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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Clinical laboratory medicine - In vitro diagnostic medical devices - Validation of user quality control procedures by the manufacturer

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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.

This document is modified to adopt ISO 15198.2004 "Quality control provided to users by manufacturers of in vitro diagnostic medical devices for laboratory medicine".

Confirmation of Manufacturing Procedures.

Compared with ISO 15198.2004, this document has made the following structural adjustments.

--- Deleted 3.3, 3.7, 3.12, 3.16~3.20, 3.23 of ISO 15198.2004;

--- Merge 3.10 and 3.11 of ISO 15198.2004 into one term.

The technical differences between this document and ISO 15198.2004 and their reasons are as follows.

--- Deleted the normative references ISO 3534-1, ISO 5725-1, added GB/T 29791.1, JJF1001 (see Chapter 3).

---The basic vocabulary and common terms of international metrology (VIM), BIPM, IEC, IFCC, ISO, IUPAC, IUPAP,

OIML, the second edition is replaced by ISO /IEC Guide 99 to adapt to the national conditions of our country.

---Change the term names and contents originally quoted in 3.2, 3.4~3.6, 3.8~3.11, 3.22, 3.24~3.26 to GB/T 29791.1-

The corresponding term names and contents in.2013 are adapted to my country's national conditions.

--- 3.1, 3.14, adopt the definition of terms in JJF1001-2011, 3.13 adopt the definition of ISO 13485.2016, 3.21 adopt

The definition in ISO 14971.2019 to adapt to my country's national conditions.

Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents.

Introduction

Manufacturers of in vitro diagnostic medical devices usually incorporate quality control procedures into their instructions for use. The quality control program serves to provide

Provide the user with assurance that the device will perform as specified so that the results are consistent with the intended diagnostic use. For some medical devices, quality control

Procedures may be an essential risk control measure. Through the design of the medical device quality control program, the quality control program can also be passed

The following aspects help users ensure the quality of results.

a) verify the suitability of the analytical system (sample, reagents, instrument and/or operator);

b) monitoring the precision and correctness of measurement results;

c) prevent false negative and false positive results;

d) identify fault conditions that may lead to inaccurate results; and/or

e) Eliminate faults requiring corrective action.

In addition, manufacturers usually design in vitro diagnostic medical devices so that they can detect potential failures and warn users to take corrective actions.

ability to measure. These internal control systems can potentially reduce or even eliminate the need for users to run quality control samples to monitor device performance.

need.

This document can be used as part of the design controls and risk management program for manufacturers of in vitro diagnostic medical devices. This document also enables manufacturers to

Provides validated quality control procedures for clinical diagnostic laboratory users.

This document describes how manufacturers can validate the quality control procedures for their devices. Validation procedures ensure that the manufacturer is running quality controls

as intended.

control procedures, and to ensure that the manufacturer's recommendations meet certain special medical devices, such as separation systems, products with built-in electronic controllers, and devices

The need for products with chemical and/or biological controls. Information on validated quality control procedures enhances user confidence in the overall quality of the device

Understanding of quality assurance requirements and making informed choices about appropriate control procedures.

Although laboratory directors are ultimately responsible for determining appropriate quality control procedures for their laboratory, in vitro diagnostic medical device

Manufacturers are responsible for providing users with sufficient information on device performance, risk control methods, and performance verification methods in the instructions. because

Thus, in fact, quality control is a shared responsibility of both the manufacturer and user of in vitro diagnostic medical devices.

Due to the essential differences in design, technology, function and intended use of in vitro diagnostic medical devices, no matter now or in the future,

No single quality control program will cover all IVD medical devices. Established quality control practices over the years have provided the laboratory with

provides some level of assurance that the results are valid. Although these quality controls have been widely accepted by laboratories, regulatory agencies, and accreditation bodies

Practice, but these practices originated from the manual operation of laboratory analysis and the stage of laboratory self-preparation of reagents. Regarding current in vitro diagnostic medical devices

However, they may not always be optimal. Therefore, when a quality control program is required, it is the responsibility of the manufacturer to design and validate

Appropriate quality control procedures.

Quality system standards for medical device manufacturers are evolving with the times. For example, ISO 13485 and most regulations at the time included design

control and risk management requirements. Design control requires a risk analysis of the design, and requires that the design meet the user requirements before the product is released to the market.

identified in terms of user requirements and intended use. Quality control procedures in instructions for use are considered inseparable from the design of in vitro diagnostic

medical devices

Therefore, it is necessary to design the confirmed requirements.

Laboratory Medicine In Vitro Diagnostic Medical Devices

The manufacturer's quality control for the user

program confirmation

1 Scope

This document describes the process by which manufacturers of in vitro diagnostic medical devices validate quality control procedures recommended to users. Quality Control Procedures

The purpose of the test is to provide the user with assurance that the performance of the device is consistent with its intended use and the manufacturer's declaration.

This document applies to all in vitro diagnostic medical devices.

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/T 29791.1 Information provided by manufacturers of in vitro diagnostic medical devices (labelling) Part 1.Terms, definitions and general requirements

Seek (GB/T 29791.1-2013, ISO 18113-1.2009, IDT)

ISO 13485 medical device quality management system for regulatory requirements (Medicaldevices-Qualitymanagement

Note. YY/T 0287-2017 Medical Device Quality Management System is used for regulatory requirements (ISO 13485.2016, IDT)

Note. Application of YY/T 0316-2016 Medical Device Risk Management to Medical Devices (ISO 14971.2007 Corrected Edition, IDT)

JJF1001 General Metrology Terms and Definitions

3 Terms and Definitions