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

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**In-house Preparation of Quality Control Materials(QCMs)
(English Translation)**

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Introduction

As the market demands for testing and product quality expand rapidly, the demand for quality control substances continues to grow. quality Use of controlled substances include but are not limited to.

- 1) Make a quality control chart to prove that the measurement process is controllable and effective;
- 2) compare the results, confirm the equivalence of the measurement results or normalize the result;
- 3) Method development to establish consistency;
- 4) instrument performance check;
- 5) Repeatability/Reproducibility studies;
- 6) as a verification sample, such as the equivalence of two or more laboratory measurements confirmed;
- 7) operator change monitoring;
- 8) Monitoring of the impact of changes in environmental conditions.

The application of quality control substances is of great significance to promote the detection quality and product quality in various fields.

The quality control substance is only a supplement to the certified reference substance, not an alternative. Usually there is no suitable standard Quality, or the need for large quantities of standard material, the cost is high, the laboratory needs to develop quality control substances.

This specification is equivalent to the ISO Guide 80.2014 "internal control of quality control materials", elaborated the quality control Material internal research and development processes and uniformity assessment, stability assessment, assignment and other technical requirements to promote China's high water Quality control of the development and application of substances to ensure that the laboratory developed quality control material can effectively play a "quality control System "role.

This specification is first released.

Internal Control of Quality Control Materials

1 Scope

This Code outlines the basic characteristics of quality control of raw materials, and gives the quality control of the internal development of the material base this procedure, as well as the development of uniformity assessment, stability assessment, the basic principles of assignment, suitable for guiding experiment Room to carry out internal control of quality control material.

2 reference documents JJF 1001 common measurement terms and definitions JJF 1005 standard terms and definitions commonly used General Principles and Statistical Principles of JJF 1343 Standard Substance Setting Selection and Application of JJF 1507 Standard Substance GB/T 3358.1 statistical terms and symbols - Part 1. General statistical terms and terms used in probability (ISO 3534-1, IDT) ISO Guide 80 Internal Development of Quality Control Materials [ISO Guide80.Guidanceforin-house Preparation of Quality Control Materials (QCMs)] for dated references, only the dated version applies to this specification. For undated references the latest version (including all amendments) applies to this specification.

3 Terms and definitions JJF 1001 "Common measurement terms and definitions", JJF 1005 "common terms and definitions of standard substances" and GB/T 3358.1 "Glossary and symbols of statistics Part 1. General statistical terms and terms used in probability" Chinese regulations the term applies to this specification.

3.1 Quality Control Materials QualityControlMaterials (QCMs) [ISO Guide 302.1.22] the standard substance used to measure quality control.

Notes 1. "Quality control" refers to the use of such substances and not to another category

of reference substances.

Note 2: Quality control standards do not require evaluation results have traceability and measurement uncertainty, but must have to meet the pre-Period of use of the uniformity and stability.

Note 3: Certified Reference Materials can also be used for measurement quality control.

4 quality control material development steps the basic use of quality control substances is to detect changes in order to measure repeatability, measure the precision during or Recurring assessment, etc. (but not limited to). The assessment of uniformity and stability is usually based on the actual situation Achieve the balance between R & D costs and intended use.

Figure 1 shows the key steps in a typical quality control material development process. However, not all steps

It will be done by the agency that needs the substance. Materials procurement, handling, packaging and packaging can be a matter of experience