

International Standard

ISO 33408

Guidance for the production of pure inorganic substance certified reference materials

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Recommandations pour la production des matériaux de référence a l'est certifiés pour des substances inorganiques pures

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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.

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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 conforming to the general requirements of ISO 17034 for production of pure metal or their corresponding crystalline salt CRMs intended for direct use for calibration of appropriate measurement instrumentation or subsequent preparation of solution calibration CRMs. Technical guidance is provided on key aspects of the production of such CRMs, including assessment of their homogeneity and stability as well as recommended approaches for characterization and assignment of certified purity values.

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Guidance for the production of pure inorganic substance certified reference materials

1 Scope

This document gives specific technical guidance for the production of pure metals or their corresponding crystalline salt certified reference materials (CRMs) in accordance with the general requirements of ISO 17034.

This document is only applicable to solid pure metal and crystalline salt CRMs, 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/IEC 9000, Quality management systems — Fundamentals and vocabulary

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

ISO 17034:2016, General requirements for the competence of reference material producers

ISO/IEC 80000-9, Quantities and units — Part 9: Physical chemistry and molecular physics

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)* https://standards.iteh.ai/catalog/standards/iso/795db89e-0357-453e-81f2-7f05878ff0bd/iso-33408-2025

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO 9000, ISO 80000-9, ISO Guide 30, 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 remains an ideal concept because chemical species other than the PC will always be present in a material, even in very small amounts.

Note 2 to entry: The chemical species of interest is either an element or a compound of an element.

Note 3 to entry: For certain elements, unambiguous definition of the chemical species requires the specification of isotopic composition or molar mass.