INTERNATIONAL STANDARD

ISO 18113-1

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In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) —

Part 1: Terms, definitions, and general requirements

Dispositifs médicaux de diagnostic in vitro — Informations fournies par le fabricant (étiquetage) —

Partie 1: Termes, définitions et exigences générales

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 18113-1:2009), which has been technically revised.

The main changes are as follows:

— Updated terms and definitions;

— References to the UDI (Unique Device Identifier/Identification) requirement added;

— Updated Bibliography to align with updates of standards and publications;

— Updated to align with European Union and other regulations;

— Added additional detail for clarification.

A list of all parts in the ISO 18113 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Manufacturers of in vitro diagnostic (IVD) medical devices supply users with information to enable the safe use and expected performance of their devices. Traditionally, this information has been provided in the form of labels, package inserts and user manuals, where the type and level of detail would depend on the intended uses and country-specific regulations.

The International Medical Device Regulators Forum (IMDRF) encourages convergence of the evolution of regulatory systems for medical devices at the global level. The goal is to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means. Consistent worldwide labelling requirements offer significant benefits to manufacturers, users, patients and regulatory authorities. Eliminating differences among regulatory jurisdictions can allow patients earlier access to new technologies and treatments by decreasing the time necessary to gain regulatory compliance. This document provides a basis for harmonization of labelling requirements for IVD medical devices. As per ISO 20417, the ISO 18113 series represents a group standard and, therefore, has precedence with regards to the labelling requirements for IVDs.

The Global Harmonization Task Force (GHTF) now replaced by IMDRF (See Reference [52]) has established guiding principles that apply to the labelling of medical devices and IVDs. These principles have been incorporated into the ISO 18113 series. Of particular note, IMDRF states that country-specific requirements for the content, wording and format of labels and instructions for use should be kept to a minimum and eliminated over time as the opportunities arise.

This document contains a comprehensive list of terms and definitions necessary to develop the labelling for IVD medical devices. Internationally agreed-upon definitions of important concepts promote greater consistency in IVD medical device labelling. While the goal is to standardize the terminology used in IVD medical device labelling to the extent possible, it is also recognized that current national and regional usage by medical laboratories, healthcare providers, patients and regulatory authorities should be taken into consideration

An obstacle to the timely and affordable availability of IVD medical devices in some countries is the requirement for information to appear in multiple languages. Wherever practical, IMDRF encourages the use of standardized, internationally recognized symbols as long as safe use of the device is not compromised by diminished understanding on the part of the user. This document provides support for the use of symbols consistent with the IMDRF objectives.

IMDRF also encourages manufacturers to employ the most appropriate methods of delivering information. Until recently, most information had been supplied as printed materials accompanying the IVD medical device. Modern technologies enable instructions for use and technical information to be provided using a more efficient means of delivery. Information can be digitally encoded on magnetic or optical media, displayed on a screen, incorporated in the device, or even transmitted over the internet at the time of use. These advances offer users the possibility of more timely availability of critical information, such as performance changes, and offer manufacturers more effective means of disseminating the information.

The ISO 18113 series specifies requirements for information supplied by the manufacturer of IVD medical devices. It consists of five parts, allowing it to address the specific needs of professional users and self-testing users in the most appropriate manner. Furthermore, since manufacturers provide different types of information for IVD reagents and instruments, their requirements are addressed in separate parts of the ISO 18113 series.

This document is not intended to be used alone. It contains terms, definitions and general principles that apply to all parts of the ISO 18113 series. While the terms and definitions in International Standards are preferred, the terms and definitions used in the information supplied by an IVD manufacturer should follow 4.6.2. Where synonyms are given, either term may be used but the first term is preferred. Some definitions had to be modified for relevance to IVD labelling or to conform to ISO terminology rules. In these cases, the source is given and indicates that the definition has been modified. In some cases, additional notes or modifications to existing notes were needed to clarify the application to IVD medical devices, and notes that did not apply to IVD medical devices were omitted.

In addition, guidelines that describe the performance characteristics of IVD medical devices are given in Annex A. This information is not repeated in the subsequent parts, therefore this document is indispensable to the application of ISO 18113-2, ISO 18113-3, ISO 18113-4 and ISO 18113-5.

ISO 18113-2 specifies the requirements for labels and instructions for use supplied with IVD reagents, calibrators and control materials for professional use. ISO 18113-3 specifies the requirements for labels and instructions for use supplied with IVD instruments for professional use. ISO 18113-4 specifies the requirements for labels and instructions for use supplied with IVD reagents, calibrators and control materials for self-testing. ISO 18113-5 specifies the requirements for labels and instructions for use supplied with IVD instruments for self-testing.

ISO 18113-1 (this document), ISO 18113-2 and ISO 18113-3 are the International Standards necessary for IVD medical devices intended for medical laboratories and other professional uses; ISO 18113-1, ISO 18113-4 and ISO 18113-5 are the International Standards necessary for IVD medical devices intended for self-testing. However, recognizing that manufacturers often provide systems comprising an instrument with dedicated reagents, these International Standards allow the flexibility to provide the necessary information in the most appropriate format for the intended users, for example, a single operator's manual for an integrated IVD medical device system.

In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) —

Part 1: Terms, definitions, and general requirements

1 Scope

This document defines concepts, establishes general principles, and specifies essential requirements for information supplied by the manufacturer of IVD medical devices.

This document does not address language requirements since that is the domain of national laws and regulations.

This document does not apply to:

a) IVD medical devices for performance evaluation (e.g. for investigational use only);

b) shipping documents;

c) material safety data sheets / Safety Data Sheets;

d) marketing information (consistent with applicable legal requirements).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 General terms and definitions for use with in vitro diagnostic medical devices

3.1.1
accessory
article intended explicitly by its *manufacturer* (3.1.42) to be used together with an *IVD medical device* (3.1.33):

— to enable the *IVD medical device* (3.1.33) to achieve its intended purpose; or

— to augment or extend the capabilities of the *IVD medical device* (3.1.33) in the fulfilment of its intended purpose

Note 1 to entry: Adapted from IMDRF/UDI/WG/N7, FINAL:2013, 5.

3.1.2
advisory notice
communication issued by an organization, subsequent to delivery of a *medical device* (3.1.53), to provide supplementary information and/or to advise what action should be taken in:

— the use of a *medical device* (3.1.53);

— the modification of a *medical device* (3.1.53);

— the return of a *medical device* (3.1.53) to the *manufacturer* (3.1.42);

— the destruction of a *medical device* (3.1.53)

Note 1 to entry: Issue of an advisory notice can be required to comply with applicable national or regional regulations.

[SOURCE: ISO 13485:2016, 3.1, modified — "notice" has been replaced with "communication", "or" has been replaced with "and/or", "return of the medical device to the organization that supplied it" has been replaced with "return of the medical device to the manufacturer, "]

3.1.3
aid to diagnosis IVD medical device
device used to provide additional information to assist in the determination or verification of a patient's clinical status

Note 1 to entry: The device is not the sole determinant.

[SOURCE: GHTF/SG5/N8:2012, Appendix Table 1, modified — "tests" has been replaced with "device" in the definition and Note 1 to entry.]

3.1.4
analyte
component represented in the name of a measurable quantity

EXAMPLE In "the type of quantity "mass of protein in 24-hour urine", "protein" is the analyte. In "amount of substance of glucose in plasma", "glucose" is the analyte . In both cases, the long phrase represents the *measurand* (3.1.45)

[SOURCE: ISO 17511:2020, 3.1]

3.1.5
authorized representative
any natural or legal person established within a country or jurisdiction who has received a written mandate from the *manufacturer* (3.1.42) to act on its behalf for specified tasks with regard to the latter's obligations under that country's or jurisdiction's legislation

Note 1 to entry: In the European Union, Directive 98/79/EC[54] and Regulation 2017/746/EU require the *manufacturer* (3.1.42) to designate an "authorized representative", established in the European Community if the *manufacturer* (3.1.42) is not located in the European Community.

[SOURCE: GHTF/SG1/NO55:2009, 5.2, modified — Note 1 to entry has been added.]

3.1.6
automatic identification and data capture
AIDC
technology used to automatically capture data

Note 1 to entry: AIDC technologies include bar codes, data matrix, and *radio frequency identification (RFID)* (3.1.69).

[SOURCE: IMDRF/UDI WG/N7:2013, Clause 5, modified — "smart cards, biometrics" has been replaced with "data matrix".]

3.1.7
batch
lot
specified amount of material that is uniform in its properties and has been produced in one process or series of processes

Note 1 to entry: The material can be either starting material, intermediate material, or finished product.

3.1.8
batch code
batch number
lot number
set of numbers and/or letters that specifically identifies a *medical device* (3.1.53) or an *IVD medical device* (3.1.33) and permits its manufacturing, packaging, *labelling* (3.1.35) and distribution history to be traced

Note 1 to entry: This can be referred to as the lot code, batch number, or batch code.

[SOURCE: IMDRF/GRRP WG/N52 2019,[52] 3.20]

3.1.9
biological reference interval
reference interval
specified interval of the distribution of values taken from a *biological reference population* (3.1.10)

EXAMPLE The 95 % biological reference interval for sodium ion concentration values in serum from a population of healthy male and female adults is 135 mmol/l to 145 mmol/l.

Note 1 to entry: A reference interval is commonly defined as the central 95 % interval. Another size or an asymmetrical location of the reference interval could be more appropriate in particular cases.

Note 2 to entry: A reference interval can depend upon the type of *primary samples* (3.1.65) and the *examination* (3.1.21) procedure used.

Note 3 to entry: In some cases, only one biological reference limit is important, for example an upper limit, "x", so that the corresponding biological reference interval would be less than or equal to "x".

Note 4 to entry: Terms such as "normal range", "normal values", and "clinical range" are ambiguous and therefore discouraged.

[SOURCE: ISO 15189:2012, 3.4]

3.1.10
biological reference population
reference population
group of individuals in a well-defined state of health or disease

Note 1 to entry: When *biological reference intervals* (3.1.9) are provided by a *manufacturer* (3.1.42) in the instructions for use, laboratories using the *IVD medical device* (3.1.33) are responsible for verifying that the biological reference populations represent the populations serviced by the laboratories.

Note 2 to entry: A biological reference population can be a specified homogenous group of apparently healthy individuals or individuals with a specific medical condition. The concept allows for relating the reference interval to age, gender, and ethnicity of the reference population, as appropriate.

3.1.11
calibration
operation that, under specified conditions, in a first step, establishes a relationship between the quantity values with *measurement* (3.1.46), uncertainties provided by *measurement standards* (3.2.36), and corresponding *measurement indications* (3.2.31) with associated *measurement* (3.1.46) uncertainties and, in a second step, uses this information to establish a relationship for obtaining a *measurement result* (3.1.51) from an indication

Note 1 to entry: Calibration permits either the assignment of values of the *measurands* (3.1.44) to the *measurement indications* (3.2.31) provided by the measuring instrument, or the determination of a correction with respect to the values provided by the measuring instrument.

Note 2 to entry: Calibration is sometimes confused with adjustment of a *measuring system* (3.2.40), often mistakenly called self-calibration, or with *calibration verification* (3.1.12).

[SOURCE: ISO/IEC Guide 99:2007,[27] 2.39, modified — Notes 1 and 3 to entry have been deleted and new Note 1 to entry has been added]

3.1.12
calibration verification
verification of calibration
confirmation that stated trueness claims for an *IVD measuring system* (3.2.40) are achieved

Note 1 to entry: Calibration verification requires *reference materials* (3.1.71) with assigned values at concentrations appropriate for the *intended use* (3.1.37).

Note 2 to entry: Calibration verification is sometimes confused with *calibration* (3.1.11), linearity, *verification* (3.1.92), or routine *control procedures* (3.1.16).

3.1.13
calibrator
measurement standard (3.2.36) used in the *calibration* (3.1.11) of an IVD instrument or system

[SOURCE: ISO/IEC Guide 99:2007, 5.12, modified — “calibration” has been replaced with "calibration of an IVD instrument or system” and Note 1 to entryhas been deleted.]

3.1.14
component
part of a finished, packaged, and labelled *IVD medical device* (3.1.33)

EXAMPLE Raw material, substance, piece, part, software, firmware, *labelling* (3.1.35) or assembly.

Note 1 to entry: Typical *kit* (3.1.38) components include antibody solutions, buffer solutions, *calibrators* (3.1.13), and/or control materials.

[SOURCE: Reference [59], c), modified — “device” has been replaced with “IVD medical device (3.1.33)”, and Note 1 to entry has been added.]

3.1.15
control material
substance, material, or article intended by its *manufacturer* (3.1.42) to be used to verify the *performance characteristics* (3.1.57) of an *IVD medical device* (3.1.33)

3.1.16
control procedure
set of operations at the point of use, described specifically, intended to monitor the *performance characteristics* (3.1.57) of an *IVD medical device* (3.1.33) and fulfil requirements for quality

Note 1 to entry: Control procedures can be intended to monitor all or part of the IVD *examination* (3.1.21) process, from the collection of the *sample* (3.1.77) to reporting the result of the *examination* (3.1.21).

Note 2 to entry: Adapted from ISO 15198:2004, 3.5.

3.1.17
determination of physiological state
common test purpose or function for an *in vitro diagnostic medical device* (3.1.33) whereby the test is used to evaluate the physiological state of an individual for the purpose of identifying a human condition or characteristic

Note 1 to entry: Determination of physiological state is one of the common *examination* (3.1.21) purposes for *IVD medical devices* (3.1.33).

Note 2 to entry: Physiological status determination tests are designed to evaluate a patient's current state.

Note 3 to entry: Adapted from GHTF/SG5/N8:2012,[46] Appendix Table 1.

3.1.18
device identifier
unique device identifier-device identifier
UDI-DI
unique numeric or alphanumeric code specific to a model of *medical device* (3.1.53) and that is also used as the “access key” to information stored in a unique device identifier-device identifier (UDI-DI)

EXAMPLE Include GS1 GTIN (Global Trade Item Number), HIBC-LIC (Labeler Identification Code)

[SOURCE: IMDRF/UDI WG/N7:2013, Clause 5 modified — ISBT 128-PPIC is not included in the list of examples.]

