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

Matériaux de référence — Approches pour la caractérisation et l'évaluation de l'homogénéité et la stabilité

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Contents

Page

Foreword ..... **vi**
Introduction ..... **vii**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 Symbols **2**
5 Conventions **3**
6 Overview of reference material production **3**
6.1 General 3
6.2 Summary of project design 3
6.3 Acquisition of starting material 5
6.4 Feasibility studies 6
6.5 Reference material processing 6
6.6 Homogeneity assessment 6
6.7 Stability assessment 6
6.8 Choice of measurement procedures 7
6.9 Metrological traceability 7
6.10 Characterization and uncertainty evaluation 7
6.11 Commutability assessment 7
6.12 Transport issues 7
6.13 Value assignment 8
6.14 Stability monitoring 8
6.15 Reference materials produced in repeated batches 8
7 Assessment of homogeneity **8**
7.1 Preamble 8
7.2 Need for an experimental homogeneity study 9
7.3 Properties to be studied 10
7.4 Statistically valid sampling schemes 10
7.4.1 Minimum number of units for a homogeneity study 10
7.4.2 Use of statistical power analysis 12
7.4.3 Sampling strategies for a homogeneity study 12
7.5 Choice and conduct of the measurement procedure for a homogeneity study 13
7.5.1 Choice of measurement procedure 13
7.5.2 Conduct of measurements for homogeneity studies 13
7.6 Homogeneity study designs 15
7.6.1 Objective of a homogeneity study 15
7.6.2 The basic homogeneity study design – measurement in a single run 16
7.6.3 Randomized block design 17
7.6.4 Balanced nested design 17
7.6.5 Alternative strategies 17
7.7 Evaluating a homogeneity study 18
7.7.1 Initial inspection for measurement trends and outliers 18
7.7.2 Inspection for processing trends 19
7.7.3 Evaluation of the between-unit term – basic design 19
7.7.4 Evaluation of the between-unit term – randomized block design 20
7.7.5 Evaluation of the between-unit term – balanced nested design 21
7.7.6 Other homogeneity designs and alternative estimation methods 21
7.8 Insufficient repeatability of the measurement procedure 22
7.9 Within-unit homogeneity 22
7.9.1 Assessing the need for within-unit homogeneity study 22
7.9.2 Testing for significant within-unit heterogeneity 22
7.9.3 Assessing minimum sample size 24

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7.10 Check for sufficient homogeneity ... 25
7.11 Uncertainty evaluation from homogeneity studies ... 26

8 Assessment and monitoring of stability ... 26
8.1 Preamble ... 26
8.2 Assessment of stability ... 27
8.2.1 Requirement for stability assessment ... 27
8.2.2 Types of (in)stability ... 27
8.2.3 General methods for assessment of stability ... 28
8.2.4 Need for experimental study of stability ... 28
8.3 Classification of stability studies ... 29
8.3.1 General ... 29
8.3.2 Classification according to conditions of measurement ... 29
8.3.3 Classification according to stability study duration and conditions ... 30
8.3.4 Classification by study objective ... 30
8.3.5 Designs for different storage and treatment conditions ... 31
8.4 General requirements for effective stability studies ... 32
8.4.1 Overview of requirements ... 32
8.4.2 Selection of RM units ... 32
8.4.3 Suitable measurement procedure(s) for stability studies ... 32
8.4.4 Appropriate experimental design ... 32
8.5 Evaluation of stability study results ... 33
8.5.1 General considerations for stability study data treatment ... 33
8.5.2 The basic stability study: multiple points in time at a single storage condition ... 34
8.5.3 Isochronous designs ... 36
8.5.4 Accelerated stability studies with multiple exposure conditions ... 38
8.5.5 Additional sources of random variation in stability studies ... 41
8.6 Action on finding a significant trend in a stability study ... 41
8.7 Uncertainty evaluation from stability studies ... 42
8.7.1 General considerations for uncertainty evaluation from stability studies ... 42
8.7.2 Sources of uncertainty in predicted change over time ... 42
8.7.3 Estimation of stability uncertainties in the absence of significant trends ... 43
8.7.4 Evaluation of stability uncertainties in the case of a known significant trend ... 43
8.8 Estimation of storage lifetime ("shelf life") from a stability study ... 44
8.9 Instructions for use related to management of stability ... 44
8.10 Stability monitoring ... 44
8.10.1 Requirements for monitoring ... 44
8.10.2 Choice of initial monitoring point and monitoring interval(s) ... 45
8.10.3 Experimental approaches and evaluation for stability monitoring ... 46

