



Technical Report

ISO/TR 33402

Good practice in reference material preparation

Bonne pratique pour la préparation des matériaux de référence

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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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 of ISO/TR 33402 cancels and replaces ISO Guide 80:2014, which has been technically revised.

The main changes are as follows:

- this document provides guidance for the preparation of reference materials and does not include information about characterization or the assessment of homogeneity and stability;
- the scope of this document has been broadened to include all types of matrix reference materials and not only reference materials used for statistical quality control.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Reference materials (RMs) are widely used in measurement laboratories for a variety of purposes, and it is important to ensure that the material most appropriate for a particular application is used. Certified reference materials (CRMs), i.e. those which have at least one certified value with associated uncertainty assigned by a metrologically valid procedure, are primarily used for method validation and calibrations providing metrological traceability.

While many RMs do not require characterization by metrologically valid procedures, they can be prepared to meet specific measurement requirements, including quality control. The key requirements for these RMs are sufficient homogeneity and stability, with respect to specific properties, for the intended use. Proper preparation processes can ensure the material's homogeneity and stability.

This document provides general information on key steps in material preparation of candidate matrix RMs. It is intended for laboratory staff involved in preparing and using matrix materials for specific applications. Reference material producers (RMPs) can also use it as an information source for the preparation steps of RM production.

The document includes case studies highlighting key considerations in RM preparation. Most of the case studies describe the production of matrix RMs used for statistical quality control and include information about the preparation of the materials as well as additional information about the characterization of the property values and the assessment of homogeneity and stability, as applicable.

The general requirements for the competence of reference material producers (RMPs) are outlined in ISO 17034, specifying necessary sample preparation steps. ISO 33405 covers guidance for assessing homogeneity and stability, characterization, and value assignment of property values. ISO 33403 provides guidance for the correct use of RMs. The requirements and guidance in these documents rely on the competent preparation of the candidate RM. However, preparation steps, especially for candidate matrix RMs, are intricate, and there is a lack of guidance focusing on these steps.

Good practice in reference material preparation

1 Scope

This document gives general information on the key steps for the preparation of candidate matrix reference materials (RMs) including the material specification, sourcing and selection of bulk material, and the processing of the material, which are important steps for the production of matrix RMs.

The document provides information on the preparation of candidate RMs for laboratory staff who prepare and use matrix materials for their specific applications. This document can also be used by reference material producers (RMPs) as an information source for the preparation of the RMs that they produce.

This document also offers examples of specific case studies covering the preparation of matrix RMs in different fields of application (see [Annexes A to F](#)). These are not complete "production manuals" but highlight key considerations for the preparation steps of RMs.

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 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 3534-1, *Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO Guide 30, ISO/IEC Guide 99 and ISO 3534-1 apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

4 Overview of preparation of candidate reference materials (RMs)

Many RMs and CRMs are produced by RMPs and are commercially available. However, laboratories conducting routine tests frequently encounter difficulties in acquiring matched matrix RMs that possess a comparable matrix and analyte content level, or even just one of these aspects. In cases where matched matrix RMs are challenging to obtain from the market, the capability to prepare samples closely matched to those used in routine tests becomes crucial.

For such RM users, the preparation of homogeneous and stable materials prior to conducting assessment of homogeneity and stability is crucial. If the preparation steps are inadequate to ensure a sufficient level of homogeneity and stability, the material will not be suitable for the intended use. Therefore, the preparation of any candidate RM requires a level of technical and organizational competence. It is acknowledged that in