STRATEGIC BUSINESS PLAN (SBP)

Clause 2.1.2 of the ISO/IEC Directives, Part 1

ISO/TC 334
Reference materials
Secretariat:

Why are standards important?

Standards on reference materials are fundamental to ensure confidence in measurement results

What benefits can standards bring?

Reference materials are essential tools for measurement, calibration, or testing procedures and controlling performance.

Who participates in standards development in this topic?

International laboratory accreditation and metrology institutes, certification bodies, end users and regulators

What actions will the committee take in the next 3 years?

The committee will develop a series of publications focused on the production and use of reference materials

How can you get involved?

Speak with your national standards body or one of the extensive range of international-level liaisons to TC 334

Message from the Chair, Mrs Angelique Botta

Reference materials are vital to ensuring globally comparable and reliable measurement results, supporting safe trade, effective regulation, and high-quality outcomes in science, industry, and public health.

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ISO's role in supporting the SDGs

ISO/TC 334 standards support the following SDGs

Introduction

The evolution of formal strategic planning in ISO Technical Committees is a key measure in supporting the ISO 2030 Strategy vision of making lives easier, safer and better. This document is designed to aid committees and their stakeholders in:

- Identifying benefits and vision of standardization within the committee's field of activity
- Linking benefits to higher strategic imperatives (ISO 2030 Strategy, SDGs , London Declaration Action Plan)
- Prioritizing among projects and allocating resources
- Providing transparency and communicating through a format adapted to three key audiences (general public, TMB and other TCs, and internal TC stakeholders
- Supporting data-driven continuous improvement, including user perspectives where available
- Maintaining strategic flexibility for different market cadences

International standards embody the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in ISO Technical committees, representative of all interested parties, supported by a WTO TBT-compliant public enquiry phase.

International standards are developed through a member-driven market-centric process, where any P- member may submit a proposal for new work.

This document represents an important filter through which new work items should be considered by P-members of a committee and shall be referenced in new work item proposals submitted to the committee per clause 2.3.4 of the ISO/IEC Directives, Part 1.

Beginning in 2026, deviations from this strategy shall be rationalized in new work item proposals.

Meeting global needs

To realize our vision, we must develop consensus-based standards that are relevant and respond to current and future challenges. We must focus on getting the right standards to market at the right time, and with the right content and in the right format.

Business environment and future trends

ISO/TC 334 standards provide procedures for maximizing 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. The production of a new reference material requires a strong knowledge of metrology, material handling and preparation and estimation of measurement uncertainty, in addition to the knowledge on the targeted property, the measurement methods involved, and the associated problems with obtaining the best estimate of the quantity value or 'qualitative property' to be certified for a particular material. ISO/REMCO Guides were a source of this understanding and knowledge. Equally important is that these Guides laid out the "generic characteristics" of reference materials.

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 the use of reference materials.

