ICS 35.240.80 PREDBEŽNÁ SLOVENSKÁ TECHNICKÁ NORMA Jún 2023

STN P	**Zdravotnícka informatika Koncepcia požiadaviek na syntax na výmenu štrukturovaných informácií o dávkovaní liekov (ISO/TS 17251: 2023)**	**STN P CEN ISO/TS 17251** 84 8127

Health informatics - Business requirements for a syntax to exchange structured dose information for medicinal products (ISO/TS 17251:2023)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 05/23

Táto predbežná slovenská technická norma je určená na overenie. Prípadné pripomienky pošlite do marca 2025 Úradu pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky.

Obsahuje: CEN ISO/TS 17251:2023, ISO/TS 17251:2023

Oznámením tejto normy sa ruší
STN P CEN ISO/TS 17251 (84 8127) z decembra 2016

136823

TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN ISO/TS 17251

March 2023

ICS 35.240.80

Supersedes CEN ISO/TS 17251:2016

English Version

Health informatics - Business requirements for a syntax to exchange structured dose information for medicinal products (ISO/TS 17251:2023)

Informatique de santé - Exigences d'affaire pour une syntaxe d'échange d'informations de dose structurée pour les produits médicaux (ISO/TS 17251:2023)

Medizinische Informatik - Geschäftsanforderungen an eine Syntax zum Austausch von Dosierungsinformationen für Arzneimittel (ISO/TS 17251:2023)

This Technical Specification (CEN/TS) was approved by CEN on 24 February 2023 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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (CEN ISO/TS 17251:2023) 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 shall not be held responsible for identifying any or all such patent rights.

This document supersedes CEN ISO/TS 17251:2016.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO/TS 17251:2023 has been approved by CEN as CEN ISO/TS 17251:2023 without any modification.

TECHNICAL SPECIFICATION

ISO/TS 17251

Second edition
2023-02

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

Informatique de santé — Exigences d'affaire pour une syntaxe d'échange d'informations de dose structurée pour les produits médicaux

Reference number
ISO/TS 17251:2023(E)

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO/TS 17251:2016), which has been technically revised.

The main changes are as follows:

— editorial corrections and clarifications;

— added Clause 4 on the relationship to other standards;

— updated Clause 3;

— Clause 4 includes discussion on the relationship to the IDMP standards and clarifies the use of IDMP terms;

— Subclause 6.4.9: removed height, added optional laboratory observations;

— Subclause 6.4.5 and 6.4.7.1 for elements described as a range (e.g. max/min dose, range for interval or frequency) added discussion of 2-term and 3-term representations;

— Subclause 6.4.1: added discussion on complex instructions (e.g. multiple schedules, multiple dose amounts);

— Subclause 6.4.5: clarified language around selection of unit of measurement versus unit of presentation;

— Subclause 6.4.8: clarified that conditional administration is not necessarily the indication for the medication order;

— Subclause 6.4.9.4: added capability to provide date and/or time for subject of care characteristics;

— Subclause 6.4.4.1: added description and conformance for administration method;

— Subclause 6.4.7.1: added the option to have frequency based upon a period of time, such as “2 times over 3 days”.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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. Precise, unambiguous, structured, and codified dose instructions permit the prescriber, pharmacy, and other clinical systems to utilize that information for dose checking and other clinical decision support. Ultimately, precise and unambiguous dose instructions are essential for the subject of care or caregiver to appropriately use the medication for optimal benefit.

The primary audiences for this document are software developers building IT systems in the healthcare sector.

The intent of this document is that all prescribing and dispensing systems can build and recognized unambiguous dose instructions, preferably with structured and codified content which can enable additional system capabilities (e.g. Clinical Decision Support).

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

1 Scope

This document 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.

This document is focused on the dose instructions as will be presented to the individual subject of care or caregiver. Comprehension of dose instructions by the subject of care or caregiver is an overarching consideration for subject of care safety and the best outcomes. Related factors are discussed but are not part of the primary scope.

This document 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 document are:

— The implementation of dose instructions, i.e. assembling the structured elements into a form appropriate for the patient or caregiver;

— The content of a medication order (see ISO 17523) beyond content related to dose instructions;

— The content of a record of dispense of a medicinal product (see ISO/TS 19293);

— 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:

  — A drug knowledge database (see ISO/TS 22756);

  — A decision support system (see ISO/TS 22756 and ISO/TS 22703);

  — A complete medical record (EHR);

  — A medicinal product dictionary (see ISO/TS 19256);

  — Verification of the medicinal product and dose being administered.

— Some concepts from Identification of Medicinal Products are referenced, but not defined, in this document. See Clause 4 for discussion of the relationship of this document with IDMP.

2 Normative references

There are no normative references in this document.

