



# SLOVENSKI STANDARD

## SIST-TS CEN/TS 15699:2009

01-april-2009

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Health informatics - Clinical knowledge resources - Metadata

Medizinische Informatik - Klinische Wissensressourcen - Metadaten

Informatique de Santé - Ressources des connaissances cliniques - Métadonnées

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Ta slovenski standard je istoveten z: CEN/TS 15699:2009

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**ICS:**

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

English Version

**Health informatics - Clinical knowledge resources - Metadata**

Informatique de Santé - Ressources des connaissances  
cliniques - Métadonnées

Medizinische Informatik - Klinische Wissensressourcen -  
Metadaten

This Technical Specification (CEN/TS) was approved by CEN on 6 November 2008 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

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## CEN/TS 15699:2009 (E)

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## Foreword

This document (CEN/TS 15699:2009) has been prepared by Technical Committee CEN/TC 251 “Health informatics”, the secretariat of which is held by NEN.

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

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### Introduction

The internet is rapidly changing the way we access medical knowledge. Health professionals use web based knowledge sources and digital documents are provided from databases and via e-mail. Also the patients/citizens turn to the internet, particularly in those countries in Europe where more than 50 % of households already have internet access in their homes. The European Commission eEurope action plan 2002 describes the following challenge:

“Health related information is amongst the most frequently accessed information on the Internet. Yet at present, the European citizen has very few resources with which to assess the quality and authenticity of this vital information.”

The European Commission has in response to this requirement published a set of quality criteria for health related websites<sup>1</sup>.

One way to help navigate in the multitude of information of various quality is to establish a “Trustmark” to label web documents that meet certain criteria. This was proposed in the TEAC-Health project of the 4<sup>th</sup> framework and was the basis for the start of the MEDCERTAIN project started in September 2000. There are, however, other possible solutions as well that may have advantages and may exist in parallel. A trustmark indicating a “minimum” level of trustworthiness requires:

- A) set of quality requirements. *This might be very difficult to agree on as relevant for all contexts. The agreed criteria may be regarded as too low or too high for certain purposes.*
- B) third party control by governmental bodies or professional associations of all possible documents to receive the mark.
- C) reliance on a self-declaration by the issuer *in which case the user of the information has no real guarantee that the criteria are met even if the mark is there.*

Instead of reviewing the actual content of the medical knowledge resources, we can define processes behind their development, which may put requirements on professional education, quality assurance principles in general, scientific reviews, etc.

This whole area requires collaboration of many different parties with different roles. Important work has started in several professional associations and among web publishers of health information. Health authorities in many countries and in collaboration with the Commission have considered the possible requirement for legislation and control procedures, but generally the conclusions have been that rather than trying to ban bad quality information, one should facilitate for the citizens as well as for the health professionals to find the type of information they request where quality criteria behind a knowledge resource are easily accessible.

One feasible and important approach is to establish a set of metadata to describe the content and procedures behind its production.

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<sup>1</sup> COM(2002) 667, eEurope 2002: Quality Criteria for Health related Websites.

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Many different types of documents are produced with the broad intent of providing "clinical knowledge", e.g. advice to patients for certain clinical problems, reports of research in the medical literature, guidelines issued by governmental authorities and researcher's protocols for clinical trials.

In some cases, document type may have legal implications - a health professional is obliged to follow them, or they may define the officially recommended treatment. Some guidelines are based on extensive high quality scientific review/meta quality systems involving scientific reviews and can be influenced also by other (e.g. financial) considerations. In many areas of clinical care, the patients and professionals use advice of lesser status produced by one or a group of qualified experts.

Such clinical guidelines are increasingly available on the internet and it is very important to provide information to assist in judgment about the nature, status and scientific background of such documents.

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### 1 Scope

This Technical Specification defines a number of metadata elements that describe documents containing medical knowledge, primarily digital documents provided as web resources, accessible from databases or via file transfer, but can be applicable also to paper documents, e.g. articles in the medical literature.

The metadata should:

- support unambiguous and international understanding of important aspects to describe a document  
*e.g. purpose, issuer, intended audience, legal status and scientific background;*
- be applicable to different kinds of digital documents  
*e.g. recommendation from consensus of a professional group, regulation by a governmental authority, clinical trial protocol from a pharmaceutical company, scientific manuscript from a research group, advice to patients with a specific disease, review article;*
- be possible to present to human readers  
*including health professionals as well as citizens/patients*
- be potentially usable for automatic processing  
*e.g. to support search engines to restrict matches to documents of a certain type or quality level.*

The metadata here described is not intended to:

- describe documents about a single patient, such as medical records;
- describe details of the medical content of the document (but some idea of the content can be described via keywords or codes);
- prescribe criteria for the quality of the document content.

### 2 Normative references

Not applicable.

### 3 Terms and definitions

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

#### 3.1

##### **medical knowledge**

field of knowledge pertaining to the structure, function or dysfunction of the human body and how these can be influenced by external or internal factors and interventions

NOTE Medical does not imply “physician” – all health professionals have medical knowledge according to this definition.



**3.2****clinical knowledge**

part of medical knowledge pertaining promoting good health and the management and prevention of ill health

NOTE Used to diagnose, treat and alleviate disease/dysfunction.

