TECHNICAL REPORT

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Health informatics — Guidelines for terminology development organizations

Informatique de santé — Lignes directrices pour établir une normalisation de la terminologie internationale des soins de santé

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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.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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/TR 12309 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

Healthcare terminological systems (terminologies) are developed to support accurate representation, communication and analysis of information about the healthcare of individuals and populations. The development and maintenance of healthcare terminologies require a robust and sustainable infrastructure and processes so that safe and consistent representation and interpretation of data and information can be supported over time.

Those wishing to use a specific terminological system (terminology), adopt it as a national or International Standard or incorporate it into other International Standards, need assurance that the required infrastructure, policies and processes are in place. This Technical Report gives a non-exhaustive list of principles and high-level processes that should be exhibited by a terminology development organization (hereafter referred to as *organization* in order to distinguish it from other kinds of organization) if it is to provide this assurance and support international healthcare terminology standardization.

Terminology standardization in general differs from other standardization in that it should address the language and cultural differences inherent in terminology itself. Standardization related to healthcare terminologies differs significantly from many other International Standards activities because of the technical nature of the content and the rapid versioning that is required. Specifically, terminologies often require a highly responsive *organization* that can accommodate the complex harmonization of nuanced “concepts”, while maintaining longitudinal consistency and utility. Furthermore, terminologies often form the foundation of many dependent systems, applications and operations, and thus should achieve a reliability and rigour coupled with availability and dissemination that are not always required of other standards. A “safety-critical” example is the use of terminologies in healthcare decision support systems such as drug interaction warnings for prescribing support.

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1 Scope

1.1 Main purpose

This Technical Report specifies principles and processes that should be exhibited by developers of healthcare terminologies in support of international healthcare terminology standardization. The primary target group for this Technical Report is those establishing or reviewing *organizations*, and those evaluating the services or products maintained by such *organizations*, in the context of international healthcare terminology standardization. It complements standards such as ISO 17115 [1] and ISO 17117 [2] (which address the content of terminologies) by specifying good governance requirements for the lifecycle of those terminologies.

1.2 Topics considered outside the scope

Detailed specifications of appropriate governance structures and how *organization*s should undertake good governance are outside the scope of this Technical Report, which is limited to high-level principles and processes. Standards and guidance for the development, identification, maintenance and evaluation of healthcare terminological systems are provided elsewhere and are therefore outside the scope of this Technical Report.

2 Conformance

There is considerable literature on standards conformance assessment of organizations in general, for example related to ISO 9000 standards [3] for management systems. However, there is little experience specific to the domain of health informatics. One exception is the HITSP Standards Harmonization Committee, which uses a four-point scoring system against performance criteria relevant to its “preferred standards developer organization and process”. See reference [4]. Those evaluating healthcare terminology standards development organizations could consider using such a scoring system to demonstrate conformance to the subclauses in Clause 4 of this Technical Report.

3 Terms and definitions

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

3.1
standard
document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context

[ISO/IEC Guide 2:2004, definition 3.2]

NOTE In the health informatics context the term “standard” can also refer to specifications, implementation guides, code sets, terminologies, integration profiles and other artefacts. See reference [4].