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Healthcare informatics - Structure for nomenclature, classification, and coding of properties in clinical laboratory sciences

Structure pour les nomenclatures, les classifications et les systemes de codage des propriétés dans le domaine des laboratoires d'analyses médicales

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English version

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Structure pour les nomenclatures, les classifications et les systèmes de codage des propriétés dans le domaine des laboratoires d'analyses médicales

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CEN

European Committee for Standardization
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Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

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Contents

Annexes

Foreword

This European Prestandard has been prepared by the Technical Committee CEN/TC 251 "Electrically propelled road vehicles" of which the secretariat is held by AFNOR.

According to the CEN/CENELEC Internal Regulations, the following countries are bound to announce this European Standard:
Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

Introduction

This European Prestandard provides a system of concepts for the nomenclature, classification, and coding of ***properties, including quantities***[1] in Clinical Laboratory Sciences.

The need for this work stems from the increasing use of computerized clinical laboratory information systems, and the increasing need for reliable communication between laboratory information systems and between laboratory and other health information systems. Previous work in this area has in general been motivated by restricted purposes such as reimbursement, and has not included critical analysis of the basic concepts and their relationships to existing standards and recommendations.

Potential users of this European Prestandard are:

- International and national organizations responsible for development, maintenance or registration of nomenclatures, classifications and coding systems;
- Designers and developers of health care information systems (HCIS);
- Persons responsible for acquisition of HCIS and checking compliance with standards;
- Designers and developers of computerized diagnostic devices and data acquisition systems.

The degree to which a message (such as a clinical laboratory report) needs to be expressed in a formal, systematic language depends on the geographical, linguistic, social or professional distance between the communicating parties. The greater the distance, the greater the risk of misunderstanding.

Within any one clinical laboratory, local jargon terms may be used which are usually well understood between colleagues, but which would not be sufficiently widely known for communication with the outside world. Likewise, a laboratory and its local community of users, such as hospital or community physicians, may use a "local dialect" of the language of clinical laboratories which is well understood by all concerned; but if communication possibilities are wider, even transnational, risks of serious misunderstanding arise (Figure 1).

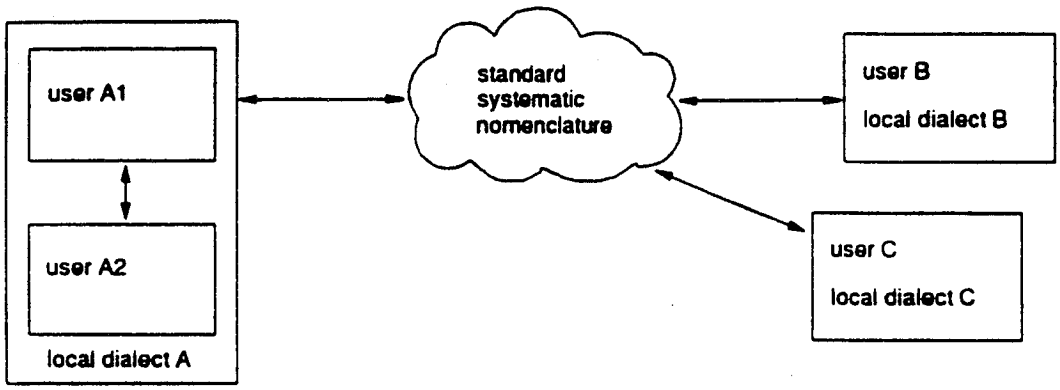

Figure 1: Systematic nomenclature as the bridge between local dialects

1) The terms "test", "assay", and "laboratory procedure" are sometimes used as synonyms for "quantity" or "property". Their use in this sense is deprecated for the purposes of this Prestandard.

Risks of misunderstanding also increase when the "professional distance" between communicating parties increases, e.g. laboratory to health administrator rather than laboratory to clinician.

Two approaches to reducing this risk are:

1. To standardize the technical language used by clinical laboratory workers, users of the service, and other interested parties throughout the whole area in which communications may take place by eliminating all "local dialects".

This is obviously impracticable. Laboratory workers and clinicians would object to any such attempt from medical informatics. In the long run, agreement between professional bodies, with the cooperation of educational institutions, may lead to a greater degree of uniformity in the language of clinical laboratories, but this will not happen quickly and cannot be forced.

2. To create a standard nomenclature which can be used as the basis for coding clinical laboratory messages for transmission between different locations and which contains sufficient information to allow the message to be translated from and to the required "local dialect" at each end.

