Final Report

Development of National GLP Guidelines & Identification and selection of National Regulatory Guidelines for Testing and Evaluation of Medical Devices

Prepared by

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In Association with

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NGLP/MD/HOR/001(2012)

Horizontal Standards

Identification and Selection of Standards for Testing and Evaluation of Medical Devices

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Contents

1. Introduction

This guidance document describes the role of technical standards both during the design of a medical device and subsequently to demonstrate a device conforms to essential safety and performance criteria.

The document 'Identification and Selection of Horizontal Standards for Testing and Evaluation of Medical Devices' NGLP/MD/HOR/001(2012), is prepared by Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum, Kerala in association with National GLP Compliance Monitoring Authority, Department of Science and Technology, Govt. of India. The Task Force for the development of horizontal standards for Medical devices consists of representatives from various disciplines from design to commercialization of medical devices. The guideline provides non-binding guidance to test facilities or manufacturers for use in the regulation of medical devices.

The early models of medical device regulation have been that of drugs, which led to serious difficulties as evidenced by the history of device regulation in USA. A wide spread sale of low quality devices in the country exposes public to unwanted hazards emphasis the need for appropriate guidelines for the evaluation of medical devices and regulatory system for approval and licensing. Hence SCTIMST, in association with National GLP Compliance Monitoring Authority, Dept. of Science and Technology, New Delhi initiated to develop horizontal standards based on national and international regulatory guidelines for testing and evaluation of medical devices that complement the global ones.

The purpose of this document is to

- encourage use of relevant / national / international consensus standards for medical devices during the design, development and evaluation of medical devices.

- encourage manufacturers to comply with appropriate national / international standards;

- support the concept that in general, the use of standards is voluntary and stake holders have the option to select alternative solutions to demonstrate their medical device meets the relevant safety and efficacy requirements.

To achieve uniformity in the selection horizontal and vertical standards for the evaluation of medical devices, the following guidelines are recommended.

- Preference should be given to national standards developed in India.

- If proper Indian standards does not exist, then standard made by Bureau of Indian Standard (BIS), International Organization for Standardisation (ISO), Standard developed by professional bodies like International Electrotechnical Commission (IEC), Institution of Electrical and Electronics Engineers (IEEE) OR other National Standards Organization like American National Standards

Institute (ANSI), American Association for Medical Instrumentation (AAMI), American Society for Testing Methods (ASTM) could be selected in the order of preference.

- Standards selected should represent the generally acknowledged state of technology and practice. The preference for the use of recognised standards should not discourage the use of new technologies. Not all devices, or elements of safety and/or performance, may be addressed by recognised standards, especially for new types of devices and emerging technologies.

The National GLP Compliance Monitoring Authority, India will have procedures for "recognition" of other international voluntary standards and notify them. The process of recognition includes mechanism of regular review and realignment of locally recognized standards to the international standards. Recognition may occur by publication of lists identifying existing standards.

Recognised standards may be revised or superseded from time to time for various reasons, for example:

- changes in state of technology and accepted practice necessitate revising the technical specifications in the standard;

- a requirement in a specific standard is determined to be inadequate to ensure safety of the device, e.g. there is a safety implication;

- Where the recognised standard has been revised to address safety concerns, the stake holders are expected to implement a risk mitigation strategy and take appropriate action to address these concerns.

- During the transition period both the existing and the revised version of the recognised standard may be adopted.

- Devices designed and manufactured, using either version of the recognised standard, and first introduced to the market prior to the end of the transition period, remain in compliance.

- Devices first introduced to the market after the end of the transition period should comply with the revised version of the recognised standard.

2. ENERGY HAZARDS	
Safety testing of medical electrical equipment	BS 5724 or IEC 60601
Safety devices for protection against excessive pressure - Part 9: Application and installation of safety devices excluding stand-alone bursting disc safety devices	ISO 4126-9
Ionizing-radiation warning - Supplementary symbol	ISO 21482
Safety of machinery - Pressure-sensitive protective devices - Part 2: General principles for the design and testing of pressure-sensitive edges and pressure-sensitive bars	ISO 13856-2

Abstract

ISO 13856-2 specifies the general principles and requirements for the design and testing of pressure-sensitive edges and pressure-sensitive bars for use as safety devices and not as actuating devices for normal operation. It is applicable to pressure-sensitive edges and pressure-sensitive bars, with or without an external reset facility, used to detect persons or parts of persons who may be exposed to danger such as hazardous moving parts. Its purpose relates primarily to safety and reliability rather than suitability.

It is restricted to the functioning of pressure-sensitive edges and pressure-sensitive bars and does not specify the requirements for their application, but does contain requirements for the information for use to be provided by the manufacturer. It does not specify the dimensions of the pressure-sensitive edges or bars in relation to a particular application. It is not applicable to stopping devices according to IEC 60204-1 used only for normal operational, including emergency stopping, of machinery. Additional requirements could be necessary where pressure-sensitive edges and pressure-sensitive bars are used in locations accessible to elderly or disabled people or children.

Mechanical Vibration and Shock - Evaluation of Human Exposure to Whole Body Vibration - Part 1 : General Requirements	IS 13276 : Part 1
Mechanical vibration -- Criteria and safeguards for the in-situ balancing of medium and large rotors	ISO 20806

Abstract

ISO 20806 specifies procedures to be adopted when balancing medium and large rotors installed in their own bearings on site. It addresses the conditions under which it is appropriate to undertake *in-situ* balancing, the instrumentation required, the safety implications and the requirements for reporting and maintaining records. ISO 20806 can be used as a basis for a contract to undertake *in-situ* balancing. It does not provide guidance on the methods used to calculate the correction masses from measured vibration data.

Safety devices for protection against excessive pressure - Part 3: Safety valves and bursting disc safety devices in combination	ISO4126-3

Abstract

ISO 4126-3 specifies the requirements for a product assembled from the in-series combination of safety valves or CSPRS (controlled safety pressure relief systems) according to ISO 4126-1, ISO 4126-4 and ISO 4126-5, and bursting disc safety devices according to ISO 4126-2 installed within no more than five pipe diameters from the valve inlet. It specifies the design, application and marking requirements for such products, which are used to protect pressure vessels, piping or other enclosures from excessive pressure, and which comprise the bursting disc safety device, a safety valve or CSPRS and, where applicable, a short length of connecting pipe or spool piece. In addition, it gives a method for establishing the combination discharge factor used in sizing combinations.

Safety of machinery - Two-hand control devices - Functional aspects and design principles	ISO 13851

Abstract

This International Standard specifies the safety requirements of a two-hand control device and the dependency of the output signal from the input signals.

It describes the main characteristics of two-hand control devices for the achievement of safety and sets out combinations of functional characteristics for three types. It does not apply to devices intended to be used as enabling devices, as hold-to-run devices or as special control devices.

This International Standard does not specify with which machines two-hand control devices shall be used. It also does not specify which types of two-hand-control device shall be used. Moreover, it does not specify the distance between the two-hand control device and the danger zone.

This International Standard provides requirements and guidance on the design and selection (based on a risk assessment) of two-hand control devices including their assessment, the prevention of defeat and the avoidance of faults. It also provides requirements and guidance for two-hand control devices containing a programmable electronic system.

This International Standard applies to all two-hand control devices, independent of the energy used, including:

- two-hand control devices which are or are not integral parts of a machine;
- two-hand control devices which consist of one or more than one separate element.

Graphical symbols -- Safety colors and safety signs - Part 2: Design principles for product safety labels	ISO 3864-2

Abstract

ISO 3864-2 establishes additional principles to ISO 3864-1 for the design of safety labels for products, i.e. any items manufactured and offered for sale in the normal course of commerce, including but not limited to consumer products and industrial equipment. The purpose of a product safety label is to alert persons to a specific hazard and to identify how the hazard can be avoided.

ISO 3864-2 is applicable to all products in all industries where safety-related questions can be posed. However, it is not applicable to safety labels used for chemicals, for the transport of dangerous substances and preparations, and in those sectors subject to legal regulations which differ from certain provisions of this document.

The design principles incorporated in ISO 3864-2 are intended to be used by all ISO Technical Committees and anyone designing product safety labels in the development of product safety label standards for their industries or services.

Statutory or regulatory requirements in some countries may differ from some requirements given in ISO 3864-2. To facilitate international standardization of product safety labels, ISO 3864-2:2004 should be considered when revising regulations.

IMPORTANT -- The colors represented in the electronic file of ISO 3864-2 can be neither viewed on screen nor printed as true representations. Although the copies of ISO 3864-2 printed by ISO have been produced to correspond (with an acceptable tolerance as judged by the naked eye) to the colour requirements, it is not intended that these printed copies be used for colour matching. Instead, refer to the colorimetric and photometric properties specified in ISO 3864-1and ISO 3864-2. As guidelines, references from colour order systems are provided in ISO 3864-2 for safety colour orange and ISO 3864-1:2002 for other safety colors.

Life-threatening components of fire - Guidelines for the estimation of time available for escape using fire data	ISO 13571

Abstract

ISO 13571 is only one of many tools available for use in fire safety engineering. It is intended to be used in conjunction with models for analysis of the initiation and development of fire, fire spread, smoke formation and movement, chemical species generation, transport and decay and people movement, as well as fire detection and suppression. ISO 13571is to be used only within this context.

ISO 13571 is intended to address the consequences of human exposure to the life threat components of fire as occupants move through an enclosed structure. The time-dependent concentrations of fire effluents and the thermal environment of a fire are determined by the rate of fire growth, the yields of the various fire gases produced from the involved fuels, the decay characteristics of those fire gases and the ventilation pattern within the structure. Once these are determined, the methodology presented in ISO 13571 can be used for the estimation of the available escape time.

ISO 13571 provides guidance on establishing the procedures to evaluate the life threat components of fire hazard analysis in terms of the status of exposed human subjects at discrete time intervals. It makes possible the determination of a tenability endpoint, at which time it is estimated that occupants are no longer able to take effective action to accomplish their own escape. The life threat components addressed include fire-effluent toxicity, heat and visual obscuration due to smoke. Two methods are presented for assessment of fire-effluent toxicity: the toxic-gas model and the mass-loss model. ISO 13571 does not consider aspects such as the initial impact of visual obscuration due to smoke on factors affecting the time required for occupants to escape, the toxic effects of aerosols and particulates and any interactions with gaseous fire-effluent components and adverse health effects following exposure to fire atmospheres	
Guidance for assessing the validity of physical fire models for obtaining fire effluent toxicity data for fire hazard and risk assessment - Part 1: Criteria	ISO 16312-1
Abstract ISO 16312-1 provides technical criteria and guidance for evaluating physical fire models (i.e. laboratory combustion devices and operating protocols) used in effluent toxicity studies for obtaining data on the effluent from products and materials under fire conditions relevant to life safety. Relevant analytical methods, calculation methods, bioassay procedures and prediction of the toxic effects of fire effluents can be referenced in ISO 19701, ISO 19702, ISO 19703, ISO 19706, ISO 13344 and ISO 13571	
Protection against radiation Constructional requirements of nuclear instruments to afford personal protection against ionizing radiation	IS 11868
Protection against mechanical risks. General and safety requirements for electrical equipment used in medical practice: Part 3 Protection against mechanical hazards	IS 8607: Part 3
Radiation protection -- Sealed radioactive sources -- General requirements and classification	ISO 2919
Medical electrical equipment – Part 2-59: Particular requirements for basic safety and essential performance of screening thermographs for human febrile temperature screening	IEC 80601-2-59
Medical supply units	ISO 11197
Abstract ISO 11197 specifies requirements and test methods for medical supply units intended for use in healthcare facilities to supply electric power and/ medical gases and/or liquids and anesthetic gas scavenging systems. It is applicable in conjunction with IEC 60601-1. The requirements of ISO 11197:2004 take priority over those of IEC 60601-1.	

Radioactive materials - Packaging - Test for contents leakage and radiation leakage	ISO 2855
Abstract Specifies some methods for prototypes of transport packaging, but may not be considered universally applicable. The leak test is provided for the containment system of containers and type A packaging for low specific activity liquid or powder sources. The homogeneity test refers to the outer surface of the shielding or the whole packaging. Both methods are inappropriate when the containment system is too large or of a type that they become impracticable.	
Components for containment enclosures - Part 4: Ventilation and gas-cleaning systems such as filters, traps, safety and regulation valves, control and protection devices.	ISO 11933-4
Fire protection - Vocabulary - Part 3: Fire detection and alarm	ISO 8421-3
Abstract Concepts are given in English in alphabetical order. English and French alphabetical indices are provided. General use terms are covered by ISO 8421-1.	
Radiation protection - Clothing for protection against radioactive contamination -- Design, selection, testing and use.	ISO 8194
Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use	IEC 80601-2-35
Abstract IEC 80601-2-35 establishes particular basic safety and essential performance requirements, which minimize hazards to patients, and operators for heating devices using blankets, pads or mattresses and intended for heating in medical use and specifies tests for demonstrating compliance with these requirements. This second edition cancels and replaces the first edition published in 1996. This edition constitutes a technical revision. This new edition provides consistency with the third edition of IEC 60601-1, as well as with the four other particular standards related to pediatric equipment for which the committee is responsible.	
Health informatics - Classification of safety risks from health software	ISO/TS 25238

Abstract

ISO/TS 25238 is concerned with the safety of patients and gives guidance on the analysis and categorization of hazards and risks to patients from health software products, in order to allow any product to be assigned to one of five risk classes. It applies to hazards and risks which could cause harm to a patient. Other risks, such as financial or organizational risks, are outside the scope of ISO/TS 25238 unless they have the potential to harm a patient.

ISO/TS 25238 applies to any health software product, whether or not it is placed on the market and whether it is for sale or free of charge. Examples of the application of the classification scheme are given.

ISO/TS 25238 does not apply to any software which is necessary for the proper application or functioning of a medical device.

Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	IEC60601-1-11

Abstract

IEC 60601-1-11 applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems which are intended by their manufacturer for use in the home healthcare environment, regardless of whether the medical electrical equipment or medical electrical system is intended for use by a lay operator or by trained healthcare personnel. The object of IEC 60601-1-11 is to specify general requirements that are in addition to those of the general standard IEC 60601-1 and to serve as the basis for particular standards. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

Health informatics - Interoperability of tele health systems and networks - Part 1: Introduction and definitions	ISO/TR16056-1

Abstract

ISO/TR 16056-1 gives a brief introduction to interoperability of telehealth systems and networks, along with definitions of telehealth and related terms.

