INTERNATIONAL STANDARD

ISO 11240

First edition
2012-11-01

Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement

Informatique de santé — Identification des médicaments — Éléments de données et structures pour l'identification unique et l'échange d'informations sur les unités de mesure

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Reference number
ISO 11240:2012(E)

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Published in Switzerland

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Contents

Page

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ISO 11240:2012
https://standards.iteh.ai/catalog/standards/sist/625a1edf-fcd5-4a79-bd1b-4dd11493ca19/iso-11240-2012

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11240 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

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Introduction

This International Standard was developed in response to a worldwide demand for internationally harmonized specifications for medicinal products. It is one of five standards which together provide the basis for the unique identification of medicinal products. The group of standards comprises:

ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*;

ISO 11616, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*;

ISO 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*;

ISO 11239, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*;

ISO 11240, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement*.

These standards for the Identification of Medicinal Products (IDMP) support the activities of medicines regulatory agencies worldwide by jurisdiction. These include a variety of regulatory activities related to development, registration and life cycle management of medicinal products, as well as pharmacovigilance and risk management.

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To meet the primary objectives of the regulation of medicines and pharmacovigilance, it is necessary to reliably exchange medicinal product information in a robust and reliable manner. The IDMP standards therefore support the following interactions (this is not an exhaustive list):

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— regulator to regulator;

— pharmaceutical company to regulator;

— sponsor of clinical trial to regulator;

— regulator to other stakeholder;

— regulator to worldwide-maintained data sources.

The necessary messaging specifications are included as an integral part of the IDMP standards to secure the interactions above.

Unique identifiers produced in conformance with the IDMP standards are aimed to support applications where it is necessary to reliably identify and trace the use of medicinal products.

There are many terms in use to describe basic concepts in the regulatory, pharmaceutical and healthcare standards development domain for different purposes and in different contexts. The terms and definitions given in this International Standard are to be applied for the concepts which are required to uniquely identify, characterize and exchange regulated medicinal products and associated information.

The terms and definitions adopted in this International Standard are intended to facilitate the interpretation and application of legal and regulatory requirements but they are without prejudice to any legally binding document. In case of doubt or potential conflict, the terms and definitions contained in legally binding documents prevail.

In the context of measurement terminology, currently there are several alternative approaches possible for expressing units of measurement that can be used in a given instance. For purposes of electronic data exchange, it is therefore necessary to promote and encourage the adoption of a single standardized vocabulary that can be used as an international reference for:

— unit concepts,

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— concept definitions, where applicable, and

— concept identifiers.

This standardized vocabulary also needs to provide standardized structures that describe the mapping from and to the reference vocabulary, taking into consideration the various approaches currently being applied. This helps to ensure that terms and identifiers currently used to represent units of measurement in the drug regulatory, pharmacovigilance and healthcare environments are mapped in a standardized and traceable way to the underlying metrological concepts, especially to the SI system of units. This will help ease implementation of this International Standard without impacting on the unit terms currently in use.

The purpose of this International Standard is twofold:

a) to address the issues outlined above by connecting to existing unit vocabularies in current use;

b) to facilitate electronic information exchange and interoperability that enables the unique and categorical identification of a medicinal product.

Results of measurements are essential for the identification of medicinal products. However, often different ways are used to express these results. The situation is further complicated by differences in the ways they are expressed in national legislation and in local administration. From the many available conventions, a consensus should therefore be reached on how to express the results of measurements on medicinal products, particularly for exchange between information systems. Standardized structures are required in order to capture and exchange the terms representing the coded concepts for purposes of displaying and printing the concept representations in various languages suitable for human readability.

Universal principles for the expression of measurements have been specified in the ISO 31, ISO 1000 and ISO 80000 series of standards, which implement the International System of Units (SI) defined by the General Conference on Weights and Measures. The implications of those standards are summarized in 4.2.

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Implementation of this International Standard will provide wider comprehension and interaction between countries and specialists in the field of medicinal product identification and pharmacovigilance.

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While the immediate scope is medicinal product identification, this International Standard was designed with a rather general view on units of measurement. Therefore, it is also potentially applicable in other contexts.

