BS EN ISO 11240:2012

BSI Standards Publication

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

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The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

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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 (ISO 11240:2012)

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Foreword

This document (EN ISO 11240:2012) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2013, and conflicting national standards shall be withdrawn at the latest by May 2013.

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Foreword

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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.

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):

— 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.

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

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.

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

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.

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

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.

NOTE 4 Adapted from ISO/IEC Guide 99.

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

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.

NOTE 5 Adapted from ISO/IEC Guide 99.

3.1.16
measurement procedure
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.

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.

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

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).

NOTE 2 Adapted from ISO/IEC Guide 99.

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

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

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.

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:

— 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;

— 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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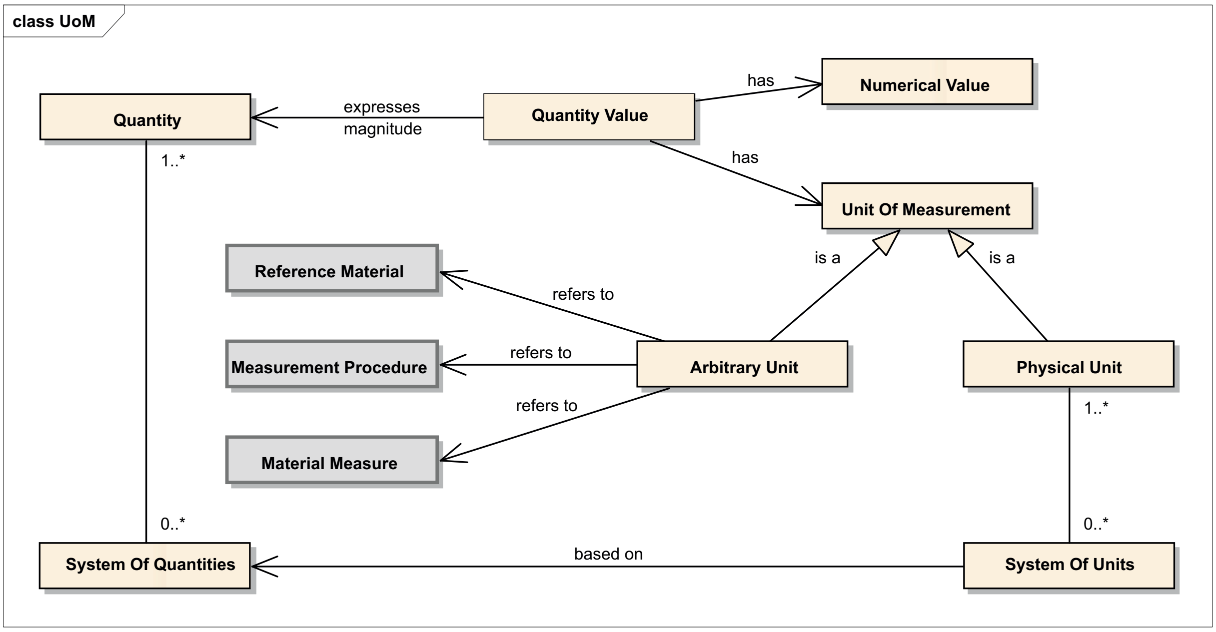

NOTE This figure provides a schematic representation of concepts defined in 4.2.1 and their relation to other concepts described in Clause 3. It highlights the advantages of using a standardized system of units (e.g. SI units) that provide formal mathematical relationships to a common system of quantities. 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.

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

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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The quantity dimension of each unit representing a particular kind-of-quantity shall equal the dimension of that kind-of-quantity.

If two units do not have the same quantity dimension they shall not be used to represent the same kind-of-quantity.

When two units describe the same kind-of-quantity, the numerical conversion factor between the units shall be defined as the ratio of the two measurement units.

The expression for the coherent unit of a derived quantity shall be obtained from the dimension of that quantity by formally replacing the quantity dimension symbols by the symbols of the corresponding base units.

NOTE 1 Quantities having the same quantity dimension are not necessarily of the same kind. Therefore, knowledge of the dimension of a quantity is not sufficient to determine the kind-of-quantity. For the same reason, a given unit of measurement does not imply a particular quantity.

NOTE 2 Quantity dimensions (or coherent units) can be used to categorize or classify units. A formal parent-child relationship exists between a quantity dimension and its associated unit concepts.

NOTE 3 Unit conversions do not include conversions between different kind-of-quantities. Quantity conversions generally require knowledge of additional parameters (e.g. pressure, temperature) or substance-specific properties (e.g. molecular mass).

EXAMPLE 1 The quantities mass concentration and substance concentration do not have the same dimension, therefore they are not quantities of the same kind.

EXAMPLE 2 The quantities mass fraction, relative volume and number of entities have the same quantity dimension. However, by convention they are not regarded to be of the same kind.

EXAMPLE 3 A mass can be expressed in grams, pounds or tonnes but not in millilitres or seconds.

EXAMPLE 4 Rainfall measured as volume per area has the same quantity dimension as length.

4.2.4 Counted entities and units of presentation

Units of measurement shall be distinguished from other notions of the word “unit”, such as counted entities or “units of presentation”.

NOTE 1 Units of presentation are conventional terms that can be used to describe the properties of a pharmaceutical product, e.g. tablet, vial, puff. They are not the same as units of measurement. Units of measurement are always defined through some reference quantities, which units of presentation are not. The vocabulary for units of presentation is addressed in ISO 11239.

NOTE 2 Concepts like “tablet”, “patch”, “bottle”, etc., are often used to characterize the various types of countable items. In the context of measurements they simply represent the quantity “1”, corresponding to the number of items they represent.

EXAMPLE A product in the form of a tablet contains as an ingredient the amount of 500 mg of a substance per tablet. The strength of the product (a tablet) is 500 mg.

4.2.5 Arbitrary units

Arbitrary units shall be indicated by using names and symbols that cannot be confused with SI units.

In the field of medicinal products many quantities cannot (yet) be expressed using physical units alone, e.g. the biological activity of a certain substance. Values of such a kind-of-quantity should be expressed using a defined arbitrary reference quantity assigned to a particular standardized preparation or measurement procedure.

Quantity values expressed in arbitrary units are only comparable if they use the same arbitrary unit definition, including reference material and measurement procedure. Due to the arbitrariness in the unit definition, an arbitrary unit cannot be converted to any other unit.

NOTE 1 Some arbitrary unit definitions include the definition of an equivalent physical quantity, usually expressed in SI units. This equivalence generally depends on the reference material, the measurement procedure and other parameters.

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NOTE 2 Because these units are typically defined for one particular substance or procedure only, the same names and symbols are conventionally used for a number of arbitrary units and across multiple substances, instead of, for example, creating a different unit name for each substance-specific arbitrary unit defined via a WHO reference preparation for an IU. Therefore, quantity values are only comparable when the same reference is used, i.e. only when the measurement result refers to the same kind-of-quantity, system and component.

NOTE 3 For every available WHO IU reference standard, the name of the reference standard and its identifying code are provided. Further discussion of this topic is found in Reference [46]. See ISO 11238 for rules on referencing such reference preparations.

EXAMPLE 1 The unit code "[IU]" relates the quantity value to a particular substance-specific WHO international unit, where the exact reference is to be provided in the definition of the related substance given in context, i.e. as defined in ISO 11238.

EXAMPLE 2 Results of quantitative immunoassays are often expressed in terms of "ELISA units", which are usually defined as the reciprocal value of the serum dilution which gave a certain optical density (e.g. OD 1,0 at 490 nm) in a titration using serial dilution. The resulting quantity value is assumed to be proportional to the activity of a certain biological substance in the original specimen. ELISA units are then used as arbitrary units for the substance activity. If an appropriate reference preparation exists, the assay can be calibrated and the result given in WHO IUs of activity, but this is not always the case. Therefore the exact definition of ELISA units depends on the test method.

4.3 Semantics of units of measurement

4.3.1 Ratios and dimensionless quantities

A ratio is a quantity constructed as the quotient of a numerator quantity divided by a denominator quantity. If the numerator and the denominator have the same quantity dimension, the ratio is a dimensionless quantity. For dimensionless quantities, the coherent unit in any system of units is the unit one (symbol 1), often called unity. Therefore, the unit code for a dimensionless quantity cannot be used to convey information on the measured quantity or the kind-of-quantity. However, if the numerator and denominator of a ratio are expressed as two separate quantity values, their units can be used to discriminate between different kinds-of-quantity, e.g. mass ratio versus volume ratio.

If it is required to discriminate between different quantities based on the units of the quantity values, the quantity value of each ratio shall be expressed using separate quantity values for the numerator and denominator. Common factors in the numerator and denominator shall not be cancelled out, even if they have the same quantity dimension (e.g. 50 mg/100 g).

NOTE 1 Where dimensionless quantities are communicated, the respective kind-of-quantity should also be reported. This additional information allows the receiver to discriminate if the reported dimensionless value represents, for example, a mass ratio, a relative volume or a concentration fraction.

NOTE 2 Various notations exist to include context information in the unit symbol to indicate the kind-of-quantity: % volume, vol%, ml% or % volume fraction, volume ratios or relative volumes; % mass, Gew.%, g% or % mass fraction for mass fractions, mass ratios or relative masses; mol% for substance fractions, substance ratios or relative amounts-of-substance. As described in 4.2.1, the general rule is that the kind-of-quantity should not be mixed with the unit of measurement but belongs to the context of a quantity value.

NOTE 3 Within the LOINC coding system, concepts that represent arbitrary and dimensionless quantities are associated with distinct property types (e.g. mass concentration, volume fraction, arbitrary concentration).

4.3.2 Information structures for the communication of quantity values

Information structures for the communication of quantity values shall employ the ISO datatype PQ defined in ISO 21090. The specification of datatype PQ requires that quantity values are expressed as a numerical value and a unit code. The datatype PQ prescribes the usage of a standardized vocabulary for the unit code (UCUM) and also defines additional data structures accommodating one or more alternative representations of the same unit of measurement concept (see ISO 21090 for a definition of the PQ attribute "translation" and specification of datatype PQR). This includes:

— code values from other code systems,

— translation of names and symbols to other languages and character sets, and

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— additional synonym values for original text, display text or symbols.

The ISO 21090 compound datatype RTO < PQ,PQ > allows the representation of quantities that are a ratio of two separate quantity values; the numerator and denominator are regarded as two independent expressions and shall not be cancelled out.

If it is required to discriminate certain quantities based on units of measurement, the quantity value shall be expressed using RTO < PQ,PQ > in order to ensure that units are not cancelled out. This can also be applied in the case of a single quantity by regarding the numerical quantity value as the numerical value of the numerator quantity and setting the numerical value of the denominator to 1.

NOTE Ratio expressions occur in dosage expressions (e.g. 100 ml/24 h), where the numerator defines the dose and the denominator expresses the length of a time interval. This may also apply for expressions that would otherwise yield dimensionless quantities (50 mg/100 g), as often encountered when expressing the strength of a medicinal product.

EXAMPLE Mass ratios (50 mg/g = 50 mg/1 g), volume ratios (10 ml/l = 10 ml/1 l).

4.4 Vocabulary for units of measurement

4.4.1 Reference vocabulary

For the electronic communication of units of measurement a single common reference vocabulary shall be used.

This reference vocabulary shall employ a single coding system for units that is complete, free of all ambiguities, and that assigns to each defined unit code a concise meaning and definition in terms of SI units or other references where units cannot be converted to SI units. The codes shall be publicly available and the expectation is that their use will be royalty free. All SI units and their prefixed derivatives shall be expressible using this coding system.

The coding system shall provide unambiguous machine-processable rules for converting quantity values between SI base units and other units in practical use, where applicable.

Subsets of codes for the encoding of units of measurement shall be selected from this reference vocabulary only, as appropriate for the purpose of communication and in order to meet the requirements of different jurisdictions.

The reference vocabulary shall support traceability of all coded concepts of units of measurement across all subsets to internationally agreed and defined metrological unit definitions, e.g. the SI.