3.1.19
diagnostic IVD medical device
device used to determine, verify, or confirm a patient’s clinical condition as a sole determinant

Note 1 to entry: This type of *examination* (3.1.21) also includes sole confirmatory assays (to verify the results of previous testing) and sole exclusion assays (to rule out a particular condition). Specimen receptacles are also considered as in vitro diagnostic medical devices.

[SOURCE: GHTF/SG5/N8:2012[46] modified — Term "examination" replaces the word ”testing". Clarification added that specimen receptacles are in vitro diagnostic medical devices.]

3.1.20
distributor
any natural or legal person in the supply chain who, on his or her own behalf, furthers the availability of a *medical device* (3.1.53) to the end user

Note 1 to entry: More than one distributor can be involved in the supply chain.

Note 2 to entry: Persons in the supply chain involved in activities such as storage and transport on behalf of the *manufacturer* (3.1.42), *importer* (3.1.31), or distributor, are not distributors under this definition.

[SOURCE: GHTF/SG1/N055:2009,[47] 5.3]

3.1.21
examination
set of operations having the object of determining the value or characteristics of a property

Note 1 to entry: In some disciplines (e.g. microbiology) an examination is the total activity of a number of tests, observations or *measurements* (3.1.46).

Note 2 to entry: Laboratory examinations that determine the value of a property are called quantitative examinations; those that determine the characteristics of a property are called qualitative examinations.

Note 3 to entry: In clinical chemistry, laboratory examinations have been called assays or tests.

[SOURCE: ISO 15189:2012, 3.7]

3.1.22
expiry date
expiration date
upper limit of the time interval during which the *performance characteristics* (3.1.57) of a material stored under specified conditions can be assured

Note 1 to entry: Expiry dates are assigned to *IVD reagents* (3.1.34), *calibrators* (3.1.13), *control materials* (3.1.15), and other *components* (3.1.14) by the *manufacturer* (3.1.42), based on experimentally determined *stability* (3.1.85) properties.

Note 2 to entry: Guidelines for determining the *stability* (3.1.85) of *IVD medical devices* (3.1.33) are found in ISO 23640:2011.

3.1.23
graphical symbol
visually perceptible figure with a particular meaning used to transmit information independently of language

[SOURCE: ISO/IEC 80416-1:2008, 3.4]

3.1.24
harm
physical injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO/IEC Guide 63:2019, 3.1, modified — Added 'physical' as first word in definition.]

3.1.25
hazard
potential source of *harm* (3.1.24)

[SOURCE: ISO/IEC Guide 63:2019, 3.2]

3.1.26
hazardous situation
circumstance in which people, property or the environment are exposed to one or more *hazards* (3.1.25)

Note 1 to entry: Incorrect IVD *examination* (3.1.21) results can contribute to a hazardous situation for a patient. See ISO 14971, Annex C.

[SOURCE: ISO/IEC Guide 63:2019, 3.3, modified — Note 1 to entry has been added.]

3.1.27
hazardous waste
waste that is potentially harmful to human beings, property, or the environment

EXAMPLE Used reagent strips contaminated with human blood; reagent solution containing sodium azide; decommissioned instruments containing heavy metals.

Note 1 to entry: Includes waste that is flammable, combustible, ignitable, corrosive, toxic, reactive, injurious or infectious.

[SOURCE: ISO 15190:2020, 3.14, modified — "flammable, combustible, ignitable, corrosive, toxic, reactive, injurious or infectious has been replaced with "harmful to human beings, property", and EXAMPLE and Note 1 to entry have been added.]

3.1.28
healthcare provider
individual authorized to deliver health services to a patient

EXAMPLE Physician, nurse, ambulance attendant, dentist, diabetes educator, laboratory technician, medical assistant, medical specialist, respiratory care practitioner.

3.1.29
human readable interpretation
HRI
legible interpretation of the data characters encoded in the *unique device identifer carrier* (3.1.88)

[SOURCE: IMDRF/UDI/ WG/N7 Final: 2013,[50] Clause 5]

3.1.30
immediate container
primary container
packaging that protects the contents from contamination and other effects of the external environment

EXAMPLE Sealed vial, ampoule or bottle, foil pouch, sealed plastic bag.

Note 1 to entry: Does not include package liners.

3.1.31
importer
any natural or legal person who is the first in a supply chain to make a *medical device* (3.1.53), manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed

Note 1 to entry: Importers are not permitted to repackage the goods or change their container, packaging, or *labelling* (3.1.35) in some jurisdictions.

[SOURCE: GHTF/SG1/N055:2009,[47] 5.4, modified — Note 1 to entry has been added.]

3.1.32
in vitro diagnostic instrument
IVD instrument
equipment or apparatus intended by a *manufacturer* (3.1.42) to be used as an *IVD medical device* (3.1.33)

3.1.33
in vitro diagnostic medical device
IVD medical device
medical device (3.1.53), whether used alone or in combination, intended by the *manufacturer* (3.1.42) for the in vitro *examination* (3.1.21) of *specimens* (3.1.65) derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes

Note 1 to entry: *IVD medical devices* (3.1.33) include reagents, *calibrators* (3.1.13), *control materials* (3.1.15), *specimen* (3.1.65) receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, *predisposition* (3.1.62), prognosis, prediction, *determination of physiological state* (3.1.17).

Note 2 to entry: In some jurisdictions, certain *IVD medical devices* (3.1.33) can be covered by other regulations.

[SOURCE: IMDRF GRRP WG/N52,[52] 3.18]

3.1.34
in vitro diagnostic reagent
IVD reagent
chemical, biological, or immunological components, solutions or preparations intended by the manufacturer to be used as an *IVD medical device* (3.1.33)

3.1.35
information supplied by the manufacturer
labelling
label (3.1.39), *instructions for use* (3.1.36), and any other information that is related to identification, technical description, *intended purpose* (3.1.37) and proper use of the *medical device* (3.1.53), but excluding shipping documents

EXAMPLE Labels, instructions for use, manual.

Note 1 to entry: *Labelling* (3.1.35) can also be referred to as "information supplied by the manufacturer".

Note 2 to entry: *Labelling* (3.1.35) can be in printed or electronic format and may either physically accompany the *medical device* (3.1.53) or direct the user to where the *labelling* (3.1.35) information can be accessed (such as through a website), as permitted by the applicable regulatory jurisdiction.

Note 3 to entry: In IEC standards, documents provided with a *medical device* (3.1.53) and containing important information for the responsible organization or operator, particularly regarding *safety* (3.1.76), are called "accompanying documents".

Note 4 to entry: Catalogues and material *safety* (3.1.76) data sheets are not considered *labelling* (3.1.35) of *IVD medical devices* (3.1.33).

[SOURCE: IMDRF/GRRP WG/N52 final 2019,[52] 3.18, modified — Title of term "information supplied by the manufacturer" has been added; Notes 3 and 4 to entry have been added.]

3.1.36
instructions for use
general and technical information provided by the *manufacturer* (3.1.42) to inform the user of a device's *intended purpose* (3.1.37) and proper use and of any contraindications, *warnings* (3.1.93) or *precautions* (3.1.64) to be taken

Note 1 to entry: It is provided by the *manufacturer* (3.1.42) to support and assist the device users in its safe and appropriate use.

Note 2 to entry: Includes the directions supplied by the *manufacturer* (3.1.42) for the use, maintenance, troubleshooting and disposal of an *IVD medical device* (3.1.33), as well as *warnings* (3.1.93) and *precautions* (3.1.64).

Note 3 to entry: Instructions for use can also be referred to as 'package insert' or manual for instruments.

[SOURCE: IMDRF/GRRP WG/N52 FINAL:2019,[52] 3.15, modified — Note 2 to entry has been added.]

3.1.37
intended use
intended purpose
objective intent of an IVD *manufacturer* (3.1.42) regarding the use of a product, process or service as reflected in the specifications, instructions and information supplied by the IVD *manufacturer* (3.1.42)

Note 1 to entry: Intended use statements for IVD *labelling* (3.1.35) can include two components: a description of the functionality of the *IVD medical device* (3.1.33) (e.g. an immunochemical *measurement procedure* (3.1.50) for the detection of *analyte* (3.1.4) "x" in serum or plasma), and a statement of the intended medical use of the *examination* (3.1.21) results.

Note 2 to entry: The intended use can include the indications for use.

[SOURCE: GHTF SG1/N77:2012,[48] 4.0, modified — "the manufacturer" has been replaced with "an IVD manufacturer" and "provided by the manufacturer" has been replaced with "supplied by the IVD manufacturer".]

3.1.38
kit
set of components that are packaged together and intended to be used to perform a specific in vitro diagnostic *examination* (3.1.21), or a part thereof

Note 1 to entry: Kit components can include reagents (e.g. antibodies, enzymes, buffer, and diluents), calibrators, controls and other articles and materials.

[SOURCE: European Union Regulation 2017/746[54] Article 2, modified — Note 1 to entry has been added.]

3.1.39
label
written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices

Note 1 to entry: A label permanently affixed to an IVD instrument is considered *marking* (3.1.43).

[SOURCE: European Union Regulation 2017/746[54] – Article 2, modified — Note to entry has been added.]

3.1.40
lay person
lay user
individual who does not have formal education in a relevant field of healthcare or medical discipline

EXAMPLE Person who performs *self-testing* (3.1.79) without having a medical education.

Note 1 to entry: Principles for lay person(s) may also apply to *self-testing* (3.1.79) for an *IVD medical device* (3.1.33).

Note 2 to entry: For an *IVD medical device* (3.1.33) for self-collection or *self-testing* (3.1.79), a self-collector or self-tester is considered a lay user.

[SOURCE: IMDRF/GRRP/WG/N52,[52] 3.21, modified — The phrase " in a relevant field of healthcare or medical discipline" has been added, the EXAMPLE has been added, Note 1 to entry has been modified and Note 2 to entry was replaced by a new Note 2 to entry.]

3.1.41
limitation of the procedure
specific situation in which an IVD *examination* (3.1.21) procedure cannot perform as intended

Note 1 to entry: Factors that affect the performance of an IVD *examination* (3.1.21) procedure can be physiological as well as analytical.

3.1.42
manufacturer
any natural or legal person with responsibility for design and/or manufacture of a *medical device* (3.1.53) with the intention of making the *medical device* (3.1.53) available for use, under that person's name; whether or not such a *medical device* (3.1.53) is designed and/or manufactured by that person or on that person's behalf by another person(s)

Note 1 to entry: Provisions of national or regional regulations can apply to the definition of manufacturer.

Note 2 to entry: 'Design and/or manufacture', as referred to in the above definition, can include specification development, production, fabrication, assembly, processing, packaging, repackaging, *labelling* (3.1.35), *relabelling* (3.1.35), sterilization, installation, or remanufacturing of a *medical device* (3.1.53); or putting a collection of devices, and possibly other product, together for a medical purpose.

Note 3 to entry: An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.

Note 4 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.

Note 5 to entry: to the extent that an accessory is subject to the regulatory requirements of the *IVD medical device* (3.1.33), the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

[SOURCE: ISO 13485:2016, 3.10, modified — Definition modified for inclusive terminology, Notes 1, 2 and 5 to entry have been deleted, and new Note 1 to entry has been added.]

3.1.43
marking
inscription, in writing or as a *graphical symbol* (3.1.23), permanently affixed to a *medical device* (3.1.53)

Note 1 to entry: Marking is a *label* (3.1.39) permanently affixed to an *IVD instrument* (3.1.32).

3.1.44
material safety data sheet
MSDS
document prepared in accordance with regulatory requirements for occupational *safety* (3.1.76) to convey information about a hazardous chemical substance

Note 1 to entry: Typically describes physical properties, health *hazards* (3.1.25), toxicity, fire and reactivity properties, and provides storage and handling *precautions* (3.1.64).

Note 2 to entry: Material safety data sheets are not considered part of *IVD medical device* (3.1.33) *labelling* (3.1.35).

EXAMPLE 1 In Europe, the material safety data are known as the Safety Data Sheet according to European Union "REACH" Regulation 2006/1907 (as amended).

EXAMPLE 2 In the US, the Safety Data Sheet (SDS) is written or printed and is prepared in accordance with certain requirements.

[SOURCE: OSHA Hazard Communication 1910.1200, modified — the phrase "document prepared in accordance with regulatory requirements" has been added, Notes 1 and 2 to entry were added.]

3.1.45
measurand
quantity intended to be measured

Note 1 to entry: The specification of a measurand in laboratory medicine requires knowledge of the kind of quantity (e.g. mass concentration), a description of the matrix carrying the quantity (e.g. blood plasma), and the chemical entities involved, e.g. the *analyte* (3.1.4).

Note 2 to entry: The measurand can be a biological activity.

Note 3 to entry: See 3.1.4 for other examples of IVD measurands.

Note 4 to entry: In chemistry, "*analyte*" (3.1.4), or the name of a substance or compound, are terms sometimes used for "measurand". This usage is erroneous because these terms do not refer to quantities.

[SOURCE: ISO/IEC Guide 99:2007, 2.3, modified — Notes 2 and 3 to entry have been deleted and new Note 1 to entry has been added.]

3.1.46
measurement
process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity

Note 1 to entry: Measurement implies comparison of quantities or counting of entities.

Note 2 to entry: Measurement presupposes description of the quantity commensurate with the *intended use* (3.1.36) of the *measurement result* (3.1.51), of a *measurement procedure* (3.1.50), and of a calibrated *measuring system* (3.2.40) operating according to the specified measurement.

Note 3 to entry: The operations can be performed automatically.

[SOURCE: ISO/IEC Guide 99:2007, 2.1, modified — Note 1 to entry has been deleted, and a new Note 3 to entry has been added.]

3.1.47
measurement method
generic description of a logical organization of operations used in a *measurement* (3.1.46)

Note 1 to entry: A measurement method is used in a specific *measurement procedure* (3.1.50).

Note 2 to entry: Measurement methods can be qualified in various ways such as direct measurement method and indirect measurement method. See IEC 60050-300 for further information.

[SOURCE: ISO/IEC Guide 99:2007, 2.5, modified — Note 1 to entry has been deleted and a Note 1 and 2 to entry have been added].