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Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of units of measurement

1 Scope

This International Standard:

— specifies rules for the usage and coded representation of units of measurement for the purpose of exchanging information about quantitative medicinal product characteristics that require units of measurement (e.g. strength) in the human medicine domain;

— establishes requirements for units in order to provide traceability to international metrological standards;

— provides rules for the standardized and machine-readable documentation of quantitative composition and strength of medicinal products, specifically in the context of medicinal product identification;

— defines the requirements for the representation of units of measurement in coded form;

— provides structures and rules for mapping between different unit vocabularies and language translations to support the implementation of this International Standard, taking into account that existing systems, dictionaries and repositories use a variety of terms and codes for the representation of units.

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The scope of this International Standard is limited to the representation of units of measurement for data interchange between computer applications.

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2 Normative references

The following referenced documents are indispensable for the application 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 639 (all parts), *Codes for the representation of names of languages*

ISO 3166 (all parts), *Codes for the representation of names of countries and their subdivisions*

ISO 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*

ISO 11239, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*

ISO 21090, *Health informatics — Harmonized data types for information interchange*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

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

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3.1.1
arbitrary unit
arbitrarily defined unit of measurement, where a relation of the unit to a physical unit of the SI does not exist or is unknown

NOTE Arbitrary units represent references to materials or procedures that are defined outside the SI system. A quantity value is arbitrarily assigned to the reference preparation or the result of a measurement procedure, usually specific for a particular substance. This generally precludes comparability of quantity values across different systems and components for this type of units.

3.1.2
base quantity
quantity in a conventionally chosen subset of a given system of quantities, where no subset quantity can be expressed in terms of the others

NOTE 1 A base quantity is used to define a base unit (e.g. Length, Time, Temperature).

NOTE 2 Adapted from ISO/IEC Guide 99.

3.1.3
base unit
measurement unit that is adopted by convention for a base quantity

NOTE 1 A set of base units defines a system of units.

EXAMPLE In the SI, the metre is the base unit of length.

NOTE 2 Adapted from ISO/IEC Guide 99.

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3.1.4
coherent derived unit
derived unit that, for a given system of quantities and for a chosen set of base units, is a product of powers of base units with no other proportionality factor than one

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NOTE Adapted from ISO/IEC Guide 99.

3.1.5
controlled vocabulary
controlled terminology
finite set of values that represent the only allowed values for a data item

NOTE 1 The allowed values can be codes, text, or numeric.

NOTE 2 Adapted from CDISC Clinical Research Glossary V8.0, 2009.

3.1.6
conversion factor between units
ratio of two measurement units for quantities of the same kind

NOTE Adapted from ISO/IEC Guide 99.

3.1.7
derived quantity
quantity, in a system of quantities, defined in terms of the base quantities of that system

NOTE Adapted from ISO/IEC Guide 99.

3.1.8
derived unit
measurement unit for a derived quantity

NOTE Adapted from ISO/IEC Guide 99.

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3.1.9
dimension of a quantity
quantity dimension
expression of the dependence of a quantity on the base quantities of a system of quantities as a product of powers of factors corresponding to the base quantities, omitting any numerical factor

NOTE Adapted from ISO/IEC Guide 99.

3.1.10
dimensionless quantity
quantity of dimension one
quantity for which all the exponents of the factors corresponding to the base quantities in its quantity dimension are zero

NOTE 1 The term “dimensionless quantity” is commonly used and is kept here for historical reasons. It stems from the fact that all exponents are zero in the symbolic representation of the dimension for such quantities. The term “quantity of dimension one” reflects the convention in which the symbolic representation of the dimension for such quantities is the symbol 1 (see ISO 31-0:1992, 2.2.6).

NOTE 2 Some quantities of dimension one are defined as the ratios of two quantities of the same kind.

EXAMPLE 1 Plane angle, solid angle, refractive index, relative permeability, mass fraction, friction factor, Mach number.

NOTE 3 Numbers of entities are quantities of dimension one.

EXAMPLE 2 Number of turns in a coil, number of cells in a given sample, degeneracy of the energy levels of a quantum system.