An informative annex describing the Telehealth Technical Reference Architecture has also been included to describe more clearly the various components of a telehealth system and the elements that need to be addressed in formulating a set of requirements for these various components.

The scope of the document does not include conformity and interoperability tests or functional specifications for telehealth systems and networks.

Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	IEC 60601-1-8

Abstract

Specifies basic safety and essential performance requirements and tests for alarm systems in medical electrical equipment and medical electrical systems and to provide guidance for their application. This is accomplished by defining alarm categories (priorities) by degree of urgency, consistent alarm signals and consistent control states and their marking for all alarm systems

3. BIOLOGICAL HAZARDS

Biological evaluation of medical devices- Guidance on a risk-management process	ISO/TS20993

Abstract

ISO/TS 20993 describe a process by which a manufacturer can identify the biological hazards associated with medical devices, estimate and evaluate the risks, control these risks and monitor the effectiveness of the control.

Guide for evaluation of medical devices for biological hazards.	IS 12572 : 3-11
In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures	ISO 15193

Abstract

ISO 15193 specifies requirements for the content of a reference measurement procedure for *in vitro* diagnostic medical devices and medical laboratories.

ISO 15193 applies to reference measurement procedures providing values of differential or rational quantities. Annex A provides information on nominal properties and ordinal quantities.

ISO 15193 is valid for any person, body or institution involved in one of the various branches of laboratory medicine whose intention is to write a document to serve as a reference measurement procedure.

Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management	ISO22442-1

Abstract

ISO 22442-1 applies to medical devices other than *in vitro* diagnostic medical devices manufactured utilizing materials of animal origin, which are non-viable or have been rendered non-viable. It specifies, in conjunction with ISO 14971, a procedure to identify the hazards and hazardous situations associated with such devices, to estimate and evaluate the resulting risks, to control these risks, and to monitor the effectiveness of that control. Furthermore, it outlines the decision process for the residual risk acceptability, taking into account the balance of residual risk, as defined in ISO 14971, and expected medical benefit as compared to available alternatives. ISO 22442-1 is intended to provide requirements and guidance on risk management related to the hazards typical of medical devices manufactured utilizing animal tissues or derivatives such as:

- contamination by bacteria, moulds or yeasts;
- contamination by viruses;
- contamination by agents causing Transmissible Spongiform Encephalopathies (TSE);
- material responsible for undesired pyrogenic, immunological or toxicological reactions.

4. ENVIRONMENTAL HAZARDS

Molecular Contamination	ISO-14644-8

Abstract

ISO 14644-8 covers the classification of airborne molecular contamination (AMC) in cleanrooms and associated controlled environments in terms of airborne concentrations of specific chemical substances (individual, group or category) and provides a protocol to include test methods, analysis and time weighted factors within the specification for classification. ISO 14644-8 currently considers only concentrations of AMC between 10^0 and 10^{12} g/m^3 under clean room operational conditions. ISO 14644-8 is not relevant for application in those industries, processes or production, where the presence of airborne molecular substances is not considered a risk to the product or process. It is not the intention of ISO 14644-8 to describe the nature of airborne molecular contaminants. ISO 14644-8 does not give a classification of surface molecular contamination.

Biocontamination: Control General Principles	ISO-14698-1-3

Abstract

ISO 14698 establishes the principles and basic methodology of a formal system of biocontamination control (Formal System) for assessing and controlling biocontamination when clean room technology is applied for that purpose. It specifies the methods required for monitoring risk zones in a consistent way and for applying control measures appropriate to the degree of risk involved. In zones where risk is low, it can be used for information.

ISO 14698-2 gives guidance on methods for the evaluation of microbiological data and the estimation of results obtained from sampling for viable particles in risk zones for

biocontamination control. It should be used, where appropriate, in conjunction with ISO 14698-1.

ISO-14698-3: This document outlines the methodology to measure the effectiveness of cleaning and/or disinfection of inert surfaces having biocontaminated wet soiling or biofilms

Methods of sampling and microbiological examination of water	IS 1622
Clean room Design & Construction	ISO-14644-1-8

Abstract

This part of ISO 14644 covers the classification of air cleanliness in clean rooms and associated controlled environments exclusively in terms of concentration of airborne particles. Only particle populations having cumulative distributions based on threshold (lower limit) sizes ranging from 0, 1 µm to 5 µm are considered for classification purposes.
This part of ISO 14644 does not provide for classification of particle populations that are outside of the specified particle size range, 0, 1 µm to 5 µm. Concentrations of ultra fine particles (particles smaller than 0,1 µm) and macro particles (particles larger than 5 µm) may be used to quantify these populations in terms of U descriptors and M descriptors, respectively.

This part of ISO 14644 cannot be used to characterize the physical, chemical, radiological, or viable nature of airborne particles.

NOTE The actual distribution of particle concentrations within incremental size ranges normally is not predictable and typically is variable over time.

ISO-14644-2 This part of ISO 14644 specifies requirements for testing and monitoring of a cleanroom or clean zone to prove its continued compliance with ISO 14644-1 for the designated classification of air cleanliness by particle concentration. These requirements invoke the test described in ISO 14644-1 for classification of a cleanroom or clean zone. Additional tests are also specified, to be carried out in accordance with the requirements of this part of ISO 14644. This part of ISO 14644 also specifies requirements for monitoring of a cleanroom or clean zone to provide evidence of its continued compliance with ISO 14644-1 for the designated classification of airborne particulate cleanliness.

ISO 14644-3 specifies test methods for designated classification of airborne particulate cleanliness and for characterizing the performance of cleanrooms and clean zones. Performance tests are specified for two types of cleanrooms and clean zones: those with unidirectional flow and those with non-unidirectional flow, in three possible occupancy states: as-built, at-rest and operational.

ISO 14644-3 is not applicable to the measurement of products or of processes in cleanrooms or separative devices.

ISO-14644 installations but does not prescribe specific technological or contractual means

to meet these requirements. It is intended for use by purchasers, suppliers and designers. This part of ISO 14644 specifies requirements for the design and construction of cleanroom of cleanroom installations and provides a checklist of important parameters of performance. Construction guidance is provided, including requirements for start-up and qualification. Basic elements of design and construction needed to ensure continued satisfactory operation are identified through the consideration of relevant aspects of operation and maintenance.
NOTE Further guidance in respect of the above requirements is given in annexes A to H. Other parts of ISO 14644 may provide complementary information.

Application of this part of ISO 14644 is restricted in the following:

- user requirements are represented by purchaser or specifier;
- specific processes to be accommodated in the clean room installation are not specified;
- fire and safety regulations are not considered specifically; the appropriate national and local requirements should be respected;
- process media and utility services are only considered with respect to their routing between and in the different zones of cleanliness;

regarding initial operation and maintenance, only clean room construction-specific requirements are considered.

ISO 14644-5 specifies basic requirements for clean room operations. It is intended for those planning to use and operate a clean room. Aspects of safety that have no direct bearing on contamination control are not considered in this part of ISO 14644 and national and local safety regulations must be observed. This document considers all classes of clean rooms used to produce all types of products. Therefore, it is broad in application and does not address specific requirements for individual industries. Methods and programmes for routine monitoring within clean rooms are not covered in detail in this part of ISO 14644 but reference should be made to ISO 14644-2 and ISO 14644-3 for monitoring particles, and ISO 14698-1 and ISO 14698-2 for monitoring micro-organisms.

This part of ISO 14644-7 specifies the minimum requirements for the design, construction, installation, test and approval of separative devices, in those respects where they differ from cleanrooms as described in ISO 14644-4 and 14644-5. The application of this part of ISO 14644 takes into account the following limitations.

- User requirements are as agreed by customer and supplier.
- Application-specific requirements are not addressed.
- Specific processes to be accommodated in the separative-device installation are not specified.
- Fire, safety and other regulatory matters are not considered specifically; where appropriate, national and local regulations apply.

Clean rooms and associated controlled environments - Part 5: Operations	ISO 14644-5

Abstract

ISO 14644-5 specifies basic requirements for cleanroom operations. It is intended for those planning to use and operate a cleanroom. Aspects of safety that have no direct bearing on contamination control are not considered in this part of ISO 14644 and national and local safety regulations must be observed. This document considers all classes of cleanrooms used to produce all types of products. Therefore, it is broad in application and does not address specific requirements for individual industries. Methods and programmes for routine monitoring within cleanrooms are not covered in detail in this part of ISO 14644 but reference should be made to ISO 14644-2 and ISO 14644-3 for monitoring particles, and ISO 14698-1 and ISO 14698-2 for monitoring micro-organisms.

Buildings and environment	CFR 820

Abstract

Buildings in which manufacturing, assembling, packaging, packing, holding testing, or labeling operations are conducted shall be of suitable design and contain sufficient space to facilitate adequate cleaning, maintenance, and other necessary operations. The facilities shall provide adequate space designed to prevent mix ups and to assure orderly handling of the following: Incoming components; rejected or obsolete components; in-process components; finished devices; labeling; devices that have been reprocessed reworked, or repaired; equipment; molds, patterns, tools records, drawings, blueprints; testing and laboratory operations; and quarantined products.

Environmental control.
Where environmental conditions at the manufacturing site could have an adverse effect on a device's fitness for use, these environmental conditions shall be controlled to prevent contamination of the device and to provide proper conditions for each of the operations performed pursuant to 820.40. Conditions to be considered for control are lighting, ventilation, temperature, humidity, air pressure filtration, airborne contamination, and other contamination. Any environmental control system shall be periodically inspected to verify that the system is properly functioning. Such inspections shall be documented.

Water quality - Vocabulary	ISO 6107-1
Water quality - Evaluation of membrane filters used for microbiological analyses	ISO 7704

Abstract

Gives a procedure for the evaluation and comparison of water-testing filters intended for the enumeration of specific organisms and mixed microbial populations. The procedure provides general guidelines for comparative testing of the recoveries of bacteria, yeasts and other fungi on membrane filters, as compared to recoveries by the spread plate and pour plate techniques.

Water quality - Determination of electrical conductivity	ISO 7888

Abstract

Specifies a method for the measurement of all types of water. The quantity can be used

to monitor the quality of surface waters, process waters in water supply and treatment plants, and waste waters. Interferences are given.	
Water quality - Detection and enumeration of intestinal enterococci - Part 2: Membrane filtration method	ISO 7899-2
Air quality - General aspects - Vocabulary	ISO 4225
Abstract Explains the meanings, in English and French, of a selection of terms commonly used in connection with the sampling and measurement of gases, vapours and particles for the determination. The terms are arranged in alphabetical order in English. An alphabetical index of the French terms is also given.	
Air quality - General aspects - Units of measurement.	ISO 4226
Abstract ISO 4226 lays down the units to be used when reporting results of air quality measurements.	
Air quality - Exchange of data - Part 1: General data format	ISO 7168-1
Air quality - Exchange of data - Part 2: Condensed data format	ISO 7168-2
Air quality - Handling of temperature, pressure and humidity data	ISO 8756
Abstract Describes procedures for adjusting air quality measurements for changes in temperature, pressure and humidity during the sampling period. Specifies the reference conditions of temperature, pressure and humidity to be used when reporting the results. The procedures and reference conditions are applicable to air quality measurement methods and apply to measurements made in ambient and workplace atmospheres and to the measurement of stationary source emissions.	
Air quality - Definition and determination of performance characteristics of an automatic measuring system	ISO 9169
Abstract Describes procedures for adjusting air quality measurements for changes in temperature, pressure and humidity during the sampling period. Specifies the reference conditions of temperature, pressure and humidity to be used when reporting the results. The procedures and reference conditions are applicable to air quality measurement methods and apply to measurements made in ambient and workplace atmospheres and to the measurement of stationary source emissions.	
Stationary source emissions - Automated monitoring of mass concentrations of particles - Performance characteristics, test methods and specifications	ISO 10155

Abstract

Specifies conditions and criteria for the automated monitoring of the mass concentration of particulate matter in stationary source gas streams, including performance characteristics and test procedures. Provides the field evaluation test program and its application to automated monitoring systems. Applicable only on a site-specific basis by direct correlation with the manual testing method in ISO 9096.

Air quality - Test method for filtration characterization of cleanable filter media.	ISO 11057

Abstract

ISO 11057 specifies a standard reference test method for the comparative characterization of pulse-jet cleanable filter media, to be used in filter elements (e.g. bag filters, pocket filters, cartridge filters) applied in dry gas cleaning under standardized test conditions. The main purpose of testing is to gain information about both the operational performance and the particle emission of cleanable filter media.

It should be noted that while one test apparatus and operating method has been chosen and described herein, it is recognized that other apparatus and operating arrangements can be found acceptable. In order for a candidate apparatus to become an equivalent apparatus, a comparison has to be performed with the standard reference apparatus according to a specified procedure. The test procedure, the characteristics of the required test facility, and the test conditions, as well as the evaluation and presentation of the results, are specified.

The results obtained from this test method are not intended for prediction of the absolute performance of full-scale filter facilities. However, they are helpful for the selection and development of appropriate cleanable filter media and the identification of suitable operating parameters.

Additional tasks such as verifying filter media concerning $PM_{2,5}$ emissions, the classification of different media according to their filtration performance or the cleanability and durability of filter elements (i.e. projection of bag lifetime) can be addressed using the test method specified.

Indoor air - Part 1: General aspects of sampling strategy	ISO 16000-1

Abstract

ISO 16000-1 is intended to aid the planning of indoor pollution monitoring.
Before a sampling strategy is devised for indoor air monitoring, it is necessary to clarify for what purposes, when, where, how often and over what periods of time monitoring is to be performed. The answers to these questions depend, in particular, on a number of special characteristics of the indoor environments, on the objective of the measurement and, finally, on the environment to be measured. ISO 16000-1 deals with the significance of these factors and offers suggestions on how to develop a suitable sampling strategy.

ISO 16000-1 is applicable to indoor environments such as dwellings having living rooms, bedrooms, do-it-yourself rooms, recreation rooms and cellars, kitchens and bathrooms; workrooms or work places in buildings which are not subject to health and safety inspections in regard to air pollutants (for example, offices, sales premises); public buildings (for example hospitals, schools, kindergartens, sports halls, libraries, restaurants and bars, theatres, cinemas and other function rooms), and also cabins of vehicles.

