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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 19489-2008

Replacing GB 19489-2004

Laboratories - General requirements for biosafety

实验室 生物安全通用要求

Issued on: December 26, 2008 **Implemented on: July 1, 2009**

Issued by: General Administration of Quality Supervision, Inspection and Quarantine;
Standardization Administration of the PRC

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Foreword

This standard is the first 3.1.10,6.3.1.5,6.3.10.4,6.3.10.5,

6.5.1.9 Article recommendatory, others are strong Compulsory provisions. This standard replaces GB 19489-2004 "General requirements for laboratory biosafety." This standard compared with GB 19489-2004, the main changes are as follows:

--- Criteria for the classification of the elements have been adjusted, a clear distinction between technical elements and management elements (2004 edition, Chapter 6 to Chapter 20, Excerpts of Chapter 5 to Chapter 7);

--- Remove the 2004 edition of some of the terminology and definitions (2004 version 2.2,2.3,

--- Revised 2004 edition of some of the terminology and definitions (2004 edition 2.1,2.4,2.6,2.7,2.9,2.10,2.12,2.13,

--- Adding new terms and definitions (Excerpts 2.2,2.8,2.9,2.11,2.12,2.14,2.17,

2.18 and 2.19) ;

--- Delete harm degree classification (Chapter 3 of the 2004 edition);

--- Revised and increased the risk assessment and risk control requirements (2004 edition, Chapter 4, Section 3 of this edition);

--- Revised the design principles of laboratory facilities and equipment, part of the requirements (2004 edition, Chapter 6, Section 7 and Section 9.3, this The first version of Chapter 5 and Chapter 6);

--- Added laboratory facilities automation system requirements (this version 6.3.8);

--- Increased its laboratory facilities in invertebrates operating requirements (this version 6.5.5);

--- Added management requirements (Excerpts 7.4,7.5,7.8,7.9,7.10,7.11,

--- Removed some and GB 19781-2005 "Medical Laboratory Safety requirements" duplicate content (2004 edition Chapter 3, , Chapter 13, Chapter 14, Chapter 15 and Chapter 17, Chapter 12);

1 Scope

The foundation document of laboratory biosafety in China, and the one every other biosafety standard in the country refers back to. It sets the general requirements for the biosafety of laboratories: the risk assessment and risk control that everything else follows from, the classification of laboratories into biosafety levels 1 to 4, the design principles and basic requirements, the requirements for the facilities and equipment of each level in turn - BSL-1, BSL-2, BSL-3 and BSL-4, and then the animal biosafety laboratories - and, at greater length than any of them, the management requirements. It applies to the laboratories in which biological agents are handled and is the basis on which such a laboratory is designed, accredited and inspected. The half of the standard given over to management is what distinguishes it from a design code and is the reason it is written the way it is: containment is not a property of a building but of an organisation, and a BSL-3 laboratory whose documents are out of date, whose staff have not been trained or whose failures are not reported is not a BSL-3 laboratory whatever its ventilation drawings show. That clause therefore reads as a management system in the manner of the accreditation standards: organisation and management, management and personal responsibility, the

safety management system documentation and its control, the safety plan and the safety inspection, the identification and control of nonconformities, corrective and preventive action, continual improvement, internal audit and management review, and then the operational chapters - personnel, materials, the management of laboratory activities, housekeeping, facilities and equipment, waste disposal, emergency preparedness, fire safety and accident reporting. Issued on 26 December 2008 and in force since 1 July 2009, it replaces GB 19489-2004. GB 27421-2015 extends it to mobile laboratories.

This standard specifies the basic requirements for different levels of biosafety laboratory facilities, equipment and safety management. Chapter 5,

6.2 as well as biological safety requirement is based biosafety laboratories, if necessary, apply a higher level of protection Laboratory and animal biosafety laboratory. Infected animals for breeding and related laboratory activities, this standard provides for laboratory animal breeding facilities and environment of the basic begging. If desired,

6.4 for the appropriate level of protection of animal biosafety laboratory. This standard applies to biological factors involved in laboratory operations.

2 Terms and definitions

The following terms and definitions apply to this standard.

2.1 Suspended in a gaseous medium particle size is generally 0.001μm ~ 100μm tiny solid or liquid particles form relatively stable points Bulk system.

2.2 Resulting in death, unexpected illness, injury, damage and other losses.

2.3 With mechanical ventilation system, the overall sterilization conditions, chemical spray (when applicable) and the pressure can be monitored airlock, its doors have mutual Lock function can not be turned on.

2.4 Microorganisms and bioactive substances.

2.5 With air control and efficient air filtering device operation panel, which can effectively reduce harmful aerosols produced during the experiment operator And harm the environment.

2.6 Set in a closed chamber is the probability of contamination between different laboratory areas, if necessary, install a mechanical ventilation system, which has a door interlock function, It can not be turned on.

2.7 Especially the flow of pollution from small regional pollution probability of the probability of large areas controlled airflow.

2.8 It may result in death, injury or illness, property damage, environmental damage working conditions or a combination of these root causes or state.

2.9 Identify hazards exist and to determine the characteristics of the process.

2.10 Usually 0.3μm particle test substance under the conditions specified above 99.97% removal efficiency air filter.

2.11 Causes or could cause an accident.

2.12 Biological factors involved in the operation of the laboratory.

2.13 Laboratory biosafety conditions and the state of not less than the allowable level, to avoid laboratory staff, visitors, communities and the environment is not Acceptable damage, in line with relevant regulations, standards and other laboratory biosafety liability requirements.

3 Risk assessment and risk control

3.1 The laboratory shall establish and maintain a risk assessment and risk control procedures to ongoing hazard identification, risk assessment and implement the necessary control Control measures. Content Lab to consider include.

3.1.1 When laboratory activities involving pathogenic biological agents, biological laboratories should be a risk assessment. Risk assessment should consider (but not limited to, To) the following.

a) biological agents known or unknown characteristics of biological factors such as species, source, infectious, transmission, susceptibility to latency agent Amount - effect (response) relationship, pathogenicity (including acute and long-term effects), variability, stability in the environment, and other creatures And interactions, the relevant experimental data, epidemiology, prevention and treatment programs and other environments;

b) Where applicable, the laboratory itself or accidents have occurred related laboratory analysis;

c) routine laboratory activities and unconventional activities in the process of risk (limited to biological factors), including all the people into the workplace Members and staff may be involved (eg. contractor personnel) activities; Risks associated with

d) facilities, equipment and so on;

e) if applicable, the risks associated with experimental animals;

f) people related risks, such as physical condition, ability, may affect the working pressure;

g) accident, accident risks;

h) has been misused and the risk of malicious use;

i) the scope of the risk, nature and timing; Probability

j) risk assessment;