The reference vocabulary shall be the UCUM code system, as required for conformance with ISO 21090 and HL7 V3 data exchange standards. The OID for the UCUM code system is 2.16.840.1.113883.6.8. The unit codes provided by UCUM for units of measurement are constructed by algebraic rules that reflect the underlying system of units and quantities. Each code expression for a unit of measurement represents a particular unit quantity and refers to the underlying definitions, i.e. the SI base units.

NOTE 1 All expressions for physical units are intrinsically linked to base units by their definition. This is reflected through the construction principles of UCUM unit codes. For each physical unit a canonical representation can be unambiguously derived from the UCUM code, together with conversion factors or functions, to other units having the same quantity dimension and with computable relations to base units.

NOTE 2 UCUM codes are designed to enhance human readability. Therefore, the codes closely resemble commonly used symbols for units of measurement. However, the symbols conventionally used for units of measurement may differ from the UCUM codes for the same concepts.

NOTE 3 Conversion factors and functions for conversion to SI coherent units are provided in the UCUM terminology for all UCUM “unit atoms” related to physical units. Factors and functions for all unit concepts expressed as UCUM unit codes can be formally derived following the UCUM rules.

NOTE 4 UCUM historically provided a separate case-insensitive variant of codes in a different code system. For the purposes of this International Standard, only the case-sensitive code system shall be used.

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NOTE 5 The quantities and units that are represented by unit codes are defined by international standards and conventions (see ISO 31 and ISO 80000) together with relating equations and conversion factors. UCUM uses algebraic rules to express the concepts in a machine-processable form. The exact concept definition can be formally deduced directly from each code using the algebraic construction principles and the numeric conversion factors provided as an integral part of the UCUM code system. Therefore, a separate term identifier is not required and not provided.

NOTE 6 Following the mathematics of the underlying physical quantities and metrological unit concepts, UCUM codes are constructed from "atomic" unit concepts using multiplication, division and exponentiation. However, these code construction rules are not to be confused with expression syntax found in other code systems that allow post-coordinated expression of concepts. Each UCUM code is a fully defined term. The constituting relations of each coded concept are entirely defined within the reference terminology.

4.4.2 Application in data exchange

Usage of ISO datatypes and HL7 V3 messaging requires UCUM as the code system for units of measurement (see ISO 21090 for the definition of datatype PQ).

While UCUM may not be implemented as the unit of measurement code system within a particular instance of a point of service computer application, UCUM shall be used in the messages to communicate electronically between such applications.

Other vocabularies for units may be used additionally in data exchange, e.g. for fulfilment of local regulatory requirements or for compatibility with existing data. Data type PQ allows the addition of an alternative representation of the same physical quantity expressed in a different unit from a different unit code system and possibly with a different value. If no corresponding code exists in UCUM, an alternative code shall be sent in the form of a UCUM annotation.

For provisional or local requirements, additional unit definitions and codes shall be added to the standard vocabulary using UCUM annotations (unit codes with curly brackets). Addition of unit codes to the vocabulary and the mapping tables shall be governed by a set of documented rules.

Refer to the following sources for guidance and examples of structures and vocabularies for expressions that form the context around a quantity value:

a) LOINC definitions for laboratory-related context information on test methods, procedures and kind-of-quantities;

b) ISO 11238 for substance-related context information;

c) ISO 11239 for unit of presentation-related context information.

NOTE Units of measurement are used to express quantity values in many domains, including laboratory results, physical characteristics of substances, clinical measurements, and medical devices. However, the information structures specified in this International Standard are provided for the regulatory requirements of medicinal product identification.

4.4.3 Vocabulary for arbitrary units

Arbitrary units shall be represented using appropriate UCUM codes. The corresponding codes are marked as "arbitrary" in the UCUM code system.

The definition of a particular arbitrary reference quantity generally is not included in the definition of the arbitrary unit code (e.g. "IU" is used for a multitude of WHO reference quantities). Therefore, conformant structures and vocabularies for communication shall be able to provide the required reference information explicitly or implicitly in the context of the quantity value. This is a requirement for the vocabularies for substances and methods and is outside the scope for this International Standard.

NOTE WHO IUs are a prominent case of such arbitrary units. UCUM provides codes for "international units" and a number of commonly used other arbitrary units. Additional codes will be added to UCUM as required for commonly used arbitrary units, wherever a traceable source of reference is defined and publicly available.

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4.5 Domain model

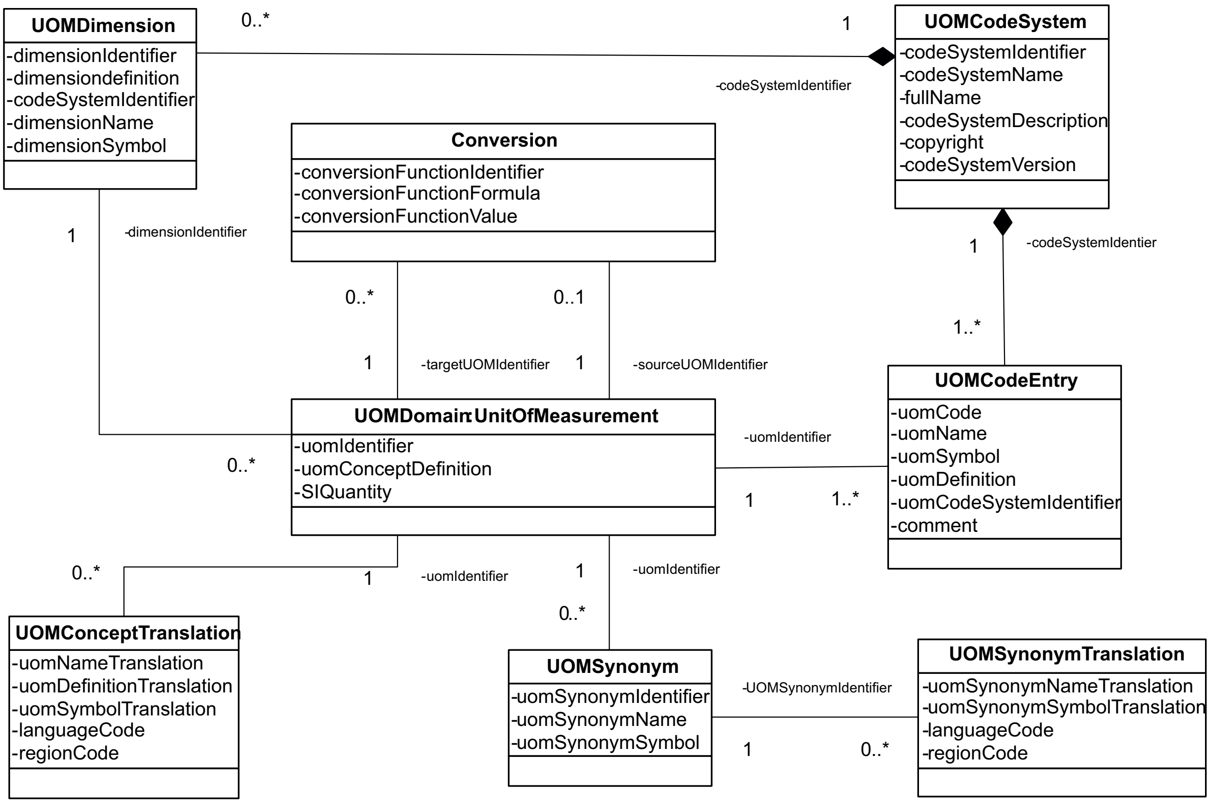
4.5.1 Introduction to the unit of measurement domain

Several applicable approaches have been identified for the standardized communication of units of measurement, which represent well-established terminologies used worldwide. Each represents viable controlled terminologies with broad coverage for units of measurement. Recognizing that the UCUM reference vocabulary may not be implemented within specific computer applications, or that certain useful unit of measurement concepts may not have a code within UCUM, this International Standard provides guidance on mapping of specific unit of measurement concepts across the different terminologies and on expressing all units in a way conformant to the requirements of communication based on the data types of ISO 21090.

This International Standard defines data structures for a controlled vocabulary for the electronic communication of units of measurement required for identification of medicinal products. This includes mappings to other code systems, and translations and synonyms to be used in the information structures for communication mentioned above. Implementation of such a controlled vocabulary shall be in conformance with the data structures established in 4.6.

4.5.2 Domain object model

The concepts in this model are rendered in Figure 2 (below), which presents a UML class diagram capturing the logical structure of the data items and their relationship to the unit of measurement domain space, and more formally defines each object, its data attributes, and the relationships between the objects in the model. The model classes and elements rendered in Figure 2 are detailed in the data model provided in 4.6 and 4.7.



NOTE This figure shows the classes constituting the domain information model for units of measurement, as described in detail in 4.6. To enhance readability, only a representative subset of attributes is displayed.

Figure 2 — UML class diagram of unit of measurement entries

The classes UnitOfMeasurement, Dimension and Conversion represent the general concepts described in the domain analysis model in Annex D.

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UoMCodeEntry enables the mapping of a code from an existing code system to a common UnitOfMeasurement concept. This allows the identification of common concepts across different alternative terminologies and coding systems in practical use.

Names, Symbols and Definitions used to denote the same concept in different languages are represented by classes at the bottom line. These classes also provide mapping capabilities for synonyms in different languages.

The above model is provided to orient the reader to the major concepts present in the unit of measurement data model, to show the attributes associated with these logical concepts, and to provide linkages to concepts outside the core unit of measurement model (such as kind-of-quantity).

Also, this model provides structures for mapping between different terminologies and coding systems and for multilingual translation of names, synonyms, symbols and definitions of each unit of measurement concept.

NOTE In UoMCodeEntry, names and symbols for a unit may be specified for each code system separately. However, Synonyms and Translations are not considered to be specific for a particular code system.

4.5.3 Structures for codes and concept definition

One entry shall be provided for every unit of measurement used in information exchange. Each entry shall use a unique code from the reference vocabulary defined in 4.4.1 (UCUM). This code represents the unit of measurement concept and shall be used as the unit of measurement identifier in electronic communication.

While the formal definition of each concept in terms of metrological concepts is implied by the code through its formal relationship to base units, a specific definition may be added for clarification and readability. Such a definition should describe the common usage and meaning of the concept in natural language.

Codes that include annotations (UCUM codes with curly bracket expressions) shall have a definition that defines the precise meaning of the annotation.

NOTE 1 UCUM annotations have no semantic meaning in the metrological domain of the reference terminology. They are equivalent to unity (“1”).

NOTE 2 Effectively, this structure can be used to define controlled vocabularies and value sets based on the reference terminology. It therefore serves the purpose of defining constrained lists of units to be used for information exchange, e.g. thus fulfilling specific regulatory requirements.

4.5.4 Structures for names and symbols

The information structures specified by this International Standard (see 4.6) also provide data fields to capture names and symbols for units. A name or symbol may not be present if the code is an expression for which no display name has been assigned or can be derived. If populated, each name and symbol shall be a valid human readable representation of the concept as defined by the code system at the time of data entry. Names and symbols are included both as a courtesy to an unaided human interpreter of a code value and as a documentation of the name or symbol used to display the concept to the user, possibly also fulfilling regulatory requirements. The names and symbols have no functional meaning; they shall not exist without a code and shall not modify the meaning of the associated code.

Therefore, names and symbols should not be presented to the user on a receiving application system without ascertaining that they adequately represent the concept referred to by the code value. Communication shall not rely on the name or the symbol. The main purpose of names and symbols is to support implementation debugging.

4.5.5 Structures for translations

This International Standard provides structures to capture alternate human readable representations of unit names and symbols that are used for other languages and geographical locations, for countries or jurisdictions that need a translation of a concept.

Translations shall be representations of the same concept (concerning one or more attributes of that same concept, such as name, symbol or definition) using a different language. The model allows association of a unit concept with any number of translations that are provided in different languages. If more than one name

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or symbol is used in a given language and region, the translation shall render the preferred name and symbol while other names or symbols shall be provided as synonyms, using the respective structures.