Workplace atmospheres - Protocol for evaluating the performance of diffusive samplers	ISO 16107

Abstract

ISO 16107 specifies methods for evaluation of sampler performance in terms of workplace conditions: wind speed, humidity, temperature, atmospheric pressure, and analyte variation. The concise set of experiments specified aims to minimize cost to the user. The evaluation is limited to conditions commonly encountered in personal sampling in the indoor workplace setting, namely wind speeds of up to 0, 5 m/s and for sampling periods typically from 2 h to 8 h.

Static or area sampling, unlike personal sampling where movement of the subject is significant, may sometimes be subject to sampling-rate reduction due to stagnation at very low wind speeds. ISO 16107 therefore does not apply to wind speeds of less than 0,1 m/s relative to static samplers. Samplers are also tested for compliance with the manufacturer's stated limits on capacity, possibly in the presence of interfering compounds. Given a suitable exposure chamber, the sampler evaluation protocol can be extended to cover sampler use for other sampling periods and conditions.

ISO 16107 indicates how to measure diffusive sampler uncertainty for characterizing concentration estimates obtained subsequent to the evaluation. It is impractical continually to re-evaluate diffusive sampler performance under various environmental conditions prevailing during application.

Air quality - Guidelines for estimating measurement uncertainty.	ISO 20988

Abstract

ISO 20988 provides comprehensive guidance and specific statistical procedures for uncertainty estimation in air quality measurements including measurements of ambient air, stationary source emissions, indoor air, workplace atmospheres and meteorology. It applies the general recommendations of the *Guide to the Expression of Uncertainty in Measurement* (GUM) to boundary conditions met in air quality measurement. The boundary conditions considered include measurands varying rapidly in time, as well as the presence of bias in a series of observations obtained under conditions of intended use of methods of air quality measurement.

The methods of measurement considered comprise methods corrected for systematic effects by repeated observation of reference materials, methods calibrated by paired measurement with a reference method, methods not corrected for systematic effects because they are unbiased by design, and methods not corrected for systematic effects in

intended use deliberately taking into account a bias.

Experimental data for uncertainty estimation can be provided either by a single experimental design in a direct approach or by a combination of different experimental designs in an indirect approach.

5. HAZARD RELATED TO USE OF DEVICE

Devices with a diagnostic or measuring function.	GHTF/SG1/N41R9

Abstract

Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits o the patient and are compatible with a high level of protection of health and safety.

Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management**.**	US FDA, CDRH
Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	ISO 15223-1

Abstract

ISO 15223-1 identifies requirements for the development and use of symbols that may be used to convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of ISO 15223-1.

ISO 15223-1 is limited to symbols applicable to a broad spectrum of devices that may be marketed globally. These symbols may be used on the device itself or its package or in the associated documentation.

6. HAZARDS FROM PRODUCT REALISATION PROCESS

Quality management systems -- Guidelines for quality plans	ISO 10005

Abstract

ISO 10005 provides guidelines for the development, review, acceptance, application and revision of quality plans. It is applicable whether or not the organization has a management system in conformity with ISO 9001.

ISO 10005 is applicable to quality plans for a process, product, project or contract, any product category (hardware, software, processed materials and services) and any industry. It is focused primarily on product realization and is not a guide to organizational quality management system planning.

ISO 10005 is a guidance document and is not intended to be used for certification or registration purposes.

Product identification and traceability In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials	ISO17511

Abstract

ISO 17511 specifies how to assure the metrological traceability of values assigned to calibrators and control materials intended to establish or verify trueness of measurement. The calibrators and control materials are those provided by the manufacturers as part of, or to be used together with, *in vitro* diagnostic medical devices.

External quality assessment (survey) samples, with proven commutability, whose values have been assigned by means of internationally agreed reference measurement systems or internationally agreed conventional reference measurement systems fall within the scope of ISO 17511.

ISO 17511 is not applicable to control materials that do not have an assigned value and are used only for assessing the precision of a measurement procedure, either its repeatability or reproducibility (precision control materials); control materials intended for intralaboratory quality control purposes and supplied with intervals of suggested acceptable values, each interval obtained by interlaboratory consensus with respect to one specified measurement procedure, and with limiting values that are not metrologically traceable; correlation between results of two measurement procedures at the same metrological level, purporting to measure the same quantity, because such "horizontal" correlation does not provide metrological traceability; calibration derived from correlation between the results of two measurement procedures at different metrological levels, but with quantities having analytes of different characteristics; metrological traceability of routine results to the product calibrator and their relations to any medical discrimination limit; and properties involving nominal scales, i.e. where no magnitude is involved (e.g. identification of blood cells).

Process Control Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	ISO11137-1

Abstract

ISO 11137-1 specifies requirements for the development, validation and routine control of a radiation sterilization process for medical devices. Although the scope of ISO 11137-1 is limited to medical devices, it specifies requirements and provides guidance that may be applicable to other products and equipment.

ISO 11137-1 covers radiation processes employing irradiators using the radionuclide ^{60}Co or ^{137}Cs, a beam from an electron generator or a beam from an X-ray generator.

ISO 11137-1 does not specify requirements for development, validation and routine control of a process for inactivating the causative agents of spongiform

encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease;

detail specified requirements for designating a medical device as sterile; specify a quality management system for the control of all stages of production of medical devices;
specify requirements for occupational safety associated with the design and operation of irradiation facilities; specify requirements for the sterilization of used or reprocessed devices.

Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilization process for medical devices	ISO20857

Abstract

ISO 20857 specifies requirements for the development, validation and routine control of a dry heat sterilization process for medical devices.

Although ISO 20857 primarily addresses dry heat sterilization, it also specifies requirements and provides guidance in relation to depyrogenation processes using dry heat.

Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	ISO11135-1

Abstract

ISO 11135-1 specifies requirements for the development, validation and routine control of an ethylene oxide sterilization process for medical devices.

Sterilization processes validated and controlled in accordance with the requirements of ISO 11135-1 are not assumed to be effective in inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeld Jacob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

Sterilization of health care products - Moist heat Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.	ISO17665-1

Abstract

ISO 17665-1 specifies requirements for the development, validation and routine control of a moist heat sterilization process for medical devices.
Moist heat sterilization processes covered by ISO 17665-1 include but are not limited to:

- saturated steam venting systems;
- saturated steam active air removal systems;
- air steam mixtures;
- water spray;
- water immersion.

Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	ISO14937

Abstract

ISO 14937 specifies general requirements for the characterization of a sterilizing agent and for the development, validation and routine monitoring and control of a sterilization process for medical devices.

It applies to sterilization processes in which microorganisms are inactivated by physical and/or chemical means and is intended to be applied by process developers, manufacturers of sterilization equipment, manufacturers of medical devices to be sterilized, and organizations responsible for sterilizing medical devices.

ISO 14937 specifies the elements of a Quality Management System which are necessary to assure the appropriate characterization of the sterilizing agent, development, validation and routine monitoring and control of a sterilization process.

Sterilization of medical devices - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices	ISO25424

Abstract

ISO 25424 specifies requirements for the development, validation and routine control of a Low Temperature Steam and Formaldehyde (LTSF) sterilization process for medical devices.

ISO 25424 is intended to be applied by process developers, manufacturers of sterilization equipment, manufacturers of medical devices to be sterilized and the organizations with responsibility for sterilizing medical devices.

ISO 25424 covers sterilization processes that use a mixture of low temperature steam and formaldehyde as sterilant, and which are working below ambient pressure only.

Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	ISO14160

Abstract

ISO 14160 specifies requirements for the characterization of a liquid chemical sterilizing agent and for the development, validation, process control and monitoring of sterilization by liquid chemical sterilizing agents of single-use medical devices comprising, in whole or in part, materials of animal origin.

ISO 14160 covers the control of risks arising from contamination with bacteria and fungi by application of a liquid chemical sterilization process. Risks associated with other microorganisms need to be assessed.
ISO 14160 is not applicable to material of human origin.

ISO 14160 does not describe methods for the validation of the inactivation of viruses and transmissible spongiform encephalopath (TSE) agents.

ISO 14160 does not describe methods for validation of the inactivation, elimination, or elimination and inactivation of protozoa and parasites.

The requirements for validation and routine control described in ISO 14160 are only applicable to the defined sterilization process of a medical device, which is performed after the manufacturing process, and do not take account of the lethal effects of other bioburden reduction steps.

ISO 14160 does not specify tests to establish the effects of any chosen sterilization method upon the fitness for use of the medical device.

ISO 14160 does not cover the level of residual sterilizing agent within medical devices.
ISO 14160 does not describe a quality management system for the control of all stages of manufacture.

Medical devices - Application of risk management to medical devices	ISO14971

Abstract

ISO 14971 specifies a process for a manufacturer to identify the hazards associated with medical devices, including *in vitro* diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

The requirements of ISO 14971 are applicable to all stages of the life-cycle of a medical device.

Biological evaluation of medical devices -- Guidance on a risk-management process	ISO/TS20993

Abstract

ISO/TS 20993 describes a process by which a manufacturer can identify the biological hazards associated with medical devices, estimate and evaluate the risks, control these risks and monitor the effectiveness of the control.

Clinical laboratory medicine - *In vitro* diagnostic medical devices - Validation of user quality control procedures by the manufacturer	ISO15198

Abstract

ISO 15198 describes a process for manufacturers of *in vitro* diagnostic medical devices to validate quality control procedures they recommend to their users. These quality control procedures are intended to provide users with assurance that device performance is consistent with its intended use and the manufacturers' claims. ISO 15198 applies to all *in vitro* diagnostic medical devices.

Inspection and testing Conformity assessment - Guidance on the use of an organization's quality management system in product certification	ISO/IECGuide53

Abstract

ISO/IEC Guide 53 outlines a general approach by which certification bodies can develop and apply product certification schemes utilizing requirements of an organization's quality management system. The provisions given are not requirements for the accreditation of a product certification body and do not substitute the requirements of ISO/IEC Guide 65.

The schemes contained in ISO/IEC Guide 53 are for product certification only and in all cases involve the following principles:

assessment of an organization's quality management system and its capability to consistently supply products conforming to specified requirements;

testing, inspection or comparable verification of the product's conformity to scheme criteria and specified requirements;

application of a suitable surveillance scheme to ensure continual conformity to specified requirements of products supplied by the organization;

control of the mark of conformity and/or logo of the certification body

Random sampling and randomization procedures	ISO24153

Abstract

ISO 24153 defines procedures for random sampling and randomization. Several methods are provided, including approaches based on mechanical devices, tables of random numbers, and portable computer algorithms.

ISO 24153 is applicable whenever a regulation, contract, or other standard requires random sampling or randomization to be used. The methods are applicable to such situations as

a) acceptance sampling of discrete units presented for inspection in lots,
b) sampling for survey purposes,
c) auditing of quality management system results, and
d) selecting experimental units, allocating treatments to them, and determining evaluation order in the conduct of designed experiments.

Information is also included to facilitate auditing or other external review of random sampling or randomization results where this is required by quality management personnel or regulatory bodies.

ISO 24153 does not provide guidance as to the appropriate random sampling or randomization procedures to be used for any particular experimental situation or give guidance with respect to possible sampling strategy selection or sample size determination. Other ISO International Standards (such as ISO 2859, ISO 3951, ISO 8422, ISO 8423, ISO 13448, ISO 14560, ISO 18414, ISO 21247 and ISO 11648) or authoritative references should be consulted for guidance in such areas.

Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software	IEC/TR80002-1

This technical report provides guidance for the application of the requirements contained in ISO 14971, Medical devices— Application of risk management to medical devices to medical device software with reference to IEC 62304, Medical device software— Software life cycle processes. It does not add to, or otherwise change, the requirements of ISO 14971 or IEC 62304. This technical report is aimed at risk management practitioners who need to perform risk management when software is included in the MEDICAL DEVICE/SYSTEM, and at software engineers who need to understand how to fulfil the requirements for risk management addressed in ISO 14971. ISO 14971, recognized worldwide by regulators, is widely acknowledged as the principal standard to use when performing medical device risk management. IEC 62304, makes a normative reference to ISO 14971 requiring its use. The content of these two standards provides the foundation for this technical report. The structure of this technical report follows the structure of ISO 14971. It should be noted that even though ISO 14971 and this technical report focus on medical devices, this technical report may be used to implement a safety risk management process for all software in the healthcare environment independent whether it is classified as a medical device. this technical report does not address: – areas already covered by existing or planned standards, e.g. alarms, human factors engineering, networking, etc. – production or quality system software – software development tools This technical report is not intended to be used as the

basis of regulatory inspection or certification assessment activities. For the purposes of this technical report: – "should" is used to indicate that amongst several possibilities to meet a requirement in ISO 14971, one is recommended as being particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required; – "can" and "may'' are used to indicate permissible possibilities or options. These terms are not to be interpreted as indicating requirements.

Inspection and test status General requirements for the competence of testing and calibration laboratories	ISO/IEC17025

Abstract

ISO/IEC 17025 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.
It is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification.

ISO/IEC 17025 is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When a laboratory does not undertake one or more of the activities covered by ISO/IEC 17025, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

ISO/IEC 17025 is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. ISO/IEC 17025 is not intended to be used as the basis for certification of laboratories.

Compliance with regulatory and safety requirements on the operation of laboratories is not covered by ISO/IEC 17025.

Control of nonconforming product Sampling procedures for inspection by variables - Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL	ISO3951-1

Abstract

ISO 3951-1 specifies an acceptance sampling system of single sampling plans for inspection by variables, in which the acceptability of a lot is implicitly determined from an estimate of the percentage of nonconforming items in the process, based on a random sample of items from the lot.

ISO 3951-1 is primarily designed for application under the following conditions:
where the inspection procedure is to be applied to a continuing series of lots of discrete

products all supplied by one producer using one production process;
where only a single quality characteristic *x* of these products is taken into consideration, which must be measurable on a continuous scale;

where the measurement error is negligible, i.e. with a standard deviation no more than 10% of the process standard deviation;

where production is stable (under statistical control) and the quality characteristic *x* is distributed according to a normal distribution or a close approximation to the normal distribution;

where a contract or standard defines an upper specification limit *U*, a lower specification limit *L*, or both;

an item is qualified as conforming if and only if its measured quality characteristic *x* satisfies the appropriate one of the following inequalities:
x greater than or equal to *L* (i.e. the lower specification limit is not violated);
x greater than or equal to *U* (i.e. the upper specification limit is not violated);
x greater than or equal to *L* and *x* less than or equal to *U* (i.e. neither the lower nor the upper specification limit is violated).