This is the more practical approach. The terminology used in this Prestandard is a selection from the highest authoritative sources, supplemented by additional concepts with terms as far as possible derived from the basic terms, for coherence.

Much work has already been done in producing lists, coding schemes, and classifications, of the concepts used in clinical laboratory requests and reports. Brief descriptions of two existing systems are given in Annexes D and E (informative). In contrast, this prestandard is not intended to create a coding or classification system, but to create a structure for coding and classification schemes. The model used here is based on that of IUPAC/IFCC for quantities in clinical laboratory sciences (Annex C (informative)). Since its origin in 1966, this model has been successfully applied in clinical chemistry and related fields, and extensive lists of systematic quantity names have been published (references H.7 and H.10, Annex H (informative), Bibliography). In this Prestandard the model has been extended to the more general concept of "property".

Because of the interdisciplinary nature of this work (see Annex F, informative), parts of this document may be difficult to understand for readers who are not familiar with the concepts of metrology and object oriented analysis. This applies in particular to parts of Clause 3, Definitions. It is recommended that such readers should read Annex F before reading the normative clauses of this Prestandard. For more detailed background information, the normative references VIM and ISO 1087 (see Clause 2) and references H.10 and H.14 (Annex H (informative), bibliography) may be consulted.

Title

Health care informatics.
Structure for nomenclature, classification, and coding of properties in clinical laboratory sciences.

1. Scope

1.1 Purpose

This Prestandard provides a coherent system of concepts underlying systematic names, classifications, and coding for properties, including quantities, in clinical laboratory sciences. The system is intended to facilitate the communication of messages about such properties through computing and telecommunications equipment.

1.2 Field of application

This Prestandard is applicable to all branches of clinical laboratory sciences. It also applies to related areas such as measurement in the physician's office, at the bedside, and in the home.

1.3 Uses

This system of concepts constitutes the essential basis for development of nomenclatures, classifications and coding systems intended for use in unambiguous and fully informative communication about properties which fall within the field of application. Every such communication, including requests to and reports from clinical laboratories, and information retrieval for management reporting, research and reimbursement, will require additional concepts which are outside the scope of this Prestandard.

1.4 Limitations

It is not the purpose of this Prestandard to standardize the language used by health care practitioners in requesting or reporting clinical laboratory data. It may, however, be used as a guide by those who wish to adopt systematic names for routine requesting and reporting of laboratory data.

2. Normative references

This European Prestandard incorporates by dated or undated reference provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to, or revisions of, any of these publications apply to this European Prestandard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML.
International vocabulary of basic and general terms in metrology / Vocabulaire international des termes fondamentaux et généraux de métrologie. 2nd ed. Geneva: ISO, 1993.

NOTE: This document is referred to by the abbreviation VIM

ISO 31-0. Quantities and units - Part 0: General principles.

ISO 31-1/13. Quantities and units - Parts 1/13 (specific fields).

ISO 31-11. Mathematical signs and symbols for use in the physical sciences and technology.

ISO 1087. Vocabulary of terminology.

ISO 5127-1. Documentation and information - Vocabulary - Part 1: Basic concepts; Part 6: Documentary languages.

NOTE: Additional references (non-normative) are given in Annex H (bibliography, informative).

3. Definitions

NOTE 1: Additional definitions which may be found useful in understanding the non-normative parts of this document are given in Annex G (informative), Vocabulary.

NOTE 2: In this Clause, entries in the list of terms are shown in **bold** type, terms defined elsewhere in Clause 3 are in *italic* (oblique) type, and examples of defined concepts are underlined where necessary to distinguish them from the surrounding text.

NOTE 3: Sources of definitions are given in square brackets. Where no source is shown, the definition has been conceived for the purpose of this Prestandard.

For the purposes of this Prestandard, the following definitions apply:

3.1 Metrological concepts

3.1.1 property (in a general sense): Attribute of a phenomenon, body or substance that may be distinguished qualitatively.

EXAMPLES:
Colour; transparency; length; amount of substance.

NOTE 1: In this Prestandard *property* has the concept sub-type measurable property, also known as *quantity in a general sense*. All properties may be related to nominal and ordinal scales, but "measurable properties" are generally related to difference or ratio scales.

NOTE 2: The words "in a general sense" can most often be left out without causing ambiguity, cf. 3.1.3 NOTE 2.

NOTE 3: Authoritative lists of *quantities* are issued by ISO (in ISO 31), IFCC, and IUPAC.

