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INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

WS 233-2017

Replacing WS 233-2002

General biosafety standard for causative bacteria laboratories

(English Translation)

Issued on: July 24, 2017 **Implemented on: February 1, 2018**

Issued by: National Health and Family Planning Commission of the People's Republic of China

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Foreword

This standard is mandatory.

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

This standard replaces WS 233-2002 "Microbiological and Biomedical Laboratory Biosafety General Guidelines." Since the implementation of this standard date, WS 233-2002 Repealed at the same time.

This standard compared with WS 233-2002, the main changes are as follows.

- revised terms and definitions (see Chapter 2, Chapter 2 of the 2002 edition);

- Revised the basic principles of laboratory bio-safety protection, requirements, from the laboratory facilities, design, environment, equipment, people Staff management, practices, sterilization and other detailed specifications (see Chapter 4,5,6,7, 2002 edition of 4,5,6,7 chapter);

- revised risk assessment and risk control (see Chapter 5, version 4.7 of 2002);

- Added enhanced BSL-2 laboratory (see 6.3.2);

- Revised biosafety design principles, basic requirements, etc. for vertebrate laboratories

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(see 6.6.1, 6.6.2, 6.6.3, 6.6.4, 2002 edition of Chapter 7);

- Increased basic requirements for biological safety of invertebrates in laboratories (see 6.6.5);

- Added disinfection and sterilization (see 7.7);

- The.2002 edition of the Appendix was deleted (see the 2002 edition of Appendix A, Appendix B, Appendix C);

- Added informative Appendix A, Appendix B, Appendix C, Appendix D.

This standard was drafted. China Center for Disease Control and Prevention virus prevention and control, China Center for Disease Control and Prevention, China disease pre Prevention and Control Center of Infectious Diseases Prevention and Control, Institute of Medical Laboratory Animal, Chinese Academy of Medical Sciences, Chinese Academy of Medical Sciences, Pathogenic Biology Institute of Microbiology and Epidemiology, Fudan University, Academy of Military Medical Sciences, Wuhan Institute of Virology, Chinese Academy of Sciences, Tianjin National Institute for Biological Protection Equipment Engineering Technology Research Center, Shandong Provincial Center for Disease Control and Prevention, Fujian Provincial Center for Disease Control and Prevention, Jiangsu Province Disease Prevention and Control Heart, China National Accreditation Center for Conformity Assessment.

1 Scope

This standard specifies the basic principles, grading and basic requirements for biological safety of pathogenic microorganisms in laboratories.

This standard applies to carry out microbial related research, teaching, testing, diagnosis and other activities laboratory.

2 Terms and definitions

The following terms and definitions apply to this document.

Laboratory biosafety Laboratory biosafety conditions and conditions are not below allowable levels to avoid exposure of laboratory personnel, visitors, communities and the environment Acceptable damage, in line with relevant laws and regulations, standards and other laboratory biosafety requirements.

Risk

The probability of the occurrence of the danger and the consequences of the severity of the combination.

Risk assessment

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Assess the size of the risk and determine if it is acceptable.

Risk control

Comprehensive measures to reduce risk.

Personal protective equipment; PPE Equipment and supplies that prevent personal injury to individuals such as biological, chemical or physical hazards.

Biosafety cabinet; BSC Control cabinet with air flow control and high efficiency air filtration device can effectively reduce the harmful effects of pathogenic microorganisms or biological experiments Hazards of aerosols to operators and the environment.

Aerosols

The particle size suspended in the gas medium is generally relatively stable dispersion of solid or liquid fine particles of 0.001 μm to 100 μm system.

Biosafety laboratory Through the protective barriers and management measures to meet the biosafety requirements of the pathogenic microorganism laboratory.

Laboratory containment area Laboratory physical partitions, the biological risk in this area is relatively large, the need for laboratory graphic design, confinement of the envelope, gas Flow, as well as personnel access, personal protection and other control of the area.

2.10

Laboratory auxiliary work area non-contamination zone Refers to a region with a relatively small biological risk and also refers to a region outside a protected area in a biosafety laboratory.

2.11

Core workplace

Is the main area for conducting laboratory activities in the Biosafety Laboratory, and usually refers to the area where the Biosafety Cabinets or Animal Rearing and Operations Room room.

2.12

Enhanced biosafety level 2 laboratory on the basis of the ordinary biosafety level-2 laboratory, measures such as mechanical ventilation are required to enhance the laboratory's biosafety requirements laboratory.

2.13

Accident

Accidental human or animal infections, injuries, deaths, or damage to facilities and equipment, and other unforeseen circumstances.

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2.14

Incident

A situation that may or may cause an accident.

2.15

High efficiency air filter (HEPA filter) Usually 0.3 μm particles for the test object, under the conditions specified filter efficiency of more than 99.97% of the air filter.

2.16

Air lock air lock

With mechanical ventilation system, the overall disinfection conditions, chemical spray (when applicable) and the pressure can be monitored airtight, the door has Interlock function, can not be on at the same time.

3 Pathogenic microorganism hazard classification

According to the infectious of pathogenic microorganisms, the degree of harm to individuals or groups after infection, the pathogenic microorganisms are divided into four categories.

a) The first type of pathogenic microorganisms, refers to microorganisms that cause very serious diseases in humans or animals, as well as our country has not yet found or those who have declared the destroyed microbes;

b) The second type of pathogenic microorganisms, is able to cause serious human or animal diseases, more easily, directly or indirectly, in humans, Animals and humans, animals and animals spread between microorganisms;

c) The third type of pathogenic microorganisms, refers to the human or animal disease can cause, but under normal circumstances, no human or animal or environment Seriously harmful, limited risk of transmission, few post-laboratory infection serious illnesses, and effective treatment and preventative measures of microorganisms;

d) The fourth type of pathogenic microorganisms refers to microorganisms that normally do not cause disease in humans or animals.

Note 1: The first and second types of pathogenic microorganisms are collectively referred to as highly pathogenic microorganisms.

4.1 Classification

4.1.1

According to the laboratory on the level of biological safety of pathogenic microorganisms, and in accordance with the provisions of the national laboratory biosafety standards will be

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