The first two inequalities are called cases with a single specification limit, and the third a case with double specification limits.

If double specification limits apply, it is assumed in ISO 3951-1 that conformance to both specification limits is equally important to the integrity of the product; in such cases it is appropriate to apply a single AQL to the combined percentage of product outside the two specification limits. This is referred to as combined control.

Acceptance sampling procedures by attributes - Accept-zero sampling system based on credit principle for controlling outgoing quality	ISO 18414

Abstract

ISO 18414 specifies a system of single sampling schemes for lot-by-lot inspection by attributes. All the sampling plans of the system are of accept-zero form, i.e. no lot is accepted if the sample from it contains one or more nonconforming items. The schemes depend on a suitably-defined average outgoing quality limit (AOQL), the value of which is chosen by the user; no restrictions are placed on the choice of the value of the AOQL or on the sizes of successive lots in the series. The methodology ensures that the overall average quality reaching the customer or market-place will not exceed the AOQL in the long run.

ISO 18414 is designed for use under the following conditions: 1) where the inspection procedure is to be applied to a series of lots of discrete items that are intended to be identical, and which are all supplied by one producer using one production process; 2) where one or more quality characteristics of these products are taken into consideration,

which must all be classifiable as either conforming or nonconforming; 3) where the inspection error involved in classifying the state of a product's quality characteristic(s) is negligible; and 4) where inspection is non-destructive.

ISO 18414 can be suitable for regulatory purposes, as control of the expected quality of items reaching the market-place is achieved with the smallest possible sample sizes, and long-term control of the realized, or actual quality level in the market-place is achieved with certainty, regardless of how long or short individual suppliers' series may be. ISO 18414 can be used by suppliers/producers, buyers/consumers and regulatory agencies to provide control of the expected quality of the totality of accepted product of each type from each source.

Sampling procedures for inspection by variables - Part 3: Double sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	ISO 3951-3

Abstract

ISO 3951-3 specifies an acceptance sampling system of double sampling schemes for inspection by variables for percent nonconforming. It is indexed in terms of the acceptance quality limit (AQL).

The objectives of the methods laid down in ISO 3951-3 are to ensure that lots of acceptable quality has a high probability of acceptance and that the probability of non-accepting inferior lots is as high as practicable. This is achieved by means of the switching rules, which provide automatic protection to the consumer (by means of a switch to tightened inspection or discontinuation of sampling inspection) should a deterioration in quality be detected, and an incentive (at the discretion of the responsible authority) to reduce inspection costs (by means of a switch to a smaller sample size) should consistently good quality be achieved.

In ISO 3951-3, the acceptability of a lot is implicitly or explicitly determined from an estimate of the percentage of nonconforming items in the process, based on either one or two random samples of items from the lot.

ISO 3951-3 is primarily designed for use under the following conditions: where the inspection procedure is to be applied to a continuing series of lots of discrete products all supplied by one producer using one production process; where the items of product have a single quality characteristic; where the quality characteristic is measurable on a continuous scale; where the measurement error is negligible (i.e. with a standard deviation no more than 10% of the corresponding process standard deviation); where production is stable (under statistical control) and the quality characteristic is distributed, at least to a close approximation, according to a normal distribution; where the possibility of having to select and inspect a second sample is administratively acceptable; and where a contract or standard defines an upper specification limit, a lower specification limit, or both on the quality characteristic.

The procedures in ISO 3951-3 are not suitable for application to lots that have been

screened previously for nonconforming items	
Sequential sampling plans for inspection by variables for percent nonconforming (known standard deviation)	ISO 8423

Abstract

ISO 8423 specifies sequential sampling plans and procedures for inspection by variables of discrete items. The plans are indexed in terms of producer's risk point and the consumer's risk point. Therefore, they are suitable not only for the purposes of acceptance sampling, but for the more general purpose of the testing of simple statistical hypotheses for proportions. The purpose of ISO 8423 is to provide procedures for the sequential assessment of inspection results that may be used to induce the supplier to supply lots of a quality having a high probability of acceptance. At the same time, the consumer is protected by a prescribed upper limit to the probability of accepting a lot (or process) of poor quality.

ISO 8423 is primarily designed for use under the following conditions: where the inspection procedure is to be applied to a continuing series of lots of discrete products all supplied by one producer using one production process; where only a single quality characteristic of these products is taken into consideration, which must be measurable on a continuous scale; where the measurement error is negligible (i.e. with a standard deviation no more than 10 % of the process standard deviation); where production is stable (under statistical control) and the quality characteristic has a known standard deviation, and is distributed according to a normal distribution or a close approximation to the normal distribution; where a contract or standard defines an upper specification limit, a lower specification limit, or both. It is assumed that, where double specification limits apply, conformance to both specification limits is either equally important to the integrity of the product or is considered separately for both specification limits.
The procedures in ISO 8423 are not suitable for application to lots that have been screened previously for nonconforming items.

Control of quality records Sequential sampling plans for inspection by attributes	ISO8422

Abstract

ISO 8422 contains sequential sampling plans and procedures for inspection by attributes of discrete items. The plans are indexed in terms of the producer's risk point and the consumer's risk point. Therefore, they can be used not only for the purposes of acceptance sampling, but for a more general purpose of the verification of simple statistical hypotheses for proportions. ISO 8422 provides procedures for sequential assessment of inspection results that may be used to induce the supplier, through the economic and psychological pressure of non-acceptance of lots of inferior quality, to supply lots of a quality having a high probability of acceptance. At the same time, the consumer is protected by a prescribed upper limit to the probability of accepting lots of poor quality.

ISO 8422 provides sampling plans that are applicable, but not limited, to inspection of different fields, such as: end items, components and raw materials, operations, materials in process, supplies in storage, maintenance operations, data or records, and

administrative procedures.
The sampling plans from ISO 8422 should primarily be used for the analysis of samples taken from processes. For example, they may be used for the acceptance sampling of lots taken from a process that is under statistical control. However, they may also be used for the acceptance sampling of an isolated lot when its size is large, and the expected fraction nonconforming is small (significantly smaller than 10%).

In the case of the acceptance sampling of continuing series of lots, the system of sequential sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection published in ISO 2859-5 should be applied.

Internal quality audits Guidelines for quality and/or environmental management systems auditing	ISO19011

Abstract

ISO 19011 provides guidance on the principles of auditing, managing audit programmes, conducting quality management system audits and environmental management system audits, as well as guidance on the competence of quality and environmental management system auditors.
It is applicable to all organizations needing to conduct internal or external audits of quality and/or environmental management systems or to manage an audit programme.
The application of ISO 19011 to other types of audits is possible in principle provided that special consideration is paid to identifying the competence needed by the audit team members in such cases

Training Quality Management - Guidelines for Training	IS/ISO 10015
Condition monitoring and diagnostics of machines- Requirements for qualification and assessment of personnel- Part 3: Requirements for training bodies and the training process	ISO18436-3

Abstract

ISO 18436-3 defines the requirements for bodies operating training programmes for personnel who perform machinery condition monitoring, identify machine faults, and recommend corrective action. Procedures for training of condition monitoring and diagnostic personnel are specified.

Quality management systems - Guidelines for process improvements in health service organizations	IWA 1

Abstract

IWA 1 provides additional guidance for any health service organization involved in the management, delivery, or administration of health service products or services, including training and/or research, in the life continuum process for human beings, regardless of type, size and the product or service provided.

Quality management systems -- Fundamentals and vocabulary	ISO 9000
Quality management and quality system elements - Part 1: Guidelines	IS/ISO 9004-1-4

Guidelines for Quality Management System Documentation	IS/ISO/TR 10013
Guidelines for Managing the Economics of Quality	SP 67
Guidelines for Auditing Quality Systems - Part1 : Auditing (SEE IS/ISO 10011-1)	IS 14011 : Part 1
Product Verification and Validation Safety of machinery - Safety-related parts of control systems- Part 2: Validation	ISO 13849-2

Abstract

ISO 13849-2 specifies the procedures and conditions to be followed for the validation by analysis and testing of:
the safety functions provided and

the category achieved for the safety-related parts of the control system in compliance with EN 954-1 (ISO 13849-1), using the design rationale provided by the designer.

This International Standard does not give complete validation requirements for programmable electronic systems and therefore can require the use of other standards.

Product verification and validation, Aerosol drug delivery device design verification - Requirements and test methods	ISO 20072

Abstract

ISO 20072 applies to the design, labelling, instructions for use and testing requirements for hand-held single- and multi-use aerosol drug delivery devices (ADDDs) intended to deliver a metered or pre-metered aerosolized medication to or by means of the human respiratory tract (including nasal, oral, tracheal, bronchial and alveolar sites). This International Standard applies to both refillable and disposable devices intended for personal use.

ISO 20072 is intended for device design verification and not for drug product quality assessment. The objective of this International Standard is to verify, by laboratory (*in-vitro*) testing, that the ADDD design consistently meets the manufacturer's design specification by satisfying a device functionality profile and system verification test both of which are determined from a risk assessment and evaluated in accordance with the instructions for use.

Conformity assessment - Guidance on the use of an organization's quality management system in product certification.	ISO/IECGuide53

Abstract

ISO/IEC Guide 53 outlines a general approach by which certification bodies can develop and apply product certification schemes utilizing requirements of an organization's quality management system. The provisions given are not requirements for the accreditation of a product certification body and do not substitute the requirements of ISO/IEC Guide 65.

The schemes contained in ISO/IEC Guide 53 are for product certification only and in all cases involve the following principles:

assessment of an organization's quality management system and its capability to consistently supply products conforming to specified requirements; testing, inspection or comparable verification of the product's conformity to scheme criteria and specified requirements;

application of a suitable surveillance scheme to ensure continual conformity to specified requirements of products supplied by the organization;

control of the mark of conformity and/or logo of the certification body.

Biocompatibility Biological evaluation of medical devices- Part 2: Animal welfare requirements	ISO10993-2

Abstract

ISO 10993-2 is aimed at those who commission, design and perform tests or evaluate data from animal tests undertaken to assess the biocompatibility of materials intended for use in medical devices, or of the medical devices themselves. It specifies the minimum requirements to be satisfied to ensure and demonstrate that proper provision has been made for the welfare of animals used in animal tests to assess the biocompatibility of materials used in medical devices.

ISO 10993-2 also makes recommendations and offers guidance intended to facilitate future further reductions in the overall number of animals used, refinement of test methods to reduce or eliminate pain or distress in animals, and the replacement of animal tests by other scientifically valid means not requiring animal tests.

It applies to tests performed on living vertebrate animals, other than man, to establish the biocompatibility of materials or medical devices

Medicinal Substances Implants for surgery- Active implantable medical device- Part 4: Implantable infusion pumps	ISO14708-4

Abstract

ISO 14708-4 is applicable to active implantable medical devices intended to deliver medicinal substances to site-specific locations within the human body.

ISO 14708-4 is also applicable to some non-implantable parts and accessories of the devices.

The tests that are specified in ISO 14708-4 are type tests intended to be carried out on a sample of a device to show compliance, and are not intended to be used for the routine testing of manufactured products.

Method of test for determining deleterious substances in fibrous insulating materials	IS 5596
Biological Safety Biological evaluation of medical devices- Part 18: Chemical characterization of materials	ISO10993-18

Abstract

ISO 10993-18 describes a framework for the identification of a material and the identification and quantification of its chemical constituents. The chemical characterization information generated can be used for a range of important applications, for example, as part of an assessment of the overall biological safety of a medical device (ISO 10993-1 and 14971), as a measurement of the level of a leachable substance in a medical device in order to allow the assessment of compliance with the allowable limit derived for that substance from health based risk assessment (ISO 10993-17), for judging equivalence of a proposed material to a clinically established material, for judging equivalence of a final device to a prototype device to check the relevance of data on the latter to be used to support the assessment of the former, or for screening of potential new materials for suitability in a medical device for a proposed clinical application.

ISO 10993-18 does not address the identification or quantification of degradation products, which is covered in ISO 10993-9, ISO 10993-13, ISO 10993-14 and ISO 10993-15.

The ISO 10993 series of standards is applicable when the material or device comes into contact with the body directly or indirectly (see 4.2.1 of ISO 10993-1).

ISO 10993-18 is intended for suppliers of materials and manufacturers of medical devices, when carrying out a biological safety assessment.

Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process	ISO10993-1

Abstract

ISO 10993-1 describes:
the general principles governing the biological evaluation of medical devices within a risk management process;

the general categorization of devices based on the nature and duration of their contact with the body;

the evaluation of existing relevant data from all sources;
the identification of gaps in the available data set on the basis of a risk analysis;
the identification of additional data sets necessary to analyse the biological safety of the medical device;
the assessment of the biological safety of the medical device.

Sterilization Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	ISO 11135-1

Abstract

ISO 11135-1 specifies requirements for the development, validation and routine control of an ethylene oxide sterilization process for medical devices.

Sterilization processes validated and controlled in accordance with the requirements of ISO 11135-1 are not assumed to be effective in inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeld Jacob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

Abstract

ISO/TS 11135-2 provides guidance for the requirements in ISO 11135-1. It does not repeat the requirements and is not intended to be used in isolation. The exclusions in ISO 11135-1 apply also to this Technical Specification.

This guidance document is intended for people who have a basic knowledge of the principles of EO sterilization but may need help in determining how to best meet the requirements contained in ISO 11135-1. This document is not intended for people lacking a basic knowledge of the principles of EO sterilization.

Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	ISO 11137-1-3

Abstract

ISO 11137-1 specifies requirements for the development, validation and routine control of a radiation sterilization process for medical devices. Although the scope of ISO 11137-1 is limited to medical devices, it specifies requirements and provides guidance that may be applicable to other products and equipment.

ISO 11137-1 covers radiation processes employing irradiators using the radionuclide ^{60}Co or ^{137}Cs, a beam from an electron generator or a beam from an X-ray generator.