NOTE Synonym translation may occur when a different character set rendering would require different language specific character conversion. For example the ASCII character “u” when used as a synonym for the Greek letter “μ” may translate into different character sets in non-European character sets.

4.5.6 Structures for mapping

Mapping of terms and codes from other vocabularies to UCUM shall be documented using the structures defined in this International Standard.

In order to facilitate adaption to existing unit vocabularies and communication infrastructures, mapping tables between commonly used coding systems and UCUM codes should be provided. Such a mapping shall include codes and may include term symbols, textual representations from different languages and character sets and synonym relations between terms and symbols. Any mapping infrastructure conformant to this International Standard shall be implemented using the data model in 4.6. Each mapping table will effectively define a set of unit codes appropriate for a given domain (i.e. a value set). An example of mapping of existing code systems to UCUM codes is provided for informative purposes in Annex C.

In mapping entries for derived physical units, the corresponding coherent SI units should be given, together with the appropriate conversion factor or conversion function, respectively.

Domain-specific mapping tables should contain appropriate definitions, requirements and constraints for all contained arbitrary unit concepts. Such definitions shall be given for all unit concepts and especially for arbitrary units, e.g. for all concepts specific to substances or procedures and for all mappings to UCUM codes using annotations (“curly bracket expressions”). Requirements for context information like substances or procedures shall be explicitly defined in the unit definition.

NOTE 1 Due to the construction principles of UCUM, each mapping to a corresponding UCUM code will automatically provide a canonical representation in terms of base units and conversion factors to other units of the same quantity dimension, especially to SI units, thereby ensuring interoperability between different unit vocabularies (e.g. SNOMED, NCI Thesaurus).

NOTE 2 While mapping tables link different code systems, language-specific terms, symbols and synonyms via UCUM codes, the construction rules of UCUM codes link different representations of the underlying unit concepts via SI base and coherent units. This allows for machine-processible conversion between all quantity values of the same quantity dimension, regardless of the particular representation of the unit of measurement.

4.6 Data elements and technical data model

4.6.1 Overview of technical data model

This model defines the domain objects that shall be represented in implementations for the purpose of exchanging information on vocabularies for units of measurement. The relationship between the reference vocabulary (represented by the UnitOfMeasurement class) and the associated classes (mappings, translations, synonyms, dimensions, etc.) shall be implemented according to this International Standard.

Starting with the core concept represented by an instance of the UnitOfMeasurement class, a unit of measurement concept shall have an identifier and provide a definition of the concept. The same concept may be represented in other code systems using a different identifier.

Adhering to this concept are classes containing names, synonyms and print symbols in different languages. A unit of measurement concept (and its code representations) may have one or more language translations, thus having multiple display names or print label associations. However, each translation shall be associated with one and only one unit of measurement concept.

The unit of measurement concept may also have one or more variant synonyms that produce a variant name and/or print label (e.g. liter versus litre). The unit of measurement concept may also have one or more symbol synonyms.

Each such synonym may have one or more language translations. Each such translation shall belong to one and only one synonym, and each synonym shall be associated with one and only one unit of measurement concept.

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A conversion shall provide information necessary for converting a specified unit of measurement to a related unit of measurement of the same quantity dimension. Such a function may be a prefix conversion e.g. when a power of 10 is used to convert micro- to milli- to centi- to deci-) or may be a unit conversion (e.g. when converting inch to centimetre or Kelvin to degree Celsius). Elements and attributes are defined as necessary for the definition of a conversion between units of measurement.

NOTE Symbol synonyms occur, for example, when a case sensitive and case insensitive form of the print symbol are allowed (e.g. “L” or “l” for litre) or when different character sets are used (e.g. the ASCII “ug” versus the UTF-8 “μg”). Each symbol synonym shall be associated with one and only one unit of measurement concept (see 4.6.3.2).

The tables in the following subclauses define the classes and their attributes that shall be used for the exchange of information on vocabularies for units of measurement. For each class the associations to other classes in the model are listed as the second entry, after the class name, together with the cardinality of each association. Succeeding lines define the attributes of the class. For each attribute, the tables list first the name of the attribute, then the ISO datatype of the attribute, an indication of whether a value for this attribute is mandatory or optional and, finally, a textual description of the attribute.

4.6.2 Structures for unit of measurement concepts

4.6.2.1 Unit of measurement — Reference entry

The UnitOfMeasurement class specifies the attributes that are needed to properly define each entry of a unit of measurement concept.

The two core attributes (identifier and definition) refer to the abstract concept, and shall be part of its core definition. The identifier represents a particular unit quantity and refers to the underlying metrological or published definitions, e.g. the SI base units, through the intrinsic formalism that is provided by the reference code system (see 4.4.1). For convenience, each identifier is accompanied by a human readable representation of the formal algebraic definition.

Each core unit of measurement concept may have one or more associated unit of measurement code entries from different CodeSystems, reflecting the fact that a unit of measurement concept can be present in multiple unit of measurement dictionaries or coding systems (e.g. UCUM, NCI Thesaurus, SNOMED). Further translations and synonyms present within such a dictionary or coding system can be represented through instances of UoMConceptTranslation, UoMSynonym, and UoMSynonymTranslation associated to the UnitOfMeasurement concept.

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Table 1 — Attributes for the description of unit of measurement

Class: UnitOfMeasurement	
Associations An instance of a UnitOfMeasurement shall be associated with — one to many instances of CodeEntry — zero to many instances of ConceptTranslation — zero to many instances of Synonym — one instance of Dimension — zero to one instances of a UoMConversion (as a source) — zero to many instances of a UoMConversion (as a target) — one to many instances of OperationalAttributes	
Unit of measurement Identifier	**Type: String**
	Mandatory
The unique identifier for the unit of measurement entry within the ISO lexicon. This code represents the unit of measurement concept and shall be used as the unit of measurement identifier in electronic communication. This identifier shall be a Unified Code for Units of Measure (UCUM). A valid code shall be provided for each concept included in an implementation of this International Standard. The OID of the coding system for the unit of measurement identifier is 2.16.840.1.113883.6.8.	
Unit of measurement Concept Definition	**Type: ST**
	Mandatory
A human readable definition of the unit of measurement concept, with a definition complete enough to differentiate the concept from all other unit of measurement concepts. For well know physical quantities, a reference to the definition in terms of SI units shall be made. The entry shall be a journal citation, if an arbitrary or biological unit has been defined in that source, and the published definition is robust enough to clearly differentiate the concept. Arbitrary unit concepts often have substance-specific definitions (e.g. WHO IUs of biological activity). In these cases this field shall contain a detailed description of the additional context information that is required in order to get a complete definition. The definition of the unit of measurement concept will be in English.	
SI Quantity	**Type: BL**
	Mandatory
A Boolean that indicates that the unit of measurement Concept is an SI quantity, or is based on an SI quantity.	

4.6.2.2 Unit of measurement Code Entry

The unit of measurement Code Entry class specifies the attributes that are needed to identify the representation of a unit of measurement concept in a code system. A definition of the concept within the code system may be given. This ensures the consistency of the association with a unit of measurement concept and its definition.

All alternate unit of measurement Code Entries that relate to a common UnitOfMeasurement are considered as equivalent representations of the same unit of measurement concept in multiple unit of measurement dictionaries or coding systems (e.g. UCUM, NCI Thesaurus, SNOMED).

Each unit of measurement reference entry according to 4.6.2.1 shall be associated with one unit of measurement Code Entry from the code system UCUM.

NOTE Using UCUM as the reference vocabulary, an example of mapping of a concept in alternate coding systems (NCI Thesaurus, SNOMED) is provided in Clause C.1.

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Table 2 — Attributes for the representation of unit of measurement in a Code System

Class: CodeEntry	
Associations An instance of CodeEntry shall be associated with — one instance of UnitOfMeasurement — one instance of CodeSystem — one to many instances of Operational Attributes	
Unit of measurement Identifier	**Type: String**
(Connector to UnitOfMeasurement)	**Mandatory**
The unique identifier for the unit of measurement entry within the ISO lexicon. All equivalent instances of unit of measurement CodeEntry shall refer to the same UnitOfMeasurement Identifier.	
Unit of measurement Definition	**Type: ST**
	Optional
Alternative wording of the Definition of the same concept. This definition shall be consistent with the UnitOfMeasurement Definition. Content is copied from a particular coding system. This entry serves to ensure that concept mapping between various code systems is consistent and traceable.	
Code System Identifier	**Type: UID**
(Connector to unit of measurement CodeSystem)	**Mandatory**
A unique identifier for the coding system or lexicon used to represent the unit of measurement.	
Unit of measurement Name	**Type: ST**
	Optional
The human readable textual representation of the unit of measurement Term as defined in the source of information system. NOTE The preferred term should be captured under this field, whereas different names used in different representations should be captured as synonyms.	
Unit of measurement Code	**Type: ST**
	Mandatory
The code/identifier (or whatever can support the unique identification of the term in the referenced source) for the term within the referenced source code system. NOTE The unit of measurement code should not be confused with a “short name” or an “abbreviation” and is not language dependent.	
Unit of Measurement Symbol	**Type: ST**
	Mandatory
The symbol for the unit of measurement concept as defined in the source coding system. NOTE Under this field the preferred unit of measurement symbol within the context of the coding system should be captured, whereas alternative symbols used in different representations should be captured elsewhere as synonyms, e.g. L or l for litre, ul or μl for microlitre (see below).	
Comment	**Type: ST**
	Optional
Additional information related to the unit of measurement code, which cannot be provided in a structured format.	
Language Code	**Type: CD**
	Mandatory
Indicates the language of this entry using ISO 639.	
Region Code	**Type: CD**
	Mandatory
Indicates a geographic refinement of the language of this entry using ISO 3166.	

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4.6.2.3 Code System

A Code System may define zero or more coded concepts. A coded concept represents a class or concept within a particular domain of discourse. Every coded concept shall be defined in exactly one Code System. Once defined, the meaning of a coded concept may not change. Existing coded concepts may be retired and new coded concepts may be added, but once defined, the meaning of a coded concept shall remain static. The Code System class specifies the attributes necessary for the description of a Code System.

NOTE The definition of this class and its attributes is taken from ISO/HL7 27951.

Table 3 — Attributes of the unit of measurement Code System

Class: CodeSystem	
Associations An instance of CodeSystem may be associated with — either one or more instances of CodeEntry — or one or more instances of Dimension	
Code System Identifier	**Type: UID**
	Mandatory
A globally unique identifier for the code system. A Code System Identifier should take the form of an ISO Object Identifier (OID).	
Code System Name	**Type: ST**
	Mandatory
A short token that uniquely identifies the code system. The name is used strictly for communication between humans. The Code System Identifier should be used for all computer-to-computer communication.	
Full Name	**Type: ST**
	Mandatory
The official name of the CodeSystem.	
Code System Description	**Type: ST**
	Mandatory
A description of the purpose and content of the CodeSystem.	
Copyright	**Type: ST**
	Optional
An optional copyright notice that, if present, should be displayed whenever the code system is accessed or used.	
Code System Version	**Type: ST**
	Optional
The coding system or lexicon version (number of the currently used coding system). A Code System shall represent zero or one Code System Versions at any given point in time.	

4.6.3 Structures for translations and synonyms

4.6.3.1 Unit of measurement Concept Translation

This is a human readable representation of the core UnitOfMeasurement concept in a particular language. It provides the term name, symbol and the concept definition in that language (including regional variants). Multiple instances enable the translation of the term name, symbol and the concept definition for the core concept into multiple different languages.

NOTE 1 Translations are representations of the same concept (concerning one or more attributes of that same concept, such as name, symbol and definition) using a different language, other than the preferred one. This should not be confused with alternative names/synonyms, which are different representations of the same concept using the same language as the preferred one.

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NOTE 2 The Translation includes the language and the country to express the concept of Locale: e.g. English UK and English US.

NOTE 3 The preferred term name and symbol within a particular code system are given in CodeEntry (see 4.6.2.2).