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NOTE 4 Adapted from ISO/IEC Guide 99.

3.1.11
kind-of-property
common defining aspect of mutually comparable properties

ISO 11240:2012
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EXAMPLE Colour, mass, amount-of-substance concentration.

NOTE 1 The hyphens are used to clarify that the modifier “kind” should be seen as part of a connected whole.

NOTE 2 A kind-of-property may be related to nominal scale (e.g. green, blue), ordinal scale (e.g. small, large), differential scale [e.g. 10 °C (i.e. 10 °C more than an arbitrary zero)], or rational scale (length 2 or 5 m); the last two types are related to kind-of-quantity.

3.1.12
kind-of-quantity
aspect common to mutually comparable quantities

NOTE 1 The hyphens are used to clarify that the modifier “kind” should be seen as part of a connected whole.

NOTE 2 This concept is necessary for the definition of a measurable quantity, along with a system and often a component.

NOTE 3 Quantities of the same kind within a given system of quantities have the same quantity dimension. However, quantities of the same dimension are not necessarily of the same kind. The division of the concept of “quantity” according to “kind-of-quantity” is to some extent arbitrary.

EXAMPLE 1 The quantities diameter, circumference and wavelength are generally considered to be quantities of the same kind, namely of the kind-of-quantity called length.

EXAMPLE 2 The quantities number of entities, relative substance concentration, and mass fraction are, by convention, not regarded as being of the same kind, although they have the same quantity dimension.

NOTE 4 Adapted from ISO/IEC Guide 99.

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3.1.13
mapping
alternative representation of the same concept expressed in a different code from a different code system

EXAMPLES Concept mapping, code mapping.

NOTE Because units of measurement represent defined physical quantities, this mapping is always exact. The mapped terms represent exactly the same concept.

3.1.14
material measure
something that reproduces or supplies one or more quantities, each with an assigned quantity value

EXAMPLES Ruler, standard weight, volume measure.

3.1.15
measurement
process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity

NOTE 1 Measurement does not apply to nominal properties.

NOTE 2 Measurement implies comparison of quantities and includes counting of entities.

NOTE 3 Measurement presupposes a description of the quantity commensurate with the intended use of a measurement result, a measurement procedure, and a calibrated measuring system operating according to the specified measurement procedure, including the measurement conditions.

NOTE 4 Measurement usually involves using a measuring instrument, such as a ruler or scale, which is calibrated to compare the object to some standard, such as a metre or a kilogram.

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NOTE 5 Adapted from ISO/IEC Guide 99.

3.1.16
measurement procedure
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detailed description of a measurement according to one or more measurement principles (i.e. phenomena, observables) and to a given measurement method, based on a measurement model and including any calculation to obtain a measurement result

NOTE 1 A measurement procedure is usually documented in sufficient detail to enable an operator to perform a measurement.

NOTE 2 A measurement procedure can include a statement concerning a target measurement uncertainty.

NOTE 3 A measurement procedure is sometimes called a standard operating procedure, abbreviated SOP.

EXAMPLE Lowering of the concentration of glucose in blood in a fasting rabbit is an observable that can be applied to the measurement of insulin concentration in a preparation. Together with a description of the measurement method this can be used to define a measurement procedure.

NOTE 4 Adapted from ISO/IEC Guide 99.

3.1.17
medicinal product
any substance, or combination of substances, which may be administered to human beings for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions

NOTE 1 A medicinal product may contain one or more manufactured items and one or more pharmaceutical products.

NOTE 2 In certain jurisdictions a medicinal product may also be defined as any substance or combination of substances which may be used to make a medical diagnosis.

NOTE 3 Adapted from ENV 13607:2000 and ENV 12610:1997.

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3.1.18
metrology
science of measurement and its application

NOTE Metrology includes all theoretical and practical aspects of measurement, whatever the measurement uncertainty and field of application.

[ISO/IEC Guide 99:2007, definition 2.2]

3.1.19
numerical quantity value
numerical value of a quantity
numerical value
number in the expression of a quantity value, other than any number serving as the reference

NOTE 1 A number may serve as a "reference". This can be explained by a dimensionless unit which appears as a number. For example, the unit (1) or a "pair" (2), a "dozen" (12) or 1 percent (0,01), ppm etc.

