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

RB/T 199-2015

**Technical code for evaluating biosafety performance of
laboratory equipment
(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. China National Accreditation Center for Conformity Assessment, Academy of Military Medical Sciences, Tianjin National Bio-protection Equipment Engineering Technology Research Center, Harbin Veterinary Research Institute, Chinese Academy of Agricultural Sciences, Wuhan Institute of Virology, Chinese Academy of Sciences, Medical Biotechnology, Chinese Academy of Medical Sciences Institute of Research, China Academy of Building Research, China Animal Disease Control and Prevention Center, China Center for Disease Control and Prevention, Jiangsu Provincial Disease Prevention Control Center, Guangdong Entry-Exit Inspection and Quarantine Bureau.

Introduction

The laboratory equipment covered in this standard is mostly used in biosafety laboratories. Biosafety laboratories usually refer to engaging with pathogenic microbes Laboratory of (toxic) species, sample-related research, teaching, testing, diagnosis, etc. Biosafety performance evaluation of laboratory equipment is laboratory an important component of the evaluation of biosafety levels.

Evaluation of biosafety performance of equipment can control biosafety risks of biosafety laboratory equipment and safeguard biosafety laboratories Biosafety protection to prevent human infection or pathogenic microbial leakage in biosafety laboratories.

This standard can regulate the biosafety performance testing and evaluation activities of equipment, and provide biosafety laboratory tube maintenance and management equipment.

Provide biosecurity for biosafety laboratory experiments.

Technical specifications for laboratory equipment biosafety performance evaluation

1 Scope

This standard specifies the biosafety performance evaluation requirements for 12 types of equipment related to biosafety in laboratories.

This standard applies to biosafety performance evaluation of equipment involved in biosafety laboratories. Hospitals, pharmaceutical companies and other places use this standard for the equipment involved, the biosafety performance evaluation can also refer to this standard.

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 18466-2005 Water pollutant discharge standards for medical institutions GB 19489 General requirements for laboratory biosafety GB 50346 Biosafety Laboratory Building Technical Specifications GB 50591 clean room construction and acceptance specifications EJ/T 1096 sealed box chamber sealing classification and its inspection method JG170 biological safety cabinet YY0569 Class II biological safety cabinet Disinfection Technical Specifications Ministry of Health of the People's Republic of China (2002)

3 Terms and definitions

The following terms and definitions defined by YY0569 and JG170 apply to this document.

Equipment biosafety performance biosafetyperformanceofequipment Equipment performance that protects people and the environment from pathogenic microorganisms.

Animal isolation equipment animalisolatedequipment Negative pressure isolation in animal biosafety laboratories to prevent the escape of pathogenic microorganisms and to effectively prevent animals from escaping and breeding animals the general name of the device.

Note: Rewrite GB 50346-2011, definition 2.0.9.

Independent ventilation cage with individuallyventilatedcageIVC an independent ventilation barrier device in the form of a feeding box, the clean air is separately sent to each independent cage box to keep the breeding environment constant Pressure and cleanliness to avoid environmental pollution of animals (positive pressure) or animal pollution (negative

pressure).

Note 1: Rewrite GB 50346-2011, definition 2.0.8.

Note 2: This equipment is used to raise clean, no specific pathogens or infected (negative pressure) animals. Biosafety laboratory for feeding infected animals using negative pressure independent ventilation