ISO 11137-1 does not:

- specify requirements for development, validation and routine control of a process for inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease;
- detail specified requirements for designating a medical device as sterile;
- specify a quality management system for the control of all stages of production of medical devices;
- specify requirements for occupational safety associated with the design and operation of irradiation facilities;
- specify requirements for the sterilization of used or reprocessed devices.

Abstract

ISO 11137-2 specifies methods of determining the minimum dose needed to achieve a specified requirement for sterility and methods to substantiate the use of 25 kGy or 15 kGy as the sterilization dose to achieve a sterility assurance level (SAL) of 10^{-6}. It also specifies methods of dose auditing in order to demonstrate the continued effectiveness of the sterilization dose.

ISO 11137-2 defines product families for dose establishment and dose auditing.

Abstract

ISO 11137-3 gives guidance on the requirements in ISO 11137 parts 1 and 2 relating to dosimetry. Dosimetry procedures related to the development, validation and routine control of a radiation sterilization process are described.

Sterilization of single-use medical devices incorporating materials of animal origin - Validation and routine control of sterilization by liquid chemical sterilants	ISO14160

Abstract

ISO 14160 specifies requirements for the characterization of a liquid chemical sterilizing agent and for the development, validation, process control and monitoring of sterilization by liquid chemical sterilizing agents of single-use medical devices comprising, in whole or in part, materials of animal origin.

ISO 14160 covers the control of risks arising from contamination with bacteria and fungi by application of a liquid chemical sterilization process. Risks associated with other microorganisms need to be assessed.

ISO 14160 is not applicable to material of human origin.
ISO 14160 does not describe methods for the validation of the inactivation of viruses and transmissible spongiform encephalopath (TSE) agents.

ISO 14160 does not describe methods for validation of the inactivation, elimination, or elimination and inactivation of protozoa and parasites.

The requirements for validation and routine control described in ISO 14160 are only applicable to the defined sterilization process of a medical device, which is performed after the manufacturing process, and do not take account of the lethal effects of other bioburden reduction steps.

ISO 14160 does not specify tests to establish the effects of any chosen sterilization method upon the fitness for use of the medical device.
ISO 14160 does not cover the level of residual sterilizing agent within medical devices.
ISO 14160 does not describe a quality management system for the control of all stages of manufacture.

Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	ISO 14937

Abstract

ISO 14937 specifies general requirements for the characterization of a sterilizing agent and for the development, validation and routine monitoring and control of a sterilization process for medical devices.

It applies to sterilization processes in which microorganisms are inactivated by physical and/or chemical means and is intended to be applied by process developers, manufacturers of sterilization equipment, manufacturers of medical devices to be sterilized, and organizations responsible for sterilizing medical devices.

ISO 14937 specifies the elements of a Quality Management System which are necessary to assure the appropriate characterization of the sterilizing agent, development, validation and routine monitoring and control of a sterilization process.

Software Verification and Validation Ergonomics- Computer manikins and body templates- Part 2: Verification of functions and validation of dimensions for computer manikin systems	ISO15536-2

Abstract

ISO 15536-2 establishes the requirements for the verification of the functions and validation of dimensions of computer manikins. These requirements concern the documentation of the data employed to construct computer manikins and the methods employed to verify and validate their functions with regards to their dimensional accuracy.

ISO 15536-2 extends to anthropometric and biomechanical data and to software functions as they are applied to create computer manikins. Although this document primarily refers to anthropometric data and methods, some biomechanical parameters are required to build and apply computer manikins and are therefore included.

ISO 15536-2 provides a framework for reporting computer manikin accuracy and human-source data. The standard is intended to enable even non-specialist users of the manikin systems to independently perform measurements of each function under field testing conditions using automated software tools provided by developers.

It is not intended to require developers to perform specific verification and validation of their manikin systems.

Information technology - Software measurement- Functional size measurement - Part 3: Verification of functional size measurement methods	ISO/IECTR14143-3

Abstract

ISO/IEC TR 14143-3 establishes a framework for verifying the statements of an FSM Method and/or for conducting tests requested by the verification sponsor, relative to the following performance properties:

- repeatability and reproducibility;
- accuracy;
- convertibility;
- discrimination threshold;
- applicability to Functional Domains.

NOTE Statements and test requests relative to other performance properties are outside the scope of ISO/IEC TR 14143-3.

ISO/IEC TR 14143-3 aims to ensure that the output from the verification is objective, impartial, consistent and repeatable.

The verification report, produced as a result of applying ISO/IEC TR 14143-3, will enable the prospective user to select the FSM Method which best meets their needs.

Animal Studies Implants for surgery- Active implantable medical devices- Part 5: Circulatory support devices	ISO14708-5

Abstract

ISO 14708-5 specifies requirements for safety and performance of active implantable circulatory support devices. It is not applicable to extracorporeal perfusion devices, cardiomyoplasty, heart restraint devices and counter-pulsation devices, such as extra- or intra-aortic balloon pumps.

ISO 14708-5 specifies type tests, animal studies and clinical evaluation requirements.

Clinical Evaluation Clinical laboratory testing and in vitro diagnostic test systems - Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices - Part 2: Evaluation of performance of antimicrobial susceptibility test devices	ISO20776-2

Abstract

ISO 20776-2 establishes acceptable performance criteria for antimicrobial susceptibility test (AST) devices that are used to determine minimum inhibitory concentrations (MIC) and/or interpretive category determinations of susceptible, intermediate and resistant (SIR) strains of bacteria to antimicrobial agents in medical laboratories. ISO 20776-2 specifies requirements for AST devices (including diffusion test systems) and procedures for assessing performance of such devices. It defines how a performance evaluation of an AST device is to be conducted. ISO 20776- 2 has been developed to guide manufacturers in the conduct of performance evaluation studies.

7. HAZARD FROM DEVICE MANUFACTURING

Design And Manufacturing Requirements of safety and performance.	IEC62366 ISO 12100

IEC62366

Medical devices - Application of usability engineering to medical device

Abstract

Specifies a process for a manufacturer to analyze, specify, design, verify and validate usability, as it relates to safety of a medical device. This usability engineering process assesses and mitigates risks caused by usability problems associated with correct use and use errors, i.e. normal use. It can be used to identify but does not assess or mitigate risks associated with abnormal use.

If the usability engineering process detailed in this International Standard has been complied with and the acceptance criteria documented in the usability validation plan have been met, then the residual risks, as defined in ISO 14971, associated with usability of a medical device are presumed to be acceptable, unless there is objective evidence to the contrary.

This International Standard does not apply to clinical decision-making relating to the use of

a medical device.

ISO 12100
Safety of machinery - General principles for design - Risk assessment and risk reduction

Abstract

ISO 12100 specifies basic terminology, principles and a methodology for achieving safety in the design of machinery. It specifies principles of risk assessment and risk reduction to help designers in achieving this objective. These principles are based on knowledge and experience of the design, use, incidents, accidents and risks associated with machinery. Procedures are described for identifying hazards and estimating and evaluating risks during relevant phases of the machine life cycle, and for the elimination of hazards or sufficient risk reduction. Guidance is given on the documentation and verification of the risk assessment and risk reduction process.

ISO 12100 is also intended to be used as a basis for the preparation of type-B or type-C safety standards.

It does not deal with risk and/or damage to domestic animals, property or the environment.

Chemical, physical and biological properties of materials	GHTF/SG1/N41R9 Australian Regulatory Guidelines for Medical Devices – Version 1.0 April 2010 Page 29 of 330. Part 1 Introduction Section 3.

GHTF/SG1/N41R9: Essential Principles of Safety and Performance of Medical Devices

Abstract

Consistent identification, selection and application of safety and performance principles to a medical device offers significant benefits to the manufacturer, user, patient or consumer, and to Regulatory Authorities since it allows its manufacturer to design, manufacture and demonstrate the device is suitable for its intended use. To describe six general requirements of safety and performance that applies to all medical devices.

Australian Regulatory Guidelines for Medical Devices
Principle: 7 Meeting the Essential Principles - Principles about design and construction.

Abstract

In choosing materials for medical devices particular attention must be given to (a) the chemical and physical properties of the materials used in the device; and (b) the compatibility between the materials used and biological tissues, cells and body fluids; having regard to the intended purpose of the device.

Essential principles of safety and performance of medical devices Medical devices - Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices	ISO/TR16142

Abstract

ISO/TR 16142 considers and identifies certain significant standards and guides that can be useful in the assessment of conformity of medical devices with recognized essential principles of safety and performance.

ISO/TR 16142 is intended for use by manufacturers, standardization bodies, regulatory bodies, and for conformity assessment purposes.

Quality system requirements Medical devices - Quality management systems Requirements for regulatory purposes**.**	ISO13485

Abstract

ISO 13485 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

The primary objective of ISO 13485 is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management systems conform to all the requirements of ISO 9001.

All requirements of ISO 13485 are specific to organizations providing medical devices, regardless of the type or size of the organization.

If regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulations can provide alternative arrangements that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with ISO 13485 reflect exclusion of design and development controls.

If any requirement(s) in Clause 7 of ISO 13485 is (are) not applicable due to the nature of the medical device(s) for which the quality management system is applied, the organization does not need to include such a requirement(s) in its quality management system.

The processes required by ISO 13485, which are applicable to the medical device(s), but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system.

Medical devices - Quality management systems - Guidance on the application of ISO 13485	ISO/TR14969

Abstract

ISO/TR 14969 provides guidance for the application of the requirements for quality management systems contained in ISO 13485. It does not add to, or otherwise change, the requirements of ISO 13485. It does not include requirements to be used as the basis of regulatory inspection or certification assessment activities.

This guidance can be used to better understand the requirements of ISO 13485 and to illustrate some of the variety of methods and approaches available for meeting the requirements of ISO 13485.

Medical devices - Application of risk management to medical devices	ISO 14971

Abstract

ISO 14971 specifies a process for a manufacturer to identify the hazards associated with medical devices, including *in vitro* diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

The requirements of ISO 14971 are applicable to all stages of the life-cycle of a medical device.

Medical devices - Quality management - Medical device nomenclature data structure	ISO 15225

Abstract

ISO 15225 provides rules and guidelines for a medical device nomenclature data structure, in order to facilitate cooperation and exchange of data used by regulatory bodies on an international level between interested parties, e.g. regulatory authorities, manufacturers, suppliers, health care providers and end users.

ISO 15225 includes guidelines for a minimum data set and its structure. These guidelines are provided for system designers setting up databases that utilize the nomenclature system described herein.

The requirements contained in ISO 15225 are applicable to the development and maintenance of an international nomenclature for medical device identification.
ISO 15225 does not include the nomenclature itself, which is provided as a data file.

Design control Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design	ISO13849-1

Abstract

ISO 13849-1 provides safety requirements and guidance on the principles for the design and integration of safety-related parts of control systems (SRP/CS), including the design of software. For these parts of SRP/CS, it specifies characteristics that include the performance level required for carrying out safety functions. It applies to SRP/CS, regardless of the type of technology and energy used (electrical, hydraulic, pneumatic, mechanical, etc.), for all kinds of machinery. It does not specify the safety functions or performance levels that are to be used in a particular case.

ISO 13849-1 provides specific requirements for SRP/CS using programmable electronic system(s).

It does not give specific requirements for the design of products which are parts of SRP/CS. Nevertheless, the principles given, such as categories or performance levels, can be used.

In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials	ISO:18153

Abstract

ISO 18153 specifies how to assure the metrological traceability of values assigned to calibrators and control materials intended to establish or verify trueness of measurement of the catalytic concentration of enzymes.

The calibrators and control materials are those provided by the manufacturers as part of, or to be used together with, *in vitro* diagnostic medical devices.

The following subjects are outside the scope of ISO 18153: requirements for the design or selection of a reference measurement procedure; quantities involving mass of enzyme or immunoreactivity of enzymes; control materials that do not have an assigned value and are used only for assessing the precision of a measurement procedure, either its repeatability or reproducibility (precision control materials); control materials intended for intralaboratory quality control purposes and supplied with intervals of suggested acceptable values, each interval obtained by interlaboratory consensus with respect to one specified measurement procedure, and with limiting values that are not metrologically traceable; metrological traceability of routine results to the product calibrator and their relations to any medical discrimination limit; properties involving nominal and ordinal scales.

Document and data control Medical devices - Application of usability engineering to medical devices	IEC 62366

Abstract

Specifies a process for a manufacturer to analyse, specify, design, verify and validate usability, as it relates to safety of a medical device. This usability engineering process assesses and mitigates risks caused by usability problems associated with correct use and use errors, i.e. normal use. It can be used to identify but does not assess or mitigate risks associated with abnormal use

If the usability engineering process detailed in this International Standard has been complied with and the acceptance criteria documented in the usability validation plan have been met, then the residual risks, as defined in ISO 14971, associated with usability of a medical device are presumed to be acceptable, unless there is objective evidence to the contrary.

This International Standard does not apply to clinical decision-making relating to the use of a medical device.

Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities	IEC80001-1

Abstract

IEC 80001-1 Recognizing that medical devices are incorporated into IT-networks to achieve desirable benefits (for example, interoperability), defines the roles, responsibilities and activities that are necessary for risk management of IT-networks incorporating medical devices to address safety, effectiveness and data and system security (the key properties). IEC 80001-1 does not specify acceptable risk levels. IEC 80001-1 applies after a medical device has been acquired by a responsible organization and is a candidate for incorporation into an IT-network. It applies throughout the life cycle of IT-networks incorporating medical devices. IEC 80001-1 applies where there is no single medical device manufacturer assuming responsibility for addressing the key properties of the IT-network incorporating a medical device. IEC 80001-1 applies to responsible organizations, medical device manufacturers and providers of other information technology for the purpose of risk management of an IT-network incorporating medical devices as specified by the responsible organization. It does not apply to personal use applications where the patient, operator and responsible organization are one and the same person.

Health informatics - Point-of-care medical device communication - Part 90101: Analytical instruments - Point-of-care test	ISO11073-90101

Abstract

ISO 11073-90101 establishes a set of specifications to allow seamless multivendor interoperability and communication between point-of-care devices, data concentrators, and clinical information systems. CLSI document POCT1 provides the framework for engineers to design devices, workstations and interfaces that allow multiple types and brands of point-of-care devices to communicate bidirectionally with access points, data concentrators and laboratory information systems from a variety of vendors.

