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Reference materials — Approaches for characterization and assessment of homogeneity and stability

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 334, *Reference materials*.

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This first edition cancels and replaces ISO Guide 35:2017, which has been technically revised.

The main changes are as follows:

— ~~—~~technical requirements for the characterization and the assessment of homogeneity and stability of reference materials as stipulated in ISO 17034 is reiterated in ~~ISO 33405~~this document with additional guidance on approaches that can be used.

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Introduction

The production of reference materials (RMs) is a key activity for the improvement and maintenance of a worldwide coherent measurement system. As detailed in ISO 33403~~,~~[1], RMs with different characteristics are used in measurements, such as calibration, quality control, proficiency testing and method validation, as well as for the assignment of values to other materials. Certified reference materials (CRMs) are also used to confirm or establish metrological traceability to conventional scales, such as the octane number, hardness scales and pH.

To be comparable across borders and over time, measurements need to be traceable to appropriate and stated references. CRMs play a key role in implementing the concept of traceability of measurement results in chemistry, biology and physics among other sciences dealing with substances and materials. Laboratories use these CRMs as readily accessible measurement standards to establish traceability of their measurement results to International Standards. The property values carried by a CRM can be made traceable to the International System of Units (SI) or other internationally agreed references during production. This document explains how approaches can be developed that will lead to well established property values, which are made traceable to appropriate stated references.

For reference material producers (RMPs), this document refers to ISO 17034, ~~one other standard of the 33400 series~~ISO 33401[2] and ISO- Guide 30 that support the production and certification of RMs:

— ~~—~~ISO 17034 outlines the general requirements to be met by an RMP to demonstrate competence~~.~~;

— ~~—~~ISO 33401[3] describes the contents of certificates for CRMs and of accompanying documents for other RMs~~, respectively.~~;

— ISO Guide 30 contains terms and definitions related to reference materials.

Alongside developments in RM production approaches, the range of classes of RMs is growing with advances in technology, increasing the need for more widely applicable technical guidance in RM production. In addition, increasing use of ISO/IEC 17025 and ISO 15189 by laboratories has led to greater demand for clear statements of metrological traceability.

This document describes examples of possible designs for homogeneity, stability and characterization studies that are in line with ISO 17034. It also contains specific provisions concerning the establishment of metrological traceability in RM production.

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