

PD CEN ISO/TS 17251:2016



BSI Standards Publication

Health Informatics - Business requirements for a syntax to exchange structured dose information for medicinal products (ISO/TS 17251:2016)

bsi.

National foreword

This Published Document is the UK implementation of CEN ISO/TS 17251:2016.

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 2016. Published by BSI Standards Limited 2016

ISBN 978 0 580 84765 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 July 2016.

Amendments issued since publication

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

ICS 35.240.80

English Version

Health Informatics - Business requirements for a syntax to
exchange structured dose information for medicinal
products (ISO/TS 17251:2016)

Informatique de santé - Exigences d'affaire pour une
syntaxe d'échange d'informations de dose structurée
pour les produits médicaux (ISO/TS 17251:2016)

Medizinische Informatik - Geschäftsanforderungen an
eine Syntax zum Austausch von Dosisinformationen für
Arzneimittel (ISO/TS 17251:2016)

This Technical Specification (CEN/TS) was approved by CEN on 10 July 2016 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years, the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European Foreword

This document (CEN ISO/TS 17251:2016) 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.

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.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: 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.

Endorsement notice

The text of ISO/TS 17251:2016 has been approved by CEN as CEN ISO/TS 17251:2016 without any modification.

Contents

	Page
Foreword.....	iv
Introduction.....	v
1 Scope.....	1
2 Terms and definitions.....	1
3 Conformance.....	7
4 Business requirements for structured dose instructions.....	3
4.1 General.....	3
4.2 Use cases.....	3
4.3 Elements of a dose instruction.....	3
4.4 Information requirements.....	4
4.4.1 General.....	4
4.4.2 Infrastructure.....	5
4.4.3 Text representation.....	5
4.4.4 Administration amount.....	5
4.4.5 Route/site of administration.....	5
4.4.6 Timing of dose event(s).....	6
4.4.7 Conditional administration.....	7
4.4.8 Patient-specific information.....	7
4.4.9 Ancillary information.....	8
Bibliography.....	9

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

The requirements for the exchange of structured dose instructions are intended to be independent of any technology standard or software platform and have been developed with the aim of specifying the necessary clinical and business requirements precisely and unambiguously. Implementation of the requirements within a suitable medium designed to support communication of healthcare information can provide support to clinicians and their applications in storing, retrieving, using, and above all, communicating dose instructions information to other clinicians, their applications, and most importantly, to the patient.

The primary audiences for this Technical Specification are software developers building clinical IT systems.

Currently in preview, click buy full version.

Currently in preview, click buy full version

Health informatics — Business requirements for a syntax to exchange structured dose information for medicinal products

1 Scope

This Technical Specification specifies the business requirements for the structured content of structured or semi-structured dose instructions for recording dose instructions in the electronic health record (EHR), supporting clinical decision support, and in exchanging medication orders, as applicable to primary, secondary and tertiary care.

NOTE See 2.9, note to entry, regarding the use of “medication order” and “prescription”.

Comprehension of dose instructions by the patient is an overarching consideration for patient safety and the best patient outcomes. Related factors are discussed, but are not part of the primary scope.

This Technical Specification does not define an information model, except to the extent that those information model concepts are necessary to define business requirements.

Outside the scope of this Technical Specification are:

- the functionality of health, clinical and/or pharmacy systems;
- other kinds of content of health, clinical or pharmacy systems that are needed to support the whole process of health care providers, such as:
 - wide range of knowledge about medicines that would be handled in drug knowledge databases and decision support systems;
 - the complete medical record (EHR);
 - a medicinal product dictionary.

2 Terms and definitions

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

2.1

dose instructions

instructions pertaining to the medication, which describe the amount of medication per dose, method of administration, the frequency or interval of dose, associated instructions for dosing or skipped doses, and other associated parameters necessary for appropriate administration of the medication

2.2

dose syntax

structured dose instructions

structured set of data elements which represent the dose instructions in a consistent, computable format

2.3

structured information

information assembled from predefined concepts (vocabulary or code set) using an organizational scheme (information model)