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

GB/T 46376-2025

**Cleanrooms and associated controlled environments -
Operation and maintenance service**

洁净室及相关受控环境 运维服务

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting. Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed and is under the jurisdiction of the National Technical Committee on Standardization of Cleanrooms and Related Controlled Environments (SAC/TC319). This document was drafted by: Henan Zhengjing Environmental Technology Co., Ltd., Shenzhen Yitian Purification Technology Co., Ltd., and Xiamen Leading Future Technology. Limited Liability Company, China Association for Standardization, China Power Investment Engineering Research, Testing and Evaluation Center Co., Ltd., China Academy of Building Research Co., Ltd. Wuhan Huakang Century Clean Technology Co., Ltd., Shenzhen Zhongming Technology Co., Ltd., Xi'an Siteng Environmental Technology Co., Ltd. Shandong Taihong Biotechnology Development Co., Ltd., Shanghai Zhongzeng Educational Equipment Co., Ltd., Nanjing University of Technology, Jianke Environmental Energy Technology Co., Ltd. Shanghai Indoor Environment Purification Industry Association, Zhengzhou Qingchen Air Purification Co., Ltd., Jiangxi Provincial Institute of Inspection, Testing and Certification Food Inspection and Testing Research Institute Research Institute, Guangzhou Mingxuan Purification Equipment Technology Co., Ltd., Chengdu Saigeer Clean Technology Engineering Co., Ltd., China Three Gorges Corporation Company, Shenzhen Qianhai Lifeng Clean System Co., Ltd., Zhongkai University of Agriculture and Engineering, Guangdong Provincial Association for Standardization, Jiangsu Fenghe Medical Equipment Co., Ltd. Limited Liability Company, Shenzhen Hongyi Technology Group Co., Ltd., Henan Shengchuan Purification Engineering Co., Ltd., Shenzhen Yardian Environmental Technology Co., Ltd. Company, Shanghai Yanjie Environmental Technology Co., Ltd., Tianjin Renai College, Shanghai Tianji Clean Engineering Technology Co., Ltd., Henan Weigong Testing Technology Co., Ltd. Limited Liability Company, Guangzhou Bishengbang Laboratory Technology Co., Ltd., Guangdong Zhongke Air Conditioning Technology Co.,

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Cleanrooms are widely used in industries with extremely high requirements for environmental quality, such as electronics, semiconductors, pharmaceuticals, medical care, bioengineering, and aerospace. In semiconductor manufacturing, even extremely fine particles and chemical contamination can reduce product yield; in the pharmaceutical industry, a clean environment is essential for ensuring drug quality. Cleanrooms and related controlled environments are crucial for product quality and safety. With the rapid development of these industries, the demand for high-quality operation and maintenance services for cleanrooms and related controlled environments is increasing. Higher requirements have been set, necessitating unified standards to regulate and guide operation and maintenance services, in order to ensure that cleanrooms and related controlled environments remain in normal working order. The system is in operation and meets the needs of production and scientific research activities. Currently, the cleanroom and related controlled environment operation and maintenance service market is somewhat chaotic, lacking unified regulations and standards. Different... Maintenance service providers may employ different service processes, technologies, and quality standards, resulting in inconsistent service quality. This not only affects the cleanliness of the environment but also... The effectiveness of cleanrooms and related controlled environments has constrained the development of related industries and created difficulties for companies in selecting suitable operation and maintenance services. Disturbances increase communication costs and management difficulty. For example, some maintenance services may not follow proper cleaning and disinfection procedures, failing to effectively remove contaminants. The equipment may be damaged or damaged, or the maintenance of the equipment may be delayed, affecting the normal operation of the cleanroom and related controlled environment. This document establishes clear service standards and specifications for cleanroom and related controlled environment operation and maintenance service providers, including service processes and technologies. Requirements, quality control, etc. Ensure all environmental parameters of the cleanroom and related controlled environments (including dust particle concentration, chemical contamination, microorganisms, etc.) are met. The biological quantity, temperature and humidity, pressure difference, noise, illuminance, vibration, electromagnetic interference, airflow pattern, etc., always meet the relevant industry standards and production process requirements. Request. Through standardized operation and maintenance services, we can promptly

identify and resolve quality issues in controlled environments, reducing and preventing product quality problems caused by environmental factors. Risks of quantity issues or production accidents. Internationally, there are corresponding standards and requirements for the operation and maintenance services of cleanrooms and related controlled environments. my country has also established national standards. Aligning with international standards will help Chinese companies compete in the international market and improve my country's cleanroom and related controlled environment technologies and services. This reflects China's international influence. When some of my country's high-end manufacturing enterprises participate in international projects, cleanrooms and related controlled environments that meet national standards are essential. Environmental maintenance services can enhance its competitiveness and reputation in the international market. Cleanroom and related controlled environment operation and maintenance services

1 Scope

GB/T 46376-2025 is the Chinese national standard covering keeping a cleanroom clean once it is handed over - the filter changes and the pressure cascades, the monitoring and its trending, the cleaning regime and the gowning discipline, and the requalification after any work that opens the envelope. First edition, in force from 1 May 2026. Issued on 31 October 2025, it has been in force since 1 May 2026.

This document specifies the principles, content, requirements, evaluation, and improvement of operation and maintenance services for cleanrooms and related controlled environments. This document applies to the operation and maintenance services of cleanrooms and related controlled environments.

Note. The content and requirements of operation and maintenance services are selected based on the industry's process requirements and application scenarios.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB/T 8174 Testing and evaluation of thermal insulation performance of equipment and piping

GB/T 11446.1 Electronic Grade Water

GB/T 25915.1-2021 Cleanrooms and related controlled environments - Part

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 cleanroom A room with controlled and graded concentration of airborne particles is designed, constructed, and operated in a way that minimizes the entry, generation, and retention of particles within the room. controlled. Note

1.The levels are defined based on the concentration of airborne particles. Note

2.Other factors affecting cleanliness levels, such as the concentration of airborne chemicals, microorganisms, or nanoscale particles, as well as factors affecting surface cleanliness, can also be considered. Other factors related to the grade, such as the concentration of particles, nanoparticles, chemicals, or microorganisms, are specified and controlled. Note

3.Related physical parameters such as temperature, humidity, pressure, vibration and static electricity can also be controlled as required. [Source: GB/T 25915.1-2021, 3.1.1]

3.2 clean zone A confined space where the concentration of airborne particles is controlled and graded. Its construction and operation control the entry, generation, and retention of particles within the space. controlled. Note