3.1.2 particular property: *Property* of a given object (phenomenon, body or substance).

NOTE 1: Some *particular properties* are of the sub-type *particular quantity*, cf. 3.1.1 NOTE 1.

NOTE 2: The adjective "particular" may be omitted, if no ambiguity is caused, cf. 3.1.4 NOTE.

3.1.3 (measurable or physical) quantity (in a general sense): Attribute of a phenomenon, body or substance that may be distinguished qualitatively and determined quantitatively [VIM].

EXAMPLES:
Length; amount of substance.

NOTE 1: The adjectives "measurable" and "physical" are used in VIM and in ISO 31, respectively, when required to point out that the word "quantity" is used in its metrological sense. In general, the adjectives can be omitted.

NOTE 2: The term *quantity* may refer to a *quantity in a general sense* or to a *particular quantity* [VIM]. The words "in a general sense" can most often be left out without causing ambiguity.

3.1.4 particular quantity: *Quantity* of a given object (phenomenon, body or substance).

NOTE: The term *quantity* may refer to a *quantity in a general sense* or to a *particular quantity* [VIM]. The adjective "particular" may be omitted, if no ambiguity is caused.

3.1.5 system: Demarcated arrangement of a set of elements and a set of relationships between these elements.

EXAMPLES:
Examples of systems relevant to clinical laboratories are: a man; a portion of urine; the thrombocytes in the blood of a person.

NOTE 1: The *component* parts of a *system* and therefore the *system* itself may have *particular properties*.

NOTE 2: A *system* which contains other *systems* (subsystems) may be referred to as a "supersystem" of those systems.

NOTE 3: The above definition is that of Gottschalk (reference H.5, Annex H (informative) Bibliography).

3.1.6 component: Definable part of a *system*.

EXAMPLES:
Blood plasma of a person; glucose in a portion of urine; the process of coagulation of a sample of blood. (The process of coagulation is conventionally regarded as a component of blood in the Quantities and Units work of IUPAC/IFCC. This has been accepted by the International Society of Thrombosis and Haemostasis — reference H.7, Annex H (informative) Bibliography).

3.2 Terminological concepts

3.2.1 nomenclature: System of terms which is elaborated according to pre-established naming rules [ISO 1087].

3.2.2 systematic name: Name reflecting the principles of a *nomenclature*.

EXAMPLES: The systematic names for enzymes of the International Union of Biochemistry and Molecular Biology, reference H.6, Annex H (informative), Bibliography.

4. Requirements

4.1 Axes

The following axes shall be used for the nomenclature, classification, and coding of **particular properties** in clinical laboratory sciences.

system
component
property (in a general sense)

Additional concepts shall be appended to any or all of the axes when this is necessary to define the particular property to the degree required for a given purpose.

NOTE 1: A concept, or group of concepts, used in this way is called a *specification*. Examples are: to the system *plasma*, the specification *venous blood*; to the component *chromium*, the specification *Stock notation IV*. Additional concepts may also be required to provide further independent axes in actual nomenclatures or systems of classification or coding, depending on their purpose.

NOTE 2: **Particular quantity** is a special case of **particular property**. When the nomenclature, classification or coding system in question is concerned only with **particular quantities**, the term **quantity (in a general sense)** may be substituted for **property (in a general sense)** to describe the third axis.

NOTE 3: Figures 2 to 4 illustrate relationships between particular property, particular quantity, their axes, and some closely related concepts. The notation used in the figures is that of Martin and Odell (1992) (reference H.14, Annex H (informative), Bibliography). It is briefly described in Annex A (informative). In figures 2 and 4, the shaded area includes the particular property and its axes. Examples of particular properties, following the above model and presented in the style of Figure 2, are shown in Figures 5 to 7.

4.2 Syntax rules for systematic names of particular properties[2)]

The systematic name of a particular property shall have the format

System(specification)—
Component(specification);
property (in a general sense)(specification)

The element "(specification)" shall have a null value when no specification is required. The em dash following the name of the system and the semicolon following the name of the component shall not be used within names of system, component and property. Semicolons may however be used within any parenthetic specification.

4.3 Coding systems

Syntactic rules for the construction of codes are outside the scope of the Prestandard; any coding system which allows unambiguous mapping between the codes and systematic names of particular properties may be regarded as complying with the requirements of this Prestandard.

