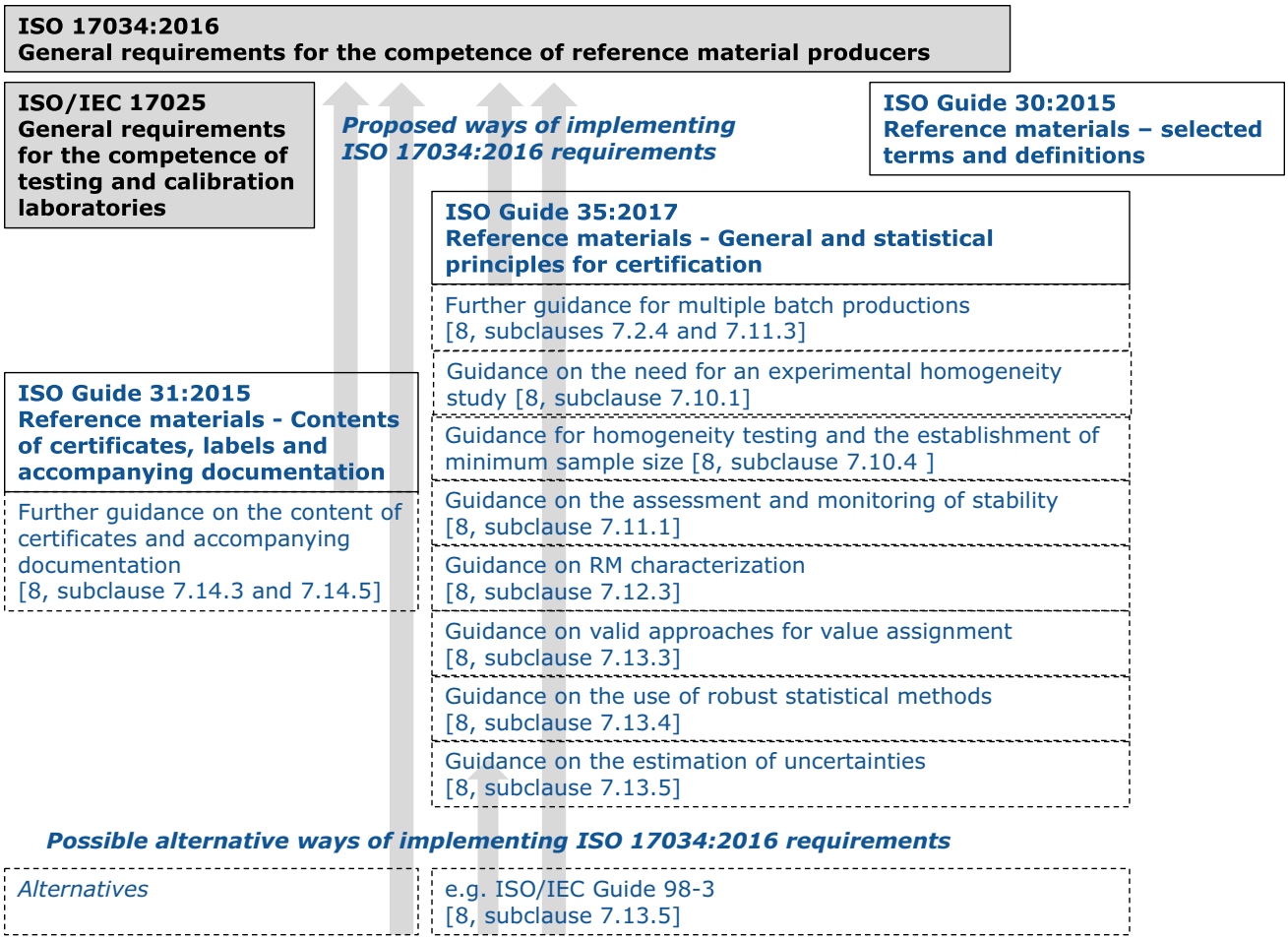

Fig. 2 International Standard ISO 17034:2016 and its relation to relevant REMCO Guides and other documents

some ISO Guides provide guidance for the implementation of ISO 17034.

This had significant implication for the status of ISO Guide 35. While adherence was obligatory in the old system (ISO Guide 34 and Guide 35), in the new system (ISO 17034 and ISO Guide 35) ISO Guide 35 proposes some approaches to implement ISO 17034. The suggested approaches do not claim to be exhaustive, i.e. other approaches may be acceptable as well. As a consequence, certain key provisions from the previously obligatory ISO Guide 35 were moved to ISO 17034.

