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**CERTIFICATION AND ACCREDITATION INDUSTRY STANDARD OF THE  
PEOPLE'S REPUBLIC OF CHINA**

**RB/T 028-2020**

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**Laboratory information management system management  
specifications  
(English Translation)**

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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 Certification and Accreditation

Administration Committee:

Drafting organizations of this standard: Shandong Entry-Exit Inspection and Quarantine Bureau Technology Center, National Food Safety Risk Assessment Center, Longkou Entry-Exit Inspection Quarantine Bureau, Yantai Entry-Exit Inspection and Quarantine Bureau, Shenzhen Entry-Exit Inspection and Quarantine Bureau Technology Center, China National Accreditation Center for Conformity Assessment, Beijing National Real Testing Technology Research Institute, Beijing Bantu Information Technology Co., Ltd., Hangzhou Goss Information Technology Co., Ltd:

## 1 Scope

This standard specifies management requirements for management planning, construction, operation, maintenance, and decommissioning of laboratory information management systems:

This standard applies to laboratories and related parties that design, construct and use laboratory information management systems:

## 2 Normative references

The following documents are indispensable for the application of this document: For dated reference documents, only the dated version applies to this article Pieces: For undated references, the latest version (including all amendments) applies to this document:

GB/T 8566 Information Technology Software Life Cycle Process GB/T 8567 Specification for computer software documentation GB/T 9385 Computer Software Requirements Specification Specification GB/T 9386 Computer Software Test Document Preparation Specification ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories (General requirements for the competition of testingandcalibrationlaboratories)

## 3 Terms and definitions

GB/T 8566, GB/T 8567, GB/T 9385, GB/T 9386, ISO/IEC 17025 and the following terms and definitions are applicable Used in this document:

Laboratory information management system iaboratoryinformationmanagementsystem; LIMS it is composed of computers and related supporting equipment, facilities (including networks) and software to realize the data and information (including calculation Computer and non-computer system) management, which has the ability to collect, record, report, store, and store data and information in accordance with laboratory management rules:

Processing functions such as transmission, retrieval, statistics, and analysis:

## **4 Management planning**

### **4.1**

#### **General**

##### **4.1.1**

LIMS is an information tool for laboratory activities and management: It is closely related to laboratory activities and is used for collection, processing, recording, and reporting:

Report, store or retrieve laboratory activity data and information:

##### **4.1.2**

The laboratory shall check the LIMS and its auxiliary equipment and facilities through daily monitoring, internal audit, external review, management review, etc:

The safety, applicability and advancement of the company, respond to the risks and opportunities of LIMS construction, operation, maintenance and decommissioning, and improve laboratory management efficiency and Efficiency, so as to continue to meet the requirements of relevant laws and regulations, customers and management agencies:

##### **4.1.3**

The management shall organize laboratory management experts, LIMS engineers and relevant laboratory personnel, and refer to external LIMS products when necessary:

Based on the opinions of product and service suppliers, plan and develop documents covering the entire life cycle of LIMS based on risk thinking:

### **4.2**

#### **Functional scope**

##### **4.2.1**

The laboratory shall ensure the convenience and applicability of LIMS, and its functions generally include but are not limited to: