



BSI Standards Publication

**Health informatics — Principles
and guidelines for the
measurement of conformance
in the implementation of
terminological systems**

National foreword

This Published Document is the UK implementation of ISO/TR 12310:2015.

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.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2015. Published by BSI Standards Limited 2015

ISBN 978 0 580 83759 3

ICS 35.240.80

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 May 2015.

Amendments issued since publication

Date	Text affected
------	---------------

First edition
2015-05-15

**Health informatics — Principles and
guidelines for the measurement of
conformance in the implementation of
terminological systems**

*Informatique de santé — Principes et lignes directrices pour le
mesurage de la conformité dans la mise en oeuvre des systèmes
terminologiques*



Reference number
ISO/TR 12310:2015(E)

© ISO 2015



COPYRIGHT PROTECTED DOCUMENT

© ISO 2015. Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Objective	1
3 Terms and definitions	1
4 Purposes for conformance	3
4.1 Interoperability.....	4
4.2 Data analysis.....	4
4.3 Consistency of user experience.....	4
4.4 Application functionality.....	4
4.5 Acceptance filter.....	4
5 Conformance process	4
5.1 Documenting expectations.....	4
5.1.1 Optionality.....	5
6 Terminology artefact conformance considerations	6
6.1 Code system considerations.....	6
6.1.1 What is the code system being referenced?.....	6
6.1.2 What version(s) of the code system are supported?.....	6
6.1.3 How are codes represented?.....	7
6.1.4 What are the version migration expectations, if any?.....	7
6.1.5 What is the authoritative source that will be used for processing updates to a given terminology?.....	7
6.1.6 What status must usable code system elements have?.....	8
6.1.7 Which codes and concepts are usable for what purpose?.....	8
6.1.8 What representations are allowed for what purposes?.....	8
6.1.9 What code system relationships must be understood and navigated?.....	8
6.1.10 Are the semantics clearly defines?.....	9
6.1.11 What are the expectations for post-coordination?.....	9
6.1.12 What partitions are included?.....	9
6.1.13 What code system supplements are supported?.....	10
6.2 Reference sets: sets of codes that are allowed.....	10
6.2.1 What code systems are drawn from?.....	10
6.2.2 How is the reference set defined?.....	10
6.2.3 Which representations are allowed from a code system?.....	11
6.2.4 What constraints are there on post-coordinated concepts?.....	11
6.2.5 What is post-coordinated vs. Pre-coordinated?.....	11
6.2.6 What happens if the concept exists more than once in the reference set?.....	11
6.3 Reference set bindings.....	11
6.3.1 Is the binding to the reference set static or dynamic?.....	12
6.3.2 What reference set representation capabilities are supported?.....	12
6.3.3 Is the reference set extensible?.....	12
6.3.4 What expectation is there to support all codes within the bound reference set?.....	12
6.4 What is the reference set bound to?.....	13
6.5 When and where does the binding apply?.....	13
7 Terminology usage conformance considerations	13
7.1 Data capture.....	14
7.1.1 Are the code system contents expected to be exposed directly?.....	14
7.1.2 What aspects may be or must be exposed to users?.....	14
7.1.3 Are the available codes to be displayed in a particular order?.....	14
7.1.4 Are there constraints on how the codes are to be navigated?.....	14
7.1.5 Are deprecated, retired, or pending codes expected to be presented differently?.....	14

7.1.6	Shall the reference set or version be captured?.....	14
7.1.7	Can external knowledge be applied to the selection of codes?.....	14
7.2	Data exchange.....	15
7.2.1	Identification of code systems.....	15
7.2.2	Identification of code system versions.....	15
7.2.3	Syntax for post-coordination.....	15
7.2.4	Presence and representation of translations between code systems.....	16
7.2.5	Presence of original text.....	16
7.2.6	Terminology specifications.....	16
7.3	Data analysis and searching.....	17
7.3.1	Are subsumed codes included?.....	17
7.3.2	What mathematical support is expected?.....	17
7.3.3	How are post-coordinated results handled?.....	17
7.3.4	How is cross code-system analysis managed?.....	17
7.3.5	Unknown data.....	18
8	Sharing and persisting conformance expectations.....	19
9	Asserting conformance.....	19
9.1	Conformance and non-conformance.....	19
9.2	Why conformance statements?.....	20
9.3	What is conforming?.....	20
9.4	What is being conformed to?.....	20
9.5	Assumptions.....	21
9.6	Support for optional elements.....	21
9.7	Variations.....	22
9.8	Completeness.....	22
10	Evaluating conformance statements.....	23
11	Verifying conformance.....	23
11.1	What is verified?.....	23
11.2	Who verifies?.....	24
11.3	Can verification be automated?.....	24
12	Other considerations.....	24
12.1	Comparing conformance statements.....	24
12.2	Conformance with conflicting terminology specifications.....	25
12.3	What IP considerations are associated with the code system?.....	25
12.4	Terminology services.....	25
	Bibliography.....	27

