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Health informatics — Metadata repository requirements (MetaRep)

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National foreword

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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).

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 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*.

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.

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Introduction

This document is intended to be an extension to and a clarification of the ISO/IEC 11179 series.

Healthcare has a fundamental requirement for describing the meaning, provenance and governance of data, and for setting standards for how that data is stored and communicated. Unsurprisingly, it uses metadata registries and repositories extensively for a wide range of purposes supporting care delivery, reporting and research. However, these registries are only partially interoperable, with consequences to cost of ownership and utility that lead to under-use, particularly where simple, read-only repositories are required. There is also considerable unmet need resulting from the community's focus on message-based interoperability at the expense of the description of the meaning of the data in the systems that are the source of that data, and how that data maps to the meaning of the large quantities of data communicated between providers and national bodies in tables or simple XML.

Data in healthcare systems should persist in content and meaning across organizations and time for a wide variety of uses including patient care, patient safety, service management, service improvement, public health and healthcare research. The sharing and adoption of record or message designs offer immediate and tangible benefits to these ends, entailing organizations to adopt common standards for the exchange of the specifications of records and messages in terms of the representation and definition of individual elements of data; the inter-relationships of those elements in data models and where sets of data that accord to those models can be found together with any contextual information about those data sets that is required for their understanding and appropriate reuse.

Settings where metadata collections are assembled include individual clinics and hospitals, organizations managing a portfolio of clinical studies, organizations providing cloud applications in support of healthcare and regional and national bodies who commission standard reports and datasets in pursuit of policy objectives. The intent is to support an ecosystem of interoperable registries and repositories which facilitate both the development and implementation of content standards – and thus interoperable content – and the publication of interoperable metadata about the kinds of data available in both care and research.

This document includes a review of existing components of ISO/IEC 11179-3, i.e. Metadata Registry (MDRMetamodel), and ISO/IEC 19763-12 Metamodel for Information Models (MFIInformationModel) to specify where variations from or additions to the requirements of these standards are required for specific healthcare use cases. Registries conforming to this document are also likely to reference of ISO/IEC 11179-7[1)] Metamodel for dataset registration (MDRDatasets) and ISO/IEC TS 19763-13 Metamodel for forms registration (MFIForms), however it is less clear that simplifications or extensions to either are necessary in the healthcare or healthcare research setting and thus the original documents should be used as is.

MDRMetamodel provides a comprehensive model for an international metadata registry addressing several large communities with overlapping concerns, and the conformance statements in the 2013 edition are framed in this context. Equally MFIInformationModel is designed to represent models represented in many ways from purely conceptual entity relationship diagrams through to a concrete relational database instance. A metadata registry/repository aimed at a less diverse community such as healthcare or directed at the needs of a smaller organisation might not require the complete implementation of ISO/IEC 11179-3 and ISO/IEC 19763-12, so it is important that any restriction or simplification is shared to preserve registry interoperability.

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TECHNICAL SPECIFICATION **ISO/TS 21526:2019**

Health informatics — Metadata repository requirements (MetaRep)

1 Scope

This document describes requirements for collections of metadata about data elements and their containing models and datasets in a healthcare environment. The collection can serve as a repository or as dictionary describing a set of items in use in a particular domain, organisation or product for reference, or it can additionally serve as a registry, supporting the development and communication of standard items to an audience with shared goals.

This document specifies standard refinements that account for the detailed governance and administration requirements that are particular to healthcare data. It focuses on the description of data that is persisted in healthcare systems rather than the specification of messages between these systems. It describes necessary extensions to the ISO/IEC 11179 series and to other International Standards on metadata originating from ISO/IEC JTC 1/SC 32 to address the wider variety of value domain types found in healthcare. Where appropriate, it also suggest restrictions/simplifications to the ISO/IEC 11179 series that promote wider adoption without compromising interoperability between metadata registries and opportunities for the development of tooling that consumes metadata for the generation or the parameterization of code.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
acceptability rating
scale of acceptability

3.2
administered item
registered item for which *administrative information* (3.3) is recorded

3.3
administrative information
<metadata registry> information about the administration of an item in a *metadata registry* (3.33)

EXAMPLE Creation date, last change date, origin, change description, explanatory comment.

3.4
administration record
collection of *administrative information* (3.3) for an *administered item* (3.2)

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