

### SLOVENSKI STANDARD SIST EN 1614:2006

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## Zdravstvena informatika - Predstavitev posebnih vrst lastnosti v laboratorijski medicini

Health informatics - Representation of dedicated kinds of property in laboratory medicine

Medizinische Informatik - Darstellung von bestimmten Arten von Eigenschaften in der Laboratoriumsmedizin Teh STANDARD PREVIEW

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Informatique de santé - Représentation des différentes sortes de propriété dédiée dans la médecine de laboratoire

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ICS:

35.240.80 Uporabniške rešitve IT v IT applications in health care

zdravstveni tehniki technology

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## EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

**EN 1614** 

September 2006

ICS 35.240.80

Supersedes ENV 1614:1995

#### **English Version**

# Health informatics - Representation of dedicated kinds of property in laboratory medicine

Medizinische Informatik - Darstellung von bestimmten Arten von Eigenschaften in der Laboratoriumsmedizin

This European Standard was approved by CEN on 14 August 2006.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG

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#### **Foreword**

This document (EN 1614:2006) has been prepared by 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 March 2007, and conflicting national standards shall be withdrawn at the latest by March 2007.

This document supersedes ENV 1614:1995.

The major technical changes are that issues relating to the distinction between kinds and instances of property have been resolved and that normative references to IUPAC-IFCC C-NPU have been removed.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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#### Introduction

This European Standard provides a model for the representation of dedicated kinds of property in laboratory medicine.

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 care information systems (HCIS).

Potential users of this European Standard are:

- international and national organizations responsible for development, maintenance or registration of nomenclatures, classifications and coding systems;
- designers and developers of HCIS, e.g. laboratory information systems (LIS);
- persons responsible for acquisition of HCIS and checking compliance with standards;
- designers and developers of computerized diagnostic devices and data acquisition systems;
- developers of communication standards. A ND ARD PREVIEW

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 (Local Dialect A in Figure 1), 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.

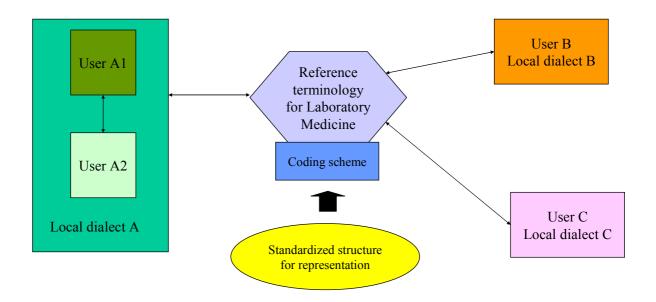


Figure 1 — Reference terminology as the bridge between local dialects

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:

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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 coding scheme and a reference terminology for laboratory medicine which can be used as the basis for coding the dedicated kind-of-property part of a 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. The coding scheme should be based on a standardized representation structure.

This is the more practical approach.

#### 1 Scope

#### 1.1 Purpose

This European Standard provides a structure aiding the representation, e.g. systematic terms or coding systems, of dedicated kinds of property, including dedicated kinds of quantity, in laboratory medicine. The structure for representation is intended to facilitate the unambiguous communication of messages containing information about properties.

#### 1.2 Field of application

This European Standard is applicable to all branches of laboratory medicine and other bodies offering laboratory analytic services. Examinations performed in the physician's office, at the bedside, or in the home are considered to be part of the laboratory medicine domain and thus this European Standard applies.

#### 1.3 Uses

This structure for representation constitutes the essential basis for development of nomenclatures 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 information which is outside the scope of this European Standard.

#### 1.4 Limitations

It should be emphasized that it is not the purpose of this European Standard 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 terms for routine requesting and reporting of laboratory data.

The syntax used for representing dedicated kinds-of-property is outside the scope of this European Standard, as are syntactic rules for the construction of codes in coding schemes.

The purpose is not to standardize the presentation of properties or kinds-of-property in user interfaces of computer systems nor the presentation in printed documents **presentation** presentation presenta

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#### 2 Normative references

Not applicable.

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#### 3 Terms and definitions

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

#### 3.1

#### system

part or phenomenon of the perceivable or conceivable world consisting of a demarcated arrangement of a set of elements and a set of relationships or processes between these elements [1]

EXAMPLE A given human being; a given portion of urine; the blood of a given person.

NOTE A system is, with the exception of the universe, a part of at least one more comprehensive super system and can itself contain one or several subsystems.

#### 3.2

#### component

part of a system (3.1)

EXAMPLE Body of a given human being; glucose in a given portion of urine; the process of coagulation of the blood of a given person.

NOTE 1 Systems are open, i.e. transport occurs across their borders, both as input and output. Such transported entities may be conveniently regarded as components of the system.

NOTE 2 Components may be complex in that they may be aggregates of other components.

#### 3.3

#### property

inherent state- or process-descriptive feature of a **system** (3.1) including any pertinent **component** (3.2) being determined

EXAMPLE Mass of the body of a given person at a given point in time; amount-of-substance concentration of glucose in a portion of urine at a given point in time.

#### 3.4

#### quantity

attribute of a phenomenon, body or substance that may be distinguished qualitatively and determined quantitatively [VIM]

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

NOTE 1 Quantity is more specific in relation to property (3.3).

NOTE 2 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, these adjectives can be omitted.

#### 3.5

#### kind-of-property

common defining aspect of mutually comparable properties (3.3) [1]

EXAMPLE Colour; mass; amount-of-substance concentration.

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

#### 3.6

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#### dedicated kind-of-property

**kind-of-property** (3.5) with a given kind of **component** (3.2) subject for determination https://standards.iteh.ai/catalog/standards/sist/f47b4007-f96f-481e-98cb-

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EXAMPLE Mass of the body of a non-specified human being; amount-of-substance concentration of glucose in urine.

#### 3.7

#### procedure

specified way to carry out an activity or a process [9]

#### 3.8

#### measurement scale

ordered set of values of quantities of a given kind, continuous or discrete, used in arranging quantities of the same kind by magnitude [12]

#### 3.9

#### unit

scalar quantity, defined and adopted by convention, with which other quantities of the same kind are compared in order to express their magnitudes [12]

#### 4 Requirements

#### 4.1 Representation of dedicated kind-of-property

The following elements stemming from the ontology of property shall be used for the representation of **dedicated kinds-of-property** (3.6) in laboratory medicine:

kind of system (3.1);