

ICS 11.100
CCS C 44



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

GB/Z 30154-2013

**Medical laboratories -- Guidance on laboratory implementation
of GB/T 22576-2008**

医学实验室 GB/T 22576-2008 实验室实施指南
(English Translation)

Issued on: December 17, 2013

Implemented on: August 1, 2014

**Issued by: General Administration of Quality Supervision, Inspection and
Quarantine of People's Republic of China, China National Standardization
Administration**

Table of Contents

Foreword

Introduction

1 Scope

2 Normative references

3 Seek approval in line with GB/T 22576-2008

4 Identify resources to help laboratories meet the requirements of GB/T 22576-2008

Foreword

This instructional document has been drafted in accordance with the rules given in GB/T 1.1-2009.

This Guidance Document is a redrafted Law Amendment adopts ISO/T R22869.2005 "Medical Laboratory ISO 15189:2003 Implementation Guide. " this guidance and technical documents and ISO/T R22869.2005 are structurally consistent.

This guidance is compared with ISO/T R22869.2005 and the ISO 15189:2003 referenced in the text is amended to ISO 15189.

2007, the terms of ISO 15189 cited in ISO/T R22869.2005 are the same in both 2003 and 2007 versions.

Please note that some of this document may be patentable. The issuing agencies of this document do not bear the responsibility of identifying these patents.

This Guidance Document is proposed by the State Food and Drug Administration.

The guidance of technical documents by the national medical clinical laboratory experiments and in vitro diagnostic system standardization Technical Committee (SAC/TC136) Focused.

The drafting of the guidance of technical documents. Beijing Medical Device Inspection Institute, China National Accreditation Board for Conformity Assessment.

Introduction

This guidance document provides guidance on how laboratories meet the quality and competency requirements. Especially for GB/T 22576-2008 Prescribed medical laboratories (in French, these laboratories are referred to as "biomedical analytical laboratories", while other languages may use the same language as English "Clinical Laboratory" equivalent

title). This guidance document describes the gradual establishment and maintenance of a quality management system in medical laboratories the basic principle. This Guidance Document is applicable to the construction of new laboratories and existing laboratories, including GB/T 22576-2008 skills requirement.

As we all know, each country may have special regulations or requirements that apply to professionals in the field and their behavior and responsibilities. In recognition of need for countries to meet a specific set of requirements, the accredited laboratory needs additional guidance on conformity from an accreditation body. This guide the technical documents also recognize that the starting point for implementing these requirements varies from lab to lab.

Therefore, each laboratory must locate itself to establish a quality management system that meets the requirements of medical laboratories. In establishing compliance GB/T 22576-2008 quality system, the first laboratory management needs to be done is to the needs of patients and customers, laboratory funding Sources as well as regional and national provisions to determine the appropriate priorities.

Medical laboratory services are the basis of patient care and therefore should cover all patients and clinicians in charge of patient care Staff needs. These services include acceptance of applications, patient preparation, patient identification, sample collection, shipping, storage, handling and testing of clinical samples and the confirmation, interpretation, reporting and presentation of recommendations. In addition, safety and ethics issues in the work of medical laboratories should also be considered. in National laws and regulations permit, the premise of the hope that the medical laboratory services in addition to diagnosis and patient management, but also the consultation cases of patients Test and actively participate in disease prevention. All medical laboratories should provide their professionals with educational and research opportunities.

This guidance document is applicable to all existing disciplines in the field of medical laboratory services; in other service areas and disciplines Class work is also applicable. In addition, accreditation bodies that recognize the competence of medical laboratories may use this guidance document as their work basis. International, national and local guidance documents also help laboratories comply with local and GB/T 22576-2008 requirements.

The guidance of technical documents for medical laboratory quality management system how to meet the requirements of GB/T 22576-2008, as well as under construction Guidance is provided on the relationship between various ISO documents of the quality management system and GB/T 22576-2008. Appendix A details How the elements of GB/T 22576-2008 help define the quality management system. Finally listed in the reference related funding Materials, including international and national standards and accreditation bodies.

Medical laboratory

Laboratory Implementation Guide

1 Scope

The guidance of technical documents for medical laboratories how to implement quality management system to meet the GB/T 22576-2008 on the quality and the technical and managerial requirements for competence provide guidance. Institutions that recognize the competence of medical laboratories may also use this technical document as guidance Help laboratories establish quality management system to meet national requirements and meet the relevant international requirements of the foundation. This guidance applies to technical documents New laboratories and existing laboratories, including the management and technical requirements of GB/T 22576-2008.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version applies to this article Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 22576-2008 medical laboratory quality and capability requirements (ISO 15189:2007, IDT)

3 Seek approval in line with GB/T 22576-2008

If the GB/T 22576-2008 endorsement as the ultimate goal, to seek expert advice can help laboratories due to inadequate preparation or do the scourge caused by defects.

Preliminary examination of the laboratory helps to clarify that it is in the establishment of quality management system and based on the standard What stage of the process can be. Medical laboratories that have maintained the best technology and management practices may simply need to document them and just start Laboratories that establish a quality management system need to be clear about the time and resources needed to meet their recognition goals.

The focus of this guidance document is to help laboratories build management requirements and technologies, including those described in ISO/Seeking management system. Because it is the management of the implementation of quality management system, management needs to consider the provisions of GB/T 22576-2008 on the personnel, environmental conditions, equipment and pre-test, inspection and testing procedures for the technical requirements of the method.

4 Identify resources to help laboratories meet the requirements of GB/T 22576-2008

Each lab may have a specific set of resources to help it meet its requirements. Laboratory management can usually meet the local needs. Other laboratories requested, specialized laboratory institutes (local, regional, national and international), government, accreditation bodies (conditionally or existent) or International organizations that provide quality assurance support to medical laboratories and relevant professional advisers for help. If the lab can not determine where it is from the beginning, may be the first to the Ministry of Health or equivalent national health organization for help. Other sources of information can also be found in the literature.

5 Seek support to establish a quality management system that meets the requirements of GB/T 22576-2008. Laboratory management should recognize that a quality management system for health care services is often described in terms of a hierarchy. From the manager's these concepts start with the principle of total quality management, that is, strive to achieve quality (safe, effective, timely and effective) Patient-centered service. This principle often includes quality management, which is to maintain a coordinated and comprehensive effort to meet the quality of the health care system aims. These efforts are known as "quality systems" and include all quality assurance activities (part of quality management, commitment to quality Seeking to be satisfied with the trust) (GB/T 19000-2008) and quality control activities (part of quality management, commitment to quality to be Seeking) (GB/T 19000-2008).