ICS 01.120
CCS A00

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 15000.5-2023

Directives for the work of reference materials - Part 5: The in-house preparation of quality control materials (QCMs)

标准样品工作导则 第5部分：质量控制样品的内部研制

Issued on: August 6, 2023 **Implemented on: August 6, 2023**

Issued by: State Administration for Market Regulation;
Standardization Administration of the PRC

Table of Contents

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents" Drafting. This document is Part 5 of GB/T 15000 "Guidelines for Standard Sample Work". GB/T 15000 has released the following parts.

1.General provisions for standard samples stated in technical standards;

2.Commonly used terms and definitions;

3.Standard sample determination and uniformity and stability evaluation;

4.Contents of certificates, labels and accompanying documents;

5.Internal development of quality control samples;

6.General rules for standard sample packaging;

7.General requirements for the capabilities of standard sample producers;

8.Use of standard samples. This document is equivalent to ISO Guide80.2014 "Guidelines for the Internal Development of Quality Control Samples". The file type is determined by the ISO guideline document. The parts are adjusted to my country's national standards. Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed and coordinated by the National Standard Sample Technical Committee (SAC/TC118). This document was drafted by: China Standardization Association, Wuhan University of Science and Technology, Dalian University for Nationalities, China Jiliang University, China Inspection and Certification Group Tuan Liaoning Co., Ltd., Shandong Analysis and Testing Center, Winning Energy Efficiency Technology (Qingdao) Co., Ltd., Beijing Huasu Chenguang Technology Co., Ltd. The main drafters of this document. Xu Jianping, Xu Dajun, He Ping, Tian Wen, Chen Ying, Li Jinxia, Yang Chunsheng, Tang Benling, Hu Xiaoyan, An Ziyi, Shi Yuting, Cao Jijuan, Zi Zihong, Wu Bin, Wang Xiao, Chen Jian, Chen Hongyuan.

Reference samples (RM) are widely used in measurement laboratories because of their multiple uses. Laboratories recognize that depending on the specific use It is important to choose the appropriate sample. Certified reference samples (CRM), i.e. those whose characteristic values and associated uncertainties are determined by metrologically valid Samples determined by procedures are mainly used for method validation and calibration to provide metrological calibration traceability. The development of standard samples for metrological quality control (that is, the control of measurement quality rather than product quality) is an important activity and provides the basis for the measurement system.

Routine monitoring under statistical control provides suitable samples. This sample is not required to be determined through metrological verification procedures and can be determined by actual Developed by laboratory personnel familiar with sample characteristics within the laboratory (hereinafter referred to as "in-house"), it can meet specific quality control needs. A sufficiently uniform and stable RM is necessary for metrological quality control purposes such as. certifying the measurement system It is under statistical control, performs as expected and provides reliable results; the accuracy of the measurement results is not critical here. Collect from different fields Use different terms to describe these samples (e.g., internal standards, quality control samples, check samples, etc.). To simplify and avoid duplication Note, this document uses the term "quality control sample (QCM)" uniformly. In the standard sample technology system, GB/T 15000 "Guidelines for the Work of Standard Samples" is the basic and general guide for the work of standard samples in our country. Usability standards. GB/T 15000 aims to establish a standard that is universally applicable to the preparation, valuation, packaging, storage, distribution and application of standard sample producers. The guidelines consist of 8 parts.

1.General provisions for standard samples stated in technical standards. The purpose is to provide for the statement of standards in the formulation of technical standards General requirements for samples, the relationship between standard samples and technical standards, technical criteria for selecting standard samples, etc.

2.Commonly used terms and definitions. The purpose is to specify terms and definitions related to standard samples, especially those used for standard samples. terminology in product product instructions, certificates and corresponding development reports.

3.Standard sample determination and uniformity and stability evaluation. The purpose is to provide more specific guidance on technical issues Guide, and provide a basic model for the homogeneity, stability evaluation and setting process of standard samples.

1 Scope

GB/T 15000.5-2023 is Part 5 of the Chinese directives for reference material work, and covers the in-house preparation of quality control materials. A laboratory needs a stable material to run alongside its samples every day, and buying a certified reference material for that is usually unaffordable and often impossible for the matrix it actually analyses - so laboratories make their own, generally without any guidance on how. The material does not need a certified value, but it does need to be homogeneous, stable and available in enough units to last. The standard sets what a quality control material is and what it is for, the steps of in-house development, the technical requirements on the raw material including unit size and total batch size, the preparation - collection, processing, dispensing and packaging - the homogeneity assessment with its analysis methods and statistics, the stability and validity period assessment, and the documentation. It took effect on 6 August 2023.

This document provides the basic characteristics of standards for use in quality control

(QC), suitable for use in laboratories developed by competent personnel. Process for standard samples (to avoid instabilities due to shipping conditions). This document also applies to very stable samples (during transport There is no risk of significant changes in the value of the characteristic of interest). The primary users of this document are laboratory personnel who need to develop specific quality control samples (QCM). If there are transport requirements, e.g. Laboratories have different application locations or proficiency testing plans. The development of QCM should refer to the relevant ISO Guide34 and ISO Guide35. Require. The detailed description of the development of reference samples (RM) in ISO Guide34 and ISO Guide35 also applies to the development of QCM. But for "internal The requirements for "Part 1" QCM are lower than those for certified reference samples (CRM). The development of QCM includes uniformity and stability assessment, providing tables Indicative values of relevant characteristics and their changes for ease of use. This document provides the quality standards that samples should meet to demonstrate that the measurement system performs under statistical control. Guidance on the application of QCM, such as drawing quality control charts, has been included in references [3], [4], [5], [6]. cover, so it is not included in this document. The framework and structure of this document provide general information on developing QCM in the main chapters and include some industry-specific information in the appendices. case study. The case studies are not intended to be complete "how-to manuals" but highlight key considerations when developing a QCM. case study Studies vary in complexity and detail and contain industry-specific terminology, but provide a range of Information. All parties involved in the development of QCM need to have a certain understanding of the type of sample being developed, and must pay attention to aspects such as matrix effects and contamination. potential problems.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document. ISO 3534-

3 Terms and definitions

The terms and definitions defined in ISO Guide30, ISO /IEC Guide99, ISO 3534-1 and the following apply to this document.