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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 22576-2008

Replacing GB/T 22576.1-2018

Medical laboratories - Requirements for quality and competence - Part 1: General requirements

医学实验室 质量和能力的专用要求

(English Translation)

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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.

This document is Part 1 of GB/T 22576, "Requirements for Quality and Competence of Medical Laboratories". GB/T 22576 has been published.

The following section.

---Part 1: General Requirements;

---Part 2: Requirements in the field of clinical hematology testing;

---Part 3: Requirements in the field of urine testing;

---Part 4: Requirements for the Clinical Chemistry Testing Field;

---Part 5: Requirements in the field of clinical immunology testing;

---Part 6: Requirements in the field of clinical microbiology testing;

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---Part 7: Requirements in the field of transfusion medicine.

This document supersedes GB/T 22576.1-2018 "Requirements for Quality and Competence of Medical Laboratories Part 1: General Requirements", and is consistent with...

Compared with GB/T 22576.1-2018, apart from structural adjustments and editorial changes, the main technical changes are as follows.

---Risk management requirements have been added (see 5.6, 8.5);

---Added additional requirements for point-of-care testing (POCT) (formerly ISO 22870) (see Appendix A).

This document adopts ISO 15189:2022 "Requirements for quality and competence of medical laboratories".

The following minimal editorial changes have been made to this document.

---To harmonize with existing standards, the standard name has been changed to "Requirements for Quality and Competence of Medical Laboratories Part 1: General Requirements" beg".

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 by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Medical Clinical Laboratory and In Vitro Diagnostic Systems (SAC/TC136).

Introduction

Medical laboratories are crucial to patient care, and their activities must be conducted within ethical and regulatory frameworks, clearly defining the responsibilities of medical personnel towards patients.

Responsibility. These activities should be carried out promptly to meet the needs of all patients and those responsible for their healthcare, including. arranging test requests, patient preparation...

Preparation, patient identification, sample collection and transportation, patient sample processing, selection of tests appropriate for the intended use, sample testing, sample storage, and post-processing.

Follow-up explanations, reports, and recommendations. This may also include providing patients with results, arranging emergency testing, and notifying them of critical outcomes.

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GB/T 22576 specifies the competence and quality requirements of medical laboratories in all disciplines within the currently recognized areas of medical laboratory services.

The requirements are proposed to consist of 11 parts.

---Part 1: General Requirements. The purpose is to specify general requirements for the quality and competence of medical laboratories.

---Part 2: Requirements for Clinical Hematology Laboratory Testing. The purpose is to define the quality and competence requirements of medical laboratories in clinical hematology.

Specific requirements in the field of inspection.

---Part 3: Requirements in the Field of Urine Testing. The purpose is to define the quality and competence requirements of medical laboratories in the field of clinical urine testing.

Specific requirements.

---Part 4: Requirements for Clinical Chemistry Testing. The purpose is to define the quality and competence requirements of medical laboratories for clinical chemistry testing.

Specific requirements of the field.

---Part 5: Requirements for Clinical Immunology Testing. The purpose is to define the quality and competence requirements of medical laboratories in clinical immunology.

Specific requirements in the field of inspection.

---Part 6: Requirements for Clinical Microbiology Testing. The purpose is to define the quality and competence requirements of medical laboratories in clinical microbiology testing.

Specific requirements in the field of physical testing.

---Part 7: Requirements for Transfusion Medicine. The purpose is to specify the quality and competence requirements of medical laboratories in the field of transfusion medicine.

Physical requirements.

---Part 8: Requirements for Laboratory Information Systems. The purpose is to specify the requirements for laboratory information systems in medical laboratories regarding quality and competence.

Specific requirements.

---Part 9: Requirements for the Molecular Diagnostics Field. The purpose is to specify the quality and competence requirements of medical laboratories in the field of molecular diagnostics.

Physical requirements.

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