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

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Good research laboratory practice

科研实验室良好规范

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Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009. This standard was proposed and managed by the National Standardization Technical Committee for Certification and Accreditation (SAC/TC261). Drafting organizations of this standard. China National Accreditation Center for Conformity Assessment, National Nanoscience Center, Chinese Academy of Sciences, Ministry of Education Xin, Shanghai Cable Research Institute Co., Ltd., Beijing Zhongshi International Laboratory Proficiency Testing Research Co., Ltd., Jiangsu Subote New Materials Co., Ltd. Co., Ltd. The main drafters of this standard. Song Guilan, Lu Jing, Zeng Yan, Yang Yanlian, Zhang Pengjie, Zhang Xiusong, Shen Mengzhi, Tong Yanchun, Yang Chong.

The scientific research laboratory is the basic platform and place for the implementation of scientific and technological innovation. The data issued is the basis for scientific achievements, and its quality directly affects the scientific The reliability and scientificity of the academic results. Judging from the current situation at home and abroad, the management of scientific research laboratories has always been a weakness, and practical management norms documents are urgently needed to guide scientific research laboratories to build a foundation Management system based on scientific methodology.

This standard is based on the characteristics of scientific research laboratories, refers to the relevant international management standards, and takes the quality assurance of scientific research data as the core. A set of standardized systems for planning, implementation, inspection, recording, archiving and reporting of research activities. When applying this standard, scientific research laboratories must combine their own characteristics to meet international and national safety and ethical requirements for scientific research laboratories. Be brave to innovate, standardize operations, further refine requirements, and pursue excellence. Good Practice for Research Laboratories

1 Scope

China's national standard for good practice in research laboratories. It specifies the responsibilities of research laboratory personnel, the research plan and its planning, the quality assurance of the work, the facilities and equipment, the records, the archiving and the reporting of results. The standard exists because of a gap that its own introduction states directly: the research laboratory has always been the weak point of laboratory management. Testing and calibration laboratories have GB/T 27025 and an accreditation regime built on it; clinical laboratories, food laboratories and product certification laboratories all operate inside management systems. The research laboratory - the place where the data behind scientific results is actually generated - has typically had none, and the reliability of a published result rests on practices that were never written down. What this standard supplies is a management framework fitted to research rather than borrowed from routine testing, with the quality assurance of research data as its core: planning, execution, checking, recording, archiving and reporting, arranged as a system a laboratory can actually operate. The difference from a testing standard matters. A research laboratory cannot standardise its methods, because developing new ones is the work; it cannot validate everything in advance, because the outcome is unknown; and it cannot treat every deviation as a nonconformity, because the unexpected result is often the finding. So the standard concentrates on what can be required without constraining the science: that the plan is written before the work, that what was done is recorded as it was done, that the equipment and materials are known, that the data is retained and traceable, and that the report reflects the record. Issued on 19 November 2020 and in force since 1 June 2021.

This standard specifies the responsibilities of scientific research laboratory personnel, research plans and plans, quality assurance plans, research facilities and environment, research facilities Good practices for preparation, research materials and methods, research records and files, and research reports. This standard applies to the scientific management and sound operation of scientific research laboratories.

2 Normative references

The following documents are essential for the application of this document. For dated

reference documents, only the dated version applies to this document. For undated references, the latest version (including all amendments) applies to this document.

GB/T 19000 Quality Management System Foundation and Terminology

JJF1001 General measurement terms and definitions

3 Terms and definitions

The following terms and definitions defined in GB/T 19000 and JJF1001 apply to this document. For ease of use, the following repeated columns Some terms and definitions in JJF1001 are listed.

3.1 Research laboratory A laboratory established and operated for the purpose of scientific and technological research activities.

3.2 Studysite The place where one or more stages of the research process are performed.

3.3 Laboratorymanagement The person who has management authority and is officially responsible for the organization and operation of the laboratory.

3.4 Principal investigator The person responsible for the research project.

3.5 Quality assurance scheme qualityassurancescheme To ensure that the research activities, records, and reports are objective and true.

Note. In this standard, hereinafter referred to as QAS.

3.6 Standard operating procedure standardoperatingprocedure Documented and standardized operating procedures and requirements for guiding and standardizing scientific research activities.

Note. In this standard, SOP is used hereinafter.

3.7 Studyprotocol Documents detailing research objectives and research design, technical routes, materials, methods, procedures, teams, plans, etc.

Note. Including any modifications to these contents.

3.8 Deviation Inconsistent with the prescribed operating procedures, research plans, plans, etc.

3.9 Testsystem Any biological, chemical, physical system or combination used in a research.

3.10 Rawdata Original information observed and recorded in research or laboratory activities.

4.1 Responsibilities of laboratory managers

4.1.1 The laboratory manager shall assume management responsibilities through the authorization of the laboratory establishment agency or its designated person.

4.1.2 The responsibilities of the laboratory manager shall at least include.

- a) Ensure that the operation and research activities of the laboratory meet the relevant requirements;
- b) Organize the establishment of scientific research integrity and scientific research ethics culture;
- c) Ensure that the safe working conditions, warning signs and emergency equipment of the laboratory meet the requirements of relevant standards and are suitable for the research undertaken activity;
- d) Organize the establishment and maintenance of a laboratory management system, and organize the training and assessment of all relevant personnel, and the assessment should not be allowed to fail Qualified or unauthorized personnel to engage in research activities or enter the laboratory;
- e) Stop behaviors or activities that do not meet management requirements and are unsafe;
- f) Organize the establishment and maintenance of emergency plans to ensure the normal performance of emergency equipment, and organize all relevant personnel for emergency response regularly drill;
- g) Ensure that there are clear communication channels with laboratory personnel and all other relevant personnel.

4.2 Responsibilities of the research leader

4.2.1 The research activities carried out by the research leader shall be approved by the laboratory manager.

4.2.2 The research leader shall be responsible for the formulation, implementation and research report of the research plan. The responsibilities of the research leader should include at least.

- a) Ensure that the research team is familiar with and abides by the laboratory management regulations; when the laboratory management regulations do not apply to the research activities undertaken At the time, it should communicate with the laboratory manager in a timely manner and supplement, modify and improve related systems.
- b) Ensure that research activities meet international conventions, scientific ethics and relevant requirements of our country; when necessary, actively cooperate with relevant departments and organizations Review and ensure to provide true and objective materials.
- c) Ensure compliance with scientific research integrity and scientific research ethics culture,