3.1.48
measurement model
mathematical relation among all quantities known to be involved in a *measurement* (3.1.46)

EXAMPLE Four-parameter logistic function for fitting sigmoidal *measurement indications* (3.2.31) to *calibrator* (3.1.13) concentrations in immunochemical *measurement procedures* (3.1.50).

Note 1 to entry: A general form of the measurement model is the equation h(Y, X1, K, Xn) = 0, where Y, the output quantity in the measurement model, is the *measurand* (3.1.45) that is to be inferred from information about input quantities in the measurement model X1, K, Xn.

Note 2 to entry: In more complex cases where there are two or more output quantities, the measurement model consists of more than one equation.

Note 3 to entry: In clinical chemistry, measurement models have also been called *calibration* (3.1.11) models.

[SOURCE: ISO/IEC Guide 99:2007, 2.48, modified — EXAMPLE and Note 3 to entry have been added.]

3.1.49
measurement principle
principle of measurement
phenomenon serving as a basis of a *measurement* (3.1.46)

EXAMPLE

a) ion selective electrode applied to the *measurement* (3.1.46) of sodium activity;

b) antibody affinity applied to the *measurement* (3.1.46) of thyroid stimulating hormone (TSH) concentration;

c) liquid chromatography applied to the *measurement* (3.1.46) of digoxin concentration;

Note 1 to entry: The phenomenon can be of a physical, chemical, or biological nature.

[SOURCE: ISO/IEC Guide 99:2007, 2.4, modified — EXAMPLES 1, 2 and 3 have been deleted and new EXAMPLE has been added.]

3.1.50
measurement procedure
detailed description of a *measurement* (3.1.46) according to one or more *measurement principles* (3.1.49) and to a given *measurement method* (3.1.47), based on a *measurement model* (3.1.48) and including any calculation necessary to obtain a *measurement result* (3.1.51)

Note 1 to entry: A measurement procedure is usually documented in sufficient detail to enable an operator to perform a *measurement* (3.1.46).

Note 2 to entry: A measurement procedure can include a statement concerning a target *measurement uncertainty* (3.2.38).

[SOURCE: ISO/IEC Guide 99:2007, 2.6, modified — "to obtain" has been replaced with "necessary to obtain" and Note 3 to entry has been deleted.]

3.1.51
measurement result
set of quantity values being attributed to a *measurand* (3.1.45) together with any other available relevant information

Note 1 to entry: In many fields of metrology, a measurement result is expressed as a single measured *quantity value* (3.2.52) and a *measurement uncertainty* (3.2.38). In laboratory medicine, measurement results are usually expressed as single measured *quantity values* (3.2.52).

Note 2 to entry: A *measurement* (3.1.46) generally provides information about the set of quantity values, such that some are more representative of the *measurand* (3.1.45) than others. This can be demonstrated in the form of a probability density function.

Note 3 to entry: In the traditional literature and in the previous edition of the Guide 99, measurement result was defined as a value attributed to a *measurand* (3.1.45) and explained to mean a *measurement indication* (3.2.31), or an uncorrected result, or a corrected result, or an average of several values, according to the context.

[SOURCE: ISO/IEC Guide 99:2007, 2.9, modified — Notes to entry have been changed.]

3.1.52
measuring interval
set of values of quantities of the same kind that can be measured by a given measuring instrument or *measuring system* (3.2.40) with specified instrumental uncertainty, under specified conditions

Note 1 to entry: The measuring interval over which the *performance characteristics* (3.1.57) of an *IVD medical device* (3.1.33) have been validated has been called the reportable range.

Note 2 to entry: The lower limit of a *measurement* (3.1.46) interval should not be confused with the *detection limit* (3.2.16). See A.2.8 for further information.

Note 3 to entry: For a discussion of the difference between interval and range, see A.2.11.

[SOURCE: ISO/IEC Guide 99:2007, 4.7, modified — Note 1 to entry has been deleted, and new Notes 1 and 3 to entry have been added.]

3.1.53
medical device
any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the *manufacturer* (3.1.42) to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury;

— investigation, replacement, modification or support of the anatomy or of a physiological or pathological process or state;

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information for medical purposes by means of in vitro *examination* (3.1.21) of *specimens* (3.1.65) derived from the human body;

— and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body but which can be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for in vitro fertilization or assisted reproduction technologies.

Note 2 to entry: The term medical device includes *in vitro diagnostic medical devices* (3.1.33).

Note 3 to entry: The term medical device includes *in vitro diagnostic medical devices* (3.1.33).

[SOURCE: IMDRP GRRP WG/N52[52] FINAL 2019, modified — Notes 2 and 3 to entry have been added.]

3.1.54
metrological traceability
property of a *measurement result* (3.1.51) whereby the result can be related to a reference through a documented unbroken chain of *calibrations* (3.1.11), each contributing to the *measurement uncertainty* (3.2.38)

Note 1 to entry: For this definition, a reference can be a definition of a *measurement unit* (3.2.39) through its practical realization, or a *measurement procedure* (3.1.50) including the *measurement unit* (3.2.39) for a nonordinal quantity, or a *measurement standard* (3.2.36).

Note 2 to entry: Metrological traceability requires an established *calibration* (3.1.11) hierarchy. The sequence of *measurement standards* (3.2.36) and *calibrations* (3.1.11) which is used to relate a *measurement result* (3.1.51) to a reference is called a traceability chain. A metrological traceability chain is used to establish metrological traceability of a *measurement result* (3.1.51), including *calibrator* (3.1.13) values. See ISO 17511:2020 and for examples of traceability chains pertaining to *IVD medical devices* (3.1.33).

Note 3 to entry: Specification of the stated reference shall include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first *calibration* (3.1.11) in the calibration hierarchy was performed.

Note 4 to entry: For *measurements* (3.1.46) with more than one input quantity in the *measurement model* (3.1.48), each of the quantity values should itself be metrologically traceable and the *calibration* (3.1.11) hierarchy involved can form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity should be commensurate with its relative contribution to the *measurement result* (3.1.51).

Note 5 to entry: A comparison between two *measurement standards* (3.2.36) can be viewed as a *calibration* (3.1.11) if the comparison is used to check and, if necessary, correct the quantity value and *measurement uncertainty* (3.2.38) attributed to one of the *measurement standards* (3.2.36).

Note 6 to entry: The abbreviated term traceability is sometimes used to mean metrological traceability as well as other concepts, such as sample traceability or document traceability or instrument traceability or material traceability, where the history (trace) of an item is meant. Therefore, the full term of metrological traceability is preferred if there is any chance of confusion.

[SOURCE: ISO/IEC Guide 99:2007, 2.41., modified — Notes 5 and 7 to entry were removed and explanation was added to Note 2 to entry.]

3.1.55
monitoring in vitro diagnostic medical device
device used for serial *measurement* (3.1.46) of the *analyte* (3.1.4) (*measurand*)(3.1.45) levels for the purpose of adjusting treatments/interventions

Note 1 to entry: Monitoring devices include the following:

— assays which are used to ensure that an *analyte* (3.1.4) remains within physiological levels or within an established therapeutic drug range. These types of monitoring assays are designed to evaluate an individual's current state;

— assays which are used for serial *measurement* (3.1.46), whereby multiple determinations are taken over time. These types of monitoring tests are typically used for the detection/assessment of disease progression/regression, disease recurrence, minimum residual disease, response/resistance to therapy, and/or adverse effects due to therapy. These types of monitoring tests are designed to evaluate changes in an individual's state

Note 2 to entry: These tests are designed to evaluate changes in a patient's state.

[SOURCE: GHTF/SG5/N8:2012,[46] Appendix Table 1, modified — "the measurement" has been replaced with "serial measurement".]

3.1.56
outer container
sales packaging
product to be used for the containment, protection, handling, delivery, storage, transport and presentation of goods, from raw materials to processed goods, from the producer to the user or consumer, including processor, assembler or other intermediary

3.1.57
performance characteristic
metrological property
one of the parameters used to define the analytical and/or clinical performance of an *IVD medical device* (3.1.33)

EXAMPLE diagnostic sensitivity, diagnostic specificity, predictive values, *measurement accuracy* (3.2.27), *reproducibility* (3.2.34), *repeatability* (3.2.33), *stability* (3.1.85), limits of detection and *measurement* (3.1.46) range, earliest clinical detection in comparison with tests of reference (reference European Union Regulation 2017/746[54]).

Note 1 to entry: Information about more than one performance characteristic is usually required to evaluate the suitability of an *IVD medical device* (3.1.33) for its intended medical use.

3.1.58
performance claim
specification of a *performance characteristic* (3.1.57) of an *IVD medical device* (3.1.33) as documented in the *information supplied by the manufacturer* (3.1.35)

Note 1 to entry: This can be based upon prospective performance studies, available performance data or studies published in the scientific literature.

[SOURCE: EN 13612:2002,[55] 2.7, modified — Added "characteristic" text, "laid down" has been changed to "documented" and Note 1 to entry has been added.]

3.1.59
performance evaluation
assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of an *IVD medical device* (3.1.33)

EXAMPLE It can include analytical performance and, where appropriate, clinical performance.

[SOURCE: IMDF GRRP WG/N47: 2018,[51] modified — EXAMPLE added.]

3.1.60
point of care testing
near-patient testing
testing that is performed near a patient and outside of centralized laboratory testing facilities

Note 1 to entry: This is not intended to refer to *sample* (3.1.77) collection procedures.

Note 2 to entry: In certain regulatory jurisdictions, this is also referred to as Point-of-Care Testing.

[SOURCE: IMDRF GRRP WG/N47: 2018,[51] 3.27, modified — Note 1 to entry has been deleted.]

3.1.61
prediction in vitro diagnostic medical devices
measuring factors that determine the likelihood of patient responses or adverse reactions to a specific therapy

Note 1 to entry: These tests are designed to evaluate a patient's future state.

[SOURCE: GHTF/SG5/N8:2012,[46] Appendix Table 1 modified — The second sentence has been deleted.]

3.1.62
predisposition in vitro diagnostic device
device used to determine the likelihood of disease onset (i.e. assessing the *risk* (3.1.74) of developing the disease in the future) in presymptomatic patients

Note 1 to entry: For patients at sufficient *risk* (3.1.74) (as determined by test results), preventive interventions may be taken.

Note 2 to entry: These tests are designed to evaluate a patient's future state.

[SOURCE: GHTF/SG5/N8:2012,[46] Appendix, Table 1]

3.1.63
prognosis in vitro diagnostic medical device
device used to measure factors linked to clinical outcome irrespective of treatment

Note 1 to entry: Such tests may be used to estimate the natural progression of a disease (i.e. outcome in the absence of treatment), or to determine the likelihood of a clinical outcome irrespective of therapeutic intervention.

Note 2 to entry: These tests are designed to evaluate a patient's future state.

[SOURCE: GHTF/SG5/N8:2012,[46] Appendix Table 1]

3.1.64
precaution
information regarding any special care users should exercise for the safe and effective use of the *IVD medical device* (3.1.33) or to avoid damage to the *IVD medical device* (3.1.33) that can occur as a result of use, including misuse

Note 1 to entry: The distinction between *warnings* (3.1.93) and precautions is a matter of degree, considering the likelihood and seriousness of the *hazard* (3.1.43). See the definition of *warning* (3.1.93).

[SOURCE: IMDRF GRRP WG/N52 FINAL 2019, Principles of Labelling for Medical Devices and IVD Medical Devices, 3.29, modified — "device" has been deleted and Note 1 to entry has been added.]

3.1.65
primary sample
specimen
discrete portion of a body fluid or tissue taken for *examination* (3.1.21), study or analysis of one or more quantities or characteristics to determine the character of the whole

Note 1 to entry: GHTF uses the term specimen in its harmonized guidance documents to mean a *sample* (3.1.77) of biological origin intended for *examination* (3.1.21) by a medical laboratory.

[SOURCE: ISO 15189:2012, 3.16, modified — Notes 2 and 3 to entry have been deleted.]

3.1.66
primary sample collection device
specimen collection device
apparatus specifically intended by an IVD *manufacturer* (3.1.42) to obtain, contain, and preserve a body fluid or tissue for in vitro diagnostic *examination* (3.1.21)

Note 1 to entry: Includes devices intended to store a *primary sample* (3.1.65) prior to *examination* (3.1.21).

Note 2 to entry: Includes both vacuum and non-vacuum primary sample collection devices.

Note 3 to entry: In Europe, a specimen collection device can also be known as a 'specimen receptacle' (reference European Union Regulation 2017/746 – Article 2 (3)[54]).

[SOURCE: Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017, Article 2, (3),[54] modified — The words "device, whether of a vacuum-type or not" have been replaced with "apparatus", and the words "by its manufacturer for the primary containment and preservation of specimens derived from the human body for the purpose of" have been replaced with " by an IVD manufacturer to obtain, contain and preserve a body fluid or tissue for".]

3.1.67
production identifier
unique device identifier-production identifier
UDI-PI
numeric or alphanumeric code that identifies the unit of device production in the unique device identifier

Note 1 to entry: Examples of different types of UDI-PI(s) include serial number, lot/batch number, software version, manufacturing and/or expiration date.

[SOURCE: IMDRF/UDI WG/N7:2013,[50] 5, modified — "device production" has been replaced with "device production in the unique device identifier", and "Software as a Medical Device (SaMD) version" has been replaced with "software version".]

3.1.68
professional use
designation that an *IVD medical device* (3.1.33) is intended for personnel who are qualified to perform IVD *examinations* (3.1.21) through special education and *training* (3.1.86)

3.1.69
radio frequency identification
RFID
form of wireless communication that incorporates the use of electromagnetic or electrostatic coupling in the radio frequency portion of the electromagnetic spectrum to uniquely identify an object, animal or person

3.1.70
reactive ingredient
constituent that participates in a chemical reaction intended to detect or measure a quantity

EXAMPLE Antibodies, specific viral nucleotide sequences, enzyme substrates.

Note 1 to entry: Constituents such as buffers, preservatives and stabilisers that do not participate in the chemical reaction are not considered reactive ingredients.