Table 4 — Attributes for the translation of unit of measurement

Class: ConceptTranslation	
Association An instance of ConceptTranslation shall be associated with — one instance of UnitOfMeasurement — one to many instances of Operational Attributes	
Unit of measurement Identifier	**Type: String**
(Connector to UnitOfMeasurement)	**Mandatory**
The unique identifier for the unit of measurement entry within the ISO lexicon.	
Unit of measurement Name Translation	**Type: ST**
	Optional
A textual representation of the unit of measurement term name in a different language (other than the preferred one). EXAMPLE The unit of measurement Name "Liter", associated with the language English US has the unit of measurement name translation "Litre" associated to the language English UK.	
Unit of measurement Definition Translation	**Type: ST**
	Optional
A textual representation of the unit of measurement concept definition in a different language (other than the preferred one). It relates to the core unit of measurement concept definition. NOTE A unit of measurement Concept Definition Translation is provided for informative purposes only. The true concept definition will always be in the language used to specify the definition in 4.6.2.2.	
Unit of measurement Symbol Translation	**Type: ST**
	Optional
The symbol for the unit of measurement concept in a different language (other than the preferred one). EXAMPLE The unit of measurement Symbol "IU", associated with the language English UK has a Symbol translation "IE" associated to the language German.	
Language Code	**Type: CD**
	Mandatory
Indicates the language (other than the preferred one) of this entry using ISO 639.	
Region Code	**Type: CD**
	Mandatory
Indicates a geographic refinement of the language (other than the preferred one) of this entry using ISO 3166.	

4.6.3.2 Unit of measurement Synonym

Synonyms are used to capture any other possible names or symbols the unit of measurement Term might have.

NOTE Synonyms are different representations of the same concept (concerning one or more attributes of that same concept, such as name, symbol and definition) using the same language as the preferred one. This is not to be confused with translations, which are representations of the same concept using a different language, other than the preferred one.

EXAMPLE The unit of measurement symbol "μl" is associated with the English language (regardless of Geographic code), and has a Synonym Symbol "ul", associated with the English language and the ASCII 256 character set). A unit of measurement term Symbol can have more than one Synonym.

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Table 5 — Attributes of the unit of measurement Synonym

Class: Synonym	
Associations An instance of Synonym shall be associated with — one instance of UnitOfMeasurement — zero or more instances of UoMSynonymTranslation — one to many instances of Operational Attributes	
Unit of measurement Identifier	**Type: String**
(Connector to UnitOfMeasurement)	**Mandatory**
The unique identifier for the unit of measurement entry within the ISO lexicon.	
Unit of measurement Synonym Identifier	**Type: UID**
	Mandatory
The unique identifier for the unit of measurement Synonym entry including the referencing code system (this is necessary to provide a unique identifier for each instance).	
Unit of measurement Synonym Name	**Type: ST**
	Mandatory
Textual representation of the synonym.	
Unit of measurement Synonym Symbol	**Type: ST**
	Mandatory
Alternative symbol.	
Language Code	**Type: CD**
	Mandatory
Indicates the preferred language of this entry using ISO 639.	
Region Code	**Type: CD**
	Mandatory
Indicates a geographic refinement of the preferred language of this entry using ISO 3166.	

4.6.3.3 Unit of measurement Synonym Translation

These are intended as translations of the synonym term into a different language (other than the preferred one).

All of the languages in which the Synonym has been submitted should be listed. For each Synonym term there will always be the indication of the language in which the term is translated (e.g. Synonym Term: Litre, Language: English UK).

NOTE The Translation may include the language and the country to express the concept of Locale: e.g. English UK and English US.

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Table 6 — Attributes of the unit of measurement Synonym Translation

Class: SynonymTranslation	
Associations: An instance of SynonymTranslation shall be associated with — one instance of Synonym — one to many instances of OperationalAttributes	
Unit of measurement Synonym Identifier	**Type: UID**
(Connector to Synonym)	**Mandatory**
The unique identifier for the unit of measurement Synonym in the referencing vocabulary (including the vocabulary code system identifier).	
Unit of measurement Synonym Name Translation	**Type: ST**
	Mandatory
Textual representation of the Synonym name of the unit of measurement term in a different language (other than the preferred one).	
Unit of measurement Synonym Symbol Translation	**Type: ST**
	Mandatory
Textual representation of the Synonym Symbol in a different language (other than the preferred one) and its character set.	
Language Code	**Type: CD**
	Mandatory
Indicates the language (other than the preferred one) of this entry using ISO 639.	
Region Code	**Type: CD**
	Mandatory
Indicates a geographic refinement of the language (other than the preferred one) of this entry using ISO 3166.	

4.6.4 Structures for conversions

4.6.4.1 Dimension

The class Dimension specifies the attributes necessary for the description of the dimension of a unit of measurement.

The quantity dimension of a unit of measurement represents the fundamental feature of an object that the value (with its unit of measurement) is measuring. A dimension is determined by the kind-of-quantity of the measurement, which in turn is a fundamental concept for the unit of measurement system.

Physical quantities expressed in the SI system of units are equivalent to a product of powers of the SI base units with a numerical scale factor. In the same way, a kind-of-quantity (length, volume, speed, mass, etc.) corresponds to a product of powers of the base quantities. This is called a quantity dimension (e.g. speed is length per time, symbolized by L^1T^{-1}). See also Clause D.3.10.

Such fundamental quantities as length, time, mass and volume have different dimensions. A quantity dimension thus groups measures of the same fundamental feature. All unit of measurement concepts grouped within a quantity dimension have the same fundamental kind-of-quantity and can be converted from one to another.

NOTE Because arbitrary units are not defined in terms of physical base quantities, a quantity dimension cannot be assigned to those units. Formally this is represented by adding the dimension “[arb]” as an additional term as part of the quantity dimension symbol.

The following attributes shall be available in a coding system to define a dimension for a unit of measurement Concept.

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Table 7 — Attributes of the unit of measurement Dimension

Class: Dimension	
Associations An instance of Dimension shall be associated with — zero or more instances of UnitOfMeasurement — one instance of CodeSystem — one to many instances of Operational Attributes	
Dimension identifier	**Type: UID**
	Mandatory
Identifier for the Dimension entry in this vocabulary.	
Dimension Definition	**Type: ST**
	Mandatory
Description of the quantity dimension term. A textual definition of the quantity dimension or a reference to a published source that provides the standard definition.	
Code System Identifier	**Type: UID**
(Connector to CodeSystem)	**Mandatory**
A unique identifier for the coding system or lexicon used to represent the quantity dimension.	
Dimension Name	**Type: ST**
	Optional
Textual representation (print label) of the quantity dimension concept. NOTE The preferred term shall be captured under this field in the preferred language. Synonyms and translations are not captured for the dimension.	
Dimension Symbol	**Type: ST**
	Mandatory
Dimension symbol as defined by the coding system.	
Language Code	**Type: CD**
	Mandatory
Indicates the preferred language of this entry using ISO 639.	
Region Code	**Type: CD**
	Mandatory
Indicates a geographic refinement of the preferred language of this entry using ISO 3166.	

NOTE The operational terms defined in 4.7 will also apply to a dimension concept definition and its representation within a coding scheme.

4.6.4.2 Conversion functions

Coherent units and their relationship to quantity dimensions are described in D.3.10. Since by definition a Coherent unit is a unit of measurement in its own right, when it is necessary to transmit or define a Coherent unit, the class UnitOfMeasurement and its attributes defined in 4.6.2.2 shall be used.

The class Conversion Function specifies the information necessary to specify a unit of measurement conversion function that can be used to convert a given unit from and to its Coherent Unit.

All conversions can be expressed as functions. A simple scale conversion (inch to metre, millilitre to litre) is defined by scale factor, which is a single numeric ConversionFactorValue. For a conversion with a zero-offset (Celsius to Kelvin), two ConversionFactorValues are needed: slope and offset, which corresponds to a general linear function $y = ax+b$. There are more complicated conversions (log, exp, etc.) that may involve other rules or factors.

This implementation is a compromise including explicitly defined factors for “simple” conversions and having a field “Formula” for the more complicated functions.

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A conversion always has an inverse conversion. Conversion between any two units having the same dimension can be accomplished by converting from some source unit to the coherent unit related to the quantity dimension and then using the inverse conversion to get from the coherent unit to the target unit. Any set of conversions associated with units of the same dimension may be substituted by the same number of equivalent conversions, as long as it is ensured that each unit can be converted from and to its coherent unit in a unique way, either directly or through a chain of subsequent conversions. As defined in 4.6.2.1, a unit of measurement shall not be associated with more than one conversion as a source unit. A unit of measurement may be associated with more than one conversion as a target unit. A coherent unit shall not be associated with a conversion as a source unit. This defines a unique series of conversions from and to a unit and its coherent unit.

NOTE Because arbitrary units do not relate to physical quantities and SI units (or the relation is unknown), they usually cannot be converted to any other unit of measurement.

Table 8 — Attributes of the unit of measurement Conversion Function

Class: Conversion	
Associations An instance of Conversion shall be associated with — one instance of UnitOfMeasurement as a source unit of measurement — one instance of UnitOfMeasurement as a target unit of measurement — one to many instances of Operational Attributes	
Conversion Function Identifier	**Type: UID**
	Mandatory
Identifier for the conversion function and its factor(s).	
Conversion Function Formula	**Type: ST**
	Mandatory
The definition of the formula used to convert the source unit of measurement concept to the target unit of measurement concept.	
Source unit of measurement Identifier	**Type: String**
(Connector to UnitOfMeasurement)	**Mandatory**
The identifier or code for the unit of measurement of the value to be converted. This is the unique identifier for the unit of measurement concept within the ISO lexicon.	
Target unit of measurement Identifier	**Type: String**
(Connector to UnitOfMeasurement)	**Mandatory**
The identifier or code for the unit of measurement of the value to be target conversion. This is the unique identifier for the unit of measurement concept within the ISO lexicon.	
Conversion Factor Value (1...*n*)	**Type: Numeric**
	At least 1 is mandatory
In case of scale conversion: a single numeric value used to convert the source unit of measurement concept to the target unit of measurement concept. In case of linear conversion with offset: offset is given as the second value while the first value again is the scale factor. In case of complex conversions: the usage of values as parameters is defined in Conversion Function Formula.	

4.7 Operational attributes

4.7.1 General

This sub-section describes the operational attributes which are necessary in order to ensure vocabulary maintenance and local updates.

This sub-section aims to describe the attributes needed for the exchange standard.

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4.7.2 Operational attribute description

These are attributes which are appended to a unit of measurement Concept Entry or other maintainable objects for administrative and versioning purposes.

NOTE The same list of attributes is used for all maintainable objects.