**3.3****knowledge resource**

collection of knowledge about a subject area collected for a purpose and made available to a user as some manifestation

**3.4****metadata**

data that defines and describes other data

[ISO 1087-1:2000]

**3.5****lifecycle [of information resource]**

sequence of events that mark the development and use of an information resource

[ISO 15836:2003]

EXAMPLE Conception of an invention, creation of a draft, revision of an article, publication of a book, acquisition by a library, transcription to magnetic disk, migration to optical storage, translation into English and derivation of a new work (e.g. a movie).

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**4 Introduction to metadata**

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**4.1 Purpose and format**

Metadata for a knowledge resource will convey information that is non-essential for the purpose of the document, but important for other purposes, such as:

- locating a knowledge resource depending on e.g. subject, area of applicability, form of presentation;
- assessing quality of the knowledge, e.g. how old it is, how trustworthy the author is.

**4.2 Sources of generally useful metadata elements**

General metadata have been developed by an initiative from library science known as the Dublin Core Metadata, adopted and published as an ISO standard [ISO 15836:2003].

**4.3 Sources of medical metadata**

In the development of this document several sets of metadata particularly relevant for clinical knowledge were used as input and/or inspiration, including Arden syntax, ENV 13606-3, GEM (Guidelines Element Model, The US National Guidelines Center (NGC).

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### 4.4 Characteristics of the metadata element set

In the element descriptions below, each element has a descriptive label intended to convey a common semantic understanding of the element, as well as a unique, machine-understandable, single-word name intended to make the syntactic specification of elements simpler for encoding schemes.

Although some environments, such as HTML, are not case-sensitive, the best practice recommended is to always adhere to the case conventions in the element names given below to avoid conflicts in the event that the metadata is subsequently extracted or converted to a case-sensitive environment, such as XML (Extensible Markup Language).

Each element is optional and repeatable. Metadata elements may appear in any order. The ordering of multiple occurrences of the same element (e.g. Creator) may have a significance intended by the provider, but ordering is not guaranteed to be preserved in every system.

To promote global interoperability, a number of the element descriptions suggest a controlled vocabulary for the respective element values. The Dublin Core set assumes that different domains develop where necessary controlled vocabularies as specialisations of the content of the general purpose metadata element set and adding other metadata elements as required. This Technical Specification is such a specialisation for the medical knowledge domain.

## 5 Metadata element structure for medical knowledge resources

### 5.1 Introduction to the medical metadata elements

This clause introduces a categorisation of clinical knowledge resources that is intended to facilitate finding appropriate metadata elements. These metadata element groups are not intended to be represented as actual metadata for the knowledge resources.

For each Metadata Element Name, there is a proposed way of expressing the content of that metadata, often by using a controlled vocabulary presented or referenced herein. Most of these come from the Dublin Core indicate by (DC) below. In a few cases, this structure also proposes a substructure of specialisation of metadata element. Where elements or sub-elements are defined in this Health Care Technical Specification, it is indicated by (HC). The syntax for expressing this may vary dependent on the format of the metadata expression e.g. XML. Some examples are given in Annex A.

### 5.2 Resource form

#### 5.2.1 Group description

The resource form group of metadata describes the form of delivery of knowledge from the resource.

#### 5.2.2 Type

##### 5.2.2.1 General

Element name: Type (DC)

Definition: Nature or genre of the content of the resource (DC)

Healthcare specific specialisation: The following terms may be used to describe Type:

- Document
- Database for human reading
- Database for automatic processing
- Software
- Hardware

It is recommended that these terms are complemented by a type specifier.

#### 5.2.2.2 Document

Element name: Type.Document (HC)

Definition: Type of knowledge resource as a text document possibly with images in essentially free format for human reading

Specifiers of Type.Document:

- a) Journal\_article
- b) Book\_chapter
- c) Book
- d) Report
- e) Abstract
- f) Patient\_information
- g) FAQ

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NOTE 1 Frequently Asked Questions.

- h) Algorithm

NOTE 2 Formal description of a procedure e.g. a calculation method.

- i) Clinical guideline
- j) Policy-strategy
- k) Information\_standard
- l) Teaching\_material

NOTE 3 This includes learning / self-learning materials.

- m) Archetype

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NOTE 4 This is a special form of constrained information model to describe a part of an Electronic Health Record as described by EN 13606-2 or OpenEHR.

- n) Terminological\_resource
- o) Metainformation

NOTE 5 Information about other resources (bibliography, catalogue, reviews, gateway, search engine).

NOTE 6 The Metainformation may also be used to specialise a Database type.

- p) Case\_report
- q) Proposal

NOTE 7 This term may be used to label a plan for a project.

- r) Event

NOTE 8 This term may be used to label invitations, descriptions and schedules of meetings and other events where people meet.

- s) Service\_description

NOTE 9 Service in this context may include health care services as well as other services e.g. IT-related.

- t) Product\_information

**5.2.2.3 Database for human reading**

Element name: Type.DatabaseforHumans (HC)

Definition: Type of knowledge resource with structured data and established retrieval functions for human reading

Specifiers of Type.Database for human reading:

- a) Journal
- b) Metainformation
- c) Terminology
- d) Guideline\_collection
- e) Discussion\_list

**5.2.2.4 Database for automatic processing**

Element name: Type.DatabaseforAutoprocessing (HC)

Definition: Type of knowledge resource with structured data made available to external software systems