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**CERTIFICATION AND ACCREDITATION INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

RB/T 163-2017

**The specification for preparation of nucleic acid reference
materials for plant quarantine
(English Translation)**

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Foreword

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

This standard is proposed and managed by the National Certification and Accreditation Administration.

This standard was drafted. Beijing Entry-Exit Inspection and Quarantine Bureau of the People's Republic of China, Liaoning Entry-Exit Inspection of the People's Republic of China Epidemic situation.

Introduction

Standard materials are important tools for conducting calibration of measuring instruments, evaluation of measurement methods, quality control of measurement processes, etc.

The constant pursuit of reliability and comparability of test results around the world is being used more and more widely. Huge demand drives standards the rapid development of the quality field has continued to expand regardless of the variety and application field. Standard materials are being traditionally led by steel, geology, and the environment.

The field continues to expand into fields such as biology, clinical, and new materials. In recent years, it has been used in forensic identification, medical diagnosis, genetic testing, and microbial testing.

The qualitative analysis is developed rapidly with reference materials and a large number of reference materials that are used in the quality control of the laboratory. In the fields of physics and chemistry, the production system and requirements of quasi-substances have been relatively standardized. However, the research and development of reference materials such as nucleic acids and plasmids in the field of phytosanitary fields is still in its

infancy.

In the phytosanitary field, the classification of nucleic acid reference materials has its own characteristics. The measurement of nucleic acid is mainly based on content and sequence; protein measurement it mainly includes content, enzyme activity, immunity, structure, etc.; microbial measurement has just begun, mainly based on identification and quantitative research. By these classifications can it is seen that it is different from the unique requirements of physical and chemical standards, making its production and development specifications a requirement.

This standard is for the purpose of combining ISO/REMCO "International Guidelines for Reference Materials" and GB/T 15000.7-2012 "Standard Sample Work Guideline (7) General Requirements for Standard Sample Producer Capabilities, CNAS-CL04..2010 Standard Material/Standard Sample Producer Capacity Approval Guidelines, CNAS-RL07..2014 "Standard Substance/Standard Sample Producer Accreditation Rules" and Inspection and Quarantine Industry Standard SN/T 3461-the specific requirements of some of the listed documents such as the 2012 "Preparation Requirements for Plant Pathogenic Bacteria" are for reference to standardize the nucleic acid standards in the field of phytosanitary fields.

Technical procedures for the production of substances/standard samples and clear preparation requirements.

Development specification for phytosanitary nucleic acid reference materials

1 Scope

This standard specifies the terms and definitions of phytosanitary nucleic acids, general requirements, for reference materials, preparation of standard materials, and uniformity.

Sexual inspection, stability testing, valuation, packaging and transportation, preservation and management.

This standard applies to the development of phytosanitary nucleic acid reference materials/standard samples.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only dated versions apply to this article.

Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 15000.7-2012 Standard Sample Work Guidelines (7) General Requirements for Standard Sample Producer Capabilities JJF1006-1994 Technical Standard Specification for

Primary Standard Materials JJF1135-2005 Evaluation of Measurement Uncertainty in Chemical Analysis

3 Terms and definitions

The following terms and definitions apply to this document.

Reference material candidate A material used to prepare standard materials.

Long-term stability

The stability of the properties of the standard material at the specified temperature and time.

Short-term stability the stability of standard material properties during transport at specified temperatures.

4.1 Phytosanitary Nucleic Acid Standards Containing Deoxyribonucleic Acid (DNA) Standards

Qualitative, pesticidal plasmid DNA standards and harmful nucleic acid (Ribonucleic Acid, RNA) standards.

4.2 Preparation of reference materials should be carried out by standard material preparation facilities.

4.3 The standard substance preparation organization shall have a clear legal status, and the quality management system shall be established in accordance with 4.1 of GB/T 15000.7-2012.

And obtained the qualification certification based on GB/T 15000.7-2012 standard sample producer.

4.4 The reference material preparation organization shall have the producer capacity based on the requirements of GB/T 15000.7-2012, and must have the preparation of standard materials.

Conditions such as workplace, equipment, professional and management.

4.5 Sites engaged in the development of phytosanitary nucleic acid reference materials shall have the conditions and measures to prevent biosafety risks.