Table 9 — Common operational attributes used in maintenance of a unit of measurement

<table>
<tr><td colspan="2">Class: OperationalAttributes</td></tr>
<tr><td colspan="2">Associations:
One or more instances of operational attributes shall be associated with instances of either UnitOfMeasurement, CodeEntry, ConceptTranslation, Synonym, SynonymTranslation or Dimension.</td></tr>
<tr><td>Creation Date</td><td>Type: TS</td></tr>
<tr><td></td><td>Mandatory</td></tr>
<tr><td colspan="2">Date and time when the entry was created, which shall comply with the ISO 21090 TS datatype.</td></tr>
<tr><td>Created By</td><td>Type: ST</td></tr>
<tr><td></td><td>Mandatory</td></tr>
<tr><td colspan="2">Details of the entity (user name) that created the entry.</td></tr>
<tr><td>Modification Date</td><td>Type: TS</td></tr>
<tr><td></td><td>Optional with conditions</td></tr>
<tr><td colspan="2">Date and time when the entry was last modified, which shall comply with the ISO 21090 TS datatype. This shall be present when the entry was modified.</td></tr>
<tr><td>Modified By</td><td>Type: ST</td></tr>
<tr><td></td><td>Optional with conditions</td></tr>
<tr><td colspan="2">Details of the entity (user name) that last modified the entry. This shall be present when the entry was modified.</td></tr>
<tr><td>Unit of measurement Status</td><td>Type: CD</td></tr>
<tr><td></td><td>Mandatory</td></tr>
<tr><td colspan="2">CURRENT: a unit of measurement Term or other entry is approved for use in controlled vocabularies.
PROVISIONAL: a provisional term may be needed in situations when the turn-around time cannot be met, but the concept is urgently required. For example, this could be the case when a Term is entered into the system prior to approval as a valid Term.
NON-CURRENT: the Term is not currently valid and therefore should not be used in new standards/application development, but its use is allowed to continue in existing standards/applications already using the term, as it is not physically removed from the system. This may be the case, for example, when a term is made non-current since being replaced with another one. In this case, the data model should capture the new term which replaces the one made non-current, under a separate attribute, called “Current term” (see below). Non-current also includes the notion of deprecated.
NULLIFIED: used when a Controlled Term has been requested by mistake and needs to be removed. For example, a provisional term is eventually rejected.</td></tr>
<tr><td>Current Term</td><td>Type: ST</td></tr>
<tr><td>(Connector to unit of measurement Concept or instance of other class)</td><td>Optional with conditions</td></tr>
<tr><td colspan="2">In case the Status of the entry is “non-current”, the replacement unit of measurement term should be indicated here.</td></tr>
<tr><td>Version Number</td><td>Type: ST</td></tr>
<tr><td></td><td>Optional</td></tr>
<tr><td colspan="2">Incremental number to capture the version.</td></tr>
</table>

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Annex A
(informative)

Using units of measurement for expression of medicinal product strength

The term “strength” subsumes a variety of quantities that are conventionally used for the characterization of medicinal products. Strength may indicate the total amount of substance contained in a single dose or the amount of one component contained in another component, e.g. mass of ingredient substance in one tablet or a volume of liquid. In other cases, the amount of substance released per time interval is used to indicate the strength of a product, e.g. a patch that releases 500 milligrams in 24 hours. The exact quantity used to express a particular instance of medicinal product strength depends on the nature of the medicinal product, the containing component and the contained component (see ISO 11615:2012, Annex C).

The strength of a component should be expressed as an intensive quantity, i.e. a property that does not depend on the amount of material or the size of the component (as opposed to an extensive quantity that varies with the amount of material and/or the size of the component).

It is common practice to express strength as the ratio of two separate quantity values, where the numerator expresses an extensive quantity of the contained component and the denominator expresses an extensive quantity of the containing system. In this case, both quantity values should represent extensive quantities that scale with the amount of the component appropriately in a well-defined way.

Often, strength is expressed on a “per dose” basis. Many medicinal products are presented in the form of individual countable items (for units of presentation, see ISO 11239). Strength of a product is then typically expressed as the amount (e.g. mass, activity, volume, amount-of-substance) that is contained in a single item, the characteristics of this item being particular to this specific product. As the strength denominator represents the magnitude of a quantity of the containing system, it should either be the count of items (i.e. the number “1”) or any other characteristic measure (e.g. mass, volume) of the total amount constituting one item.

A different approach is the expression of strength as an intensive quantity without referring to the total amount or to a single dose. Typically, the content is expressed relative to an appropriate reference unit. In these cases, strength may be expressed as a single quantity, using the appropriate unit of measurement.

NOTE While different approaches may lead to equivalent quantity values for strength, some expressions may contain additional information (total volume, relation to dose) while others do not relate to the total amount or to an individual dose. In the case of strength given on a per dose basis, additional information on the characteristics of the countable dose item may be required when comparing to strengths of other products.

EXAMPLE 1 Expression “per dose”: Total amount of substance per total amount of solution (200 mg of substance contained in 10 ml of solution), total mass of ingredient contained in one single dose (500 mg of substance contained in one tablet). Note that the description of the component (substance, solution, tablet) is not part of the unit of measurement.

EXAMPLE 2 Expression as intensive quantity: Mass concentration 20 mg/ml, activity content 5,000 IU/g.

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Annex B
(informative)

Examples to describe data elements

B.1 Different quantities related to strength

The reference safety information for the medicinal product ProdXXX, a solution for injection, states the following:

> ProdXXX 6,6 mg/ml solution for injection. Each vial contains 1,65 mg of ABC sodium (6,6 mg/ml). The recommended dosage is 165 µg (0,025 ml).

Here, the strength in the product name is given as an intensive quantity: 6,6 mg/ml is a mass concentration using SI units; the quantity dimension is $L^{-3}M$, mass per volume. Another quantity is given in the description: the mass of a specified substance in one container (a vial) is 1,65 mg. The third sentence gives the dosage in two different quantities: mass of the substance and volume of the product.

B.2 Ratio of quantities

The ratio of quantities can be expressed as follows:

> The recommended dose is 90 µg per kg body weight.

The reported quantity is the drug mass relative to the patient's body weight. It belongs to the kind-of-quantity mass ratio and thus is a dimensionless quantity. The numerical value of the quantity is "90" and the unit of measurement is given as "µg/kg", which is equivalent to $10^{-6}/10^{3}$ or 10^{-9}.

Using datatypes defined in ISO 21090, this quantity value can be expressed as relative mass, a dimensionless physical quantity: "90×10^{-9}". Alternatively, more appropriately, it can be expressed as a ratio of two independent physical quantities (using datatype RTO < PQ,PQ >) with the numerator expressing the mass of the substance "90 µg" and the denominator the mass unit "1 kg". In both cases it is important to separate the description of the property from the unit because a unit of measurement is, per definition, independent of the particular measurement (i.e. "patient's body weight" cannot be part of a unit).

B.3 WHO international units (IU)

The description of data elements using WHO IUs can be expressed as follows:

1. Name of the medicinal product:

ProductYYY 500 IU powder and solvent for solution for injection.

2. Qualitative and quantitative composition:

— Protein YYY from human plasma purified by mouse monoclonal antibodies. ProdYYY 500 IU is prepared as a powder containing nominally 500 IU human protein YYY per container.

— The product reconstituted with 5 ml of Sterilized Water for Injections contains approximately 100 IU/ml human protein YYY.

The potency (IU) is determined using a chromogenic substrate method against the WHO international standard.

For biologically active substances, the IU is a unit of measurement for the amount of a substance, based on measured biological activity or effect. An internationally agreed unit is attributed to the first International Reference Preparation for biological activity characterization. The number of units contained in the reference preparation is arbitrarily defined and differs from substance to substance. The continuity of such units is

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ensured by replacement by a new batch of reference preparation which should be calibrated against the first or previous reference preparation (see Reference [46]).

IUs are arbitrary because biological activity generally has no simple known relation to physicochemical quantities of the sample. An IU is defined specifically for each reference preparation. Therefore the precise meaning of IU requires knowledge of the substance or ingredient being measured and of the reference preparation that accounts for the definition of IU for this substance.

IU as a concept relates to a WHO international biological reference preparation for a given substance. Similar reference preparations are provided by USP for a number of substances, so the concept “USP units” relates to the corresponding USP reference preparations for the definition of the unit.

As these units are substance specific; two quantity values measured in IU can only be compared when they refer to the same reference preparation.

Because of the close relationship of these definitions to the given substances and ingredients, the exact reference definitions are addressed as “specified substances” in the scope of ISO 11238, whereas this International Standard only defines generic concepts such as “IU” and “USP Unit”.

B.4 Using the unit symbol “U”

The unit “U” of enzymatic activity was defined in 1964 by the International Union of Biochemistry as the catalytic activity that catalyses the transformation of 1 μmol of the substrate per minute. Typical biological enzyme activities are in the range of 1 U to 100 U. This unit of measurement can also be expressed explicitly as “μmol/min”, where enzymatic activity is the property being addressed. Still, some arbitrariness is involved in the definition of “standard conditions” (e.g. temperature, pH).

This unit denoted by the symbol “U” is not an arbitrary unit. In order to ensure traceability and avoid ambiguities, it is important to discriminate this meaning against the frequently encountered usage of the same symbol “U” for other (arbitrary) units. This is especially required to ensure unique meaning of codes used for information exchange. “U” is assigned to enzymatic activity in the UCUM code system. However, the following description uses the symbol “U” for a completely unrelated concept. Here “U” stands for an arbitrary unit that is defined based on a “bioassay”:

1. Name of the medicinal product:

ProdZZZ 5 000 U/ml solution for injection.

2. Qualitative and quantitative composition:

— 1 ml contains 5 000 U SubstXYZ;

— ProdZZZ 5 000 U/ml contains less than 1 mmol sodium per ml.

As can be deduced from a more detailed description of this product, the “U” here denotes units of potency that are defined based on mouse lethality units, using a particular bioassay. This definition is specific to ProdZZZ and not related to units of other products containing SubstXYZ or other substances.

B.5 Arbitrary units defined through reference procedures

After reconstitution, one dose (0,5 ml) of VaccineABC contains:

AAA virus, strain 7788 (live, attenuated)……….not less than 1x10^3 CCID50

BBB virus, strain 111 (live, attenuated)……………not less than 12,5x10^3 CCID50

CCC virus, strain 123 (live, attenuated) ………………….not less than 1x10^3 CCID50

where CCID50 represents “50 % cell culture infectious dose”.

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The unit “CCID50” expresses the result of quantifying an infectious agent in a cell culture. It is a titre, expressing the highest dilution of the specimen which produces a cytopathic effect in 50 % of the cell cultures or wells inoculated[52][53].

Quantitative titre values are usually obtained by serial dilution. The measurement result gives the dilution that meets the qualitative criterion: killing half of the test cells in this case. The actual measurement determines the concentration CCID50/ml, but CCID50 can be used as a measure for the amount of infective entities in a given volume of the original undiluted solution. So CCID50 is a standard unit of measurement for the infectivity of a given specimen. This is a biological quantity that is related to a well-described standardized measurement procedure, typically used for vaccines. Further parameters of the measurement (organism, substances, test cells) are defined as part of the method definition. No physical quantity dimension can be assigned to infectivity. Formally it is treated as an arbitrary unit because infectivity cannot be expressed in SI units. It is comparable to other CCID50 values obtained for the same infectious agent.

A similar example is the unit “FFU”: It is used to represent viral infectivity as measured in a sensitive assay in cell culture using immunofocus technology. The titre is determined by visualizing infected areas of a cell monolayer by probing with virus-specific monoclonal antibodies and results recorded as FFU/ml[46].

This is similar to the example of CCID50. Again, a well-defined standard procedure is employed that allows FFU to be used as a standard unit of measurement of viral infectivity. As in the case of CCID50, formally this is an arbitrary unit, as relation to SI units are unknown.

B.6 Using proprietary units

The reference safety information for the medicinal product PZZZ 75000 SQ-T oral lyophilisate states the following:

1. Name of the medicinal product:

   PZZZ 75 000 SQ-T oral lyophilisate.

2. Qualitative and quantitative composition:

   Standardized allergen extract of grass pollen from Timothy (Phleum pratense) 75 000 SQ-T[1)] per oral lyophilisate.

“SQ-T” is an arbitrary unit. The definition of this unit refers to an in-house reference preparation and does not refer to a standard reference material, e.g. to the WHO International Biological Reference Preparation 82/520. The quantity value expresses the activity of grass pollen allergen in those arbitrary units. Because there is no reference to standardized units, this value is not comparable to activities measured against other reference materials.

If instead a WHO International Biological Reference Preparation for the given substance “Timothy grass pollen” would have been used, the quantity value would be comparable to other measurements relating to the same reference and the appropriate unit would be IU (UCUM code “[IU]”).

This International Standard enforces standardized unit expressions in order to enable comparability. Therefore the expressions for “in-house reference preparations” are not included in this International Standard as units of measurement but considered as context information.

Quantity values with arbitrary units are only comparable to quantity values of the same kind. The question of whether some other value is of the same kind cannot be decided from an arbitrary unit expression alone. Knowledge of the reference material or the measurement procedure is required. In other words, comparison of quantities involving arbitrary units is only possible when they refer to the same reference material and/or procedure.

