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

GB/T 15000.7-2021

**Directives for the work of reference materials - Part 7: General
requirements for the competence of reference material
producers**

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Foreword

GB/T 15000 "Guidelines for the Work of Standard Samples" is divided into the following 8 parts.

- Part 1.General provisions for stating standard samples in technical standards;
- Part 2.Commonly used terms and definitions;
- Part 3.General principles and statistical methods for the value of standard samples;
- Part 4.The content of the certificate, label and accompanying documents;
- Part 6.General Rules for Standard Sample Packaging;
- Part 7.General requirements for the ability of standard sample producers;
- Part 8.Use of certified standard samples;
- Part 9.Calibration in analytical chemistry and the use of certified standard samples.

This part is Part 7 of GB/T 15000.

This section was drafted in accordance with the rules given in GB/T 1.1-2009.

This part replaces GB/T 15000.7-2012 "Guidelines for the Work of Standard Samples (7) General Requirements for the Ability of Standard Sample Producers", and

Compared with GB/T 15000.7-2012, the main technical differences are as follows.

- Modified the scope of the standard (see Chapter 1, Chapter 1 of the.2012 edition);

---Added the 4 terms of "standard value", "fairness", "standard sample file" and "measured by operation definition" (see 3.4, 3.5, 3.6,

3.7);

--- Deleted 5 "subcontractors", "standard sample production", "standard sample interchangeability", "measurement traceability" and "measurement uncertainty"

Terminology (see 3.2, 3.3, 3.6, 3.7, 3.8 in the.2012 edition);

---Modified the three definitions of "standard sample producer", "certified standard sample" and "standard sample" (see 3.1, 3.2, 3.3,.2012 edition

3.1, 3.5, 3.4);

---Added "fairness", "confidentiality", "measures related to risks and opportunities (method A)" and other requirements (see 4.2, 4.3, 8.8);

---Added an informative appendix "Requirements for the Production of Standard Samples and Certified Standard Samples" (see Appendix A);

---Revised the "organization and management requirements", which was refined into "general requirements, structural requirements, resource requirements and management system requirements" (see section

Chapter 4, Chapter 5, Chapter 6, and Chapter 8, Chapter 4 of the.2012 edition);

--- Amended the "requirements, tenders and contract review" (see Chapter 4, Chapter 4 of the.2012 edition);

---Modified "Subcontractor" and "Procurement of Services and Supplies" (see Chapter 6,.2012 edition of 5.3 and 4.6);

---Modified the "General Provisions", "Measurement Methods", "Data Evaluation", "Measurement Traceability", "Stability Evaluation", "Determination", and "Certificate Provided to Users"

Or documents "records", "control of non-conforming work and/or non-conforming standard samples", etc.

Chapter 4, Chapter 5);

---Revised the "General Provisions", "Quality Policy", "Management System", "Document and Information Control", "Records", "Management Review", "Internal Audit", and "Correction"

"Measures", "improvements", "customer service" and other content (see Chapter 8, Chapter 4 of the.2012 edition);

--- Deleted "Measurement traceability of standard values of standard samples",

"Replaceability of standard samples", "GB/T 27025 and GB/T 15000.7-

The 2012 cross-reference table" and other informative appendices (see Appendix A, Appendix B and Appendix C of the 2012 edition).

The translation method used in this section is equivalent to the adoption of ISO 17034:2016 "General Requirements for the Ability of Standard Sample Producers".

The Chinese documents that have a consistent correspondence with the international documents cited in this section are as follows.

---GB/T 27025-2019 General requirements for the competence of testing and calibration laboratories (ISO /IEC 17025:2017, IDT)

This section also made the following editorial changes.

---In order to be consistent with the existing standards, the standard name was revised to "Guidelines for Standard Sample Work Part 7. Standard Sample Producer"

General requirements for competence.

This part is organized by the National Standard Sample Technical Committee (SAC/TC118) and the National Standardization Technical Committee for Certification and Accreditation (SAC/TC261)

Propose and focus.

Drafting organizations of this section. China Standardization Association, China National Accreditation Center for Conformity Assessment.

Introduction

Standard samples (RM) can be used in all stages of the measurement process, including method validation, calibration, and quality control. They are also used to

Inter-laboratory comparisons for the purpose of confirming and evaluating laboratory capabilities.

Proving the scientific and technological capabilities of the standard sample producer (RMP) is a common requirement to ensure the quality of RM. At the same time, with the measurement

With the continuous improvement of equipment precision and the demand for more accurate and reliable data in the field of science and technology, the demand for new RM with higher quality is also

Growing day by day. RMP not only has to provide product information in the form of RM documents, but also needs to prove that it has RM with qualified production quality.

ability.

This section specifies the general requirements for producers of standard samples (standard samples containing certificates). It replaces the ISO Guide 34.2009 Consolidated

Meet the relevant requirements of ISO /IEC 17025. Further guidance (such as the content of the certificate, the design of fixed values, uniformity and stability studies)

See ISO Guide 31 and ISO Guide 35. Although the methods specified in ISO Guide 31 and ISO Guide 35 meet the relevant requirements of this part

However, there may be other methods to meet the requirements of this section.

RM producers who meet this part can also arrange daily operations in accordance with ISO 9001. For testing in the medical field, refer to

Replace ISO /IEC 17025 with ISO 15189.

In this section, the term "identification" refers to the identification of standard samples.

In this section, the following verb forms are used.

---"Should" means a requirement;

---"Suitable" means suggestion;

---"May" means allow;

---"Enable" means possible or capable.

For details, please refer to Part 2 of the ISO /IEC Guidelines.

The original GB/T 15000 consists of 9 parts. GB/T 15000.3-1994 "Guidelines for the Work of Standard Samples (3) General Value of Standard Samples

When the Principles and Statistical Methods were revised, the ISO Guide 35.2006 was used equivalently, and its content included GB/T 15000.5-1994 Standard Samples

Working Guidelines (5) Technical General Rules for Standard Samples of Chemical Compositions". Therefore, GB/T 15000.3-1994 and GB/T 15000.5 have been

Replaced by GB/T 15000.3-2008 "Guidelines for the Work of Standard Samples (3) General Principles and Statistical Methods for the Valuation of Standard Samples", now

GB/T 15000 has 8 parts.

Guidelines for the Work of Standard Samples

Part 7. General requirements for the ability of standard sample producers

1 Scope

This part of GB/T 15000 specifies the general requirements for the ability and consistent operation of standard sample producers.