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*.

Introduction

This work item is a Technical Report that will identify and discuss principles and guidelines for the measurement of conformance in the implementation of terminological systems, in particular, as applied to Electronic Health Record (EHR) systems.

This item will leverage the current work under way in Canada and will be developed in liaison with International Health Terminology Standards Development Organization (IHTSDO) and the Vocabulary Committee of HL7 in the spirit of harmonization across organizations with similar interests. Additional terminology organizations, active projects and existing expertise will be sought out for input into this work item.

Conformance is a key step in helping stakeholders determine if implementations of terminology systems have been done in a correct and consistent manner, particularly as implemented in EHRs. Loose declarations regarding terminological systems that cannot be tested with meaningful results do very little to support the end goal of the interoperable EHR. Therefore, the principles and guidelines for establishing and measuring conformance will focus on identifying the degrees of conformance of terminological systems with or without use in messaging standards.

This Technical Report is intended to define what is meant by conformance with respect to terminology systems, particularly as applied to EHR systems, and it is expected to facilitate the formulation of policies and governance practices locally or nationally. This Technical Report is timely as the emerging IHTSDO and progressive implementation of the EHR will lead to the increasing awareness of conformance with respect to terminologies and consistent implementations that allow interoperability by all end-users.

The focus of this Technical Report is to define best practices and a framework for establishing and measuring conformance. The scope of this Technical Report will include the identification of definitions and best practice considerations for what constitutes conformance to terminology systems and the principles for which conformance can be demonstrated.

Health informatics — Principles and guidelines for the measurement of conformance in the implementation of terminological systems

1 Scope

The purpose of this Technical Report is to define a framework of good practices for terminology system maintenance and the principles for which conformance can be demonstrated. The primary focus is the application of terminology system to Electronic Health Record (EHR) systems, although the principles and guidelines can be applied broadly in health informatics.

The scope of this Technical Report will include, at a minimum, the following considerations for keeping terminology systems and associated reference material clinically and/or technically relevant and valid:

- governance models and practices;
- high level processes;
- requirements for managing the change.

The scope of this Technical Report will not include a definition of the detailed processes for performing terminology maintenance.

This Technical Report aims to define the framework of good practices for EHRs and systems regarding terminology maintenance within these systems. This Technical Report relates directly to the ability of these records to be safe and legally accurate records of healthcare in the environment of changing technologies related to the use of clinical terminologies to represent meaning within these systems.

2 Objective

This Technical Report identifies considerations for the expression and evaluation of conformance for solutions that make use of terminology. The specific focus of this Technical Report is terminology used in healthcare solutions. However, the principles should apply to solutions implementing terminology across the health industry. "Solutions" is interpreted broadly and includes both software and hardware technical implementations, as well as other specifications that are based on or claim to adhere to all or part of the specification against which conformance is being assessed. Implementation in this Technical Report does not consider procedural or governance requirements.

By using the definitions and recommendations found here-in, standards bodies, implementers, and other parties can better achieve their objectives in the development and use of specifications that make use of terminologies and can better express their terminology capabilities.

This Technical Report is intended to be independent of any particular terminology or terminological approach, though some portions of the guidance provided will only apply to certain types of terminologies.

3 Terms and definitions

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

NOTE Because "terminology" is such a broad term, conformance actually needs to be stated in terms of the various terminology components that are referenced in a specification. These components will also be defined.