NOTE In order to also provide valid UCUM codes for non-standard units, any describing text can be added as a unit annotation (e.g. “[arb’U]{SQ-T}”). The text in curly brackets has no semantic meaning within the scope of units of measurement. The addition of new unit terms to the controlled vocabulary is governed by the vocabulary maintenance rules. A concise definition of the unit concept will be necessary for the addition of a new arbitrary unit, This is also required for “in-house” references in order to ensure traceability of measured results.

1) Standardized Quality Units Tablet (SQ-T).

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B.7 Using curly brackets for undefined units

The reference safety information for SSS sublingual solution of allergen extract for specific immunotherapy states the following:

> 1. Name of the medicinal product
>
> SSS, sublingual solution of allergen extract for specific immunotherapy.
>
> 2. Qualitative and quantitative composition
>
> A vial contains:
>
> 0,1 - 1 - 10 - 100 or 300 IR/ml (standardized allergen extract)
>
> 0,1 - 1 - 10 or 100 IC/ml (non-standardized allergen extract)
>
> of one product or a mixture of several products presented in the safety documentation.

IR and IC neither relate to SI units nor to a reference preparation or procedure. They are to be considered as arbitrary units, obviously measured against proprietary references. Therefore no unit code is given in this International Standard. "[arb'U]{IR}/mL" and "[arb'U]{IC}/mL" would be formally valid UCUM codes, constructed with annotations (curly brackets). For the addition of new unit terms see the previous example. Instead of adding new codes, the units may also be expressed using the valid code "[arb'U]/mL". Then the definition of the measured property and/or the definition of the measured substance (see ISO 11238) will have to define exactly what is being measured and how.

Annotations in curly brackets can be added to any valid UCUM code without introducing any additional semantic meaning.

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Annex C
(informative)

Example — Controlled terminology mapping

C.1 Example — Units of measurement

Table C.1 contains a sample mapping to UCUM Concept Codes of concept codes from currently used controlled terminologies for units of measurement, namely those of NCI Thesaurus and SNOMED CT.

Additionally, the mapping of corresponding terms from EN 12435 has been added.

The selection of terms was guided by the intention to find representative instructive examples. A complete mapping will have to follow vocabulary maintenance rules, including quality assurance and explicit rules for inclusion and exclusion of terms in the mapping.

Table C.1 contains the following information aligned with respective columns:

— UCUM Code of Unit Concept;

— EN 12435 (Unit, Symbol, Dimension);

— NCI Thesaurus (Concept Code, Preferred Term or Synonym, Abbreviation);

— SNOMED CT Identifier.

Table entries left blank signify that no corresponding item could be identified within the respective code system.

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Table C.1 — Mapping example

UCUM Code of Unit Concept	EN Unit	EN Symbol	EN Dimension[a]	NCI Concept Code	NCI Term	NCI Abbreviation	SNOMED CT Identifier[b]
[IU]			[arb]	C70497	Anti-Xa Activity International Unit	anti-Xa activity	258997004
Bq	becquerel	Bq	T^{-1}	C42562	Becquerel	Bq	282141004
Bq/g			$M^{-1}T^{-1}$	C70522	Becquerel per gram	Bq/g	
10^9.[CFU]			[arb]	C68897	Billion Colony Forming Units	Billion CFU	
10^9			1	C71189	Billion Organisms		
m3	cubic metre	m^3	L^3	C42570	Cubic Meter	m^3	396154006
Ci/ml			$L^{-3}T^{-1}$	C71172	Curie per Millilitre	Ci/ml	
d	day	d	T	C25301	Day	d	258703001
[drp]			L^3	C48491	Drop Dosing Unit	Gtt	404218003
[IU]/ml			[arb]	C67377	International Unit per Millilitre	IU/mL	259002007
k[USP'U]			[arb]	C71202	Kilo United States Pharmacopoeia Unit	KUSP'U	
kBq/l			$L^{-3}T^{-1}$	C71167	Kilobecquerel per Liter	kBq/L	
mmol/l			$L^{-3}N$	C64387	Millimole per Liter	mmol/L	258813002
[ppm]	part per million	ppm	1	C48523	Part Per Million	ppm	258731005
Pa	pascal	Pa	$L^{-1}MT^{-2}$	C42547	Pascal	P	259016002
%	per cent	%	1	C48570	Percent	%	118582008
%			1	C48571	Percent Volume per Volume	%V/V	419569009
g/ml	per cent (w/v)	%(w/v)	$L^{-3}M$	C48527	Percent Weight Volume	%M/V	396169007
%			1	C48528	Percent Weight Weight	%W/W	118582008
[PFU]			[arb]	C73575	Plaque Forming Unit Equivalent 1000 Mouse LD50	PFU Equivalent 1000 Mouse LD50	
[lb_av]	pound	lb	M	C48531	Pound	LB	258693003
/min	revolution per minute	r.p.m., rev/min, r/min	T^{-1}	C70469	Revolution per Minute	rpm	286549009
[tb'U]			[arb]	C65132	Tuberculin Unit		415758003
[arb'U]{ELISA}				C68875	Enzyme-Linked Immunosorbent Assay Unit	EL. U	

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Table C.2 shows comments on the mapping examples.

Table C.2 — Comments on the mapping examples

[IU]	The arbitrary unit definition is specific to the substance. For Anti-Xa the unit is defined by WHO reference preparation 01/608. As this is a substance-specific attribute, the reference is not regarded as part of the unit concept definition for WHO IUs (see ISO 11238).
Bq	Becquerel is a coherent derived SI unit (1 Bq = 1 s^{-1}). Formally, this is the same definition as that of Hertz (1 Hz = 1 s^{-1}). The hertz as a unit for the quantity frequency is used only for periodic phenomena, while the becquerel is a unit for activity of a radionuclide and is used only for stochastic processes.
Bq/g	This is an SI-derived unit for the quantity of activity content. It is expressed algebraically in terms of other SI units.
10^9.[CFU]	CFU is an arbitrary unit which is used to count the number of colonies formed by viable microorganisms. It is related to a specific bioassay test method. Note that the number expression “billion” is replaced by the unambiguous power of 10. The meaning of “billion” differs between countries.
10^9	“Billion” is replaced by a power of 10. The notion of “what is counted” is not a part of the unit, but belongs to the method definition (“count of organisms” in this case).
m3	A derived SI unit for the quantity volume. It is based on the metre, the SI-base-unit for length.
Ci/ml	Curie belongs to the group of “other non-SI units accepted for use with the SI”. The algebraic combination with ml yields a derived unit for activity concentration.
d	A day is a “non-SI unit accepted for use with the SI” because it is widely used and well defined in terms of SI units. (1 d = 24 h = 86 400 s). Note that by convention certain units are not to be combined with prefixes. Therefore a “milliday” is not a valid concept.
[drp]	A drop is a variable amount of fluid and depends on the device and technique used to produce the drop and on the physical properties of the fluid. This is similar to units like cup, tablespoon and teaspoon that depend on the spoon or cup and are not exact either. However, in clinical medicine, medication is dispensed by drops and, unlike a “tablet”, a drop refers to a real physical kind-of-quantity, volume, though not very exact (1 drp = 1 ml/12).
[IU]/ml	Arbitrary units can be algebraically combined with other units but the combined unit is still considered arbitrary. The undefined quantity dimension of arbitrary units is denoted with the multiplier “[arb]” in the dimension expression.
k[USP’U]	Like WHO IUs, USP units refer to a substance-specific arbitrary unit definition. By convention they may be combined with a prefix.
kBq/l	Algebraic combination of SI-derived units, becquerel is combined with a prefix. Note that this unit has the same quantity dimension as Ci/ml. Quantity values expressed in these two units are thus “commensurable”, i.e. quantity values can be converted from one unit to the other. The conversion factors are defined as an integral part of the UCUM coding system, therefore the conversion can be done algorithmically based on the unit codes.
mmol/l	Amount-of-substance concentration with a prefix.
[ppm]	A dimensionless unit, it is equivalent to 10^{-6}. Note that this unit cannot be used for expressing a mass concentration.
Pa	The “SI coherent derived unit” for the quantity Pressure (1 Pa = 1 N/m^2 = 1 $m^{-1} \cdot kg \cdot s^{-2}$). Note that other units for pressure are widely used in healthcare, e.g. mmHg (1 mmHg = 133,322 Pa). The UCUM code for mmHg is “mm[Hg]”; the reason for introducing square brackets for some codes is the avoidance of ambiguities for electronic communication.
%	Percent, a dimensionless quantity. Equivalent to the number 0,01. Note that “%(V/V)” and “%(W/W)” are also mapped to “%”. The information on the kind-of-quantity is not considered a part of the unit definition. Thus it has to be conveyed in the context of the quantity value. Similarly, the SNOMED CT ID 419569009 includes information on the measured quantity while 118582008 stands for the “pure” concept percent.
g/ml	A unit for the quantity mass concentration. Note that “%(W/V)” does not represent a dimensionless quantity.

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Table C.2 *(continued)*

[PFU]	The NCI-concept “plaque forming unit equiv 1000 mouse LD50” is mapped to [PFU] for “plaque forming unit”. The fact that this quantity happens to be equivalent to “1000 mouse LD50” is not considered to be part of the unit concept but a component of the method definition (e.g. a titration end point).
[lb_av]	The UCUM code for the avoirdupois pound (1 [lb_av] = 0,45359237 kg). There are various definitions of “pound”. The avoirdupois system is used in the US as well as in countries that use the British imperial system. Note that in pharmacy sometimes a different definition of “pound” is used. The “apothecaries’ system of mass units” defines a pound in terms of dram; UCUM defines a different code “[lb_ap]” for this “apothecaries’ pound” (1 [lb_ap] = 0,3732417 kg). Customary units and their conversions are defined in UCUM in order to accommodate practical needs and may be used for mapping of existing vocabularies. However, SI metric units are preferred.
/min	The unit is “per minute”, regardless of “what” is being counted. “Counting revolutions” is considered to be part of the method definition.
[tb’U]	Tuberculin unit. UCUM defines codes for a number of widely used arbitrary units that have a well defined definition.
[arb’U]{ELISA}	This is an example for the “annotation mechanism” of the UCUM code system. Expressions in curly brackets can formally be added to any valid UCUM code. Any annotation is algebraically interpreted as being equivalent to the number 1. Especially for arbitrary units, this enables the addition of new codes to a vocabulary without extending the underlying code system. Note that the annotation does not provide additional information besides creating a new code for this arbitrary unit; the annotation has no semantic value in the scope of unit algebra. Because the definition of commonly used arbitrary units typically is specific to a particular substance or method, it is recommended to use the generic arbitrary unit codes ([IU], [USP’U], [arb’u] etc.) and convey the reference to the arbitrary unit definition in the context of the quantity value (see ISO 11238). The use of annotations for the addition of new unit codes is governed by the vocabulary maintenance rules.

C.2 Example — Kind–of–quantity

Table C.3 contains examples of kinds–of–quantity and Dimensions as expressed in EN 12435, NCI Thesaurus and SNOMED CT. Table entries left blank signify that no corresponding item could be identified within the respective code system.