3.1.71
reference material
material, sufficiently homogeneous and stable regarding one or more properties, with reference to specified properties, which has been established to be fit for its *intended use* (3.1.37) in *measurement* (3.1.46) or in *examination* (3.1.21) of nominal properties

Note 1 to entry: Reference materials with or without assigned quantity values can be used for *measurement precision* (3.2.32) control whereas only *reference materials* (3.1.71) with assigned *quantity values* (3.2.52) can be used for *calibration* (3.1.11) or *measurement trueness* (3.2.37) control.

Note 2 to entry: In a given *measurement* (3.1.46), a given reference material can only be used for either *calibration* (3.1.11) or quality assurance.

Note 3 to entry: Reference material comprises materials embodying quantities as well as nominal properties.

Note 4 to entry: Examples of reference materials embodying quantities include water of stated purity, the dynamic viscosity of which is used to calibrate viscometers; blood plasma containing a stated mass fraction of glucose, used as a *calibrator* (3.1.13); and human serum without an assigned quantity value for the inherent cholesterol concentration, used only as a *measurement precision* (3.2.32) control material.

Note 5 to entry: Examples of reference materials embodying properties include colour chart indicating one or more specified colours, DNA compound containing a specified nucleic acid sequence and urine containing 19-androstenedione.

Note 6 to entry: A reference material is sometimes incorporated into an *IVD medical device* (3.1.33).

EXAMPLE 1 Substance of known triple-point in a triple-point cell.

EXAMPLE 2 Glass of known optical density in a transmission filter holder.

EXAMPLE 3 Spheres of uniform size mounted on a microscope slide.

Note 7 to entry: A reference material, accompanied by documentation issued by an authoritative body and referring to valid procedures used to obtain a specified property value with associated uncertainty and traceability, is called a certified reference material.

EXAMPLE 4 Human serum with assigned quantity value for the cholesterol concentration and associated *measurement uncertainty* (3.2.38), used as a *calibrator* (3.1.13) or *measurement trueness* (3.2.37) *control material* (3.1.15).

Note 8 to entry: Some reference materials have quantities that are metrologically traceable to a *measurement unit* (3.2.39) outside a system of units. Such materials include *measurement standards* (3.2.36) of biological origin to which International Units (IU) have been assigned by the World Health Organization.

Note 9 to entry: The specifications of a reference material include its material traceability, indicating its origin and processing. Requirements for the specifications of reference materials for *IVD medical devices* (3.1.33) are described in ISO 15194.

Note 10 to entry: Uses of reference materials can include the *calibration* (3.1.11) of a *measurement system* (3.1.46), assessment of a *measurement procedure* (3.1.50), assigning values to other materials, and quality control. See also *measurement standard* (3.2.36).

Note 11 to entry: *Examination* (3.1.21) of a nominal property provides a nominal property value and associated uncertainty. This uncertainty is not a *measurement uncertainty* (3.2.38).

Note 12 to entry: ISO/REMCO (Committee on reference materials) has an analogous definition but uses the term *measurement* (3.1.46) process to mean *examination* (3.1.21), to cover both *measurement* (3.1.46) and *examination* (3.1.21) of a nominal property.

Note 13 to entry: Adapted from ISO/IEC Guide 99:2007, 5.13.

3.1.72
reference measurement procedure
measurement procedure (3.1.50) accepted as providing *measurement results* (3.1.51) fit for their *intended use* (3.1.37) in assessing *measurement trueness* (3.2.37) of measured *quantity values* (3.2.52) obtained from other *measurement procedures* (3.1.50) for quantities of the same kind, in *calibration* (3.1.11) or in characterizing *reference materials* (3.1.71)

Note 1 to entry: Requirements for reference *measurement procedures* (3.1.50) for *IVD medical devices* (3.1.33) are described in ISO 15193.

Note 2 to entry: Examples of the use of reference *measurement procedures* (3.1.50) to assign values to *IVD calibrators* (3.1.13) are given in ISO 17511:2020 and ISO 18153:2003.

Note 3 to entry: A *measurement procedure* (3.1.50) used to obtain a *measurement result* (3.1.51) without relation to a *measurement standard* (3.2.36) for a quantity of the same kind is called a primary reference measurement procedure. See ISO/IEC Guide 99:2007, 2.8).

[SOURCE: ISO/IEC Guide 99:2007, 2.7, modified — Notes 1, 2 and 3 to entry have been added.]

3.1.73
residual risk
risk (3.1.74) remaining after *risk control measures* (3.1.75) have been taken

Note 1 to entry: Residual risks are disclosed to users in the instructions for use. See ISO/TR 24971.

[SOURCE: ISO/IEC Guide 51: 2014, 3.8, modified — Note 1 to entry has been added.]

3.1.74
risk
combination of the probability of occurrence of *harm* (3.1.24) and the severity of that *harm* (3.1.24)

[SOURCE: ISO/IEC Guide 51: 2014, 3.9, modified — Note 1 to entry has been deleted.]

3.1.75
risk control (measure)
process in which decisions are made and measures implemented by which *risks* (3.1.74) are reduced to, or maintained within, specified levels

Note 1 to entry: Risk control measures based on *labelling* (3.1.35) are called information for *safety* (3.1.76) in ISO 14971 and are considered the least effective risk control option in order of *risk* (3.1.74) management priority. *Labelling* (3.1.35) intended as information for *safety* (3.1.76) includes

— *instructions for use* (3.1.36),

— *limitation of the procedure* (3.1.41),

— *precautions* (3.1.64),

— *warnings* (3.1.93),

— explanation of a *safety* (3.1.76) feature.

Note 2 to entry: General guidance on providing information for *safety* (3.1.76) is provided ISO/TR 24971. General guidance for evaluating information for *safety* (3.1.76) as a risk control measure, including review of *warnings* (3.1.93) and review of the operating instructions, is provided in ISO/ TR 24971.

Note 3 to entry: Specific guidance pertaining to information for *safety* (3.1.76) of *IVD medical devices* (3.1.33) is provided in ISO/TR 24971.

[SOURCE: ISO 14971, 3.2.1, modified — Notes 1, 2 and 3 to entry have been added.]

3.1.76
safety
freedom from unacceptable *risk* (3.1.74)

[SOURCE: ISO/IEC Guide 63:2019, 3.16]

3.1.77
sample
one or more representative parts taken from a system, which are intended to provide information on the system

EXAMPLE A portion of serum taken from a *primary sample* (3.1.65) of coagulated blood.

[SOURCE: ISO 15189:2012, 3.16, modified — The word "parts" has been replaced with "representative parts" and the phrase "a primary sample" has been replaced with "a system, which are intended to provide information on the system". EXAMPLE has been deleted and new EXAMPLE has been added.]

3.1.78
screening in vitro diagnostic medical device
device used to determine the status of a disease, disorder, or other physiological state in an asymptomatic individual

Note 1 to entry: Examples include tests for genetic screening, tests for early detection of disease, and tests used to reduce the *risk* (3.1.74) of infectious disease transmission, such as assays for prenatal screening and donor screening (transfusion or transplantation).

Note 2 to entry: Depending on the nature of the condition and the targeted patient population, screening tests may be used routinely or may be restricted to "at *risk*" (3.1.74) patients.

Note 3 to entry: These tests are designed to evaluate a patient's current state.

[SOURCE: GHTF/SG5/N8:2012,[46] Appendix Table 1, modified — The words "genetic screening assays, tests for physiological typing" have been replaced with "genetic screening, tests for early detection of disease" in Note 1 to entry.]

3.1.79
self-testing
use of a *medical device* (3.1.53) or *IVD medical device* (3.1.33) by a *lay user* (3.1.40) who is responsible for collecting the data or *specimen* (3.1.65), by themselves and on themselves, relying solely on the instructions provided by the *manufacturer* (3.1.42)

Note 1 to entry: This can also include performing the test and interpreting the results by themselves and on themselves.

Note 2 to entry: Self-testing may include a third-party caregiver.

Note 3 to entry: For the European Union this definition includes testing services offered to *lay persons* (3.1.40) by means of information society services; (ref. European Union Regulation 2017/746 – Article 2[54]).

Note 4 to entry: Typically performed in a home or other environment outside a healthcare institution without supervision by a healthcare professional. (Adapted from the definition of "device for self-testing" in Directive 98/79/EC of the European Parliament and the Council of 27 October 1998, Article 1, 2(d)[54].)

[SOURCE: IMDRF/GRRP WG/N47:2018,[51] 3.40, modified — Notes 2, 3 and 4 to entry have been added.]

3.1.80
semi-quantitative examination
set of operations that yields results in an approximate range of values (e.g. trace, moderate)

Note 1 to entry: Semiquantitative assays are essentially qualitative assays with additional option for response range (degree of positivity, dilution to which positive results are obtained, or comparison to a color chart).

[SOURCE: CLSI POCT04, 1.4.2[43], modified — the original term was “semi quantitative”; the phrase “set of operations” and Note 1 to entry were added.]

3.1.81
serial number
production control containing a combination of letters or numbers, selected by the *manufacturer* (3.1.42), intended for quality control and identification purposes to uniquely distinguish an individual *medical device* (3.1.53) from other *medical devices* (3.1.53) with the same catalogue number or model number

[SOURCE: ISO 20417:2021, 3.22]

3.1.82
shelf-life
period of time until the *expiry date* (3.1.22) during which an *IVD reagent* (3.1.34) in its original packaging maintains its *stability* (3.1.85) under the storage conditions specified by the *manufacturer* (3.1.42)

Note 1 to entry: *Stability* (3.1.85) and *expiry date* (3.1.22) are related concepts.

3.1.83
single-use device
medical device (3.1.53) or *IVD medical device* (3.1.33) that is intended to be used on an individual patient during or for a single procedure and then disposed

Note 1 to entry: It is not intended to be reprocessed and used again.

[SOURCE: IMDRF GRRP WG/N52: 2019,[52] 3.36]

3.1.84
spare part
component intended to replace an identical or similar component of an instrument or other apparatus without affecting its functionality

3.1.85
stability
ability of an *IVD medical device* (3.1.33) to maintain its performance characteristics within the limits specified by the *manufacturer* (3.1.42)

Note 1 to entry: Stability applies to:

— *IVD reagents* (3.1.34), *calibrators* (3.1.13) and controls, when stored, transported and used in the conditions specified by the *manufacturer* (3.1.42),

— reconstituted lyophilised materials, working solutions and materials removed from sealed containers, when prepared, used and stored according to the manufacturer’s instructions for use,

— measuring instruments or *measuring systems* (3.2.40) after *calibration* (3.1.11).

Note 2 to entry: Stability of an *IVD reagent* (3.1.34) or *measuring system* (3.2.40) is normally quantified with respect to time

— in terms of the duration of a time interval over which a metrological property changes by a stated amount, or

— in terms of the change of a property over a stated time interval.

Note 3 to entry: Adapted from ISO/IEC Guide 99:2007, 4.19, to make the definition applicable for IVDs in general beyond instruments.

3.1.86
training
operator-oriented, application-specific instruction required for the safe and proper use of an *IVD medical device* (3.1.33)

3.1.87
trueness control material
reference material (3.1.71) that is used to assess the bias of a *measuring system* (3.2.40)

[SOURCE: ISO 17511:2020, 3.46]

3.1.88
UDI carrier
UDI
means to convey the *UDI* (3.1.89) by using *automatic identification and data collection* (3.1.6) and, if applicable, its human readable interpretation (HRI) (3.29)

Note 1 to entry: Carriers can include, e.g. ID/linear bar code, 2D/Matrix bar code, *RFID* (3.1.69).

[SOURCE: IMDRF/UDI/ WG/N7 Final:2013,[50] Clause 5]

3.1.89
unique device identifier
UDI
series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard

Note 1 to entry: It allows the unambiguous identification of a specific *medical device* (3.1.53) on the market.

Note 2 to entry: The UDI comprises the *UDI-DI* (3.1.18) and *UDI-PI* (3.1.67).

Note 3 to entry: The word "unique" does not imply serialization of individual production units.

[SOURCE: IMDRF/UDI/ WG/N7, Final:2013,[50] Clause 5]

3.1.90
use error
act or omission of an act that has a different *medical device* (3.1.53) response to that intended by the *manufacturer* (3.1.42) or expected by the operator

Note 1 to entry: Use error includes slips, lapses and mistakes.

Note 2 to entry: IEC 62366:2015, Annexes B and D.1.3, give a discussion and examples of use errors.

[SOURCE: IEC 62366-1:2015/AMD1:2020, 3.21]

3.1.91
validation
verification (3.1.92) that the specified requirements are adequate for an *intended use* (3.1.37)

EXAMPLE A *measurement procedure* (3.1.50) for creatinine concentration in human serum can also be validated for the *measurement* (3.1.46) of creatinine concentration in human urine.

Note 1 to entry: ISO 9000:2015, definition 3.8.13, defines validation as confirmation, through the provision of objective evidence that the requirements for a specific *intended use* (3.1.37) or application have been fulfilled.

[SOURCE: ISO/IEC Guide 99:2007, 2.45, modified — "The EXAMPLE" has been deleted and a new EXAMPLE and Note 1 to entry have been added.]

3.1.92
verification
provision of objective evidence that a given item fulfils specified requirements

EXAMPLE 1 Confirmation that a given *reference material* (3.1.71) as claimed is homogeneous for the quantity value and *measurement procedure* (3.1.50) concerned, down to a *measurement* (3.1.46) portion having a mass of 10 mg.

EXAMPLE 2 Confirmation that performance properties or legal requirements of a *measuring system* (3.2.40) are achieved.

EXAMPLE 3 Confirmation that a *target measurement uncertainty* (3.2.61) can be met.

Note 1 to entry: The item can be, e.g. a process, *measurement procedure* (3.1.50), material, compound or *measuring system* (3.2.40).

Note 2 to entry: The specified requirements can be, e.g. that a manufacturer's claims or specifications are met.

Note 3 to entry: In legal metrology, verification pertains to the *examination* (3.1.21) and *marking* (3.1.43) and/or issuing of a *verification* (3.1.92) certificate for a measuring instrument.

Note 4 to entry: Verification should not be confused with *calibration* (3.1.11) or *validation* (3.1.91).

Note 5 to entry: In chemistry, verification of identity of entity involved, or of activity, requires a description of the structure or properties of that entity or activity.

