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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 15000.3-2023

**Directives for the work of reference materials - Part 3:
Reference materials - Characterization and assessment of
homogeneity and stability**

标准样品工作导则 第3部分：标准样品 定值和均匀性与稳定性评估

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Foreword

This document is in accordance with the provisions of GB/T 1:1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules for Standardization Documents" drafting: This document is part 3 of GB/T 15000 "Guidelines for Standard Sample Work": GB/T 15000 has published the following parts:

- Part 1: State the general provisions of standard samples in technical standards;
- Part 2: Common terms and definitions;
- Part 3: Determination of standard samples and evaluation of uniformity and stability;
- Part 4: Contents of certificates, labels and accompanying documents;
- Part 5: Internal development of quality control samples;
- Part 6: General rules for standard sample packaging;
- Part 7: General requirements for the ability of standard sample producers;
- Part 8: Use of standard samples: This document replaces GB/T 15000:3-2008 "Guidelines for Standard Sample Work (3) General Principles and Statistical Methods for Valuation of Standard Samples" Compared with GB/T 15000:3-2008, except for structural adjustment and editorial changes, the main technical changes are as follows:
 - Changed the scope of the standard (see Chapter 1, Chapter 1 of the:2008 edition);
 - Added "Measurement Model", "Standard Value", "Information Value", "Calibration Sample", "Quality Control Sample", "Synchronous Stability Study" and "< Standard 7 terms such as "Sample > Production" (see 3:3, 3:5, 3:6, 3:7, 3:8, 3:9, 3:10);
 - Deleted "determination", "inter-bottle uniformity", "in-bottle uniformity", "mixing", "matrix

material", "feeding", "short-term stability" and "long-term stability 10 terms such as "severance", "service life" and "validity period" (see 3:4, 3:5, 3:6, 3:7, 3:8, 3:9, 3:10, 3:11, 3:12, 3:13);

---Changed the two definitions of "standard sample" and "certified standard sample" (see 3:1, 3:2, 3:1, 3:2 of the:2008 edition);

--- Increased the relevant provisions of "agreement", "design and evaluation of valuation research", "evaluation of measurement uncertainty" and other content (see Chapter 5, appendix Record A, Appendix D);

1 Scope

GB/T 15000.3-2023 is Part 3 of the Chinese directives for reference material work, and covers characterisation and the assessment of homogeneity and stability. A certified reference material is the object that makes a measurement traceable, and its certificate rests on three separate arguments: that the assigned value is right, that every unit in the batch carries the same value, and that it will still carry it when the customer opens it a year later. Each contributes to the stated uncertainty. The standard sets out the production of a reference material end to end: the project design, the processing, the assessment of homogeneity and of stability, the choice of measurement procedures, the metrological traceability, the evaluation of the assigned value and its uncertainty, the assessment of commutability, and the shipping and certification. It took effect on 1 September 2023.

This document explains and provides methods for the following concepts related to standard sample production:

---Evaluation of uniformity;

--- Stability assessment and risk management related to the stability of characteristics;

---Determination and assignment of standard sample characteristics;

--- Uncertainty evaluation of standard value;

--- Establishment of measurement traceability of standard value: This document provides support for the implementation of ISO 17034: Other methods may also be used as long as the requirements of ISO 17034 are met: This document provides brief guidance (6:11) on the need for interchangeability assessments, but does not provide technical details; method (9:6 to 9:10) and provides brief guidance on the sampling of such standards for homogeneity testing (Chapter 7), but does not cover qualitative standards: Statistical methods for homogeneity and stability assessment of quasi-samples: This document also does not apply to multivariate, such as spectral data:

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text: Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document: 2: Applied statistics)

GB/T 3358:2-2009 Statistics Vocabulary and Symbols Part 2: Applied Statistics (

ISO 3534-2:2006, IDT) 3: Design of experiments)

GB/T 3358:3-2009 Statistical vocabulary and symbols Part 3: Experimental design (ISO 3534-3:1999, IDT)

GB/T 15000:2-2019 Standard Sample Work Guidelines Part 2: Common Terms and Definitions (ISO Guide30:2015, IDT) ISO /IEC Guide

99 International vocabulary of metrology basic and common concepts and related terms (VIM) [Internationalvocabulary]

Note: This document uses "VIM" to represent "International Metrology Vocabulary":

3 Terms and Definitions

The terms and definitions defined in ISO Guide30, ISO /IEC Guide99, ISO 3534-2, ISO 3534-3 and the following apply to this document: When there are multiple definitions for the same term, the definition in ISO Guide 30 is preferred: The addresses of terminology databases maintained by ISO and IEC for standardization are as follows:

---ISO online browsing platform: <http://www.iso.org/obp>