NOTE: An example of detailed rules for the formation and combination of the elements of the systematic name of a particular property may be found in IUPAC/IFCC "Quantities and Units in Clinical Laboratory Sciences" (reference H.10, Annex H (informative), Bibliography). The topic is briefly discussed in Annex F (informative).

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2) For further information, see Annex F (informative) and references H.1, H.2, H.3, H.7, H.11 and H.13 in Annex H (informative).

4.4 Concept diagrams

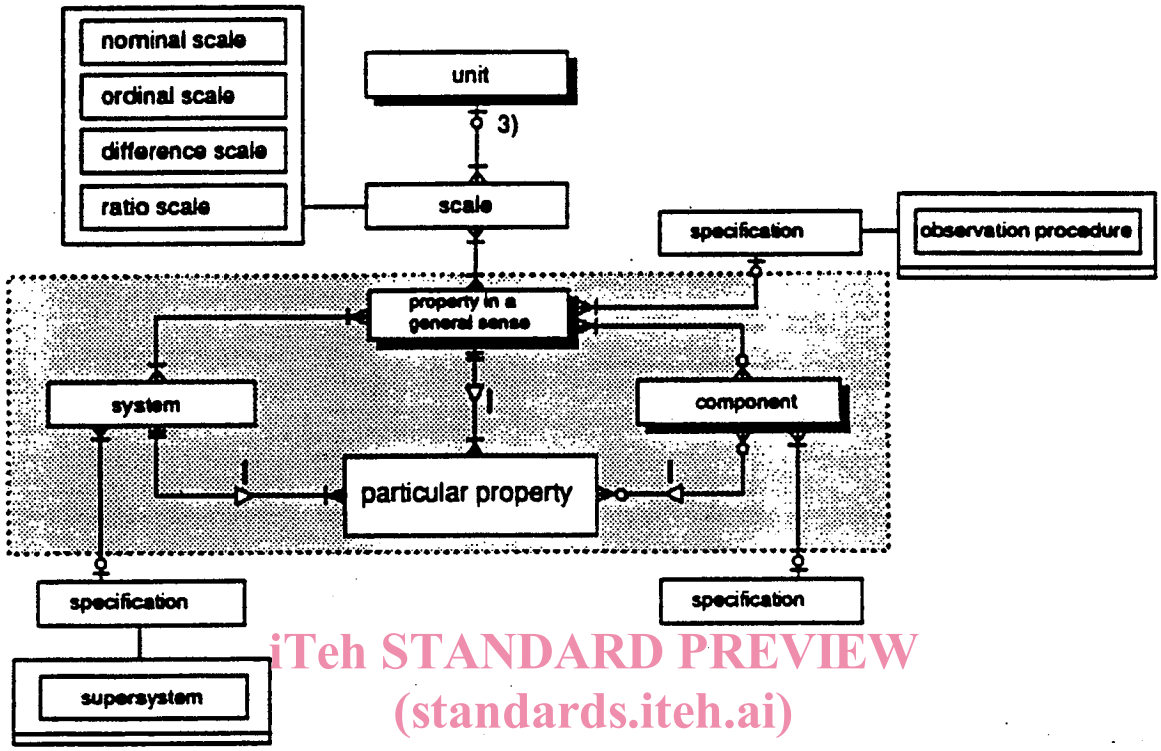

Figure 2: Concept diagram for properties in clinical laboratory sciences
Normative elements are enclosed by the shaded rectangle.

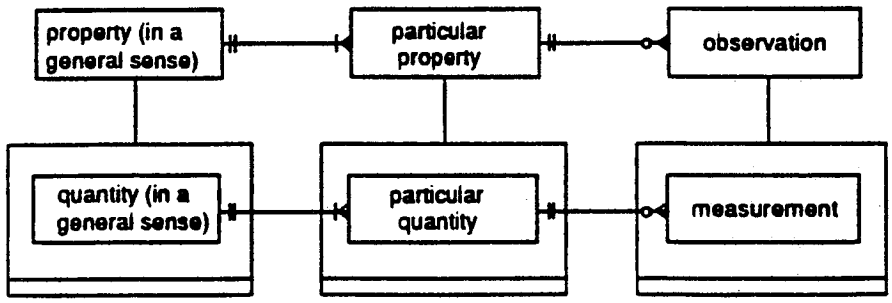

Figure 3: Relationships between properties and quantities.

3) In the great majority of cases, a scale will have at most one unit, as shown. However, it is possible to have a scale with more than one unit; for example a scale for mass with the units mg, g, kg.