Note 6 to entry: ISO 9000:2015, 3.8.12, defines verification as confirmation, through the provision of objective evidence that specified requirements have been fulfilled.

[SOURCE: ISO/IEC Guide 99:2007, 2.44, modified — Note 1 has been deleted, and new Notes 1 and 6 to entry have been added]

3.1.93
warning
statement that alerts users about a situation that, if not avoided, could result in *hazards* (3.1.25) or other serious adverse consequences from the use of an *IVD medical device* (3.1.33)

Note 1 to entry: The designation of a *hazard* (3.1.25) alert as a warning is reserved for the most significant consequences.

Note 2 to entry: The distinction between a warning and a *precaution* (3.1.64) is a matter of degree, considering the likelihood and seriousness of the *hazard* (3.1.25).

Note 3 to entry: Use includes use errors and reasonably foreseeable misuse. See ISO 14971 and IEC 62366 for discussions of these concepts.

[SOURCE: US. Food and Drug Administration, Guidance on Medical Device Patient Labelling; Final Guidance for Industry and FDA, 19 April 2001,[58] Annex E, modified — The words "the reader" have been replaced with "users", and the words "death or serious injury" have been replaced with "hazards or other serious adverse consequences from the use of an IVD medical device".]

3.2 Performance characteristic terms and definitions

3.2.1
adjustment of an IVD instrument
adjustment
set of operations carried out on an IVD instrument so that it provides prescribed *measurement* (3.1.46) indications corresponding to given values of a quantity to be measured

EXAMPLE 1 In Europe, the material safety data are known as the Safety Data Sheet according to European Union "REACH" Regulation 2006/1907 (as amended).

EXAMPLE 2 In the US, the Safety Data Sheet (SDS) is written or printed and is prepared in accordance with certain requirements.

Note 1 to entry: Types of adjustment can include zero adjustment, offset adjustment and span adjustment (sometimes called gain adjustment).

Note 2 to entry: Adjustment of an IVD instrument should not be confused with Capability of a measuring system (3.1.11), which is a prerequisite for adjustment.

Note 3 to entry: After an adjustment, usually an IVD instrument needs to be recalibrated.

Note 4 to entry: Adapted from ISO/IEC Guide 99:2007, definition 3.11.

3.2.2
analytical interference
interference
systematic effect on a *measurement* (3.1.46) caused by an influence quantity, which does not by itself produce a signal in the *measuring system* (3.2.40), but which causes an enhancement or depression of the value indicated

Note 1 to entry: Interference with *measurement* (3.1.46) results is related to the concept of *analytical specificity* (3.2.5). The more specific the *measurement procedure* (3.1.50) with respect to other constituents of the sample, the less susceptible it is to analytical interference by these compounds.

[SOURCE: ISO 15193:2009, 3.10, modified — The words "an indication" have been replaced by "a signal in the measuring system", and "indication" has been replaced by "value indicated".]

3.2.3
analytical performance
ability of an *IVD medical device* (3.1.33) to detect or measure a particular *analyte* (3.1.4)

[SOURCE: GHTF/SG5/N6: 2012, 4.4.1[44]]

3.2.4
analytical sensitivity
sensitivity of a measurement procedure
quotient of the change in a *measurement* (3.1.46) indication and the corresponding change in a value of a quantity being measured

Note 1 to entry: The sensitivity of a *measurement procedure* (3.1.50) can depend on the value of the quantity being measured.

Note 2 to entry: The change considered in the value of the quantity being measured shall be large compared with the resolution.

Note 3 to entry: The analytical sensitivity of a *measuring system* (3.2.40) is the slope of the calibration curve.

Note 4 to entry: Analytical sensitivity should not be used to mean *detection limit* (3.2.16) or *quantitation limit* (3.2.49) and should not be confused with *diagnostic sensitivity* (3.2.17).

[SOURCE: ISO/IEC Guide 99:2007, 4.12, modified — The original term was "sensitivity of the measuring system", the phrase "in an indication of a measuring system" has been replaced by "measurement indication", and Notes 3 and 4 to entry have been added.]

3.2.5
analytical specificity
selectivity of a measurement procedure
capability of a *measuring system* (3.2.40), using a specified *measurement procedure* (3.1.50), to provide *measurement results* (3.1.51) for one or more *measurands* (3.1.45) which do not depend on each other nor on any other quantity in the system undergoing *measurement* (3.1.46)

EXAMPLE Capability of a *measuring system* (3.2.40) to measure the concentration of creatinine in blood plasma by the alkaline picrate procedure without interference from the glucose, urate, ketone, or protein concentrations.

Note 1 to entry: Lack of analytical specificity is called *analytical interference* (3.2.2).

Note 2 to entry: Lack of analytical specificity in immunochemistry *measurement procedures* (3.1.50) can be due to *cross-reactivity* (3.2.14).

Note 3 to entry: Specificity of a *measurement procedure* (3.1.50) should not be confused with *diagnostic specificity* (3.2.18).

Note 4 to entry: ISO/IEC Guide 99:2007 uses the term selectivity for this concept instead of specificity.

Note 5 to entry: Adapted from ISO/IEC Guide 99:2007, 4.13.

3.2.6
blank indication
indication obtained from a phenomenon, body or substance similar to the one under investigation, but for which a quantity of interest is supposed not to be present, or is not contributing to the indication

[SOURCE: ISO/IEC Guide 99:2007, 4.2]

3.2.7
calibration curve
expression of the relation between indication and corresponding measured quantity value

Note 1 to entry: A calibration curve expresses a one-to-one relationship that does not supply a *measurement result* (3.1.51) as it bears no information about the *measurement uncertainty* (3.2.38).

[SOURCE: ISO/IEC Guide 99:2007, 4.31]

3.2.8
calibration hierarchy
sequence of *calibrations* (3.1.11) from a reference to the final *measuring system* (3.2.40), where the outcome of each *calibration* (3.1.11) depends on the outcome of the previous *calibration* (3.1.11)

Note 1 to entry: *Measurement uncertainty* (3.2.38) necessarily increases along the sequence of *calibrations* (3.1.11).

Note 2 to entry: The elements of a calibration hierarchy are one or more *measurement standards* (3.2.36) (including calibrators) and measuring systems operated according to *measurement procedures* (3.1.50).

Note 3 to entry: For this definition, the "reference" can be a definition of a measurement unit through its practical realization, or a *measurement procedure* (3.1.50) or a *measurement standard* (3.2.36).

Note 4 to entry: A comparison between two *measurement standards* (3.2.36) can be viewed as a *calibration* (3.1.11) if the comparison is used to check and, if necessary, correct the quantity value and *measurement uncertainty* (3.2.38) attributed to one of the *measurement standards* (3.2.36).

[SOURCE: ISO/IEC Guide 99:2007, 2.40, modified — "(including calibrators)" was added to Note 2 to entry.]

3.2.9
carryover
introduction of material into a reaction mixture to which it does not belong

EXAMPLE Part of a sample, reagent, diluent or wash solution which is transferred from one container or from one reaction mixture to another one during an examination.

3.2.10
clinical performance of an IVD medical device
ability of an *IVD medical device* (3.1.33) to yield results that are correlated with a particular clinical condition or physiological/pathological process/state in accordance with the *intended use* (3.1.37)

Note 1 to entry: In accordance with *intended use* (3.1.37), clinical performance can include expected values, *diagnostic sensitivity* (3.2.17) and *diagnostic specificity* (3.2.18) based on the known clinical condition or physiological/pathological process/state of the individual, and negative and positive predictive values based on the prevalence of the disease.

Note 2 to entry: Adapted from IMDRF /GRRP WG/N47:2018.[51] Also takes into account European Union Regulation 2017/746, Article 2[54].

3.2.11
commutability of a reference material
property of a *reference material* (3.1.71), demonstrated by the closeness of agreement between the relation among the *measurement results* (3.1.51) for a stated quantity in this material, obtained according to two given *measurement procedures* (3.1.50), and the relation obtained among the *measurement results* (3.1.51) for other specified materials

Note 1 to entry: The *reference material* (3.1.71) in question is usually a *calibrator* (3.1.11) and the other specified materials are usually routine *samples* (3.1.77).

Note 2 to entry: The *measurement procedures* (3.1.50) referred to in the definition are the one preceding and the one following the *reference material* (3.1.71) (calibrator) in question in a *calibration hierarchy* (3.2.8). See ISO 17511 for further information.

Note 3 to entry: The stability of commutable reference materials is monitored regularly.

[SOURCE: ISO/IEC Guide 99:2007, 5.15]

3.2.12
concentration
substance concentration
amount-of-substance of a component divided by the volume of the system

Note 1 to entry: Unless mass, volume or number concentration is specified, the term concentration is presumed to mean substance concentration.

Note 2 to entry: The unit "mole per litre" is recommended for clinical chemistry. Use of the term "molarity" for this quantity is not recommended.

Note 3 to entry: Use of the term "level" as a synonym for concentration is deprecated.

Note 4 to entry: In describing a quantity, concentration shall be clearly differentiated from content.

Note 5 to entry: The amount-of-substance of a sample or system is the physical quantity in proportion to the number of elementary entities present. The elementary entities can be atoms, molecules, ions, electrons or particles, the choice being dependent upon context and shall be stated.

Note 6 to entry: The SI unit for amount-of-substance is the mole (mol), which is defined as the amount of substance that has an equal number of elementary entities as there are atoms in 0,012 kg (or 12 g) of carbon-12. That number is the Avogadro constant, NA, which has a value of 6,022 141 79(30) × 1 023 mol–1.

Note 7 to entry: The number of defined particles, or elemental entities, of a component in a system divided by the volume of that system is called number concentration.

3.2.13
conventional quantity value
conventional value of a quantity
quantity value attributed by agreement to a quantity for a given purpose

EXAMPLE The conventional quantity value of a given mass standard, m = 100,003 47 g.

Note 1 to entry: The term "conventional true quantity value" is sometimes used for this concept, but its use is discouraged.

Note 2 to entry: Sometimes a conventional quantity value is an estimate of a true quantity value.

Note 3 to entry: A conventional quantity value is generally accepted as being associated with a suitably small *measurement uncertainty* (3.2.38), which might be zero.

[SOURCE: ISO/IEC Guide 99:2007, 2.12, modified — The variant "conventional value" and EXAMPLES 1 and 2 were deleted.]

3.2.14
cross-reactivity
degree to which a substance other than the *analyte* (3.1.4) binds to a reagent in a competitive binding immunochemical *measurement procedure* (3.1.50)

EXAMPLE Antibody binding to metabolites of the *analyte* (3.1.4), structurally similar drugs, etc.

Note 1 to entry: *Analytical specificity* (3.2.5) is a related concept.

Note 2 to entry: Cross-reactivity of metabolites can be a desirable attribute of certain *examination* (3.1.21) procedures, such as for screening for the presence of illegal drugs.

Note 3 to entry: It is important to calculate cross-reactivity on the basis of moles per litre. For guidelines in calculating cross-reactivity, see Reference [68].

3.2.15
cut-off value
quantity value used as a decision limit to identify *samples* (3.1.77) that indicate the presence or the absence of a specific disease, condition or *measurand* (3.1.45)

Note 1 to entry: *Measurement* (3.1.46) results higher than the cut-off value are considered positive and those lower than the cut-off are considered negative.

Note 2 to entry: *Measurement* (3.1.46) results near the cut-off value can be considered inconclusive.

Note 3 to entry: The selection of the cut-off value determines the *diagnostic specificity* (3.2.18) and *diagnostic sensitivity* (3.2.17) of the examination.

3.2.16
detection limit
limit of detection
measured quantity value, obtained by a given *measurement procedure* (3.1.50), for which the probability of falsely claiming the absence of a component in a material is β, given a probability α of falsely claiming its presence

Note 1 to entry: IUPAC recommends default values for α and β equal to 0,05.

Note 2 to entry: The term *analytical sensitivity* (3.2.4) is sometimes used to mean detection limit, but such usage is now discouraged. See A.2.7 and A.2.8 for further information.

Note 3 to entry: See also *quantitation limit* (3.2.49).

[SOURCE: ISO/IEC Guide 99:2007, 4.18, modified — Notes 2 and 3 to entry were deleted and replaced by new Notes 2 and 3 to entry.]

3.2.17
diagnostic sensitivity
ability of an IVD *examination* (3.1.21) procedure to have positive results associated with a particular disease or condition

Note 1 to entry: Also defined as percent positivity in samples where the target marker is known to be present. For information regarding description of the diagnostic performance characteristics of an *IVD medical device* (3.1.32), see Reference [60].

Note 2 to entry: Diagnostic sensitivity is expressed as a percentage (number fraction multiplied by 100), calculated as 100 × the number of true positive values (TP) divided by the sum of the number of true positive values (TP) plus the number of false negative values (FN), or 100 × TP/(TP + FN). This calculation is based on a study design where only one sample is taken from each subject.

Note 3 to entry: The *target condition* (3.2.60) is defined by criteria independent of the *examination* (3.1.21) procedure under consideration.

3.2.18
diagnostic specificity
ability of an IVD *examination* (3.1.21) procedure to have negative results associated with an absence of particular disease or condition.

Note 1 to entry: Also defined as percent negativity in samples where the target marker is known to be absent. For information regarding description of the diagnostic performance characteristics of an *IVD medical device* (3.1.33), see Reference [60].

Note 2 to entry: Diagnostic specificity is expressed as a percentage (number fraction multiplied by 100), calculated as 100 × the number of true negative values (TN) divided by the sum of the number of true negative plus the number of false positive (FP) values, or 100 × TN/(TN + FP). This calculation is based on a study design where only one sample is taken from each subject.

Note 3 to entry: The *target condition* (3.2.60) is defined by criteria independent of the *examination* (3.1.21) procedure under consideration.

3.2.19
high dose hook effect
negative bias in some *measurement procedures* (3.1.50) observed at high concentrations

EXAMPLE an immunochemical *measurement procedure* (3.1.50) caused by impairment of antigen-antibody cross-linking when the antigen concentration is in excess relative to the antibody concentration or when the antibody concentration is in excess relative to the antigen concentration.

Note 1 to entry: Sometimes called the prozone phenomenon.

