SLOVENSKI STANDARD
SIST EN ISO 11240:2013

01-februar-2013

Zdravstvena informatika - Identifikacija medicinskih izdelkov - Elementi in zgradba podatkov za enotno identifikacijo in izmenjavo merilnih enot (ISO 11240:2012)

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of units of measurement (ISO 11240:2012)

Medizinische Informatik - Identifikation von Arzneimitteln - Datenelemente, Struktur und kontrolliertes Vokabular für Maßeinheiten (ISO 11240:2012)

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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35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST EN ISO 11240:2013 **en**

EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN ISO 11240

November 2012

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English Version

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of units of measurement (ISO 11240:2012)

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)

Medizinische Informatik - Identifikation von Arzneimitteln - Datenelemente, Struktur und kontrolliertes Vokabular für Maßeinheiten (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of an identical text or by endorsement, at the latest by May 2013, and conflicting national standards shall be withdrawn at the latest by May 2013.

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The text of ISO 11240:2012 has been approved by CEN as a EN ISO 11240:2012 without any modification.

INTERNATIONAL STANDARD

ISO 11240

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

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

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Foreword

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

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

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

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,

— 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.

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.

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.

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.