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Health informatics — Categorial structure for terminological systems of human anatomy (ISO 16278:2016)

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National foreword

This British Standard is the UK implementation of EN ISO 16278:2016. It supersedes BS EN 15521:2007 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Health informatics - Categorial structure for terminological systems of human anatomy (ISO 16278:2016)

Informatique de santé - Structure catégorielle des systèmes terminologiques de l'anatomie humaine (ISO 16278:2016)

Medizinische Informatik - Kategoriale Struktur für terminologische Systeme der Anatomie des Menschen (ISO 16278:2016)

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European foreword

This document (EN ISO 16278:2016) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with 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of an identical text or by endorsement, at the latest by September 2016, and conflicting national standards shall be withdrawn at the latest by September 2016.

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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Endorsement notice

The text of ISO 16278:2016 has been approved by CEN as EN ISO 16278:2016 without any modification.

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health informatics*.

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Introduction

This International Standard specifies a categorial structure for terminologies of human anatomy. Computer-based processing and the interchange of medical or clinical information requires various kinds of terminological systems to represent that information, such as controlled vocabularies, classifications, nomenclatures, terminologies and thesauri, with or without coding schemes.

The specific terminological issues in the field of health informatics are the following:

— large number of different terminological systems are available in different clinical specialties;

— large overlap among the subject fields involved;

— large number of codes and rubrics, typically in the order of magnitude of 10 000 to 100 000 entries, in commonly used terminological systems;

— increasing need for re-use of coded data in different health-care contexts;

— polysemy across different clinical specialties and sometimes within them.

The integration of computer-based medical records and administrative information systems in Electronic Health Records (EHR) require rationalization in the field, and a uniform way to represent the meaning of medical concepts to ensure that the receiver EHR of a message will catch the meaning introduced by the sender EHR and not only the string of characters embedded in it.

It is not possible to impose a rigid, uniform, standardized, natural language clinical terminology on healthcare professional providers. Nevertheless, standards need to be provided for guiding the development of terminologies in the different sub domains of healthcare to allow semantic interoperability between them. To this end, a domain specific semantic representation has been developed (EN 12264) and applied in a series of specific initiatives, including European Pre standards (ENV), European Standards (EN) and International Standards (ISO) on various subject fields to describe a set of categorial structures in partially overlapping subject fields. Human anatomy is central to medical terminology (surgical procedures, carcinoma staging, annotation of radiological findings, disease, clinical laboratory and so forth) and also to many scientific and bio-informatics study beyond the scope of clinical medicine. In the US, the University of Washington has developed in the public domain an anatomical terminology for EHR named the Digital Anatomist Foundational Model of Anatomy (FMA for short), a reference ontology for biomedical informatics.

International Standardization efforts by CEN and ISO related to Electronic Health Records and semantic interoperability have resulted in a number of categorial structures which are a step towards supporting healthcare terminological systems with a full concept system or ontology that in turn will support multipurpose uses and safe communication. In the present categorial structure standard, several of the definitions of basic terms related to categorial structures have been updated to comply with the most recent version of ISO 17115.

Adequate field testing in several countries, revision and integration have provided the comprehensive basis for this International Standard.

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1 Scope

This International Standard defines the characteristics required to synthetically describe the organization and content of human anatomy within a terminological system. It is intended primarily for use with computer-based applications such as clinical electronic health records, decision support and for various bio-medical research purposes.

This International Standard will serve to

— facilitate the construction of new terminological systems in a regular form which will increase their coherence and expressiveness,

— facilitate maintenance of human anatomy within terminological systems,

— increase consistency and coherence of existing terminological system,

— allow systematic cross-references between items of human anatomy in different types of terminological systems,

— facilitate convergence among human anatomy within terminological systems,

— make explicit the overlap for human anatomy between different health care domains terminological systems,

— provide elements for negotiation about integration of different terminological systems into information systems between the respective developers, and

— enable the systematic evaluation of human anatomy within terminological systems.

The International Standard itself is not suitable or intended for use by, individual clinicians or hospital administrators.

The target groups for this International Standard are the following:

— designers of specialized standard healthcare terminological categorial structures;

— developers of healthcare terminological systems including classifications and coding systems;

— producers of services for terminological systems and designers of software including natural language processing;

— information modellers, knowledge engineers, and standards developers building models for health information management systems;

— developers of information systems that require an explicit representation of healthcare terminological systems;

— developers of marked-up standards for representation of healthcare documents.

This International Standard does not include categorial structure that might be necessary for the description of developmental anatomy during the human life cycle, which includes prenatal development, post-natal growth and aging.

This International Standard has been developed for use as an integrated part of computer-based applications and for the electronic healthcare record. It would be of limited value for manual use.

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