3.2.20
influence quantity
quantity that, in a *direct measurement* (3.1.46), does not affect the quantity that is actually measured, but affects the relation between the indication and the *measurement result* (3.1.51)

EXAMPLE 1 Concentration of bilirubin in a direct *measurement* (3.1.46) of haemoglobin concentration in human blood plasma.

EXAMPLE 2 Background pressure in the ion source of a mass spectrometer during a *measurement* (3.1.46) of amount-of-substance fraction.

Note 1 to entry: An indirect *measurement* (3.1.46) involves a combination of direct *measurements* (3.1.46), each of which can be affected by influence quantities.

Note 2 to entry: In the GUM (withdrawn ISO/IEC Guide 98, replaced by ISO/IEC Guide 98-3:2008), the concept influence quantity is defined as in the previous edition of the VIM (withdrawn ISO/IEC Guide 99:1993, replaced by ISO/IEC Guide 99:2007), covering not only the quantities affecting the *measuring system* (3.2.40), as in the definition above, but also those quantities that affect the quantities actually measured. Also, in the GUM this concept is not restricted to direct *measurements* (3.1.46).

[SOURCE: ISO/IEC Guide 99:2007, 2.52, modified — EXAMPLES 1 and 3 have been removed.]

3.2.21
interfering quantity
interferent
quantity that is not the *measurand* (3.1.45) but that affects the result of the *measurement* (3.1.46)

EXAMPLE 1 Effect of bilirubin, haemoglobin, lipids or coloured drugs on certain colorimetric *measurement* (3.1.46) procedures.

EXAMPLE 2 Cross-reacting metabolites in an immunochemical *measurement procedure* (3.1.50). See *cross-reactivity* (3.2.14).

Note 1 to entry: An interfering quantity can be an influence quantity but is not limited to direct *measurements* (3.1.46). See also *analytical interference* (3.2.2).

Note 2 to entry: Derived in part from the definition of *influence quantity* (3.2.20).

3.2.22
intermediate measurement precision
intermediate precision
measurement precision under a set of conditions of *measurement* (3.1.46) that includes the same *measurement procedure* (3.1.50), same location and replicate *measurements* (3.1.46) on the same or similar objects over an extended period of time, but can include other conditions involving changes

Note 1 to entry: The conditions changed and unchanged should be specified to a practical extent, particularly variables such as *calibrations* (3.1.11), reagent lots, *measuring systems* (3.2.40), operators and environmental conditions.

Note 2 to entry: In evaluating *IVD medical devices* (3.1.33), the intermediate precision conditions are generally selected to represent the actual use conditions of the *IVD medical device* (3.1.33) over an extended period of time.

Note 3 to entry: Relevant statistical terms are given in ISO 5725 3:1994.

Note 4 to entry: Intermediate precision can be expressed quantitatively in terms of the dispersion characteristics of the results, such as standard deviation, variance and coefficient of variation.

Note 5 to entry: Adapted from : ISO/IEC Guide 99:2007, 2.22 and 2.23.

3.2.23
likelihood ratio
likelihood that a given result would be expected in an individual with the target clinical condition or physiological state compared to the likelihood that the same result would be expected in an individual without that clinical condition or physiological state

[SOURCE: GHTF SG5/N7/2012, 7.2[45]]

3.2.24
linearity of a measuring system
linearity
ability (within a given interval) to provide results that are directly proportional to the concentration (or amount) of the *measurand* (3.1.45) in the *sample* (3.1.65)

Note 1 to entry: Linearity typically refers to overall system response (i.e. the final analytical answer rather than the raw instrument output).

Note 2 to entry: The linearity of a system is measured by testing levels of a *measurand* (3.1.45) that are known by formulation or known relative to each other (not necessarily known absolutely).

Note 3 to entry: For some applications, users may choose to verify linearity using a linear equation that includes a term for the y-intercept. In this less restrictive case, linearity is the ability of a testing system to provide results that conform to a straight line of the form Y = AX + B within a given interval. Additional information (e.g., from a comparison study or calibration verification) should be provided to check whether the term for the y-intercept is close to zero.

Note 4 to entry: Nonlinearity is a contributor to systematic measurement bias. There is no single statistic that can represent an acceptable degree of nonlinearity.

[SOURCE: CLSI document EP06-Ed2, 1.4.2,[36] modified — "test" deleted, Note 4 to entry has been added.]

3.2.25
material measure
measuring instrument reproducing or supplying, in a permanent manner during its use, quantities of one or more given kinds, each with an assigned value

EXAMPLE Certified *reference material* (3.1.71), standard weight, volume measure (supplying one or several quantity values, with or without a quantity value scale).

Note 1 to entry: The indication of a material measure is its assigned value.

Note 2 to entry: Adapted from ISO/IEC Guide 99:2007, 3.6.

3.2.26
measured quantity value
measured value
quantity value representing a *measurement result* (3.1.51)

Note 1 to entry: For a *measurement* (3.1.46) involving replicate *measurement* (3.1.46) indications, each indication can be used to provide a corresponding measured quantity value. This set of individual measured quantity values can be used to calculate a resulting measured quantity value, such as an average or median, usually with a decreased associated *measurement uncertainty* (3.2.38).

Note 2 to entry: When the range of the true quantity values believed to represent the *measurand* (3.1.45) is small compared with the *measurement uncertainty* (3.2.38), a measured quantity value can be considered to be an estimate of an essentially unique true quantity value and is often an average or median of individual measured quantity values obtained through replicate *measurements* (3.1.46).

Note 3 to entry: In the case where the range of the true quantity values believed to represent the *measurand* (3.1.45) is not small compared with the *measurement uncertainty* (3.2.38), a measured value is often an estimate of an average or median of the set of true quantity values.

Note 4 to entry: In the GUM (withdrawn ISO/IEC Guide 98, replaced by ISO/IEC Guide 98-3:2008), the terms "*measurement result* (3.1.51)", "estimate of the value of the measurand" or just "estimate of the measurand" are used for "measured quantity value"; in laboratory medicine, the term "*measurement result* (3.1.51)" or just "result" is generally used.

[SOURCE: ISO/IEC Guide 99:2007, 2.10, modified — term "value of a measured quantity" was deleted.]

3.2.27
measurement accuracy
accuracy
closeness of agreement between a measured quantity value and a true quantity value of the *measurand* (3.1.45)

Note 1 to entry: The concept "measurement accuracy" is not a quantity and is not given a numerical quantity value. A *measurement* (3.1.46) is said to be more accurate when it offers a smaller *measurement error* (3.2.30).

Note 2 to entry: The term "measurement accuracy" should not be used for *measurement trueness* (3.2.37) and the term "*measurement precision*" (3.2.32) should not be used for measurement accuracy, which, however, is related to both these concepts.

Note 3 to entry: Measurement accuracy is sometimes understood as closeness of agreement between measured quantity values that are being attributed to a *measurand* (3.1.45).

Note 4 to entry: Adapted from ISO/IEC Guide 99:2007, 2.13.

3.2.28
measurement bias
bias
estimate of a *systematic measurement error* (3.2.59)

Note 1 to entry: Bias is inversely related to trueness.

Note 2 to entry: An estimation of bias is the average value of a series of measurements minus a reference *quantity value* (3.2.52).

[SOURCE: ISO/IEC Guide 99:2007, 2.18, modified — Notes to entry 1 and 2 have been added.]

3.2.29
measurement correction
compensation for an estimated systematic effect

Note 1 to entry: See ISO/IEC Guide 98 3:2008, 3.2.3, for an explanation of systematic effect.

Note 2 to entry: The compensation can take different forms, such as an addend or a factor, or can be deduced from a table.

[SOURCE: ISO/IEC Guide 99:2007, 2.53, modifed — Added measurement to term; different to source.]

3.2.30
measurement error
measured *quantity value* (3.2.52) minus a reference *quantity value* (3.2.52)

Note 1 to entry: The error concept can be used both

— when there is a single reference *quantity value* (3.2.52) to refer to, which occurs if a *calibration* (3.1.11) is made by means of a *measurement standard* (3.2.36) with a measured quantity value having a negligible measurement uncertainty or if a *conventional quantity value* (3.2.13) is given, in which case the measurement error is known and;

— if a *measurand* (3.1.45) is supposed to be represented by a unique true quantity value or a set of true *quantity values* (3.2.52) of negligible range, in which case the measurement error is not known.

Note 2 to entry: Measurement error should not be confused with production error or mistake.

Note 3 to entry: The sign of the difference shall be noted.

[SOURCE: ISO/IEC Guide 99:2007, 2.16, modified — Terms have been removed and Note 3 to entry has been added.]

3.2.31
measurement indication
indication
quantity value (3.2.52) provided by a measuring instrument or a *measuring system* (3.2.40)

Note 1 to entry: A measurement indication can be presented in visual or acoustic form or can be transferred to another device. A measurement indication is often given by the position on the display for analogue outputs, a displayed or printed number for digital outputs, a code pattern for code outputs, or an assigned *quantity value* (3.2.52) for material measures.

Note 2 to entry: A measurement indication and a corresponding value of the *quantity* (3.2.51) being measured are not necessarily values of quantities of the same kind.

Note 3 to entry: The value read from an instrument display is called the direct indication; it can be multiplied by an instrument constant to give the measurement indication.

Note 4 to entry: The *quantity* (3.2.51) can be the *measurand* (3.1.45), a *measurement signal* (3.2.35) or another *quantity* (3.2.51) to be used in calculating the *measurement result* (3.1.51).

[SOURCE: ISO/IEC Guide 99:2007, 4.1, modified — Term "measurement indication" has been added, Notes 3 and 4 to entry have been added.]

3.2.32
measurement precision
precision
closeness of agreement between *measurement indications* (3.2.31) or measured *quantity value* (3.2.52) obtained by replicate *measurements* (3.1.46) on the same or similar objects under specified conditions

Note 1 to entry: Measurement precision is usually expressed numerically by measures of imprecision, such as standard deviation, variance or coefficient of variation under the specified conditions of *measurement* (3.1.46).

Note 2 to entry: The specified conditions can be, for example, repeatability conditions of *measurement* (3.1.46), intermediate precision conditions of measurement, or reproducibility conditions of *measurement* (3.1.46) (see ISO 5725 5:1998).

Note 3 to entry: Measurement precision is used to define *measurement repeatability* (3.2.33), intermediate measurement precision, and *measurement reproducibility* (3.2.34).

Note 4 to entry: Replicate *measurements* (3.1.46) means *measurements* (3.1.46) that are obtained in a manner not influenced by a previous *measurement* (3.1.46) on the same or similar sample.

[SOURCE: ISO/IEC Guide 99:2007, 2.15, modified — Note 4 to entry has been modified.]

3.2.33
measurement repeatability
repeatability
measurement precision (3.2.32) under a set of conditions of *measurement* (3.1.46) that includes the same *measurement procedure* (3.1.50), same operators, same *measuring system* (3.2.40), same operating conditions and same location, and replicate *measurements* (3.1.46) on the same or similar objects over a short period of time

Note 1 to entry: In clinical chemistry, the term within-run precision or intra-series precision is sometimes used to designate this concept.

Note 2 to entry: In evaluating an *IVD medical device* (3.1.32), repeatability conditions are generally selected to represent essentially unchanged conditions (called repeatability conditions) resulting in the minimum variability of *measurement results* (3.1.51). Repeatability information can be useful for troubleshooting purposes.

Note 3 to entry: Repeatability can be expressed quantitatively in terms of the dispersion characteristics of the results, such as repeatability standard deviation, repeatability variance and repeatability coefficient of variation. Relevant statistical terms are given in ISO 5725 2:2019.

Note 4 to entry: Adapted from : ISO/IEC Guide 99:2007, 2.20 and 2.21.

3.2.34
measurement reproducibility
reproducibility
measurement precision (3.2.32) under conditions of *measurement* (3.1.46) that include different locations, operators, *measuring systems* (3.2.40), and replicate *measurements* (3.1.45) on the same or similar objects

Note 1 to entry: In clinical chemistry, the term laboratory-to-laboratory precision is sometimes used to designate this concept.

Note 2 to entry: In evaluating an *IVD medical device* (3.1.32), reproducibility conditions are generally selected to represent maximally changed conditions (called reproducibility conditions) resulting in the variability of *measurement results* (3.1.51) that would be encountered when comparing results among independent laboratories, such as would occur in inter-laboratory comparison programmes (e.g. proficiency testing, external quality assurance or laboratory standardization trials).

Note 3 to entry: Reproducibility can be expressed quantitatively in terms of the dispersion characteristics of the results, such as reproducibility standard deviation, reproducibility variance and reproducibility coefficient of variation. Relevant statistical terms are given in ISO 5725 2:2019.

Note 4 to entry: The different *measuring systems* (3.2.40) can use different *measurement procedures* (3.1.50).

Note 5 to entry: A specification should give the conditions changed and unchanged, to the extent practical.

Note 6 to entry: Adapted from ISO/IEC Guide 99:2007, 2.24 and 2.25.

3.2.35
measurement signal
signal
quantity that represents the *measurand* (3.1.45) and which is functionally related to it

Note 1 to entry: A measurement signal can be a *measurement indication* (3.2.31).

Note 2 to entry: See ISO Guide 30:2015.

3.2.36
measurement standard
realization of the definition of a given *quantity* (3.2.51), with stated *quantity value* (3.2.52) and associated *measurement uncertainty* (3.2.38), used as a reference

EXAMPLE 1 1 kg mass measurement standard with an associated standard measurement uncertainty (A.3.38) of 3 µg.

EXAMPLE 2 Hydrogen reference electrode with an assigned *quantity value* (3.2.52) of 7,072 and an associated standard *measurement uncertainty* (3.2.38) of 0,006.

EXAMPLE 3 Set of reference solutions of cortisol in human serum having a certified *quantity value* (3.2.52) with *measurement uncertainty* (3.2.38) for each solution.

EXAMPLE 4 Reference material (3.1.70) providing *quantity values* (3.2.52) with *measurement uncertainties* (3.2.38) for the mass concentration of each of 10 different proteins.

