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

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**Biosafety risk control for the operation and use of special items
entering and leaving the country**

进出境特殊物品经营和使用生物安全风险控制规范

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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. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is issued by the General Administration of Customs of the People's Republic of China. This document is under the jurisdiction of the National Technical Committee on Health and Quarantine Standardization (SAC/TC582). This document was drafted by: General Administration of Customs of the People's Republic of China, Shanghai Customs of the People's Republic of China, China Institute of Inspection and Quarantine, Beijing Customs of the People's Republic of China, Hangzhou Customs of the People's Republic of China, Shanghai International Travel Health Care Center, Fudan University, Shanghai Institute of Infectious Diseases and Biosafety. The main drafters of this document are. Xu Feng, Lou Yating, Liu Lijuan, Liang Libo, Feng Gang, Tian Zhenggan, Liu Mei, Qi Runzi, Xu Wenyan, Lu Ye, Yi Zaijong, Xu Hefei, Lu Yan, Hu Kongxin, Chen Leiqiong, Chen Haijing, Qu Di, Xie Youhua. Biosafety in the operation and use of special items entering and leaving the country Risk Control Specifications

1 Scope

China's national standard for biosafety risk control in the operation and use of special items entering and leaving the country. Special items is the customs category for microorganisms, human tissues, biological products and blood and its derivatives - the materials that move constantly between countries for research, diagnostics, clinical trials and vaccine manufacture, and that carry biological risk in proportion to nothing about their size or value. A single vial can be a pathogen; a shipment of clinical samples may contain anything. Because they move under customs supervision but are handled by ordinary staff in ordinary facilities, the control has to attach to the handling rather than to the border. The standard specifies the biosafety risk control requirements - biosafety management, risk identification and classification, risk assessment, risk control, records and reporting - and applies to entities operating and using such items, or their agents, through unpacking, storage, transport, use and disposal during the period of customs supervision.

This document specifies the biosafety risk control requirements for the operation and use of

special items entering and leaving the country, including biosafety management, risk identification, classification, risk assessment, risk control, records and reports, etc. This document is applicable to entities that operate and use special items for entry and exit or their entrusted entities to manage and use special items during the period of customs supervision for entry and exit. Biosafety risk control management in packaging, storage, transportation, use, and disposal.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB 19489 General requirements for laboratory biosafety

GB/T 27921 Risk management risk assessment technology

GB/T 43429 General requirements for the preservation of pathogenic microorganisms and samples of human infections

HJ1284 Technical Specifications for Operation and Management of Medical Waste Disinfection and Treatment Facilities
SN/T 4707 Biosafety Risk Grading Management Procedures for Special Articles Entering and Leaving the Country

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Special items special product Goods or articles related to public health and safety.

Note. Special items include human tissues such as blood, pathogenic microorganisms, biological products, etc., but do not include those that have been included in the management of medicines, veterinary drugs, and medical devices.

3.2 Special items contain or may contain pathogenic microorganisms, toxins and other biological factors, which may cause potential threats to the ecological environment and human health.

3.3 According to the risk factors such as pathogenicity, pathogenicity, preparation process, use and controllability of biosafety risks of special items and relevant national The competent authorities shall control and require, follow the risk management principles, and classify special items into different biosafety risk levels. [Source: SN/T 4707-2016, 3.3, modified]