NOTE 2 Adapted from ISO/IEC Guide 99.

3.1.20
pharmaceutical product
qualitative and quantitative composition of a medicinal product in the dose form authorized for administration by a regulatory authority and as represented with any corresponding regulated product information

NOTE A medicinal product may contain one or more pharmaceutical products.

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3.1.21
physical unit of measurement
unit of measurement that is defined using a physical quantity

NOTE 1 Its definition relates measured quantities to the base quantities through a set of well-defined equations.

ISO 11240:2012
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NOTE 2 Physical units and their related scales are defined independently of the measurement procedure and the measured components. They relate to an internationally standardized system of units and equations governing the mathematical relations between those units.

3.1.22
prefix
word or symbol for attachment to the name or symbol of a unit in order to form units that are multiples or submultiples of that unit

NOTE For more details, see chapter 3.1 of the International System of Units (SI)[27].

3.1.23
property
inherent state- or process-descriptive feature of a system, including any pertinent to a component being determined

NOTE There can be a set of data elements (system, component, kind-of-property) common to a set of particular properties.

EXAMPLE Substance concentration of glucose in blood plasma.

3.1.24
quantity
property of a phenomenon, body, or substance, where the property has a magnitude that can be expressed as a number and a unit

EXAMPLE Mass of a given object at a given point in time.

NOTE 1 The unit serves as a reference.

NOTE 2 Quantity is more specific in relation to property.

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NOTE 3 A reference can be a unit of measurement, a measurement procedure, a reference material, or a combination of such.

NOTE 4 Adapted from ISO/IEC Guide 99.

3.1.25
quantity value
value of a quantity
number and unit (reference) together expressing magnitude of a quantity

NOTE 1 A quantity value expresses the magnitude of a quantity. This expression consists of a numerical value together with a unit of measurement. The unit of measurement represents a quantitative scale of reference that relates the measured (or estimated) quantity value to one or more reference quantity values. The numerical value is the result of comparing the measured quantity to this reference scale.

NOTE 2 The word “magnitude” is not defined in ISO/IEC Guide 99. However, this definition of quantity value indicates that “magnitude” is expressed as a quantity value; i.e. a quantity value is an expression of a magnitude and the same magnitude might be expressed in many quantity values.

NOTE 3 A reference can be a unit of measurement, a measurement procedure, a reference material, or a combination of such.

3.1.26
reference material
material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties

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NOTE 1 Some reference materials have assigned quantity values that are metrologically traceable to a measurement unit outside a system of units. Such materials include vaccines to which International Units (IU) have been assigned by the World Health Organization (WHO).

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NOTE 2 Adapted from ISO/IEC Guide 99.

ISO 11240:2012
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3.1.27
symbol
visually perceptible or machine-readable concept representation, used to transmit information independently of language

3.1.28
synonym
alternate symbol or name for the same concept within a given language

3.1.29
system of quantities
set of quantities together with a set of non-contradictory equations relating those quantities

NOTE Adapted from ISO/IEC Guide 99.

3.1.30
system of units
set of base units and derived units, together with their multiples and submultiples, defined in accordance with given rules, for a given system of quantities

[ISO/IEC Guide 99:2007, definition 1.13]

3.1.31
traceability
metrological traceability
property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

NOTE 1 For this definition, a “reference” can be a definition of a measurement unit through its practical realization, or a measurement procedure, or a measurement standard

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NOTE 2 Metrological traceability requires an established calibration hierarchy.

NOTE 3 The expression “traceability to the SI” means “metrological traceability to a measurement unit of the International System of Units”.

NOTE 4 Adapted from ISO/IEC Guide 99.

3.1.32
translation
alternate rendition of the same content translated into a different language or orthography

3.1.33
unit of measurement
measurement unit
real scalar quantity, defined and adopted by convention, with which any other quantity of the same kind can be compared to express the ratio of the two quantities as a number

NOTE Depending on the nature of the reference scale, the unit of measurement expression may stand either for a physical unit of measurement that is related to a system of quantities (e.g. SI units) or for an arbitrarily defined unit of measurement, which may refer to a certain reference material, a standard measurement procedure, a material measure or even to a combination of those.