As an interface standard, ISO 11073-90101 specifies the common communication

interfaces and protocols between systems and devices. It facilitates the transfer of data to support the creation of point-of-care applications, services and institutional policies. This International Standard does not directly address specific point-of-care application and service level functions, such as device lockout and operator list management. It specifies protocol, not policy. The interfaces specified support the communication required for engineers to build such application-level functionality. Specifying, building and providing the applications to support these services are left to customers, device and information system vendors.

Medical device software - Software life cycle processes	IEC62304

Abstract

Defines the life cycle requirements for medical device software. The set of processes, activities, and tasks described in this standard establishes a common framework for medical device software life cycle processes.

Document management - Information stored electronically - Recommendations for trustworthiness and reliability	ISO/TR 15801

Abstract

ISO/TR 15801 describes the implementation and operation of document management systems that can be considered to store electronic information in a trustworthy and reliable manner.

ISO/TR 15801 is for use by any organization that uses a document management system to store authentic, reliable and usable/readable electronic information over time. Such systems incorporate policies, procedures, technology and audit requirements that ensure that the integrity of the electronic information is maintained during storage.

ISO/TR 15801 does not cover processes used to evaluate whether information can be considered to be authentic prior to it being stored or imported into the system. However, it can be used to demonstrate that, once the information is stored, output from the system will be a true and accurate reproduction of the original.

Document management applications - Archiving of electronic data - Computer output microform (COM) / Computer output laser disc (COLD)	ISO 11506

Abstract

ISO 11506 specifies techniques for archiving electronic data to ensure their long-term integrity, accessibility, usability, readability and reliability, in order to protect the evidential value of the data.

Long term is considered to be a period of time lasting more than a century (see ISO 5466).

Black-and-white microforms processed with liquid chemicals are used in ISO 11506 because the result is always an irreversible record and because of the proven quality of microforms as a long-term preservation media.

ISO 11506 also specifies procedures for the parallel recording, by a single production unit, of COM and COLD output from the same data.

It applies to many different types of electronic data, such as text and two-dimensional graphic data which can be represented as a black-and-white image.

Health informatics - Security requirements for archiving of electronic health records - Principles	ISO/TS 21547

Abstract

The purpose of ISO/TS 21547 is to define the basic principles needed to securely preserve health records in any format for the long term. It concentrates on previously documented healthcare specific archiving problems. It also gives a brief introduction to the general archiving principles. Unlike the traditional approach to standardization work, where the perspective is that of modeling, code sets and messages, this Technical Specification looks at archiving from the angle of document management and related privacy protection.

In ISO/TS 21547 archiving is understood to be a wider process than just the permanent preservation of selected records.

ISO/TS 21547 defines architecture and technology-independent security requirements for long-term preservation of EHRs having fixed content.

ISO/TS 21547 and a complementary Technical Report, ISO 21548, concentrate on the security requirements (integrity, confidentiality, availability and accountability) necessary for ensuring adequate protection of health information in long-term digital preservation. This Technical Specification will also address privacy protection requirements for both the EHR and e Archiving systems used in the healthcare environment.

ISO/TS 21547 defines functional security requirements for long term archiving of EHRs, but the practical archiving models and technology required are outside the concept of this Technical Specification.

Health informatics - Directory services for security, communications and identification of professionals and patients	ISO/TS 21091

Abstract

ISO/TS 21091 defines minimal specifications for directory services for health care using the X.500 framework. This Technical Specification provides the common directory information and services needed to support the secure exchange of health care information over public networks. ISO/TS 21091 addresses the health directory from a community perspective in anticipation of supporting inter-enterprise, inter-jurisdiction and international health care communications.

ISO/TS 21091 also supports directory services aiming to support identification of health

professionals and organizations and the patients/consumers. The latter services include aspects sometimes referred to as master patient indices.

The health care directory will only support standard LDAP Client searches. Specific implementation guidance, search criteria and support are out of scope of this document.

8. HAZARD FROM DEVICE MARKETING

Packaging Packaging code: Part 2 Packaging materials Section 3 Plastics materials	IS 10106 Part 2 Sec 3
Primary packaging materials for medicinal products - Particular requirements for the application of ISO 9001, with reference to Good Manufacturing Practice (GMP)	ISO 15378

Abstract

ISO 15378 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide primary packaging materials for medicinal products, which consistently meet customer requirements, including regulatory requirements and International Standards applicable to primary packaging materials.

ISO 15378 is an application standard for the design, manufacture and supply of primary packaging materials for medicinal products. It is also applicable for certification purposes.

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	ISO 11607-1

Abstract

ISO 11607-1 specifies the requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use.

ISO 11607-1 is applicable to industry, to health care facilities, and wherever medical devices are placed in sterile barrier systems and sterilized.

ISO 11607-1 does not cover all requirements for sterile barrier systems and packaging systems for medical devices that are manufactured aseptically. Additional requirements might also be necessary for drug/device combinations.

ISO 11607-1 does not describe a quality assurance system for control of all stages of manufacture.

Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.	ISO 11607-2

Abstract

ISO 11607-2 specifies the requirements for development and validation of processes for packaging medical devices that are terminally sterilized. These processes include forming, sealing, and assembly of preformed sterile barrier systems, sterile barrier systems and packaging systems.

ISO 11607-2 is applicable to industry, to health care facilities, and wherever medical devices are packaged and sterilized.

ISO 11607-2 does not cover all requirements for packaging medical devices that are manufactured aseptically. Additional requirements may also be necessary for drug/device combinations.

Packaging - Vocabulary	ISO 21067

Abstract

ISO 21067 specifies preferred terms and definitions related to packaging and materials handling, for use in international commerce.

Packaging - Pictorial marking for handling of goods	ISO 780
Packaging - Transport packaging for dangerous goods	ISO16103

Abstract

ISO 16103:2005 specifies the requirements and test methods for the production of recycled plastics materials to be used for packaging for the transport of dangerous goods. This includes guidance on the quality assurance programme.

Packaging - Transport packaging for dangerous goods - Test methods	ISO 16104

Abstract

ISO 16104 specifies the design type test requirements for packagings intended for use in the transport of dangerous goods.

Packaging - Transport packaging for dangerous goods - Plastics compatibility testing	ISO 16101

Abstract

ISO 16101 specifies the requirements and test methods for compatibility testing of polyethylene based plastics packagings and composite packagings with plastic inners containing liquids. The testing involves storage with the packaged substance, or with a standard liquid as defined in Annex A. Annex B describes small scale laboratory tests which may be used to determine the assimilation of those products to be carried with the standard liquids.

Labeling	ISO 15223-2

Abstract

ISO 15223-2 specifies a process for developing, selecting and validating symbols for inclusion in ISO 15223-1.

The purpose of ISO 15223-2 is to ensure that symbols included in ISO 15223-1 are readily understood by the target group.

If the symbol validation process detailed in ISO 15223-2 has been complied with, then the residual risks, as defined in ISO 14971 and IEC 62366, associated with the usability of a medical device symbol are presumed to be acceptable, unless there is objective evidence to the contrary.

ISO 15223-2 is not restricted to symbols intended to meet regulatory requirements or specified in regulatory guidelines on labeling.

Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	ISO 15223-1

Abstract

ISO 15223-1 identifies requirements for the development and use of symbols that may be used to convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of ISO 15223-1.

ISO 15223-1 is limited to symbols applicable to a broad spectrum of devices that may be marketed globally. These symbols may be used on the device itself or its package or in the associated documentation.

9.References

1. Bureau of Indian Standard (BIS)
2. International Organization for Standardisation (ISO)
3. International Electrotechnical Commission (IEC)
4. Institution of Electrical and Electronics Engineers (IEEE)
5. American National Standards Institute (ANSI)
6. American Association for Medical Instrumentation (AAMI)
7. American Society for Testing Methods (ASTM)

NGLP/MD/VER/001(2012)

Vertical Standards

Identification and Selection of Standards for Testing and Evaluation of Medical Devices.

Prepared by
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In Association with
National GLP Compliance Monitoring Authority, Dept. of Science and Technology
New Delhi

INTRODUCTION

This guidance document describes the role of technical standards both during the design of a medical device and subsequently to demonstrate a device conforms to essential safety and performance criteria.

The document 'Identification and Selection of Vertical Standards for Testing and Evaluation of Medical Devices', NGLP/MD/VER/001(2012), is prepared by Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum, Kerala in association with National GLP Compliance Monitoring Authority, Department of Science and Technology, Govt. of India. The Task Force for the development of vertical standards for Medical devices consists of representatives from various disciplines from design to commercialization of medical devices. The guideline provides non-binding guidance to test facilities or manufacturers for use in the regulation of medical devices.

The early models of medical device regulation have been that of drugs, which led to serious difficulties as evidenced by the history of device regulation in USA. A wide spread sale of low quality devices in the country exposes public to unwanted hazards emphasis the need for appropriate guidelines for the evaluation of medical devices and regulatory system for approval and licencing. Hence SCTIMST, in association with National GLP Compliance Monitoring Authority, Dept. of Science and Technology, New Delhi initiated to develop vertical standards based on national and international regulatory guidelines for testing and evaluation of medical devices that complement the global ones.

The purpose of this document is to

- encourage use of relevant / national / international consensus standards for medical devices during the design, development and evaluation of medical devices.
- encourage manufacturers to comply with appropriate national / international standards;
- support the concept that in general, the use of standards is voluntary and stake holders have the option to select alternative solutions to demonstrate their medical device meets the relevant safety and efficacy requirements.

To achieve uniformity in the selection horizontal and vertical standards for the evaluation of medical devices, the following guidelines are recommended

- Preference should be given to national standards developed in India.
- If proper Indian standards does not exist, then standard made by International Organization for Standardisation (ISO), Standard developed by professional bodies like International Electrotechnical Commission (IEC), Institution of Electrical and Electronics Engineers (IEEE) OR other National Standards Organization like American National Standards Institute (ANSI), American

Association for Medical Instrumentation (AAMI), American Society for Testing Methods (ASTM) could be selected in the order of preference.

- Standards selected should represent the generally acknowledged state of technology and practice. The preference for the use of recognised standards should not discourage the use of new technologies. Not all devices, or elements of safety and/or performance, may be addressed by recognised standards, especially for new types of devices and emerging technologies

The National GLP Compliance Monitoring Authority will have procedures for "recognition" of other international voluntary standards and notify them. The process of recognition includes mechanism of regular review and realignment of locally recognized standards to the international standards. Recognition may occur by publication of lists identifying existing standards

Recognised standards may be revised or superseded from time to time for various reasons, for example:

- changes in state of technology and accepted practice necessitate revising the technical specifications in the standard;
- a requirement in a specific standard is determined to be inadequate to ensure safety of the device, e.g. there is a safety implication
- Where the recognised standard has been revised to address safety concerns, the stake holders are expected to implement a risk mitigation strategy and take appropriate action to address these concerns.
- During the transition period both the existing and the revised version of the recognised standard may be adopted.
- Devices designed and manufactured, using either version of the recognised standard, and first introduced to the market prior to the end of the transition period, remain in compliance.
- Devices first introduced to the market after the end of the transition period should comply with the revised version of the recognised standard.

Sl. No.	Medical Devices	BIS	ISO	Professional Body Standards	Other National / International Standards
ANESTHESIOLOGY DEVICES					
1.	Airway pressure monitor				US FDA 868.2600
2.	Alarm systems in medical electrical equipments			IEC 60601-1-8	
3.	Anaesthetic machines	IS/ISO 15001	ISO 5358		BS EN 740
4.	Anaesthetic vaporizers		ISO 5360		US FDA 868.5880
5.	Anesthesia conduction devices				US FDA 868.5120 US FDA 868.5130 US FDA 868.5140 US FDA 868.5150
6.	Anesthesia Workstations		ISO 80601-2-13 ISO 80601-2-12	ASTM F1850 ASTM F1101 ASTM F 1208 IEC 60601-2-12	US FDA 868.5895 US FDA 868.5905 US FDA 868.5915 US FDA 868.5935
7.	Apnea monitor				US FDA 868.2377

8.	Auto transfusion apparatus.			AAMI AT6	US FDA 868.5830
9.	Blood gas analyser				US FDA 868.1150 US FDA 868.1170 US FDA 868.1200
10.	Blood pressure monitor	IS 13450-2-30	ISO 81060:Part 1-2	IEC 60601-2-34	EN 1060-3
11.	Breathing circuit components		ISO 23328: Parts 1-2 ISO 5367		US FDA 868.5260 US FDA 868.5250 US FDA 868.2375 US FDA 868.5270 EN 12342
12.	Clinical thermometers	IS 3055: Part 1-2	ISO 80601-2-56		EN 12470: Parts 1-5
13.	Device to relieve acute upper airway obstruction.				US FDA 868.5115
14.	Electrically powered oxygen tent				US FDA 868.5710
15.	Emergency airway needle				US FDA 868.5090
16.	Esophageal obturator		ISO 14972	MIL-A-37934(1)	US FDA 868.5650

17.	Flow-metering devices		ISO 15002		
18.	Gas mixers for medical use		ISO 11195		US FDA 868.5330
19.	Heating devices using blankets, pads or mattresses			IEC 80601-2-35	
20.	High-pressure flexible connections		ISO 21969		
21.	Humidifiers	IS 5564	ISO 8185 ISO 9360	ASTM F 1690	US FDA 868.5450
22.	Hyperbaric chamber.				US FDA 868.5470
23.	Infant monitors		ISO 18778		
24.	Inhalational anaesthesia systems		ISO 8835 ISO 18835	ASTM F1101	
25.	Inspiratory airway pressure meter				US FDA 868.1780
26.	Laryngoscopes	IS 4113:Part 1-2	ISO 7376		
27.	Laryngotracheal topical anesthesia applicator				US FDA 868.5170
28.	Lung ventilators for medical use	IS 11661	ISO 10651-Parts 2-6		US FDA 868.5925
29.	Lung water monitor				US FDA 868.2450
30.	Medical devices for conserving oxygen and oxygen mixtures		ISO 18779		
31.	Medical Gas Pipeline Systems	IS/ISO 7396: Parts 1-2	ISO 7396:Parts 1-2		US FDA 868.5430 CSA Z7396.1-09

