SLOVENSKI STANDARD
oSIST prEN ISO 13119:2011

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Zdravstvena informatika - Viri kliničnega znanja - Metapodatki (ISO/DIS 13119:2011)

Health informatics - Clinical knowledge resources - Metadata (ISO/DIS 13119:2011)

Medizinische Informatik - Klinische Wissensressourcen - Metadaten (ISO/DIS 13119:2011)

Informatique de santé - Ressources des connaissances cliniques - Métadonnées (ISO/DIS 13119:2011)

Ta slovenski standard je istoveten z: **prEN ISO 13119**

ICS:

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

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EUROPEAN STANDARD

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English Version

Health informatics - Clinical knowledge resources - Metadata (ISO/DIS 13119:2011)

Informatique de santé - Ressources des connaissances cliniques - Métadonnées (ISO/DIS 13119:2011)

Medizinische Informatik - Klinische Wissensressourcen - Metadaten (ISO/DIS 13119:2011)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 251.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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Foreword

This document (prEN ISO 13119:2011) 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 document is currently submitted to the parallel Enquiry.

This document will supersede CEN/TS 15699:2009.

DRAFT INTERNATIONAL STANDARD ISO/DIS 13119

ISO/TC **215** Secretariat: **ANSI**

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INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Health informatics — Clinical knowledge resources — Metadata

Informatique de santé — Ressources des connaissances cliniques — Métadonnées

ICS 35.240.80

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the European Committee for Standardization (CEN), and processed under the **CEN-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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 13119 was prepared by Technical Committee ISO/TC 215, and by Technical Committee CEN/TC 251, in collaboration.

This EN ISO standard is a revision of the CEN/TS 15699:2009 Health informatics clinical knowledge resources – Metadata.

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[1].

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 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:

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.

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

[1] COM(2002) 667, eEurope 2002: Quality Criteria for Health related Websites.

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

This international standard for metadata is based on the general purpose metadata standardization initiative Dublin Core[2] which developed the first set of fifteen metadata elements later approved by ISO and published first in 2003 and recently in a revised version as ISO 15386:2009.

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

The basic structure (taken from Dublin Core) and the extensions provided in this standard shall be regarded as a source for possile 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 easy 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 herein will usually be 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.

[2] The Dublin Core Metadata Intitiative - www.dublincore.org