3.1.34
units of presentations
qualitative term describing the discrete countable entity in which a pharmaceutical product or manufactured item is presented, in cases where strength or quantity is expressed referring to one instance of this countable entity

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EXAMPLE 1 To describe strength: a puff, spray or tablet “contains 100 mcg per spray” (unit of presentation = spray).

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EXAMPLE 2 To describe quantity: a bottle, box or vial “contains 100 ml per bottle” (unit of presentation = bottle).

NOTE A unit of presentation can have the same name as another controlled vocabulary, such as a basic dose form or a container, but the two concepts are not equivalent, and each has a unique controlled vocabulary term identifier.

ISO 11240:2012
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3.1.35
vocabulary
terminological dictionary which contains designations and definitions from one or more specific subject fields

NOTE Adapted from ISO 1087-1:2000.

3.2 Abbreviations

3.2.1
CDISC
Clinical Data Interchange Standards Consortium

3.2.2
IHTSDO
International Health Terminology Standards Development Organisation

3.2.3
LOINC
Logical Observation Identifiers Names and Codes (Regenstrief Institute, Inc.)

3.2.4
NCI
United States National Cancer Institute (part of United States Department of Health and Human Services)

3.2.5
OID
Object identifier (see ISO/IEC 9834-1:2008)

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3.2.6
SI
International System of Units (CGPM, General Conference on Weights and Measures)

3.2.7
UCUM
Unified Code for Units of Measure (Regenstrief Institute, Inc. and The UCUM Organization)

3.2.8
UML
Unified Modeling Language (Object Management Group, Inc.)

3.2.9
WHO
World Health Organization

4 Structures and vocabularies

4.1 Overview

The following subclauses provide normative rules and structures for the electronic communication of quantity values and units of measurement in the context of data exchange between computer applications.

Semantic interoperability for electronic communication of quantity values and units of measurement is based on a common understanding of:

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— the underlying metrological concepts for the use of quantities and units to represent measurement results;

— the definition of information structures for data exchange, including a semantic model of the data elements, their attributes and their relationship to other elements;

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— the use of controlled vocabularies to represent concepts as coded elements, including the definitions, and relationships of unit concepts.

This International Standard provides basic rules for such a common understanding. Facing the necessity of adaption to various existing coding systems, a reference terminology for units is established. Usage of units in international scenarios and across different jurisdictions requires a standardized approach to mapping between code systems and translations of names and definitions to different languages. Finally, data structures are defined that provide the basis for a standardized coded representation of information on quantities and units, and to capture and exchange their relations to other coding systems, as well as names and symbols in different languages.

4.2 Metrological concepts

4.2.1 Representation of quantity values

The result of a measurement is the magnitude of a measurable quantity and is represented by a quantity value. A quantity value shall be expressed as a unit of measurement of the quantity and its numerical value in that unit.

A measurable quantity is designated by a kind-of-quantity, a component carrying the quantity and the system containing the component (e.g. a substance). Information on the kind-of-quantity, the measured component, the system containing the component, the time aspect and the measurement method shall be considered as context information. While context information may be indispensable for the interpretation of the measurement, it shall not be considered as a constituent part of a quantity value. Therefore, context information shall not be communicated as part of a unit expression itself. Information models for the communication of quantity values shall accommodate context information for quantity values, as required for the respective use case.

