

**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1861-2023

**Particular specification of picture archiving and communication
system software**

医学影像存储与传输系统软件专用技术条件

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Table of Contents

1	Scope
2	Normative references
3	Terms and Definitions
4	Requirements and inspection methods
4.1	General requirements
4.3	Performance efficiency
4.5	Network Security
4.6	Maintainability
4.7	Compatibility
10	System and software Software Quality Model
17	Reference

Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part

1. Structure and Drafting Rules for Standardization Documents" drafting. Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is sponsored by the Medical X-ray Equipment and Appliances Sub-Technical Committee of the National Standardization Technical Committee of Medical Electrical Appliances (SAC/TC10/SC1) Focus on. This document was drafted by: Liaoning Medical Device Inspection and Testing Institute, Medical Device Technology Evaluation Center of the State Drug Administration, China Peking Union Medical College Hospital of Academy of Medical Sciences, Liaoning Inspection and Testing Certification Center, Zhejiang Medical Device Evaluation Center, China Food and Drug Testing Institute Institute, Shanghai Institute of Medical Device Testing, General Electric Medical Systems Trade Development (Shanghai) Co., Ltd., Siemens Medical Systems Co., Ltd. Company, Canon Medical Systems (China) Co., Ltd., Wuhan United Imaging Medical Technology Co., Ltd., Agfa Medical System Equipment (Shanghai) Co., Ltd. Division, Fujifilm (China) Investment Co., Ltd. The main drafters of this document. Zhang Longda, Sun Zhiyong, Li Fei, Bao Yaqing, Sun Hao, Chen Fujun, Zhu Wenwu, Li Shu, Liu Chongsheng, Qin Chuan, Li Yajing, Li Wei, Mingxing, Zhang Jinping, Tang Zhiwei. Medical image storage and transmission system software special technical conditions

1 Scope

YY/T 1861 is the Chinese specification for PACS software, the system that stores medical images and delivers them to the workstations where they are read. It sets the particular technical requirements such software has to meet and how they are demonstrated, covering the integrity of the stored image, the fidelity of what is displayed against what was acquired, interoperability and data exchange, access control and the audit of who saw what. A PACS does not diagnose, but every diagnosis made from an image passes through it, and a compression artefact or a mismatched study is a clinical error waiting to happen. PACS is regulated as a medical device in China. For a vendor entering the market, this is the document a registration dossier has to address.

This document specifies the requirements and inspection methods for medical image storage and transmission system software. This document applies to medical image storage and transmission system software. This document does not apply to image storage and transmission systems that do not use the DICOM protocol.

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document.

GB 18030 Information Technology Chinese Coded Character Set

GB/T 25000.10 System and software engineering System and software quality requirements and evaluation (SQuaRE) Part

3 Terms and Definitions

The following terms and definitions defined in GB/T 25000.10 apply to this document.

3.1 Provides storage, transmission, and software for display and processing functions after medical images are acquired.

3.2 Based on the public cloud or private cloud, the storage and transmission of medical images for diagnosis can also include services such as display and processing.

3.3 Accompanying document accompanying document The contents of the documentation accompanying the software contain information for the responsible party or operator.

3.4 operator operator The person who operates the software. [Source: GB 9706.1-2020, 3.73, modified]

3.5 user An organization or individual who uses software and obtains benefits.

Note. The user role and operator role may be given to the same individual or organization at the same time or successively. [Source: GB/T 25000.51-2016, 4.1.25, modified]

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