Benefits of standards and vision for standardization in the field of activity	ISO/TC 334 has a coherent series of five ISO standards and two ISO Guides (currently also being transformed into ISO standards) focused on users and producers of reference materials. The intent, with regards to users, is to increase their understanding of how reference materials and their accompanying information can be and should be applied in measurement and testing. The intent, with regards to producers, is to promote the production of reference materials that meet current requirements in terms of metrological principles and quality standards. The standards and guides also serve as a vehicle for communication between users, producers and their assessors concerning their respective roles and responsibilities. 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/TC 334 provides guidance to experts working in a particular field to develop high-quality reference materials. 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.
Reflections on current publications and their market impacts	The production and use of reference materials (RMs) is a key activity for the improvement and maintenance of a worldwide coherent measurement system. Comparable measurements across national and international borders are critically important to support global trade, climate action, and other issues of global concern. RMs with different characteristics are used in measurements for quality control, the precision study in method validation, as well as the comparison of measurement methods and the measurement results from different analytsts. Certified reference materials (CRMs) are used for calibration or for the assignment of values to other reference materials or to confirm or establish metrological traceability to conventional scales, such as the octane number, hardness scales and pH. The adoption and acceptance of the ISO Standards in the field of Reference Materials has led to an increasing number of reference material producers (RMPs) worldwide that seek or hold accreditation. To be comparable across borders and over time, measurements need to be metrologically traceable to appropriate and stated references. CRMs play a key role in implementing the concept of metrological traceability of measurement results in chemistry, biology and physics among other sciences dealing with substances and materials.
Sustainability and climate change	Reference materials are used most often by industries and governments in networks for the monitoring of air pollution at ambient levels and for the monitoring of stack emissions by industries such as coal fired power plants, incinerators, cement manufacturing, oil and petroleum refineries, etc. The use of specific reference materials for quality assurance purposes in monitoring networks are sometimes prescribed by regulations. Reference materials are therefore seen as an important tool in the monitoring of air pollution by industries to provide reliable and accurate measurement data from monitoring networks to mitigate and reduce the impact of industry on the environment and climate change. Also, in the arena of the development of technologies for the application of green alternative energy sources, reference materials play an important role to support the development and validation of analytical methods for the accurate quantification of measurement results. Specific examples include the quality assurance of hydrogen fuel quality in the application of fuel cell technology in vehicles and other applications, as well as the quality assurance of biogas for household use in heating and cooking. TC 334 standards contribute to the following UN SDG sub-goals by providing foundational standards for comparable measurements across national and international borders to support global trade, climate action, and other issues of global concern:

- 7.a By 2030, enhance international cooperation to facilitate access to clean energy research and technology, including renewable energy, energy efficiency and advanced and cleaner fossil-fuel technology, and promote investment in energy infrastructure and clean energy technology
- 8.2 Achieve higher levels of economic productivity through diversification, technological upgrading and innovation, including through a focus on high-value added and labour-intensive sectors
- 8.3 Promote development-oriented policies that support productive activities, decent job creation, entrepreneurship, creativity and innovation, and encourage the formalization and growth of micro-, small- and medium-sized enterprises, including through access to financial services
- 9.4 By 2030, upgrade infrastructure and retrofit industries to make them sustainable, with increased resource-use efficiency and greater adoption of clean and environmentally sound technologies and industrial processes, with all countries taking action in accordance with their respective capabilities
- 13.2 Integrate climate change measures into national policies, strategies and planning
- 14.1 By 2025, prevent and significantly reduce marine pollution of all kinds, in particular from land-based activities, including marine debris and nutrient pollution

All voices heard

We need to ensure that we attract and retain the best experts and enable everyone to participate. We must listen to all voices, both in the development of standards and when making decisions as an organization.

Stakeholder mixture and engagement

ISO/TC 334 membership is open to interested ISO member bodies as participating (P) or observer (O) members and to interested ISO correspondent members as observer (O) members. All ISO members may participate in ISO/TC 334 meetings.

Prior to the annual ISO/TC 334 meeting, at the CAG meeting immediately preceding the first plenary, the participation of the existing membership is reviewed and discussed, with a view to encourage active participation of all members, and how this can be achieved. Specific factors relating to this analysis and affecting the work of ISO/TC 334 are discussed below.

Because of the great benefits that can be achieved from ISO deliverables on reference materials, ISO/TC 334 has a relatively high “P”-membership (28 members) and in turn access to a generous body of technical experts. ISO/TC 334 plenary sessions and WG meetings have been well attended. The latter, in particular, are in general fora in which lively technical debates lead to good work progress. As it is to be expected, some WGs allocated work activities of high impact draw the majority of ISO/TC 334 members, and this impacts on the progress made at other WG meetings at the same time. ISO/TC 334 strives to minimize such conflicts, but this is not always possible during the annual meeting.

Although the majority of ISO/TC 334 members participate actively in WG meetings during the annual meeting, the number of participants who continue to provide input to the ongoing work of a WG in the period between annual meetings is appreciably lower and represented in many instances only a “small” core of experts. While having the work done by a core of experts is not necessarily negative, the non-participation of other members often meant that the working result must often undergo a full review and, if appropriate, approval at the next annual meeting. This slows down the progress made in ISO/TC 334 work activities. The advent of on-line meetings has greatly stimulated the participation in the work of the committee during recent years.