Note 1 to entry: A measurement standard is frequently used as a reference in establishing measured *quantity values* (3.2.52) and associated *measurement uncertainties* (3.2.38) for other *quantities* (3.2.51) of the same kind, thereby establishing metrological traceability through *calibration* (3.1.10) of other measurement standards, measuring instruments or *measuring systems* (3.2.40).

Note 2 to entry: A realization of the definition of a given *quantity* (3.2.51) can be provided by a *measuring system* (3.2.40), a material measure, or a *reference material* (3.1.70).

Note 3 to entry: The term realization is used here in the most general meaning. It denotes three procedures of realization. The first one consists in the physical realization of the *measurement* (3.1.46) unit from its definition and is realization *sensu* stricto. The second, termed reproduction, consists not in realizing the *measurement* (3.1.46) unit from its definition but in setting up a highly reproducible measurement standard based on a physical phenomenon. The third procedure consists of adopting a material measure as a measurement standard, such as in the case of the measurement standard of 1 kg.

Note 4 to entry: The word embodiment is sometimes used in the English language instead of realization.

Note 5 to entry: The hierarchy of measurement standards includes primary measurement standards – whose quantity values and *measurement uncertainties* (3.2.38) are established using primary *measurement procedures* (3.1.50) or created as an artefact, chosen by convention, and secondary measurement standards – whose quantity values and *measurement uncertainties* (3.2.38) are assigned through calibration with respect to a primary measurement standard for a quantity of the same kind. The relation can be obtained directly between a primary measurement standard and a secondary measurement standard, or involve an intermediate measuring system calibrated by the primary measurement standard and assigning a *measurement result* (3.1.51) to the secondary measurement standard. See ISO/IEC Guide 99:2007, 5.4 and 5.5.

EXAMPLE 5 Primary measurement standard of amount-of-substance concentration prepared by dissolving a known amount of substance of a chemical component to a known volume of solution.

Note 6 to entry: A measurement standard recognized by signatories to an international agreement and intended to serve worldwide is called an international measurement standard, such as “chorionic gonadotropin, World Health Organization (WHO) 4th International Standard 1999, 75/589, 650 International Units per ampoule”. A measurement standard recognized by a national authority to serve in the country is called a national measurement standard (see ISO/IEC Guide 99:2007, 5.2).

Note 7 to entry: A measurement standard designated for the *calibration* (3.1.10) of working measurement standards for *quantities* (3.2.51) of a given kind in a given organization or at a given location is called a reference measurement standard (see ISO/IEC Guide 99:2007, 5.6). A measurement standard that is used routinely to calibrate or verify measuring instruments or *measuring systems* (3.2.40) is called a working measurement standard (see ISO/IEC Guide 99:2007, 5.7.). A working measurement standard is usually calibrated with respect to a reference measurement standard.

Note 8 to entry: A standard *measurement uncertainty* (3.2.38) associated with a measurement standard is always a component of the combined standard *measurement uncertainty* (3.2.38) (see ISO/IEC Guide 98 3:2008, 2.3.4) in a *measurement result* (3.1.51) obtained using the measurement standard. Frequently, this component is small compared with other components of the combined standard *measurement uncertainty* (3.2.38).

Note 9 to entry: *Quantity value* (3.2.52) and *measurement uncertainty* (3.2.38) shall be determined at the time when the measurement standard is used.

[SOURCE: ISO/IEC Guide 99:2007, 5.1, modifed — The term "etalon" has been removed and Examples and Notes to entry have been modified.]

3.2.37
measurement trueness
trueness
closeness of agreement between the average of an infinite number of replicate measured *quantity values* (3.2.52) and a reference *quantity value* (3.2.52)

Note 1 to entry: Measurement trueness is not a quantity and thus cannot be expressed numerically, but measures for closeness of agreement are given in ISO 5725 3:1994.

Note 2 to entry: Measurement trueness is inversely related to *systematic measurement error* (3.2.59), but is not related to *random measurement error* (3.2.53).

Note 3 to entry: The term *measurement accuracy* (3.2.27) should not be used for measurement trueness and vice versa.

[SOURCE: ISO/IEC Guide 99:2007, 2.14, modified — The term "trueness of measurement" has been replaced by "trueness", and within Note 3 to entry "and vice versa" has been added.]

3.2.38
measurement uncertainty
uncertainty of measurement
non-negative parameter characterizing the dispersion of the *quantity values* (3.2.52) being attributed to a *measurand* (3.1.45), based on the information used

Note 1 to entry: Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned *quantity values* (3.2.52) of *measurement standards* (3.2.36), as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but instead associated measurement uncertainty components are incorporated.

Note 2 to entry: The parameter cannot be negative. The parameter might be, for example, a standard deviation called standard *measurement uncertainty* (3.2.38) (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

Note 3 to entry: The standard *measurement uncertainty* (3.2.38) that is obtained from the *measurement results* (3.1.51) of the input *quantities* (3.2.51) in a *measurement model* (3.1.48) is called combined standard *measurement uncertainty* (3.2.38). The product of a combined standard *measurement uncertainty* (3.2.38) and a coverage factor larger than the number one is called the expanded measurement uncertainty in ISO/IEC Guide 99:2007, 2.35, overall uncertainty by the BIPM Working Group on the Statement of Uncertainties, and simply uncertainty in IEC documents.

Note 4 to entry: The minimum measurement uncertainty (resulting from the finite amount of detail in the definition of a measurand is called "definitional uncertainty" in ISO/IEC Guide 99:2007, 2.27. In the GUM (withdrawn ISO/IEC Guide 98, replaced by ISO/IEC Guide 98-3:2008) and in IEC 60359:2001, the concept is called intrinsic uncertainty.

Note 5 to entry: Measurement uncertainty comprises, in general, many components. Some of these can be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components, which can be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information (see ISO/IEC Guide 99:2007, 2.26, Note 3).

Note 6 to entry: The statement of a measurement uncertainty, of the components of that measurement uncertainty, and of their calculation and combination is called an uncertainty budget. An uncertainty budget typically includes the measurement model, estimates and measurement uncertainties of the quantities in the measurement model, covariances, type of applied probability density functions, degrees of freedom, type of evaluation of measurement uncertainty, and any coverage factor (see ISO/IEC Guide 99:2007, 2.33).

Note 7 to entry: In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated *quantity value* (3.2.52) attributed to the *measurand* (3.1.45). A modification of this value results in a modification of the associated uncertainty.

[SOURCE: ISO/IEC Guide 99:2007, 2.26, modified — The sentence 'The parameter cannot be negative." was added to Note 2 to entry, and Notes to entry 3, 4 and 6 have been added.]

3.2.39
measurement unit
unit of measure
real scalar quantity, defined and adopted by convention, with which any other *quantity* (3.2.51) of the same kind can be compared to express the ratio of the two quantities as a number

Note 1 to entry: Measurement units are designated by conventionally assigned names and symbols.

Note 2 to entry: For a given *quantity* (3.2.51), the short-term unit is often combined with the *quantity* (3.2.51) name, such as mass unit or unit of mass.

Note 3 to entry: Measurement units of quantities of dimension are numbers. In some cases, these measurement units are given special names, e.g. radian, steradian and decibel, or are expressed by quotients such as millimole per mole equal to 10−3 and microgram per kilogram equal to 10−9.

[SOURCE: ISO/IEC Guide 99:2007, 1.9, modified — Variant "unit" removed, Note 2 to entry was removed and replaced by a new Note 2 to entry, Note 3 to entry was amended and Note 4 to entry was removed.]

3.2.40
measuring system
set of one or more measuring instruments and often other devices, including any reagent and supply, assembled and adapted to give measured *quantity value* (3.2.52) within specified intervals for quantities of specified kinds

Note 1 to entry: A measuring system can consist of only one device used for making *measurements* (3.1.45), which can either be an indicating measuring instrument or a material measure, and which can be used alone or in conjunction with supplementary devices (see ISO/IEC Guide 99:2007, 3.1).

Note 2 to entry: Adapted from ISO/IEC Guide 99:2007, 3.2.

3.2.41
metrological comparability of measurement results
comparability of *measurement results* (3.1.51), for quantities of a given kind, that are metrologically traceable to the same reference

EXAMPLE *Measurement results* (3.1.51) from two different commercial clinical chemistry *measuring systems* (3.2.40) are comparable when they are both metrologically traceable to the same primary reference standard, for example, a Certified Reference Material for the mass concentration of glucose.

Note 1 to entry: For this definition, a reference can be a definition of a *measurement* (3.1.46) unit through its practical realization, or a *measurement procedure* (3.1.50) including the *measurement* (3.1.46) unit for a non-ordinal quantity, or a *measurement standard* (3.2.36).

Note 2 to entry: Metrological comparability of *measurement results* (3.1.51) does not necessitate that the measured *quantity values* (3.2.52) and associated *measurement uncertainties* (3.2.38) compared are of the same order of magnitude.

[SOURCE: ISO/IEC Guide 99:2007, 2.46, modified — EXAMPLE and Note 1 to entry were deleted and replaced by new EXAMPLE and Note 1 to entry.]

3.2.42
metrological compatibility of measurement results
property of a set of *measurement results* (3.1.51) for a specified *measurand* (3.1.45), such that the absolute value of the difference of any pair of measured *quantity values* (3.2.52) from two different *measurement results* (3.1.51) is smaller than some chosen multiple of the *standard measurement uncertainty* (3.2.58) of that difference

Note 1 to entry: Metrological compatibility of measurement results replaces the traditional concept of staying within the error, as it represents the criterion for deciding whether two *measurement results* (3.1.51) refer to the same *measurand* (3.1.45) or not. If in a set of *measurements* (3.1.46) of a *measurand* (3.1.54), thought to be constant, a *measurement result* (3.1.51) is not compatible with the others, either the *measurement* (3.1.46) was not correct (e.g. its *measurement uncertainty* (3.2.38) was assessed as being too small) or the measured *quantity* (3.2.51) changed between *measurements* (3.1.46).

Note 2 to entry: Correlation between the *measurements* (3.1.46) influences metrological compatibility of measurement results. If the *measurements* (3.1.46) are completely uncorrelated, the *standard measurement uncertainty* (3.2.58) of their difference is equal to the root mean square sum of their *standard measurement uncertainties* (3.2.58), while it is lower for positive covariance or higher for negative covariance.

[SOURCE: ISO/IEC Guide 99:2007, 2.47]

3.2.43
nominal property
property of a phenomenon, body or substance, where the property has no magnitude

EXAMPLE

— colour of a spot test in chemistry;

— sequence of amino acids in a polypeptide.

Note 1 to entry: A nominal property has a value, which can be expressed in words, by alpha-numerical codes, or by other means.

Note 2 to entry: Nominal property value is not to be confused with *nominal quantity value* (3.2.44).

Note 3 to entry: Examinations that identify nominal properties are called *qualitative examinations* (3.2.48) in laboratory medicine.

[SOURCE: ISO/IEC Guide 99:2007, 1.30, modified — EXAMPLES 1, 2 and 4 were removed, Note 3 to entry was added.]

3.2.44
nominal quantity value
nominal value
rounded or approximate value of a characterizing quantity of a measuring instrument or *measuring system* (3.2.40) that provides guidance for its appropriate use

EXAMPLE

— 0,1 mol/l as the nominal quantity value for amount-of-substance concentration of a solution of hydrogen chloride, HCl.

— 1 000 ml as the nominal quantity value marked on a single-mark volumetric flask.

— –20 °C as a maximum temperature for storage.

Note 1 to entry: Nominal quantity value and nominal value are not to be confused with *nominal property value* (3.2.43, Note 1 to entry).

[SOURCE: ISO/IEC Guide 99:2007, 4.6, modified — EXAMPLE 3 was removed, and Note 1 to entry was changed.]

3.2.45
predictive value
probability that a person with a positive examination result has a given condition under investigation, or that a person with a negative *examination* (3.1.21) result does not have a given condition

Note 1 to entry: In screening *examinations* (3.1.21), the predictive value is determined by the *diagnostic sensitivity* (3.2.17) and *diagnostic specificity* (3.2.18) of the *examination* (3.1.21) procedure, and by the prevalence of the condition for which the *examination* (3.1.21) is used.

Note 2 to entry: Prevalence means frequency of a condition of interest expressed as a percentage (number fraction multiplied by 100) of the total number of individuals (those with the target condition plus those without the target condition) in the population under study.

Note 3 to entry: The predictive value of positive *examination* (3.1.21) results [PV(+)] indicates how effectively an examination separates true positive *examination* (3.1.21) results from false positive *examination* (3.1.21) results for a given *target condition* (3.2.60) in a given population.

Note 4 to entry: The predictive value of negative *examination* (3.1.21) results [PV(–)] indicates how effectively an *examination* (3.1.21) separates true negative *examination* (3.1.21) results from false negative *examination* (3.1.21) results for a given *target condition* (3.2.60) in a given population.

3.2.46
positive predictive value
ability of a device to separate true positive results from false-positive results for a given attribute in a given population

[SOURCE: GHTF SG5/N7/2012,[45] 7.2]

3.2.47
negative predictive value
ability of a device to separate true negative results from false-negative results for a given attribute in a given population

[SOURCE: GHTF SG5/N7/2012,[45] 7.2]

3.2.48
qualitative examination
set of operations in which substances are identified or classified on the basis of their chemical or physical properties

EXAMPLE Chemical reactivity, solubility, molecular weight, melting point, radiative properties (emission, absorption), mass spectra, nuclear half-life.

Note 1 to entry: Adapted from Reference [67].

3.2.49
quantitation limit
limit of quantitation
lowest value of *measurand* (3.1.45) in a *sample* (3.1.76) which can be measured with specified *measurement uncertainty* (3.2.38), under stated *measurement* (3.1.46) conditions

Note 1 to entry: In IVD labelling, sometimes referred to as lower limit of determination, lower limit of quantitation, or lower limit of measurement. See A.2.8 for guidelines.

Note 2 to entry: The use of the term “functional sensitivity” to represent this concept is discouraged. See A.2.8 for further information.

Note 3 to entry: Adapted from References [35] and [49].

3.2.50
quantitative examination
set of operations in which the amount or concentration of an *analyte* (3.1.4) is measured and expressed as a numerical quantity value in appropriate *measurement* (3.1.46) units

Note 1 to entry: *Qualitative examination* (3.2.48) can take place without quantitative examination, but quantitative examination requires the identification of the *analytes* (3.1.4) for which numerical values are given.

