SLOVENSKI STANDARD
SIST EN ISO 13119:2013

01-januar-2013

Nadomešča:
SIST-TS CEN/TS 15699:2009

Zdravstvena informatika - Viri kliničnega znanja - Metapodatki (ISO 13119:2012)

Health informatics - Clinical knowledge resources - Metadata (ISO 13119:2012)

Medizinische Informatik - Klinische Wissensressourcen - Metadaten (ISO 13119:2012)

Informatique de santé - Ressources des connaissances cliniques - Métadonnées (ISO 13119:2012)

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Ta slovenski standard je istoveten z: **EN ISO 13119:2012**

ICS:

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

SIST EN ISO 13119:2013 **en**

iTeh STANDARD PREVIEW
(standards.iteh.ai)

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13119

November 2012

ICS 35.240.80

Supersedes CEN/TS 15699:2009

English Version

Health informatics - Clinical knowledge resources - Metadata (ISO 13119:2012)

Informatique de santé - Ressources des connaissances cliniques - Métadonnées (ISO 13119:2012)

Medizinische Informatik - Klinische Wissensressourcen - Metadaten (ISO 13119:2012)

This European Standard was approved by CEN on 31 October 2012.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 13119:2012: E

EN ISO 13119:2012 (E)

Contents

Page

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Foreword

This document (EN ISO 13119:2012) has been prepared by Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by NEN, in collaboration with Technical Committee ISO/TC 215 "Health informatics".

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.

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.

This document supersedes CEN/TS 15699:2009.

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

INTERNATIONAL STANDARD

ISO
13119

First edition
2012-11-01

Health informatics — Clinical knowledge resources — Metadata

Informatique de santé — Ressources des connaissances cliniques — Métadonnées

Reference number
ISO 13119:2012(E)

© ISO 2012

ISO 13119:2012(E)

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 13119:2012(E)

Contents

Page

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 13119:2012(E)

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 13119 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in collaboration with ISO Technical Committee ISO/TC 215, *Health informatics*, in accordance with the agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This International Standard is a revision of CEN/TS 15699:2009, *Health informatics — Clinical knowledge resources — Metadata*.

iTeh STANDARD PREVIEW

(standards.iteh.ai)

Introduction

The internet is rapidly changing the way we access medical knowledge. Health professionals use web-based knowledge sources while digital documents are provided from databases and via e-mail. Also, patients and the general public 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 among 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[18].

One way to help navigate the multitude of information of varying quality is to establish a "Trustmark" to label web documents that meet certain criteria. This was proposed in the TEAC-Health project of the 4th 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 the following elements.

a) 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 resources 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 the processes behind their development, which may impose 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 requirements for legislation and control procedures; 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.

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 researchers' protocols for clinical trials.

Some types of documents may have legal implications; a health professional is obliged to follow them, or they may define the officially recommended treatment. This International Standard aims to make the type of document explicit. 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.

This International Standard will not only be useful for the assessment of a knowledge resource but also to facilitate search and retrieval of knowledge resources.

ISO 13119:2012(E)

This International Standard for metadata is based on the general purpose metadata standardization initiative Dublin Core[1] which developed the first set of 15 metadata elements, later published as ISO 15836:2003, which has been cancelled and replaced by ISO 15836:2009.

This International Standard provides an international set of health care specific extensions to this set. Some of the issues covered by health specific metadata tags in the CEN/TS 15699 have been replaced by corresponding Dublin Core qualifiers now available. This area is in rapid development.

The basic structure (taken from Dublin Core), with the extensions provided in this International Standard, constitutes a source for possible use for a specific use case. An international set is certainly preferable when there is an audience for the knowledge resource outside of the country of origin. This is common for clinical knowledge resources in languages with users in many countries such as English, Spanish, French and Arabic.

However, for many use cases of metadata, it is important to provide a vocabulary that is easily understood, perhaps also by laymen and corresponding to the language used in the resource itself. This International Standard does in no way preclude the use of such national metadata vocabularies. However, even when this is the case, this International Standard can serve as an inspiration for defining important metadata.

It should also be emphasized that the extensive set of possible metadata elements defined in this International Standard is usually useful only as a subset for a specific set of resources. The compilation of a possible application profile with a minimum set of metadata elements for various purposes may be the scope of future work.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

---

1) The Dublin Core Metadata Initiative (www.dublincore.org).