9 Characterization of the material ... 47
9.1 Preamble ... 47
9.2 Establishing metrological traceability ... 48
9.2.1 Principle ... 48
9.2.2 Metrological references ... 48
9.2.3 Types of measurands ... 49
9.2.4 Effect of sample preparation or pre-treatment ... 49
9.2.5 Verification of traceability ... 50
9.3 Characterization using a single reference measurement procedure (as defined in ISO/IEC Guide 99) in a single laboratory ... 50
9.3.1 Characterization by a reference measurement procedure without direct comparison with a CRM of the same kind ... 50
9.3.2 Characterization by value transfer from a reference material to a closely matched candidate reference material using a single measurement procedure performed by one laboratory ... 51
9.3.3 Selection of RM units for single-laboratory characterization ... 52
9.3.4 Formulation methods ... 52
9.4 Characterization of a non-operationally defined measurand using two or more methods of demonstrable accuracy in one or more competent laboratories ... 53
9.4.1 Concept ... 53

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9.4.2 Study design ... 54
9.4.3 Evaluation ... 55
9.4.4 Single-laboratory multi-method studies ... 56
9.5 Characterization of an operationally defined measurand using a network of competent laboratories ... 56
9.5.1 Concept ... 56
9.5.2 Study setup ... 57
9.5.3 Evaluation ... 57
9.6 Purity ... 57
9.6.1 General ... 57
9.6.2 Direct determination of purity ... 57
9.6.3 Indirect determination of purity ... 58
9.7 Ordinal scales ... 59
9.8 Nominal properties including identity ... 59
9.9 Characterization of non-certified values ... 59

10 Evaluating measurement uncertainty ... 59
10.1 Basis for evaluating the uncertainty of a property value of a CRM ... 59
10.2 Basic model for a batch characterization ... 60
10.3 Uncertainty sources ... 61
10.4 Coverage intervals and factors ... 61

Annex A (informative) **Design and evaluation of studies for the characterization of a method-independent measurand using two or more methods of demonstrable accuracy in one or more competent laboratories ... 62**

Annex B (informative) **Statistical approaches ... 73**

Annex C (informative) **Examples ... 84**

Annex D (informative) **Measurement uncertainty evaluation ... 94**

Bibliography ... 95

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

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 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, 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 RM producers, this document refers to ISO 17034, ISO 33401 and ISO Guide 30 that support the production and certification of RMs:

— ISO 17034 outlines the general requirements to be met by an RM producer to demonstrate competence;

— ISO 33401 describes the contents of certificates for CRMs and of accompanying documents for other RMs;

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

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1 Scope

This document explains concepts and provides approaches to the following aspects of the production of reference materials (RMs):

— the assessment of homogeneity;

— the assessment of stability and the management of the risks associated with possible stability issues related to the properties of interest;

— the characterization and value assignment of properties of an RM;

— the evaluation of uncertainty for certified values;

— the establishment of the metrological traceability of certified values.

The guidance given supports the implementation of ISO 17034. Other approaches can also be used as long as the requirements of ISO 17034 are fulfilled.

Brief guidance on the need for commutability assessment (6.11) is given in this document, but no technical details are provided. A brief introduction for the characterization of qualitative properties (9.6 to 9.8) is provided, together with brief guidance on sampling such materials for homogeneity tests (7.4.1.2). However, statistical methods for the assessment of the homogeneity and stability of RMs for qualitative properties are not covered. This document is also not applicable to multivariate quantities, such as spectral data.

NOTE ISO 33406 gives more information on the production of RMs with one or more qualitative property values.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3534-2, *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

ISO 3534-3, *Statistics — Vocabulary and symbols — Part 3: Design of experiments*

ISO Guide 30, *Reference materials — Selected terms and definitions*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

ISO 17034, *General requirements for the competence of reference material producers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3534-2, ISO 3534-3, ISO Guide 30, ISO/IEC Guide 99 and the following apply.

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