### TECHNICAL SPECIFICATION

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# Health informatics — Hierarchical file structure specification for secondary storage of health-related information

Informatique de santé — Spécification de la structure hiérarchique ier. é des fichiers pour le stockage secondaire des informations relatives à la 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.

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 <a href="www.iso.org/directives">www.iso.org/directives</a>).

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 <a href="https://www.iso.org/patents">www.iso.org/patents</a>).

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 <a href="https://www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

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 <a href="https://www.iso.org/members.html">www.iso.org/members.html</a>.

#### Introduction

This document is designed for the sharing of medical information within healthcare institutions, as well as for the sharing of regional medical information among multiple institutions. In addition, this document can support clinical research, document storage, and document archive/backup for large-scale disasters and system issues. Since this document can be easily introduced through the use of existing and well-established technologies, without the necessity of adding a database engine, operational costs can actually be reduced.

This document is particularly designed to obtain the following advantages.

- a) It can be made available to any healthcare organization.
- b) It can result in reduced cost of installation and operation.
- c) It does not depend on any particular technology, nor does it require products from any company or vendor.
- d) It utilizes a simple structure that is easily understood.

This document has a simple file-folder structure and can store information in various types of documents without any special processing and additional cost.

This document is based on ISO/HL7 27931 (HL7 Ver2.5).

In Japan, it has been used by more than 1 000 hospitals across vendors.

In other parts of Asia, the convenience and economy of this case will be evaluated, so it is not limited to only domestic demand.

This document assumes that clinical data will be managed in an electronic medical record, and that the data defined in this document is not intended to be the primary clinical record.

Security issues can be solved by limiting the number of people who access the storage; however, these are considered operational issues and therefore out of scope in this document.

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## Health informatics — Hierarchical file structure specification for secondary storage of health-related information

### 1 Scope

This document defines the configuration rules required for a hierarchical structure, directory naming rules, and content identifiers for files and documents containing healthcare information. Content can be expressed as ISO/HL7 27931:2009 (also known as HL7 Ver2.5) as the data format to store clinical data such as prescriptions, lab results, and disease classifications, but can also include other types of file-type such as XML, CDA, DOC/DOCX, PDF, XLS/XLSX, JPEG, MP4, etc.

This document does not address the security and privacy attributes of the healthcare information being stored; these are considered implementation-specific.

#### 2 Normative references

There are no normative references in this document.

#### 3 Terms and definitions

No terms and definitions are listed in this document.

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

- ISO Online browsing platform: available at <a href="https://www.iso.org/obp">https://www.iso.org/obp</a>
- IEC Electropedia: available at <a href="https://www.electropedia.org/">https://www.electropedia.org/</a>

#### 4 Specifications

#### 4.1 Hierarchical file structure

#### 4.1.1 General

A hierarchical file structure is needed to receive sequentially generated data as transactions, and then store these transactions in an organized and easily-retrievable way. Transaction data is medical record. For efficiency and performance purposes, files should be stored using the directory structure directly supported by the computer operating system's file system. This alleviates the need for a specific database engine, as folders are used in a hierarchical structure to store health-related documents and files.

Metadata from the HL7 Ver2.5 messages and other documents are used to establish the folder hierarchy, which is based on the attributes of "Patient ID", "Transaction date", and "Contents description".

#### 4.1.2 Hierarchical structure of storage

The folder structure hierarchy is shown in <u>Figure 1</u>. Note that the structure utilizes a hashing of the patient identifier to facilitate rapid searching for folder names within the tree structure. This will be illustrated in the following subclauses.