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Table C.3 — Examples of kinds-of-quantity and dimensions

EN kind–of–quantity	EN Dimension	NCI Concept Code	NCI Term	SNOMED CT identifier[a]
amount-of-substance of component B	N	C48453	Unit of Amount of Substance	
arbitrary unit	[arb]	C75765	Arbitrary Unit	118521003
areic number	L^{-2}	C75752	Areic Number	118549005
mass concentration	$L^{-3}M$	C64571	Unit of Mass Concentration	118539007
molar mass	MN^{-1}	C75754	Molar Mass	
number concentration	L^{-3}	C67391	Unit of Number Concentration	118550005
partial pressure	$L^{-1}MT^{-2}$	C75755	Partial Pressure	118585005
quantity fraction	1	C75756	Quantity Fraction	118598001
quantity ratio	1	C75757	Quantity Ratio	118586006
relative molar mass	1	C75758	Relative Molar Mass	
relative quantity	1	C75759	Relative Quantity	118593005
substance concentration	$L^{-3}N$	C67386	Arbitrary Unit of Substance Concentration	118556004
substance content	$M^{-1}N$	C67389	Arbitrary Unit of Substance Content	118558003
substance ratio	1	C75760	Substance Ratio	118563004
temperature	θ	C25206	Temperature	246508008
volume	L^3	C25335	Volume	118565006
volume fraction	1	C67469	Volume Fraction	118567003
volume rate	L^3T^{-1}	C75761	Volume Rate	118568008
volumic mass; mass density	$L^{-3}M$	C75762	Mass Density	125146005

[a] This set of SNOMED CT identifiers is reproduced with the permission of IHTSDO solely for the purpose of illustrating the mapping possibilities for units of measurement (“Content”). The IHTSDO does not grant any other right or licence in respect to the Content, and all intellectual property rights in the Content remain the exclusive property of the IHTSDO.

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Annex D
(informative)

Domain analysis model

D.1 General

This annex is intended as explanatory background information. It describes the relations between basic concepts important for understanding the role of units of measurement. As every vocabulary has its own specific background and is rooted in a particular problem domain, so do units of measurement. One specific feature of units of measurement is that they are inseparably linked to concepts used in metrology.

It can safely be assumed that there is no fundamental difference in the basic principles of measurement in physics, chemistry, laboratory medicine, biology or engineering. A selection of these rules and principles will be used to explain the foundations for a vocabulary of units of measurement that is consistent with these concepts. An attempt has been made to also meet conceptual needs for measurements in fields such as biology, biochemistry, molecular biology and pharmacy.

D.2 Conceptual model for controlled vocabularies for units of measurement

Figure D.1 depicts the conceptual domain model for units of measurement, including the conventional usage of procedures and materials as a reference source when expressing a Quantity Value.

The model uses concepts and relations defined in ISO/IEC Guide 99. It is intended to represent the relevant concepts, their relationships and constraints as well as important supporting information in the context of units of measurement, such as quantity dimension and kind-of-quantity.

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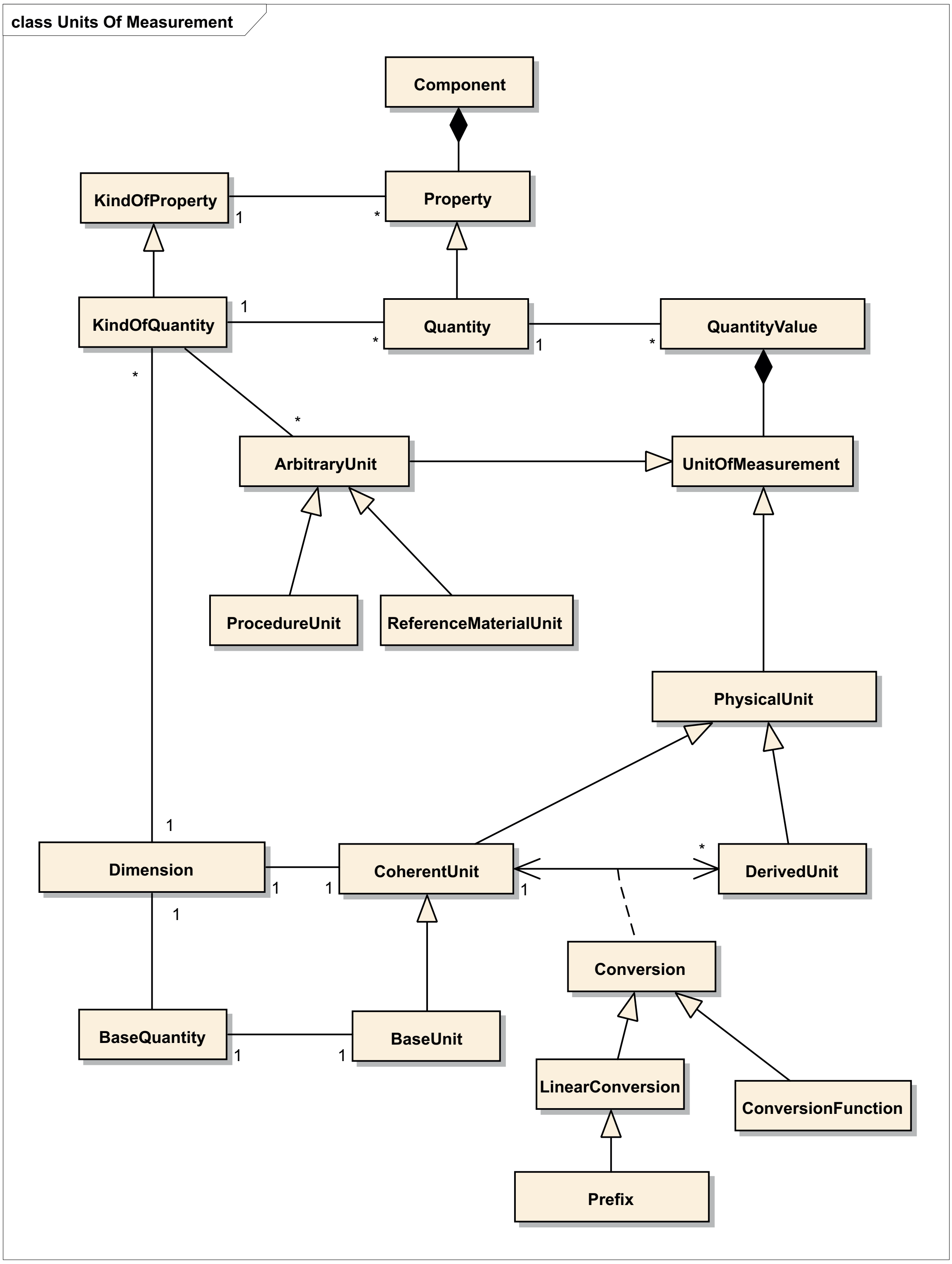

NOTE The relations in the diagram follow the notation defined for class diagrams in the Unified Model Language (UML).

Figure D.1 — Top level model

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D.3 Model description

D.3.1 Quantities and Values

Figure D.2 depicts the upper portion of the model diagram (Quantities and Values). The additional relationships between physical units of measurement and dimension have been omitted for clarity, allowing for the fact that a quantity dimension can be unambiguously assigned to each physical unit of measurement.

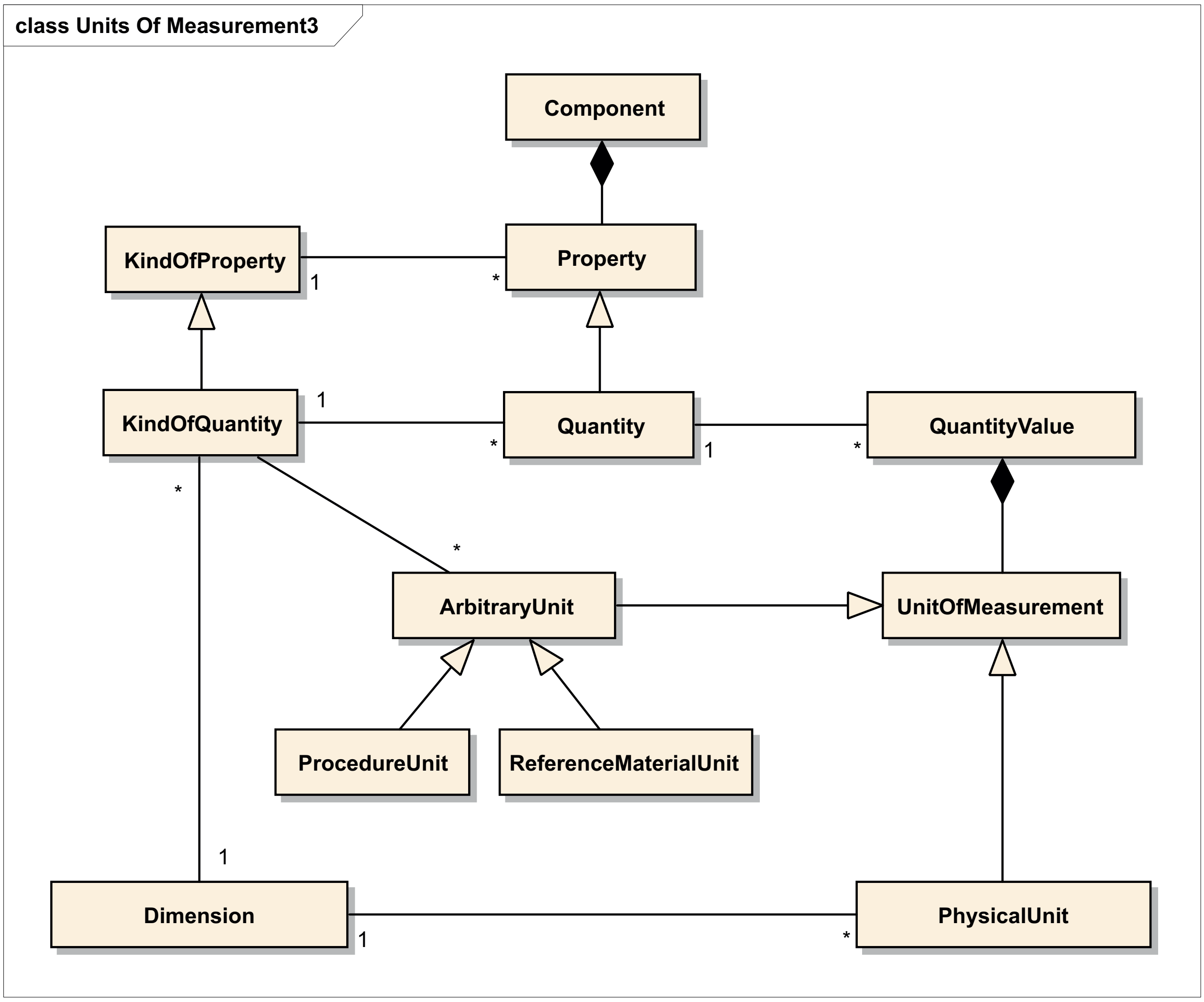

Figure D.2 — Focus on the classes in the upper half of Figure D.1

The *Quantity Value* of a measurement (or a hypothetically measurable quantity) is one of many possible representations of a quantity.

Quantity is one particular measurable property of a particular component (which may be a component of a larger system).

NOTE Quantities cannot be communicated except by expressing them as a *Quantity Value*, with a real number and a unit as a reference. It is important to note that Quantities are independent of a measurement.

D.3.2 Component, Property and Quantity

The description of a *Component* enumerates the component's *Properties* that are relevant in the given context. The *Property* of a specific Component can be classified in a hierarchical manner. This classification leads to

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the concept of a *Kind-of-Property*. In the same sense, one kind-of-property may belong to another, even more generalized, kind-of-property.

EXAMPLE 1 The substance concentration of a given component belongs to “substance concentration” (kind-of-property).

EXAMPLE 2 The circumference of a patient’s chest belongs to the “circumference” (kind-of-property) where circumference in turn belongs to the kind-of-property length.

The properties of a component are described by assigning property values using either qualitative or quantitative scales that are appropriate for the given kind-of-property.

EXAMPLE Colour and shape as qualitative attributes are properties of a component.

Properties that allow the assignment of quantitative values are called quantities.

A kind-of-property that describes such a measurable property would therefore be designated as *Kind-of-Quantity*.

D.3.3 Quantities as definitions of units of measurement

There is an important correlation between a unit of measurement and its Value and Quantity. In accordance with ISO/IEC Guide 99, each unit of measurement is itself a quantity. A unit of measurement is a representation of a Quantity, where its definition is a particular conventionally assigned Quantity with a magnitude. This International Standard quantity is used as a reference for the expression of magnitudes of other quantities of the same kind in terms of numerical values.

