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

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**Medical laboratories - Application of risk management to
medical laboratories**

医学实验室 风险管理在医学实验室的应用

(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 equivalent to ISO 22367:2020 "Application of Medical Laboratory Risk Management in Medical Laboratories":

Please note that some content in this document may be subject to patents: The publisher of this document assumes no responsibility for identifying patents:

Introduction

This document provides a framework for medical laboratories whose experience, insights and judgment can be used to manage the risks associated with laboratory testing:

The risk management process covers the full scope of medical laboratory services: pre-test, test and post-test processes, including the design and development:

ISO 15189 requires medical laboratories to review their work processes, assess the impact of potential failures on test results, and modify processes to reduce or Eliminate identified risks and document decisions and actions taken: This document describes the process for managing these security risks, focusing on patient not only operators and other personnel, equipment and other property, but also the environment: It does not address business operations covered by ISO 31000 risk:

Medical laboratories often rely on the use of in vitro medical devices to achieve their quality goals: Therefore, risk management is essential for in vitro diagnostic medical devices the shared responsibility of the (IVD) manufacturer and the medical laboratory: Since most IVD manufacturers have implemented YY/T 0316-2016, this article this document uses the same concepts, principles and framework as YY/T 0316-2016 to manage risks associated with medical laboratories:

Medical laboratory activities expose patients, staff or other interested parties to a variety of hazards that may directly or indirectly result in varying degrees of harm: The concept of risk has two components:

- a) Probability of hazard occurrence;
- b) The consequences of the hazard, that is, the possible severity of the hazard:

Risk management is complex because each stakeholder may assign different weights to the risk of harm: This document and ISO 14971 is consistent with the Global Harmonization Task Force (GHTF) guidance and is intended to facilitate laboratories, IVD manufacturers, regulatory agencies, accreditation bodies, and others Risk communication and collaboration among stakeholders benefit patients, laboratories, and public health:

Medical laboratories are accustomed to focusing on detection errors, which are usually the result of use errors in daily work: Usage errors possible it is due to poor design of the instrument working interface or insufficient information provided by the manufacturer; it may also be caused by reasonably foreseeable misuse, such as Intentional failure to follow the

IVD manufacturer's instructions for use or failure to follow generally accepted medical laboratory practices: These errors may cause or lead to dangerous Risks may appear immediately as independent events, or they may appear multiple times throughout the system, or they may remain latent until other secondary events:

occur: The emerging field of usability engineering treats all of these "human factors" as preventable "usage errors:" In addition, the laboratory needs Respond to occasional failures when IVD medical devices operate as intended: Risks arising from equipment failure and usage errors, regardless of the cause can be proactively managed:

Risk management is integrated with quality management in many elements of ISO 15189, in particular complaints management, internal audits, corrective actions, Preventive measures, safety checklists, quality control, management reviews, external reviews (including accreditation and proficiency testing): At the same time, risk management and medicine the laboratory has consistent safety management, such as the safety checklist in ISO 15190:

Risk management is a planned and systematic process that is best implemented through a structured framework: This document is intended to assist medical laboratories Integrate risk management into its daily organization, operations and management:

medical laboratory

Application of risk management in medical laboratories

1 Scope

This document sets out the requirements for medical laboratories to identify and manage the risks associated with their examinations for patients, laboratory staff and service providers:

the process of: This process includes the identification, estimation, evaluation, control and monitoring of risks:

The requirements of this document apply to all aspects of medical laboratory testing and services, including pre-inspection, inspection and post-inspection aspects:

accurate transmission of test results to electronic medical records, as well as other technical and management processes included in ISO 15189:

This document does not specify an acceptable level of risk:

This document does not apply to the risk of clinical decisions made by medical staff after testing:

This document does not apply to the management of risks affecting medical laboratory operations covered by ISO 31000, such as commercial, economic, legal and regulatory

risk:

2 Normative reference documents

This document has no normative references:

3 Terms and definitions

The following terms and definitions apply to this document:

ISO and IEC maintain terminology databases used for standardization at:

---ISO online browsing platform: available at <https://www.iso.org/obp>;

benefit

The positive impact or desired outcome of a process (3:19), procedure (3:17) or use of a medical device on an individual's health, or on patient management or the public positive effects on health:

Note: Benefits include increased lifespan, reduced pain (symptom relief), improved function, or better health:

eventevent

The occurrence or change of a certain type of situation:

Note 1: An event may be the occurrence of one or more circumstances and may be caused by multiple reasons:

Note 2: Events may include situations that did not occur:

Note 3: Events may sometimes be referred to as "incidents" or "accidents":

Note 4: Events without consequences may also be referred to as "near misses", "accidents", "imminent harm" or "near misses":

[Source: GB/T 23694-2013,4:5:1:3] 3.3 examination A set of operations for the purpose of determining the value or characteristics of a property: