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

GB/T 43051-2023

**Laboratory animal - General requirements for biosafety in
animal experiment**

实验动物 动物实验生物安全通用要求

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Foreword

This document was issued on 7 September 2023 by the State Administration for Market Regulation; Standardization Administration of the PRC and takes effect on 1 April 2024.

It is a GB/T standard: recommended rather than compulsory, but it is the text a Chinese reviewer applies when assessing a submission.

1 Scope

GB/T 43051-2023 sets the general biosafety requirements for animal experiments. An animal facility is the hardest biosafety case there is: the pathogen is inside a living, moving, shedding host, the procedures that generate aerosols are the routine ones, and the waste stream includes bedding, carcasses and a great deal of contaminated air. China has built a large number of animal facilities including high containment ones, and their safety depends as much on the competence of the staff and the assessment of each procedure as on the engineering. The standard sets the quality requirements for the laboratory animals, the qualifications required of the practitioners, the requirements on the animal experiments themselves, the risk assessment and risk control, and the management requirements. It took effect on 1 April 2024.

This document stipulates quality of laboratory animals, qualifications of laboratory animal practitioners, animal experiment requirements, risk assessment and risk control, management and other general requirements related to biosafety in animal experiment.

This document applies to the management of laboratory animals, laboratory animal

practitioners and experimental processes when conducting animal experiments such as inspection, testing, and evaluation in biosafety laboratories; as well as the daily management of the laboratory.

2 Normative references

The contents of the following documents, through normative references in this text, constitute indispensable provisions of this document. Among them, for dated references, only the edition corresponding to that date applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

GB 14922.1 Laboratory animal - Standards and monitoring for parasitology

GB 14922.2 Laboratory animal - Microbiological standards and monitoring

GB 14925 Laboratory animal - Environment and housing facilities

GB 19489 Laboratories - General requirements for biosafety

GB/T 35892 Laboratory animal - Guideline for ethical review of animal welfare

GB 50346 Architectural and technical code for biosafety laboratories

GB 50447 Architectural and technical code for laboratory animal facility

Classified Catalog of Animal Pathogenic Microbes (issued by the former Ministry of Agriculture on May 24, 2005)

Catalog of Human-Transmitted Pathogenic Microbes (issued by the former Ministry of Health on January 11, 2006)

It shall comply with the requirements of GB 14922.1 and GB 14922.2. Laboratory animal production organizations shall provide relevant testing certificates.

4.1.3 When animal experiments last for more than three months, the organization using laboratory animals shall regularly conduct microbial and parasite testing of laboratory animals. It shall pay special attention to the monitoring of zoonotic diseases AND conduct dynamic records.

4.2 Experimental animals

4.2.1 It shall come from organizations or suppliers with animal production and breeding licenses AND be accompanied by relevant qualification certificates.

4.2.2 There shall be health examination and quarantine certificates.

4.2.3 There shall be a zoonotic disease quarantine certificate for the animal.

4.2.4 For special reasons, certain experimental animals (such as rare animals), which cannot be sourced from organizations or suppliers with animal production and breeding licenses, require approval from the regulatory authorities for purchase and use. The authorities shall establish corresponding measures, to ensure the biosafety of animal facilities and laboratory animal practitioners (such as providing necessary protective equipment, etc.).

4.2.5 It shall be ensured that the clinically observed physical health status is good; such as no abnormality in activity, mental state, feeding, etc.; no damage or abnormality in the head, eyes, ears, skin, limbs, tail, coat, etc.; no abnormality in secretions and excretions, etc.

4.2.6 During the experiment, it shall regularly test animal pathogenic microorganisms. It shall pay special attention to zoonotic disease monitoring AND keep dynamic records.

5 Qualifications of laboratory animal practitioners

5.1 Basic requirements

5.1.1 It shall comply with laws, regulations, standards and institutional rules and regulations related to laboratory animals, biosafety, and laboratory biosafety.

5.1.2 It shall have the corresponding professional education background or organization-related training for the position being engaged in.

5.1.3 It shall meet health requirements for laboratory animal practitioners.

5.1.4 It shall obtain a laboratory animal practitioner position certificate or related qualification certificate AND undergo biosafety training.

5.1.5 It shall be familiar with the risks of animal laboratory facilities, equipment, experimental operations, etc.; master certain risk control knowledge and skills.

5.1.6 It shall have good animal experiment capabilities and biosafety protection capabilities.

5.1.7 It shall be familiar with animal habits; understand the characteristics of test

samples; have the ability to identify and control risks.

5.2 Special requirements for performing animal experiments on pathogenic microorganism activities

5.2.1 On the basis of meeting the requirements of 5.1, it shall master good biosafety knowledge; receive specialized biosafety training; obtain competency confirmation.

5.2.2 It shall master good knowledge of laboratory animals and animal experiment skills; including husbandry management, clinical observation, sample collection, anatomical analysis, harmless disposal of tissue materials and carcasses, etc.

5.2.3 It shall master good knowledge and skills in raising laboratory animals; have the ability to operate experimental equipment and deal with abnormal situations; understand the performance requirements of facilities.

5.2.4 It shall comply with the requirements for laboratory practitioner management in GB 19489.

6 Requirements for animal experiments

6.1 General requirements

6.1.1 Animal biosafety laboratory facilities and equipment shall comply with the requirements of GB 19489, GB 14925, GB 50346, and GB 50447. The laboratory shall be in good operating condition. The experimental equipment shall be in place.

6.1.2 The laboratory shall use internationally and nationally prescribed general identification. The laboratory identification shall be clear, conspicuous, and easily distinguishable. There shall be signs at the main entrance of the laboratory, which clearly indicate the level of biological protection, the biological factors being operated, the name of the person in charge of the laboratory, emergency contact information, and internationally accepted biohazard symbols.

6.1.3 The laboratory shall obtain approval from the management department to allow animal experiment activities.

6.1.4 The laboratory shall not engage in experimental activities beyond the scope of the license; shall comply with the requirements of the "Catalog of Human-Transmitted