EXAMPLE The mass of the platinum-iridium kilogram object in Paris or the frequency of a Caesium hyperfine transition are particular quantities used as reference quantities in the SI system of units.

NOTE It is important to distinguish proper units of measurement from other notions of the word “unit” with the meaning of “entity”, such as counted entities (e.g. “colony forming unit”, “pressure unit”), units of presentation, and any reference to component-specific “arbitrary units”. If a concept is not defined in terms of an independent quantity, it cannot be used as a unit of measurement.

D.3.4 References and units of measurement

The value of a quantity is expressed as a numeric value and a unit of measurement that defines a reference quantity.

If a physical quantity is chosen as a reference, the reference expression is called a “physical unit of measurement” that by definition relates the quantity to external reference quantities through a set of well-defined equations.

For a particular quantity a variety of units may be used.

EXAMPLE Metre per second and kilometre per hour are alternative units for expressing a value of the quantity speed.

The SI is based on a system of well-defined quantities including a set of equations defining the relations between those quantities. The relations between the quantities determine the equations relating the units.

D.3.5 References to materials and procedures

Quantities that describe biological effects are often difficult to relate to units of the SI. For example, the biological activity of certain substances used in medical diagnosis and therapy cannot yet be defined in terms of the SI base quantities.

NOTE 1 In order to provide well-defined reference quantities for the biological activity of such substances, the WHO has taken responsibility for defining a large number of substance-specific WHO IUs.

NOTE 2 In the field of biochemical measurements, references to specific materials or procedures are frequently employed for the expression of quantity values. These references are usually specific to the substance and the kind-of-quantity being investigated. On the other hand, they are not directly related to independent physical units of measurement.

Because of the *arbitrariness* involved in the definition of such references, they are commonly designated as *arbitrary units* when used in conjunction with SI units of measurement. If this type of reference is employed as a unit to express a Quantity Value, the definition of the reference should also be made available, possibly in the definition of the measurable, substance-specific kind-of-quantity.

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An arbitrary unit can be either a procedure or a reference material, often defined specifically for one component. On the other hand, all physical units of a given dimension within a system of units are related to the same common reference quantity by their definition.

D.3.6 Dimensionless quantities

Properties are often expressed as a ratio of two quantities of the same kind.

EXAMPLES Mass ratio, relative concentration, quantitative comparison to a given laboratory reference standard.

These quantities are pure numbers and they are “dimensionless”, i.e. they have a value but their unit is “1” or a multiple of “1”. Therefore, the communication of values and units generally is not sufficient to identify the measured quantity.

Where dimensionless quantities are recorded or communicated, the measured kind-of-quantity should also be reported. This additional information allows the reader to understand whether, for example, the reported dimensionless value stands for a mass ratio, a relative volume or a concentration fraction.

D.3.7 Systems of units and conversions

Figure D.3 depicts the lower portion for the model diagram.

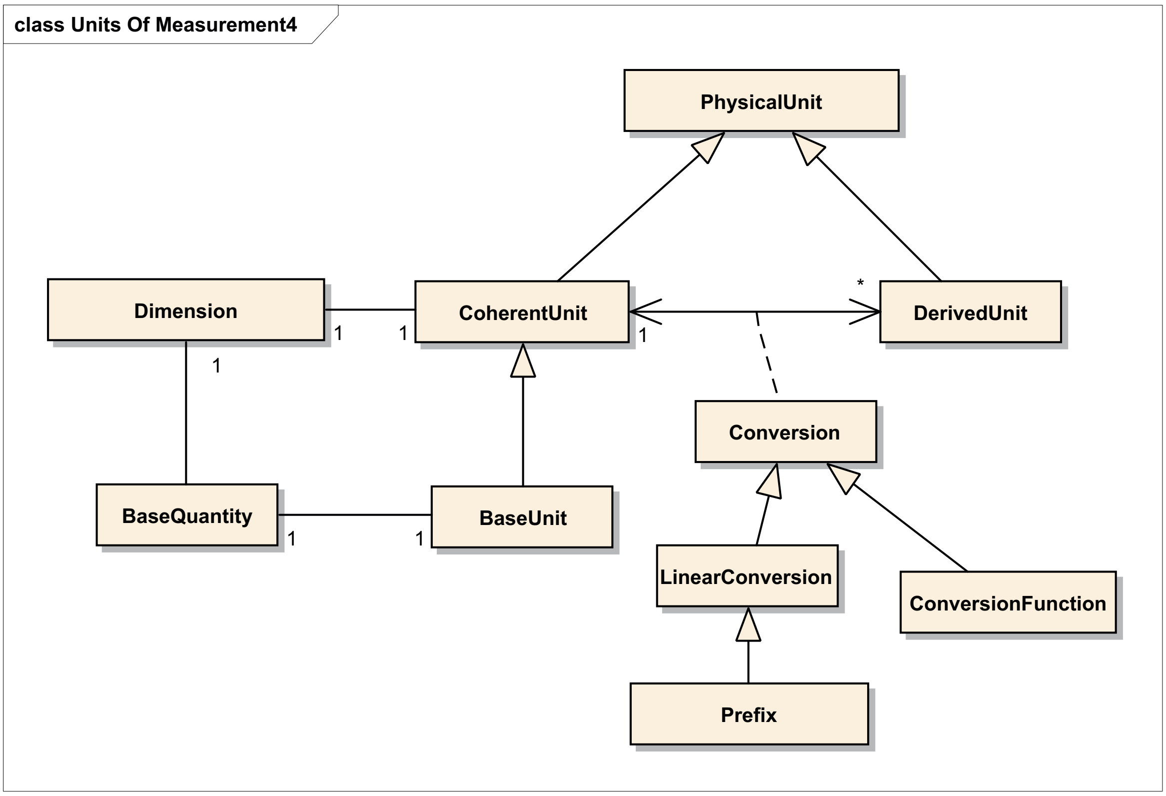

Figure D.3 — Lower section of units of measurement model

Different kinds-of-quantity may apply to a given combination of component(s) and system. Often the different quantities are interconvertible. A reference coding system for units of measurement is required to support this interconvertibility. The respective quantity relations should be reflected as concept relations in the vocabulary.

D.3.8 Systems of units

ISO/IEC Guide 99 recognizes the existence of different possible systems of units (and systems of quantities). The notions of base quantity, base unit and even dimension are dependent on the particular choice of a system of units.

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By convention a small number of base quantities is chosen that define a corresponding set of base units. All other quantities are defined as products of powers of the base quantities; the corresponding derived units are defined as products of powers of the base units.

The SI is founded on seven base quantities and defines the corresponding base units (see Table D.1).

Table D.1 — SI base units

Base quantity	Base unit	
length	metre	m
mass	kilogram	kg
time	second	s
electric current	ampere	A
thermodynamic temperature	kelvin	K
amount of substance	mole	mol
luminous intensity	candela	cd

NOTE A particular unit of measurement may be used in different Systems of Units. For example, 1 cm is a unit in the SI and in the centimetre, gram, second system of physical units. Historically, several systems of units were used and their related units (base and derived) are still conventionally used in certain domains. In the SI such units are derived units, related to the coherent units through well-defined conversion factors (or conversion functions).

D.3.9 Conversion

Unit conversion is a transformation which yields the numerical quantity value with respect to one unit from a given numerical value of the same quantity with respect to another unit.

Conversions are reversible and hence generally appear as a pair of functions, i.e. a conversion function and its inverse function.

Conversions may either be linear, or use nonlinear functions (logarithmic, exponential, etc.) A linear conversion between units on rational scales is characterized by a single number, the conversion factor. If a unit on a differential scale is involved, linear conversions is defined by two numbers, slope and intercept (e.g. Degree Celsius to Kelvin).

Unit prefixes convey the required linear conversion factors explicitly through their standardized use and meaning.

EXAMPLE The conversion factor between mmol and nmol is 10^6.

NOTE A unit conversion does not depend on the particular quantity being measured. For example, a conversion between inches and metres does not require knowledge of any aspect of the quantity itself or the component. In contrast, the conversion between different quantities of one component generally requires knowledge of additional properties of the component. For example, converting a value of mass concentration to a value of substance concentration involves the component's molar weight.

D.3.10 Coherent units and dimension

Derived units are defined as products of powers of the base units. When the product of powers includes no numerical factor other than one, the derived units are called coherent units.

Consequently, each derived unit of measurement has exactly one associated coherent unit. The conversion from and to this coherent unit is well defined for a given unit.

By convention, physical quantities are organized in a system of quantity dimensions. Each of the seven base quantities used in the SI is regarded as having its own dimension, which is symbolically represented by a single sans serif roman capital letter. The symbols used for the dimensions of SI base quantities are given as follows.

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Table D.2 — SI symbols of dimension

Base quantity	Symbol for dimension
length	L
mass	M
time	T
electric current	I
thermodynamic temperature	θ
amount of substance	N
luminous intensity	J

The conventional symbolic representation of the dimension of a quantity is the product of powers of the dimensions of the base quantities according to the definition of the derived quantity.

EXAMPLE 1 The kind-of-quantity mass concentration has the quantity dimension $L^{-3}M^{1}T^{0}I^{0}\theta^{0}N^{0}J^{0} = L^{-3}M$, which stands for mass per volume.

Each coherent unit is related to exactly one quantity dimension, where base quantities and base units carry the same exponents.

The expression for the coherent unit of a derived quantity is obtained from the dimension of that quantity by replacing the dimension symbols by the symbols of the corresponding base units.

EXAMPLE 2 The coherent unit of mechanical force is N which is defined as $1\ N = 1\ kg.m/s^{2} = 1\ m.kg.s^{-2}$ and the dimension of mechanical force is LMT^{-2}.

The quantity dimension of the unit should always match the dimension of the measured kind-of-quantity.

If two units do not have the same quantity dimension they cannot be used to describe the same kind-of-quantity.

Dimensions (or coherent units) can be used to categorize or classify units, where a formally defined parent-child relationship exists between a quantity dimension and its unit concepts.

EXAMPLE 3 Metre or inch are units in the dimension of length (L) and gallons or millilitres are units in the dimension of volume (L^{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.

D.4 Usage of units in expressions for measured quantities

A measurement can be expressed in a logical statement, which includes the following possible elements:

— system;

— component;

— kind-of-quantity;

— relational operator;

— numerical value;

— unit of measurement;

— uncertainty.

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In symbolic language:

`q = {q} • [q] ± {uc} • [q]`

where:

`q` is any measurable quantity (designated by a kind-of-quantity, a system and any component);

`[q]` is a reference or unit of measurement of the quantity `q`; and

`{q}` is its numerical value in that unit.

If the numerical value `{uc}` of the combined uncertainty of a measurement is also expressed, that same unit `[q]` is used.

ISO/IEC Guide 99 provides a slightly broader definition which extends to references that are not directly related to base quantities as it is required for units of measurement:

> “A quantity has a magnitude that can be expressed as a number and a reference. A reference can be a measurement unit, a measurement procedure, a reference material or a combination of such.”

NOTE From both definitions it can be derived that, in general, it is not sufficient to express a measurement in the form of a numerical value and a unit of measurement alone. Communication of a value using a unit of measurement therefore always requires referencing the measured kind-of-quantity. Communication of values with references other than units of measurement in this view is equivalent to referencing a well-defined kind-of-quantity, which in turn precisely defines the reference material or procedure being addressed.

In conclusion, the kind-of-quantity should always be referenced in the expression of measurement results, possibly accompanied by a unit of measurement. Though units are necessary, they are not sufficient to describe the measured quantity.

EXAMPLES Something measured in units of “Pa” could be a partial pressure of oxygen, blood pressure or the pressure of vacuum in a laboratory. Also, the volumetric fuel consumption per distance travelled is a kind-of-quantity that can be measured in $m^3/m = m^2$. The same unit of measurement m^2 can be used to express values for area measurements, which definitely are a different kind-of-quantity.

This can be seen as a requirement for the communication of measurement results: besides the measured quantity value, information on the other elements is generally required in order to fully specify the result.

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