Terms and definitions

ISO 17034:2016 covers the production of RMs and CRMs. While this was still debated when ISO Guide 34:2009 was drafted, stakeholders are now in agreement that it is appropriate to cover the needs for the production of RMs and CRMs in only one International Standard.

A continued challenge for all documents, including ISO 17034, was the twofold use of the term ‘reference material’. On the one hand side, the term is used as superordinate for the family of all RMs, including the non-certified RMs and the CRMs, and on the other hand side as subordinate in the meaning of (non-certified) RM. However, it was decided not to introduce a new term in ISO 17034 specifically addressing non-certified RMs.

The existing definitions for RM and CRM [5], also used in ISO Guide 34:2009, were maintained. They therefore continue to differ from the definitions given in ISO Guide 99 [10], the international vocabulary of metrology, the so-called VIM3 (Note: An update of ISO Guide 99:2007 has been published as JCGM Report 200:2012. ISO 17034:2016 refers to ISO Guide 99:2007 as normative reference, additionally the update does not concern the RM definitions.). The REMCO definitions are based on a broader concept which serves more adequately the needs of the RM user communities. For example, they recognise that assigned properties of RMs can be qualitative (nominal).

Following the systematic work done during the ISO Guide 34:2009 drafting, attention was paid to stick to agreed terms (e.g. processing, customer, subcontractor) and to avoid their synonyms (e.g. preparation, client,

collaborator). Also the policy to refer to the complete process from planning to after sales service as 'production' was maintained.

Specific attention was given to the correct use of the terms 'method' and 'procedure' as defined in ISO Guide 99. Methods refer to the generic description of a method while measurement procedures give the detailed description of a measurement process.

General requirements

The new common structure for CASCO documents mainly had an impact on the sequence in which requirements are organised. General requirements are followed by structural requirements, which in turn are followed by the resource requirements (including human resources), and then the process requirements (including operational functions), before the final clause is devoted to the management system requirements. 'Process requirements' were renamed as 'technical and production requirements' to avoid confusion with the term 'processing', which is a step in the production of a RM, namely the preparation of the material as such.

The term 'shall' was used throughout the text to indicate a requirement in contrast to the word 'should' indicating a recommendation. This became particularly important for the key requirements which were identified in the related ISO Guides and imported into ISO 17034.

Clause 4 of ISO 17034:2016 addresses contractual matters as well as impartiality and confidentiality and contains largely common text elements proposed for ISO/CASCO Standards. Some of the elements are additionally obligatory parts. Clause 4 has led to many discussions from the RMP's side, and some leeway was given to accommodate the practical issues for the RMPs, but nevertheless to keep the obligatory parts of the ISO/CASCO common elements. Concerning impartiality the major focus in ISO 17034:2016 is put on safeguarding impartiality of RMPs, while the subclauses on liability and financial resources were removed after the DIS balloting stage.

Structural requirements

The need for communication requirements was included in ISO 17034:2016 using the wording proposed by ISO/CASCO WG44, responsible for the revision of ISO/IEC 17025:

'The RMP management shall ensure that:

(a) Internal and external communication mechanisms are established;
(b) Communication takes place regarding the effectiveness of the management system;
(c) The importance of meeting customer and other requirements is communicated to the RMP personnel.' [8, subclause 5.4].

Resource requirements

Important to note is that accreditation to ISO/IEC 17025 is not mandatory, but that the RMP must ensure that for measurements all relevant requirements of ISO/IEC 17025 are fulfilled [8, clause 7] also in the case where subcontractors are used to perform the measurements within the frame of reference material production [8, clause 6]. Therefore, RMPs do not necessarily need ISO/IEC 17025 in their own scope of accreditation, but need to be able to safeguard that the requirements of ISO/IEC 17025 are respected.

Technical and production requirements

Within this clause, the requirements for selecting a characterisation strategy for the RM are laid down. It is the obligation of the RMP to select an appropriate approach taking the intended use of the RM into account. In a note, proposals for characterisation approaches are given [8, subclause 7.12.3].

ISO 17034:2016 covers the production of RMs, including both certified and non-certified RMs. The discussions and comments received before and during the different review stages indicated that further clarification was needed. At the same time, there was the wish to avoid as much as possible the term 'non-certified'. Therefore, ISO 17034:2016 requirements were regrouped, listing the requirements for RMs first and secondly the specific additional requirements for CRMs. It was clarified that for CRMs the general requirements for a RM need to be followed, and additionally the specific requirements for CRMs have to be met.

As a support to the user, an informative annex was added which contains a table summarising the requirements for RMs and CRMs and contains a link to the subclauses concerned.

