



**International
Standard**

ISO 33407

**Guidance for the production of
pure organic substance certified
reference materials**

*Recommandations pour la production des matériaux de référence
certifiés pour des substances organiques pures*

**First edition
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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*.

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) play an important role in measurement processes and support sound, widely recognized measurement systems. ISO 17034 specifies general requirements to be met by reference material producers (RMPs), including for the production of certified reference materials (CRMs). CRMs play a key role in ensuring that measurements are comparable across time and space and are used by laboratories to establish metrological traceability of their measurement results to appropriate references.

This document outlines recommendations, which conform to general requirements of ISO 17034, for production of pure organic substance CRMs used to calibrate measuring instruments. These materials primarily comprise organic chemicals of specified, determinable structure. Guidance provided for characterization of pure organic chemical materials is also appropriate for those used to prepare pure organic substance solution CRMs. This document provides guidance on key aspects of the production of such CRMs, including the assessment of homogeneity and stability. Recommended approaches for characterization and assignment of certified purity values are described.

Guidance for the production of pure organic substance certified reference materials

1 Scope

This document notes the requirements of ISO 17034 and provides specific guidance on technical considerations for the production of pure organic substance certified reference materials (CRMs) that are used by laboratories to calibrate measurement equipment and procedures and to establish metrological traceability of the respective results. The guidance is relevant only to CRMs comprising organic compounds whose structures are specifically defined, where polymeric materials are not included.

In this document, reference to a CRM is limited to pure organic substance certified reference materials, including candidate materials, unless otherwise noted.

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 9000, *Quality management systems — Fundamentals and vocabulary*

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

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

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)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, ISO/IEC 17000, ISO Guide 30 and ISO/IEC Guide 99 and the following 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/>

3.1

primary component

PC

principal chemical species of interest in the certified reference material

Note 1 to entry: A perfectly pure material is only an ideal concept because chemical species other than the PC will always exist in a material, even in very small amounts.