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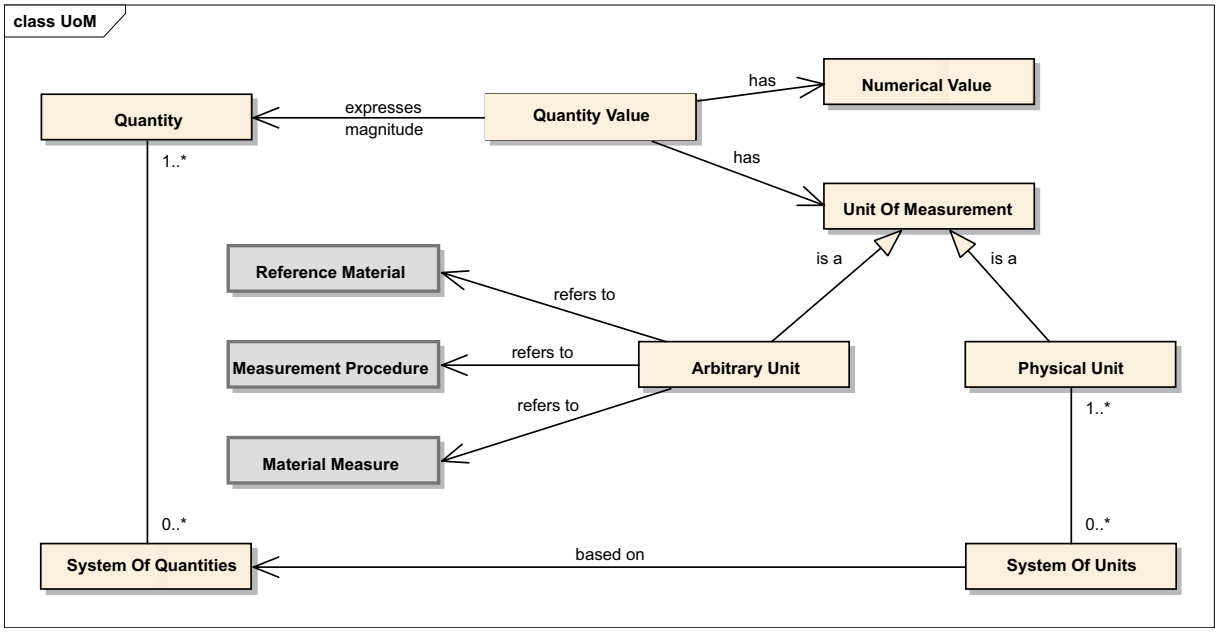

NOTE This figure provides a schematic representation of concepts defined in 4.2.1 and their relation to other concepts described in Clause 3. It highlights the advantages of using a standardized system of units (e.g. SI units) that provide formal mathematical relationships to a common system of quantities. Other arbitrarily defined units need specific additional references in order to ensure traceability and comparability. For background information on the concepts related to units of measurement, see ISO/IEC Guide 99 and the domain analysis model in Annex D.

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Figure 1 — Schematic conceptual model for units of measurement and related concepts in Clause 3, presented as a UML class diagram

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4.2.2 Traceability of quantity values

A measurement result should be traceable to a reference. Whenever comparability of measurement results is required, the compared quantity values shall be traceable to the same reference. The unit of measurement shall indicate the reference used for the assignment of the quantity value.

A unit of measurement can be a physical unit that is defined using a system of units. Alternatively, it can be an arbitrarily defined unit, i.e. a reference to a particular material, a specified procedure or a particular material measure. Examples are WHO reference preparations in the case of “WHO international units” or a reference to a well-defined and calibrated material measure.

When physical quantities are reported, units shall be used that are traceable to SI units in a defined and documented way. This includes units with established and defined conversions to SI units. All quantity values should preferably be expressed utilizing definitions derived from the SI nomenclature.

In order to maintain traceability and comparability of quantity values, uncalibrated arbitrary material measures of volume shall not be used as units of measurement (e.g. flask, vial, ampoule). Arbitrary material measures cover exceptional cases of material measures where a relation to SI units is not possible or not known (e.g. WHO International Standard for Opacity). Material measures should be calibrated to SI units and quantity values expressed accordingly.

NOTE A material measure is always a physical object and represents a particular physical quantity, so in principle it can be calibrated to SI units. Material measures are included here primarily to accommodate existing standard recommendations that are not defined using SI units (e.g. WHO Technical Report Series No. 941, 2007 Annex 6: “Manufacturers are encouraged to continue to express opacity in International Units”[50]).

4.2.3 Derived units, coherent units and quantity dimension

For a particular quantity a variety of units may be used to express quantity values. SI units should be used wherever possible.

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