Note 2 to entry: Adapted from Reference [67].

3.2.51
quantity
property of a phenomenon, body or substance, where the property has a magnitude that can be expressed as a number and a reference

Note 1 to entry: The generic concept quantity can be divided into several levels of specific concepts, as shown in the following table. The left-hand column of the table shows specific concepts under 'quantity'. These are generic concepts for the individual quantities in the right-hand column.

EXAMPLE 1

Example of quantity in a general sense	Example of particular quantity
amount-of-substance concentration of entity B, C_B	amount-of-substance concentration of ethanol in wine sample *i*, $c(C_2H_5OH)$
number concentration of entity B, C_B	number concentration of erythrocytes in blood sample *i*, C (Erys; B_i)

Note 2 to entry: A reference can be a measurement unit, a *measurement procedure* (3.1.50), a *reference material* (3.1.70), or a combination of such.

Note 3 to entry: Symbols for quantities are given in the ISO 80000 and IEC 80000 series, Quantities and units.[22] The symbols for quantities are written in italics. A given symbol can indicate different quantities.

Note 4 to entry: The preferred IUPAC-IFCC format for designations of quantities in laboratory medicine is System — Component; quantity.

EXAMPLE 2 Plasma (blood) - Sodium ion; amount of substance concentration equal to 143 mmol/l in a given person at a given time.

Note 5 to entry: The concept *quantity* (3.2.51) can be generically divided into, e.g. physical *quantity* (3.2.51), chemical *quantity* (3.2.51) and biological *quantity* (3.2.51), or base *quantity* (3.2.51) and derived *quantity* (3.2.51).

Note 6 to entry: The division of the concept of *quantity* (3.2.51) according to kind-of- *quantity* (3.2.51) is to some extent arbitrary. In English, the term quantity is often used for kind-of- *quantity* (3.2.51) (i.e. an aspect common to mutually comparable *quantities* (see ISO/IEC Guide 99:2007, 1.2).

[SOURCE: ISO/IEC Guide 99:2007, 1.1, modified — Table in source was removed and replaced by a new table in EXAMPLE 1, Note 5 to entry was removed and Note 6 to entry was added.]

3.2.52
quantity value
value
number and reference together expressing magnitude of a *quantity* (3.2.51)

EXAMPLE 1 Mass of a given body: 0,152 kg or 152 g.

EXAMPLE 2 Mass fraction of beta globulins in a given sample of serum: 0,100 g/g or 0,100.

EXAMPLE 3 Molality of glucose in a given sample of blood: 5,50 mmol/kg.

EXAMPLE 4 Arbitrary amount-of-substance concentration of luteinizing hormone in a given sample of plasma (WHO international standard 80/552[53]): 5.0 International Unit/l.

EXAMPLE 5 Time for a blood sample to clot in a WHO-standardized *measurement procedure* (3.1.50), expressed relative to a normal population average: INR 2.2.

Note 1 to entry: According to the type of reference, a quantity value is either

— a product of a number and a measurement unit (see Examples 1, 2, 3 and 4); the measurement unit one is generally not indicated for quantities of dimension one (see Example 3), or

— a number and a reference material (see Example 5), or

— a number and a reference to a *measurement procedure* (3.1.50)(see Example 6).

Note 2 to entry: The number can be complex.

Note 3 to entry: A quantity value can be presented in more than one way.

[SOURCE: ISO/IEC Guide 99:2007, 1.19, modified — The term "value of a quantity value" was replaced by "value", EXAMPLES were modified, Note 4 to entry was removed.]

3.2.53
random measurement error
random error
component of *measurement error* (3.2.30) that in replicate *measurements* (3.1.45) varies in an unpredictable manner

Note 1 to entry: A reference *quantity value* (3.2.52) for a random measurement error is the average that would ensue from an infinite number of replicate measurements of the same measurand.

Note 2 to entry: Random measurement errors of a set of replicate *measurements* (3.1.45) form a distribution that can be summarized by its expectation, which is generally assumed to be zero, and its variance.

Note 3 to entry: Random measurement error equals *measurement error* (3.2.30) minus *systematic measurement error* (3.2.59).

[SOURCE: ISO/IEC Guide 99:2007, 2.19, modified — The term "random error of measurement" was removed.]

3.2.54
recovery
proportion of the amount of *analyte* (3.1.4) present in or added to a *sample* (3.1.76), which is found by *measurement* (3.1.45)

Note 1 to entry: Typically reported as a percentage of the amount of *analyte* (3.1.4) added.

3.2.55
reference quantity value
reference value
quantity value (3.2.52) used as a basis for comparison with values of *quantities* (3.2.51) of the same kind

Note 1 to entry: A reference quantity value can be a true *quantity value* (3.2.52) of a *measurand* (3.1.45), in which case it is unknown, or a *conventional quantity value* (3.2.13), in which case it is known.

Note 2 to entry: A reference quantity value with associated *measurement uncertainty* (3.2.38) is usually provided with reference to a

a) material, e.g. a certified reference material;

b) device, e.g. a stabilized laser;

c) reference measurement procedure (3.1.71);

d) comparison of *measurement standards* (3.2.36).

[SOURCE: ISO/IEC Guide 99:2007, 5.18]

3.2.56
resolution of a measuring system
smallest change in a *quantity* (3.2.51) being measured which causes a perceptible change in the corresponding *measurement indication* (3.2.31)

Note 1 to entry: The resolution can depend on, for example, noise (internal or external) or friction. It can also depend on the value of the *quantity* (3.2.51) being measured.

[SOURCE: ISO/IEC Guide 99:2007, 4.14, modified — Term changed from "resolution" to "resolution of a measuring system", the word "that" was replaced by "which" and "indication" was replaced by "measurement indication".]

3.2.57
standard deviation
positive square root of the variance

Note 1 to entry: Can be expressed as a coefficient of variation (CV), which is calculated as 100 times the standard deviation divided by the mean and expressed as a percentage.

Note 2 to entry: The predecessor term relative standard deviation is deprecated by the term coefficient of variation.

[SOURCE: ISO 3534 1:2006, 2.37]

3.2.58
standard measurement uncertainty
measurement uncertainty (3.2.38) expressed as a standard deviation

[SOURCE: ISO/IEC Guide 99:2007, 2.30]

3.2.59
systematic measurement error
systematic error
component of *measurement error* (3.2.30) that in replicate *measurements* (3.1.45) remains constant or varies in a predictable manner

Note 1 to entry: A *reference quantity value* (3.2.55) for a systematic measurement error is a *true quantity value* (3.2.62), or a *measured quantity value* (3.2.26) of a *measurement standard* (3.2.36) of negligible *measurement uncertainty* (3.2.38), or a *conventional quantity value* (3.2.13).

Note 2 to entry: Systematic measurement error, and its causes, can be known or unknown. A correction can be applied to compensate for a known systematic measurement error.

Note 3 to entry: Systematic measurement error equals *measurement error* (3.2.30) minus *random measurement error* (3.2.53).

Note 4 to entry: For an estimation of the systematic error of a measuring instrument see the definition of *measurement bias* (3.2.28).

Note 5 to entry: Adapted from : ISO/IEC Guide 99:2007, 2.18.

3.2.60
target condition
condition of interest
particular disease, disease stage, health status or other identifiable condition, event or characteristic of a patient, including staging a disease already known to be present, or a health condition that should prompt the initiation, modification or termination of treatment or other clinical action

Note 1 to entry: A particular *measurand* (3.1.45) can serve as a target marker associated with the target condition. For further discussion of these concepts, refer to the STARD statement[60],[61].

Note 2 to entry: Adapted from Reference [35].

3.2.61
target measurement uncertainty
measurement uncertainty (3.2.38) specified as an upper limit and decided on the basis of the intended use of *measurement results* (3.1.51)

Note 1 to entry: The system accuracy performance criteria in ISO 15197:2013 and ISO 17593:2007 are based on this concept.

Note 2 to entry: In laboratory medicine, target measurement uncertainty has been called total allowable analytical error.

[SOURCE: ISO/IEC Guide 99:2007, 2.34, modified — Variant term was deleted, Notes to entry 1 and 2 added.]

3.2.62
true quantity value
true value
quantity value (3.2.52) consistent with the definition of a *quantity* (3.2.51)

Note 1 to entry: In the Error approach to describing *measurement* (3.1.46), a true quantity value is considered unique and, in practice, unknowable. The Uncertainty approach is to recognize that, owing to the inherently incomplete amount of detail in the definition of a *quantity* (3.2.51), there is not a single true quantity value but rather a set of true quantity values consistent with the definition. However, this set of values is, in principle and in practice, unknowable. Other approaches dispense altogether with the concept of true quantity value and rely on the concept of metrological compatibility of *measurement results* (3.1.51) for assessing their validity.

Note 2 to entry: In the special case of a fundamental constant, the *quantity* (3.2.51) is considered to have a single true quantity value.

Note 3 to entry: When the definitional uncertainty of the *measurand* (3.1.45) is considered to be negligible with respect to the other components of the *measurement uncertainty* (3.2.38), the *measurand* (3.1.45) can be considered to have an essentially unique true quantity value. This is the approach taken by the GUM (withdrawn ISO/IEC Guide 98, replaced by ISO/IEC Guide 98-3:2008) and associated documents, where the word true is considered to be redundant.

Note 4 to entry: The indefinite article "a" rather than the definite article "the" is used in conjunction with true value because there can be many values consistent with the definition of a given particular *quantity* (3.2.51).

Note 5 to entry: See also *conventional quantity value* (3.2.13).

[SOURCE: ISO/IEC Guide 99:2007, 2.11, modified — Term "true value of a quantity" was deleted and Notes to entry 4 and 5 were added.]

4 General requirements for information supplied by the manufacturer

4.1 General

4.1.1 The format, content, location, and accessibility of information supplied by the manufacturer shall be appropriate to the particular device, its intended purpose, and the education or training of the intended users. In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Suitability of the information supplied by the manufacturer is assessed as part of the design validation.

NOTE Some IVD medical devices can include separate information for the professional and the lay person.

4.1.2 Information on labels and in the instructions for use shall be legible for the intended lifetime of the device, accessory, kit, or component. Legibility of the information on labels and in the instructions for use is assessed as part of the design verification.

NOTE Legibility depends on, e.g quality of print, font type, point size.

4.1.3 Information supplied by the manufacturer should include a statement or symbol that indicates the need for the user to carefully read the instructions for use before attempting to use the device.

NOTE This is a requirement in Japan.

4.1.4 Where this document, ISO 18113-2, ISO 18113-3, ISO 18113-4 and/or ISO 18113-5 state a requirement, the requirement applies unless the manufacturer justifies and documents that the requirement is not appropriate to the IVD medical device. The justification may be based on risk analysis, human factors evaluation, technical assessment or documentation that the requirement does not apply.

4.1.5 Labelling shall be subject to document (version) control principles.

4.1.6 The labelling shall not contain any language regarding the manufacturer's liability in the case of damage or injury resulting from any use or malfunction of the medical device or IVD medical device that contradicts the laws or regulations in the jurisdiction of use.

4.1.7 The labelling shall not contain any disclaimers related to the safety and performance of the medical device or IVD medical device for its intended purpose that are incompatible with the laws or regulations in the jurisdiction of use, or the obligations of the manufacturer to design and manufacture a product that is safe and performs as intended throughout its expected lifetime.

4.2 Language

4.2.1 The information supplied by the manufacturer shall be written in the language(s) required by the countries in which the IVD medical device is distributed.

4.2.2 The device name and the manufacturer's name and address are not required to be expressed in multiple languages.

4.3 Symbols and identification colours

4.3.1 Graphical symbols shall be used, where appropriate.

4.3.2 Symbols and identification colours shall conform to International Standards when available. When using symbols, the requirements of ISO 15223-1 apply.

4.3.3 When no standard exists, or if there is a possibility that a symbol will not be understood by the intended user, the symbols and identification colours shall be described in the information supplied by the manufacturer.

4.4 Values and nomenclature

4.4.1 Numerical values shall be provided in units generally recognized by the intended users, and should take into account ISO 80000-1:2009.

EXAMPLES Values representing concentrations, contents, volumes, results, reference intervals, environmental parameters.

4.4.2 Examination procedures and analytes shall be named using terms generally recognized by the intended users, preferably according to internationally recognized sources.

4.5 Microbiological state

The microbiological state shall be specified, where appropriate.

EXAMPLE Sterile, microbiologically controlled.

4.6 Instructions for use

4.6.1 Instructions for use shall be provided unless the manufacturer shows by risk analysis that the IVD medical device can be used safely as intended without them. The requirements of ISO 14971 for performing a risk analysis apply.

NOTE National or regional regulations can require instructions for use for all IVD medical devices.

4.6.2 Instructions for use shall be written using terms likely to be understood by the intended users.

4.6.3 The order of information presented in the instructions for use shall be determined by the manufacturer, taking into account the intended user.

4.6.4 The date of issue or the latest revision of the instructions for use and an identifier shall be given or if they have been revised, date of issue, revision number and/or identification number of the latest revision of the instructions for use, with a clear indication of the introduced modifications.

4.6.5 The instructions for use may be on the outer container, in an operator's manual or combined with the instructions for use for a related instrument, reagent or system. If the instructions for use are not provided with the IVD medical device, it shall be clearly indicated where they can be found.

4.6.6 Instructions for use, either in paper or non-paper format, shall be supplied with the IVD medical device or be provided separately from the device by other means appropriate for the intended users. Any updates to the instructions for use need to be consistent across paper and electronic formats.

NOTE Requirements can vary by country or region.

4.6.7 The distribution of the instructions for use by other means shall be appropriate for the intended user. Other means of distribution may include the following:

a) service/sales/support organizations;

b) internet website;

c) an electronic databank;

d) coded format explained in a manual;

e) mobile application.

EXAMPLE Barcode.

4.6.8 If the instructions for use are not provided with the device in paper form, the manufacturer shall ensure that the user has the following:

a) instructions on how to obtain the information;

b) access to the correct version of the instructions for use;

c) as a minimum, information to cover safe handling and storage prior to use.