32.	Medical suction equipments	IS 12417	ISO 10079: Parts 1-3		CSA-Z10079-2-03
33.	Medical supply units		ISO 11197		
34.	Membrane lung for long-term pulmonary support.				US FDA 868.5610
35.	Nebulizing systems and components		ISO 27427		US FDA 868.5630
36.	Nerve stimulators	IS 11331 IS 14679		IEC 60601-2-10	US FDA 868.2775 CSA-C22.2-601-2.10
37.	Nonrebreathing valve.				US FDA 868.5870
38.	Oropharyngeal airways	IS 11807	ISO 5364	ASTM F 2560	
39.	Oxygen concentrators		ISO 8359, ISO 10083		
40.	Peak expiratory flow meters		ISO 23747		
41.	Physiologic closed-loop controllers			IEC 60601-1-10	
42.	Plethysmograph	IS 11753			US FDA 868.1750
43.	Pneumotachometer				US FDA 868.2550
44.	Portable air compressor				US FDA 868.6250
45.	Portable liquid oxygen unit				US FDA 868.5655
46.	Powered precursor				US FDA 868.5665

47.	Pressure regulators for use with medical gases		ISO 10524: Parts 1-4		
48.	Pulse oximeter		ISO 9919 ISO 80601-2-6		CSA-Z9919-07
49.	Rail systems for supporting medical equipment		ISO 19054		
50.	Respiratory gas monitors		ISO 21647		
51.	Rhinoanemometer.				US FDA 868.1800
52.	Sphygmomanometers	IS 3390 IS 7652	ISO 81060-2	IEC 80601-2-30 AAMI SP10	EN 1060: Parts 1-4
53.	Spirometers	IS 9462	ISO 26782		US FDA 868.1840 US FDA 868.1850 US FDA 868.1860
54.	Stethoscopes	IS 3391			US FDA 868.1920
55.	Suction catheters for use in the respiratory tract		ISO 8836		
56.	Supralaryngeal airways and connectors		ISO 11712		
57.	Tracheal tubes and connectors		ISO 5361 ISO 14408	ASTM F 2726	US FDA 868.5730 EN 1782 US FDA 868.5750

58.	Tracheobronchial tubes		ISO 16628		US FDA 868.5740
59.	Tracheostomy tubes	IS 10308	ISO 5366: Parts 1&3	ASTM F 1590	US FDA 868.5800 EN 1282-2
60.	Transportable liquid oxygen systems		ISO 18777		
61.	Ultrasonic air embolism monitor				US FDA 868.2025

CARDIOLOGY DEVICES					
Sl. No.	**Medical Devices**	**BIS**	**ISO**	**Professional Body Standards**	**Other National / International Standards**
62.	Annuloplasty ring				US FDA 870.3800
63.	Arterial blood filters	IS 4445	ISO 15675		
64.	Blood pressure monitor	IS 13450	ISO 11073-10407 ISO 81060-2	IEC 80601-2-30	
65.	Blood Pumps			ASTM F1830 , ASTM F1841	
66.	Cardiac defibrillators	IS 13450-2	ISO 11318	IEC 60601-2	CSA-CEI/IEC 1288
67.	Cardiac pacemakers		ISO 5841: 2-3 ISO 14708		ANSI/AAMI PC69 BS EN 60601-2-31
68.	Cardiac Valve Prostheses	IS 13924	ISO 5840		US FDA 870.3925
69.	Catheters		ISO 10555		US FDA 870.1280 US FDA 870.1290
70.	Endovascular devices – Stents & stented grafts		ISO 25539	ASTM F2081, ASTM F2079, ASTM F2394	

				ASTM F2477	
71.	External cardiac compressor				US FDA 870.5200
72.	External counter-pulsating device				US FDA 870.5225
73.	Forceps, Dissecting	IS 6777 , IS 6778 IS 6779, IS 6780 IS 7345	ISO 9173		
74.	Hemoconcentrator	IS 13878			
75.	Haemodialyzer	IS 13878	ISO 11336, ISO 26722		
76.	Implantable defibrillators		ISO 14708-6		
77.	Infusion pump		ISO 14708-4		US FDA 870.1800 JIS T 1563 NZS 3770
78.	Needle Holders	IS 6466	ISO 8239	ASTM F 1325	BS EN 13254
79.	Oxygenators		ISO 7199 ISO 15674		EN 12022
80.	Plasma filters		ISO 13960		
81.	Retractors	IS 7434			
82.	Rib Spreader, rib shear	IS 6436 , IS 6442			
83.	Stethoscope.				US FDA 870.1875
84.	Thermodilution probe				US FDA 870.1915

85.	Transfusion equipments		ISO 1135		
86.	Tubing packs for CPB and ECMO		ISO 15676		
87.	Valve Retractors	IS 11566			
88.	Vascular Clamps	IS 10540 , IS 8317 IS 10541 , IS 13940 IS 6395, IS 9928		ASTM F 1744	
89.	Vascular grafts		ISO 7198		EN 12006

ORTHOPAEDIC DEVICES					
Sl. No.	**Medical Devices**	**BIS**	**ISO**	**Professional Body Standards**	**Other National / International Standards**
90.	Ankle joints	IS 9471	ISO 10328	ASTM F 2665	US FDA 888.3120 US FDA 888.3110 US FDA 888.3100 JIS T 1294
91.	Bone Cements	IS 8641		ASTM F 2118 ASTM F 451	US FDA 888.3027
92.	Bone graft				US FDA 888.3015 US FDA 872.3930
93.	Elbow joints	IS 5603 IS 5607			US FDA 888.31xx US FDA 888.32xx
94.	External limb prostheses	IS 4534, IS 4535 IS 4554, IS 4555 IS 4556, IS 4557 IS 13970	ISO 22523		
95.	Finger joints			ASTM F 1781	
96.	Fixation devices	IS 14227, IS 5170	ISO 8615	ASTM F 366	US FDA

		IS 5171, IS 5392 IS 5393, IS 5395 IS 6785, IS 6787 IS 7102		ASTM F 384	888.3010
97.	Hip Joints	IS 12375 IS 6802 IS 6423	ISO 7206: Parts1-10 ISO 15032, ISO 14242 ISO 14243	ASTM F 1440, ASTM F 1814, ASTM F 2033 ASTM F 2580	US FDA 888.33xx US FDA 888.34xx
98.	Implants for osteosynthesis		ISO 14602		
99.	Intervertebral fixation devices	IS 10667			US FDA 888.3080 US FDA 888.3060
100.	Intramedullary Nailing Systems	IS 5395 : Part 1	ISO 5837/1		
101.	Knee joints	IS 5810	ISO 10328 ISO 7207	ASTM F 1223 ASTM F 1800 ASTM F 2083 ASTM F 2722-24 ASTM F 2777	US FDA 888.3490 US FDA 888.35xx
102.	Metallic bone fixation appliances	IS 8261 IS 14227		ASTM F 382 ASTM F 543	US FDA 888.3030
103.	Orthopaedic drilling instruments	IS 14239	ISO 9714-1		
104.	Orthopedic Implants	IS 5347 : Part 1-18	ISO 5834, ISO 13781 ISO 5832, ISO 13781 ISO 13782, ISO	ASTM F 1357 ASTM F 1781 ASTM F 2068	

			13356 ISO 6474		
105.	Prosthetics and orthotics		ISO 13404, ISO 22675 ISO 8548, ISO 29782		JIS T 01111
106.	Shoulder joint prosthesis			ASTM F 1378	US FDA 888.36xx
107.	Spinal fixation devices		ISO 18192	ASTM F 1582 ASTM F 1798	US FDA 888.3050
108.	Spinal interlaminal fixation orthosis.				US FDA 888.3050
109.	Surgical staples	IS 14228	ISO 8827	ASTM F 564	
110.	Tendon prosthesis			ASTM F 2903	US FDA 888.3025 US FDA 888.3020
111.	Toe joint prosthesis		ISO 22675	ASTM F 2892	US FDA 888.37xx
112.	Wrist joints	IS 5594,		ASTM F 1357	US FDA 888.38xx

	DENTISTRY				
113.	Crown and bridge materials	IS 1994	ISO 10477		US FDA 872.3060 US FDA 872.3770
114.	Dental absorbent points		ISO 7551		
115.	Dental Cement	IS 6035, IS 8864	ISO 1564, ISO 9917		US FDA 872.37xx
116.	Dental hand pieces	Is 12374	ISO 3964, ISO 7785 ISO 11498, ISO 13294 ISO 15606,		
117.	Dental implants	IS 5347	ISO 11175, ISO 14801 ISO 22112	ASTM F1609, ASTM F1876	US FDA 872.36xx US FDA 872.39xx
118.	Dental Impression Material	IS 11628, IS 6038 IS 6036, IS 6037 IS 6038, IS 6556	ISO 1563, ISO 13716 ISO 22088, ISO 21563 ISO 4823, ISO 13716		US FDA 872.3660
119.	Dental instruments	IS 3890, IS 4319, IS 4679, IS 4714 IS 4715, IS 4975, IS 4977, IS 5017 IS 5023, IS 517x, IS 5179, IS	ISO 3823		US FDA 872.1720 US FDA 872.1740 US FDA

		5180 IS 5185, IS 5212, IS 5217, IS 5540 IS, 5941, IS 6020, IS 6402, IS 6847 IS 6828, IS 6829, IS 6856, IS 6857 IS 6858, IS 6859, IS 6866, IS 6867 IS 6870, IS 7334, IS 7676, IS 7780 IS 7789, IS 8045, IS 8046, IS 8047 IS 8207, IS 8287, IS 8527, IS 8528 IS 8529, IS 9940, IS 10836, IS 11045 IS 11317, IS 11394, IS 12507 IS 1260x			872.1730 US FDA 872.1745
120.	Dental light sources		ISO 10650		
121.	Dental Units	IS 5023	ISO 7494-1		
122.	Denture Base Polymers	IS 6887	ISO 11405		
123.	Endodontic stabilizing splint				US FDA 872.3890
124.	Mandrels for rotary instruments		ISO 13295		US FDA 872.4120
125.	Mercury and alloys for dental amalgam		ISO 24234		US FDA 872.3070 US FDA

					872.18xx US FDA 872.4920
126.	Orthodontic materials	IS 3578, IS 3610 IS 4704, IS 4705	ISO 20795		US FDA 872.4475 US FDA 872.3920
127.	Orthodontics wires		ISO 15841		
128.	Periodontal curettes, dental scalers and excavators		ISO 13397		US FDA 872.4465
129.	Periodontal probes		ISO 21672		
130.	Pit and fissure sealants		ISO 6874		
131.	Restorative materials	IS 4704, IS 4705, IS 6035, IS 6043 IS 6889, IS 7225, IS 7853, IS 10012 IS 13710	ISO 4049, ISO 6872 ISO 9693, ISO 22794		US FDA 872.32xx US FDA 872.33xx US FDA 872.34xx US FDA 872.35xx
132.	Root Canal Sealing Materials	IS 12855	ISO 6876		US FDA 872.3820
133.	Rotary instruments	IS 7066, is 10307, IS 10663, IS 664 IS 13701, IS 15311	ISO 1797, ISO 7711 ISO 3630, ISO 6877 ISO 7786, ISO 7787		

	EAR, NOSE AND THROAT				
134.	Audiometers		ISO 389	IEC 60645	US FDA 874.10xx
135.	Bronchoscopes	IS 11318			US FDA 874.4680
136.	Draffin Suspension Apparatus	IS 10272			
137.	Endolymphatic shunt				US FDA 874.3820
138.	Hearing aids		ISO 4869-1	IEC 60118	
139.	Laryngeal prosthesis				US FDA 874.3730
140.	Mandibular implant facial prosthesis			ASTM F 881	US FDA 874.3695
141.	Middle ear implants			ASTM F 2504	US FDA 874.34xx
142.	Nasopharyngoscope				US FDA 874.4760
143.	Oesophagoscope	IS 11319			US FDA. 874.4710
144.	Sacculotomy tack				US FDA 874.3760
145.	Transcutaneous air conduction hearing aid system				US FDA 874.3950
146.	Tympanostomy tube				US FDA 874.3880

	GASTROENTEROLOGY / UROLOGY DEVICES				
147.	Electrogastrography system.				US FDA 876.1735
148.	Endoscopic Instruments	IS 15732		ASTM F1992 IEC 60601-2-18	US FDA 876.4300 US FDA 876.1500
149.	Enternal Feeding Devices	IS 3237, IS 7803	ISO 80369	ASTM F 2528	
150.	Enuresis alarm				US FDA 876.2040
151.	Fiberoptic light ureteral catheter				US FDA 876.4020
152.	Foley Catheter	IS 11497		ASTM F623	US FDA 876.5130
153.	Gastroenterology instruments				US FDA 876.1075 US FDA 876.4730
154.	Gastroenterology-urology evacuator				US FDA 876.4370
155.	Hemodialysis systems	IS 13878, IS 13890		IEC 60601-2-39	US FDA 876.56xx
156.	Ingestible telemetric gastrointestinal capsule imaging system.				US FDA 876.1300
157.	Lithotriptor				US FDA

					876.4480 US FDA 876.4500
158.	Penile inflatable implant				US FDA 876.3350 US FDA 876.3630 US FDA 876.3750
159.	Peritoneo-venous shunt				US FDA 876.5955
160.	Ureteral Stents			ASTM F1828	US FDA 876.4620
161.	Urethral dilator				US FDA876.5520
162.	Urinary continence device				US FDA 876.52xx US FDA 876.53xx
163.	Urodynamics measurement system				US FDA 876.1620 US FDA 876.1725

	GENERAL AND PLASTIC SURGERY				
164.	Breast Prosthesis			ASTMF2051-00	US FDA 878.3540 US FDA 878.3530
165.	Chin prosthesis.				US FDA 878.3550
166.	Cystoscope	IS 5738			
167.	Ear prosthesis.			ASTM F 2504	US FDA 878.3590
168.	Esophageal prosthesis				US FDA 878.3610
169.	Facial Implants			ASTMF881-94	
170.	Laser surgical instruments				US FDA , 878.4810
171.	Nose prosthesis.				US FDA 878.3680
172.	Sigmoidoscope	IS 5750			
173.	Soft-Tissue Expander Devices			ASTMF1441-03	
174.	Standard Specification for Implantable Breast Prostheses			ASTMF703-07	
175.	Surgical mesh.				US FDA 878.3300
176.	Tissue adhesive.				US FDA878.4010
177.	Tracheal prosthesis				US FDA 878.3720