However, the separation between RMs and CRMs did not resolve the whole issue and a clear distinction between certified property values and other assigned property values (e.g. 'indicative values' or 'information values') for RMs was introduced. Especially as one RM can have several (different types of) property values assigned to it.

Management system requirements

Management requirements are essentially the once laid down in ISO 9001 [11]. Option A describes all the relevant

requirements independent from ISO 9001, while option B refers to using ISO 9001 directly.

Important changes introduced during the transformation

ISO Guide 34 has generally served well as a basis for accreditation, either alone, or in combination with ISO/IEC 17025, which is also demonstrated by the number of ISO Guide 34 accredited RMPs. Therefore, none of the concerned parties saw a need for significant technical changes. Nevertheless, some modifications were introduced and are summarised in the following paragraphs.

The general requirements contain a new clause regarding **impartiality**. It refers to the absence of a conflict of interest and is equivalent to the requirement that RMP staff should be free from financial pressure.

A second new issue is the requirement to address **risks and opportunities**. This was also triggered by the new ISO/IEC 17000 series structure, and it has still to be seen how this is implemented in practice.

In line with the new draft ISO/IEC 17025, the term **quality manager** has been eliminated, although there is the requirement to have a staff member with this function.

The production of **multiple batches** has been addressed explicitly. Whenever data for a CRM are based on properties of previous batches, it needs to be verified that these data remain applicable [8, subclause 7.2.4].

It is now explicitly stated that **homogeneity** must be assessed for each property of interest. Whenever this is based on experimental data, this requires measurement of each property of interest unless scientific evidence or previous experience can demonstrate that particular groups of properties are sufficiently closely associated to each other that measurement of one property in such a group furnishes evidence of homogeneity for other properties in the same group [8, subclause 7.10]. The new standard states also explicitly that an uncertainty contribution of homogeneity must be included in any certified value, unless its contribution is demonstrated to be negligible [8, subclause 7.10.5].

As for homogeneity, an uncertainty contribution of **stability** must be included in the uncertainty of a certified value, unless stability of the property value can be ensured. This requirement was already included in ISO Guide 34:2009, but is made more explicit in ISO 17034:2016 [8, subclause 7.13.6].

ISO Guide 35 contained a list of possible **characterisation** approaches. This list was taken over to ISO 17034, but it is recognised that other approaches may be valid as well [8, subclause 7.12.3].

Another requirement concerns the **qualification of laboratories**. The competence of each laboratory must be demonstrated by data that were not obtained on the material to be characterised [8, subclause 7.12.4]. This in fact rules out the circular reasoning of demonstrating laboratories' competence in a PT and then using the same PT data for characterisation of a RM.

With ISO 17034:2016, the characterisation approaches which can be used by conformity-assessed RMPs have been broadened. Other requirements are not new but phrased more explicitly, i.e. the use of data from previous RM batches (multiple batch production), uncertainty contributions (homogeneity and stability) and the qualification of laboratories. Therefore, RMPs being in compliance with ISO Guide 34:2009 are likely to also be in compliance with ISO 17034:2016, provided that they intrinsically covered already the new requirements impartiality and risks and opportunities.

Conclusion and looking forward

With the transformation of ISO Guide 34:2009 into ISO 17034:2016, harmonised requirements for the competence of RMPs and harmonised criteria for the assessment of the competence by third parties have been laid down.

ISO 17034:2016 requires ISO/IEC 17025 criteria for all measurement tasks carried out during the production of RMs, but will allow an RMP to seek accreditation towards ISO 17034:20016 without holding an ISO/IEC 17025 accreditation. This became possible as ISO 17034 is a standard of the ISO/IEC 17000 series.

At the same time, the transformation ensured that standards for conformity assessment (ISO/IEC 17000 series) handled by ISO/CASCO are aligned concerning their structure and facilitates the combined use of ISO 17034 with ISO/IEC 17025 and ISO/IEC 17043, being of advantage for RMPs also involved in measurement and PT activities.

With the publication of ISO 17034, the REMCO definitions for RMs and CRMs were reconfirmed. It is hoped that the currently on-going drafting of a successor document for ISO Guide 99/VIM3 will take the ISO/REMCO definitions of RM and CRM into account.

The transformation helped to align the content of ISO 17034:2016 with the other recently revised ISO Guides, concerning terms and definitions (ISO Guide 30), content of certificates and other accompanying documentation (ISO Guide 31) and approaches for the characterisation, homogeneity and stability assessment of RMs and CRMs (ISO Guide 35).

Acknowledgements The authors acknowledge the numerous contributions of the members of the joint ISO/REMCO and ISO/CASCO Working Group 43.

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