Developing country perspectives	The accreditation of testing and calibration laboratories to the conformity assessment standard ISO/IEC 17025 is an important tool that can level the playing field for developing economies in terms of entering global markets and address issues related to climate action, which is putting a lot of pressure on the economic growth of developing economies. ISO/IEC 17025 requires the use of certified values from certified reference materials (CRMs) for the establishment of metrological traceability of measurement results especially in the fields of chemical, biological, materials, forensics testing, etc. The development of harmonized international standards related to the production and use of reference materials including certified reference materials will therefore support developing economies in terms of global market access and addressing problems related to health and the environment.

ISO Standards used everywhere

To encourage the widespread use of ISO standards and attract experts to the development process, we must clearly demonstrate the benefits of using ISO standards.

Coordination and cohesion	The implementation and completion of the ISO/TC 334 work program also depends on the effectiveness of ISO/TC 334 liaisons with other organizations (see liaisons here). But such liaisons and other forms of cooperation have also resulted in additional challenges for ISO/TC 334. The pool of experts in the field of reference materials is limited as are the financial resources available to allow them to participate in relevant committees and groups. Indeed, several ISO/TC 334 representatives participated in other committees/groups involved with reference materials or in related fields. A major advantage of this across-organization participation is that ISO/TC 334's perspective is conveyed to the other committees/groups and, conversely, the perspectives of the other committees/groups are brought to ISO/TC 334, leading to a better and broader understanding of the relevant issues and possibly to agreement on their resolution. A major disadvantage is that the availability of these ISO/TC 334 representatives is shared, and this leaves the members with less time available for ISO/TC 334 activities.
National adoption perspectives	It is still too early, following the conversion of the ISO 33400 series of standards within ISO/TC 334, to comment on the national adoption status.
Conformity assessment	The key ISO standard associated with this process is ISO 17034 under the auspices of ISO/CASCO. ISO/TC 334 played a vital role in the conversion of ISO Guide 34 into this new standard (ISO 17034).

ISO TC 334 Strategic Objectives

Objectives	Responsible SC or WG (if applicable)	Proposed actions	Priority (HIGH, MEDIUM, LOW)
To develop a series of standards and other deliverables i.e TR/TS focused on users and producers of reference materials.	WG8 – Quality control materials WG10 – Terms related to reference materials WG19 – Inorganic purity RMs	Working Group 8 developed ISO/TR 33402: Good practice in reference material preparation Working group 10 is tasked with the transformation of ISO Guide 30 into ISO 33400: Reference materials – Vocabulary Working group 19 is developing ISO 33408: Guidance for the production of pure inorganic substance certified reference materials	High
With regards to users, is to increase their understanding of how reference materials and their accompanying information can be and should be applied in measurement and testing.	WG9 – Uses of reference materials	Working group 9 developed ISO 33403: Reference materials – Requirements and recommendations for use	High
With regards to producers, is to promote the production of reference materials that meet current requirements in terms of metrological principles and quality standards.	WG13 – Qualitative reference materials	WG13 developed ISO 33406: Approaches for the production of reference materials with qualitative properties	High
To leverage ISO standards as a vehicle for communication between users, producers and their assessors concerning their respective roles and responsibilities.	ISO/TC 334 has a strong horizontal function within ISO with several other ISO technical committees in liaison category A. The committee also has strong liaison relationships with several other international organisation, such as ILAC, the BIPM, AOAC, CITAC, etc.		High

To transform all ISO/REMCO Guides into IS/TR/TS as the committee sees fit.	WG14 – Accompanying RM documents WG16 – Value assignment	Working Group 14 transformed ISO Guide 31 into ISO 33401: Reference materials – Contents of certificates, labels and accompanying documentation Working group 16 transformed ISO Guide 35 into ISO 33405: Reference materials – Approaches for characterization and assessment of homogeneity and stability	High.