	NEUROLOGICAL DEVICES				
178.	Cerebral Stereo tactic Instruments			ASTM F1266 ASTM F1719	US FDA 882.4560
179.	Clamps for Carotid Occlusion			ASTM F 982	
180.	CNS electrodes				US FDA 882.13xx
181.	Cranioplasty devices			ASTM F 452	US FDA 882.5970
182.	Dura substitute				US FDA 882.5910
183.	Electroconvulsive therapy device				US FDA 882.5940
184.	Electroencephalographs			IEC 60601-2	
185.	Evoked response auditory stimulator				US FDA 882.1900
186.	Evoked response electrical stimulator				US FDA 882.1870
187.	Evoked response mechanical stimulator				US FDA 882.1880
188.	External functional neuromuscular stimulator				US FDA 882.5810
189.	Hydrocephalus Shunts	IS/ISO 7197	SO 7197	ASTM F 647	
190.	Implantable peripheral nerve stimulators	IS 14679	ISO 14708-3	IEC 60601-2	US FDA 882.5860 US FDA 882.5890
191.	Implanted cerebellar stimulator				US FDA

					882.5820
192.	Implanted diaphragmatic/phrenic nerve stimulator				US FDA 882.5830
193.	Implanted intracerebral / subcortical stimulator				US FDA 882.5840
194.	Implanted spinal cord stimulator				US FDA 882.5850 US FDA 882.5880
195.	Intervertebral Body Fusion Device			ASTMF2267-04	
196.	Intervertebral spinal disc prostheses		ISO 18192	ASTMF2423-11 ASTMF2346	
197.	Intracranial aneurysm clips	IS 14139	ISO 9713	ASTMF700	
198.	Intracranial pressure monitoring device				US FDA 882.1620
199.	Lumbar Total Facet Prostheses			ASTMF2790 ASTMF2694	
200.	Neurological endoscope				US FDA 882.1480
201.	Neurovascular embolization device				US FDA 882.5950
202.	Radiofrequency lesion probe				US FDA 882.4725
203.	Spinal Immobilization Devices		ISO 12189	ASTM F1831	
204.	Test Methods For Intervertebral Body Fusion Devices			ASTMF2077-11	

	OBSTETRICAL AND GYNECOLOGICAL DEVICES				
205.	Abdominal decompression chamber				US FDA 884.5225
206.	Abortion systems				US FDA 884.5050 US FDA 884.5070
207.	Bipolar endoscopic coagulator-cutter				US FDA 884.4150
208.	Breast pumps				US FDA 884.5150 US FDA 884.5160
209.	Cannula, Intra-uterine, Hysterosalpingography	IS 10156			
210.	Cervical dilators				US FDA 884.42xx
211.	Colposcope.				US FDA 884.1630
212.	Contraceptive devices	IS 12418 IS 13009	ISO 4074		US FDA 884.53xx
213.	Culdoscope				US FDA 884.1640
214.	Endocervical aspirator				US FDA 884.1050
215.	Endometrial aspirator				US FDA 884.1060

216.	External uterine contraction monitor				US FDA 884.2720
217.	Fallopian tube prosthesis				US FDA 884.3650
218.	Fetal blood sampler				US FDA 884.1560
219.	Fetal cardiac monitor				US FDA 884.2600
220.	Fetal electroencephalographic monitor				US FDA 884.2620
221.	Fetal phonocardiographic monitor				US FDA 884.2640
222.	Fetal scalp electrode				US FDA 884.2675 US FDA 884.2685
223.	Fetal ultrasonic monitor				US FDA 884.2660
224.	Fetal vacuum extractor				US FDA 884.4340
225.	Gynecologic laparoscope and accessories				US FDA 884.1720
226.	Gynecologic surgical laser.				US FDA 884.4550
227.	Home uterine activity monitor				US FDA 884.2730
228.	Hysteroscope				US FDA 884.1690

					US FDA 884.1700
229.	Infant incubators			IEC 60601-2	
230.	Intra-Uterine Contraceptive Devices	IS 12418			
231.	Intrauterine pressure monitor				US FDA 884.2700
232.	Laparoscopic insufflator.				US FDA 884.1730
233.	Menstrual cup				US FDA 884.5400
234.	MTP Suction Apparatus	IS 7080			
235.	Obstetric data analyzer				US FDA 884.2050
236.	Obstetric fetal destructive instrument				US FDA 884.4500
237.	Obstetric forceps.				US FDA 884.4400
238.	Obstetric table and accessories.				US FDA 884.4900
239.	Obstetric-gynecologic ultrasonic imager				US FDA 884.2225
240.	Perinatal monitoring system				US FDA 884.2740
241.	Perineometer				US FDA 884.1425
242.	Powered vaginal muscle stimulator for therapeutic use				US FDA 884.5940

243.	Therapeutic vaginal douche apparatus				US FDA 884.5900
244.	Transcervical endoscope				US FDA 884.1660 US FDA 884.1630
245.	Unipolar endoscopic coagulator-cutter				US FDA 884.4160
246.	Uterotubal carbon dioxide insufflator				US FDA 884.1300
247.	Vaginal stent				US FDA 884.3900

	OPHTHALMIC DEVICES				
248.	Absorbable implant (scleral buckling method).				US FDA 886.3300
249.	Afterimage flasher				US FDA 886.1300
250.	Aqueous shunt.				US FDA 886.3920
251.	Contact lens.				US FDA 886.1385
252.	Corneal electrode				US FDA 886.1220
253.	Cryophthalmic unit.				US FDA 886.4170
254.	Extraocular orbital implant				US FDA 886.3340
255.	Eye movement monitor				US FDA 886.1510
256.	Eye sphere implant				US FDA 886.3320
257.	Intraocular lens.				US FDA 886.3600
258.	Intraocular pressure measuring device				US FDA 886.4280
259.	Keratoprosthesis				US FDA 886.3400
260.	Llens removal devices and vitrectomy devices for ophthalmic surgery			IEC 80601-2-58	

261.	Ophthalmic beta radiation source.				US FDA 886.5100
262.	Ophthalmic conformer.				US FDA 886.3130
263.	Ophthalmic instruments. Chart projectors		ISO 10938		
264.	Ophthalmic instruments. Direct ophthalmoscopes		ISO 10942		
265.	Ophthalmic instruments. Indirect ophthalmoscopes		ISO 10943		
266.	Ophthalmic instruments. Perimeters		ISO 12866		
267.	Ophthalmic instruments. Retinoscopes		ISO 12865		US FDA 886.1780
268.	Ophthalmic instruments. Slit-lamp microscopes		ISO 10939		
269.	Ophthalmic instruments. Synoptophores		ISO 10944		
270.	Ophthalmic isotope uptake probe				US FDA 886.1670
271.	Ophthalmic photocoagulator.				US FDA 886.4690
272.	Ophthalmic preamplifier.				US FDA 886.1640
273.	Ophthalmic refractometer.				US FDA 886.1760
274.	Ophthalmoscope	IS 8257			US FDA 886.1570
275.	Phacofragmentation system				US FDA

					886.4670
276.	Photostimulator				US FDA 886.1630
277.	Radiofrequency electrosurgical cautery apparatus.				US FDA 886.4100
278.	Rigid gas permeable contact lens				US FDA 886.5916
279.	Rigid gas permeable contact lens care products				US FDA 886.5918
280.	Scleral shell.				US FDA 886.3800
281.	Soft (hydrophilic) contact lens care products.				US FDA 886.5928
282.	Soft (hydrophilic) contact lens.				US FDA 886.5925
283.	Thermal cautery unit.				US FDA 886.4115
284.	Tonometers	IS 12947			US FDA 886.1930
285.	Visual field laser instrument				US FDA 886.1360
286.	Vitreous aspiration and cutting instrument				US FDA 886.4150

	RADIOLOGY DEVICES				
287.	Angiographic x-ray system.	IS 3237			US FDA 892.1600
288.	Automatically-controlled brachytherapy equipment	IS 13450		IEC 60601-2-17	
289.	Bone densitometer				US FDA 892.1170
290.	Bone sonometer.				US FDA 892.1180
291.	Diagnostic ultrasonic transducer				US FDA 892.1570
292.	Dosimeters with ionization chambers as used in radiotherapy			IEC60731	
293.	Gamma beam therapy equipment			IEC 60601 2-11	
294.	High-voltage generators of diagnostic X-ray generators			IEC 60601-27	
295.	Magnetic resonance equipment for medical diagnosis			IEC 60601-2-33	US FDA 892.1000
296.	Manual radionuclide applicator system.				US FDA 892.5650
297.	Medical charged-particle radiation therapy system				US FDA 892.5050
298.	Medical image digitizer				US FDA 892.2030
299.	Medical neutron radiation therapy system.				US FDA 892.5300

300.	Nonfetal ultrasonic monitor				US FDA 892.1540
301.	Positron emission tomographs			IEC 61675-	
302.	Radiation therapy simulation system			IEC 60601-2-29	US FDA 892.5840
303.	Radionuclide calibrators			IEC61303	US FDA 892.1360
304.	Short-wave therapy equipment			IEC 60601-23	
305.	Ultrasonic pulsed doppler imaging system.	IS 11701, IS 13020			US FDA 892.1550
306.	X-ray equipment for computed tomography	IS 13450, IS 13709		IEC 60601-2-44	
307.	X-ray equipment for radiography and radioscopy	IS 7620, IS 13450		IEC 60601-2-54	US FDA 892.1610
308.	X-ray tube assemblies for medical diagnosis	IS 6758, IS 7012 IS 6757, IS 6567, IS 10961		IEC 60601-2-28	

BIOMATERIALS

	Material	Indian Standards	ISO Standard	Professional Body Standards	Other National / International standards
309.	Amorphous Poly(lactide) and Poly(lactide-co-glycolide) Resins			ASTM F 2579	
310.	Beta-Tricalcium Phosphate for Surgical Implantation			ASTM F 1088	
311.	Calcium phosphate coatings			ASTM F 1609	
312.	Ceramic Materials Based on High Purity Alumina	IS 5347-9			
313.	Ceramic Materials Based on Yttria-Stabilized Tetragonal Zirconia (Y-TZP)	IS 5347-18			
314.	Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)		ISO 13356		
315.	Co based cast alloys	IS 12721 - 1			
316.	Cobalt chromium casting alloy	IS 7225			
317.	Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy			ASTM F 75	
318.	Cobalt-chromium-molybdenum Casting alloy	IS 5347-5	ISO 5832-12		
319.	Copper Phosphate - Zinc Phosphate cement	IS 6043			
320.	Dental Mercury	IS 4705	ISO 24234		
321.	Forgeable cobalt-chromium-nickel-molybdenum-iron alloy	IS 5347-8	ISO 5832-7		
322.	Glass Cements	IS 12797		ASTM 1538	
323.	Gold Alloys for Casting Investment	IS 7425			

324.	Gold solders	IS 3571			
325.	High Purity Calcium Sulfate Hemihydrate or Dihydrate			ASTM F 2224	
326.	High-Purity Dense Magnesia Partially Stabilized Zirconia (Mg-PSZ)			ASTM F 2393	
327.	Hydroxylapatite for Surgical Implants		ISO 13779	ASTM F 1185	
328.	irradiation-crosslinked ultra-high molecular weight polyethylene			ASTM F 2565	
329.	Ni based cast alloys	IS 12721 - 2			
330.	Ni-Ti Alloys			ASTM F 2004 ASTM F 2005	
331.	Poly (L-Lactide) Resins and Fabricated Forms	IS 5347-16	ISO 13781	ASTM F 1925 ASTM F 2579 ASTM F 2313	
332.	Polycarbonate Resin for Medical Applications			ASTM F 997	
333.	Polyether ether ketone (PEEK)			ASTM F 2026	
334.	Polyether ketone ether ketone ketone (PEKEKK)			ASTM F 1876	
335.	Polysulfone Resin for Medical Applications			ASTM F 702	
336.	Polytetrafluoroethylene (PTFE) Sheet, Tube, and Rod Shapes Fabricated from Granular Molding Powders			ASTM F 754	
337.	Porcelain	IS 8571			
338.	Silver-tin Amalgam Alloy	IS 4704			
339.	Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E)			ASTM F 2695	
340.	Ultra-high Molecular Weight Polyethylene, moulded Form	IS 5347-11	ISO 5834	ISO 11542	

341.	Ultra-High Molecular Weight Polyethylene, Powder Form	IS 5347-10			
342.	Unalloyed tantalum	IS 5347-17	ISO 13782	ASTM F 560	
343.	Unalloyed titanium	IS 5347-3	ISO 5832-2	ASTM F 67	
344.	Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy			ASTM F 562	
345.	Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy			ASTM F 90	
346.	Wrought cobalt-chromium-molybdenum alloy		ISO 5832-12		
347.	Wrought cobalt-nickel-chromium molyb. tungsten iron alloy	IS 5347-12			
348.	Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy	IS 5347-7	ISO 5832-6		
349.	Wrought high nitrogen stainless steel	IS 5347-13			
350.	Wrought stainless steel	IS 5347-2			
351.	Wrought stainless steel		ISO 5832-1	ASTM F 132 ASTM F 621 ASTM F 138	
352.	Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy		ISO 5832-14		
353.	Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy		ISO 5832-14		
354.	Wrought titanium 5-aluminium 2,5-iron alloy	IS 5347-14	ISO 5832-10		
355.	Wrought titanium 6-aluminium 4- vanadium alloy	IS 5347-4	ISO 5832-3	ASTM F1108 ASTM F136 ASTM F 1713	
356.	Wrought titanium 6-aluminium 7-niobium alloy	IS 5347-15	ISO 5832-11	ASTM F 1295	

357.	Wrought Titanium, 12 Molybdenum;6 Zirconium;2 Iron Alloy			ASTM F 1813	
358.	Wrought Titanium-15 Molybdenum Alloy			ASTM F 2066	
359.	Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy			ASTM F 136	
360.	Wrought, Nitrogen Strengthened 23Manganese-21Chromium-1Molybdenum Low-Nickel Stainless Steel Alloy			ASTM F 2229	
361.	Wrought-cobalt-chromium tungsten-nickel alloy	IS 5347-6	ISO 5832-5		
362.	zinc cements	IS 13710			
363.	Zinc Oxide /Eugenol Filling Materials	IS 10012			
364.	Zinc Phosphate Cement	IS 6035			
365.	Zinc, Tin and Cadmium Base alloy solders			ASTM B 907	