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

*Informatique de santé — Spécification de la structure hiérarchique
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 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.

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 <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

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 [Figure 1](#). 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.

Details regarding “HL7 Message Files” and “Document Files” are further defined in [4.2](#) and [4.3](#), respectively.

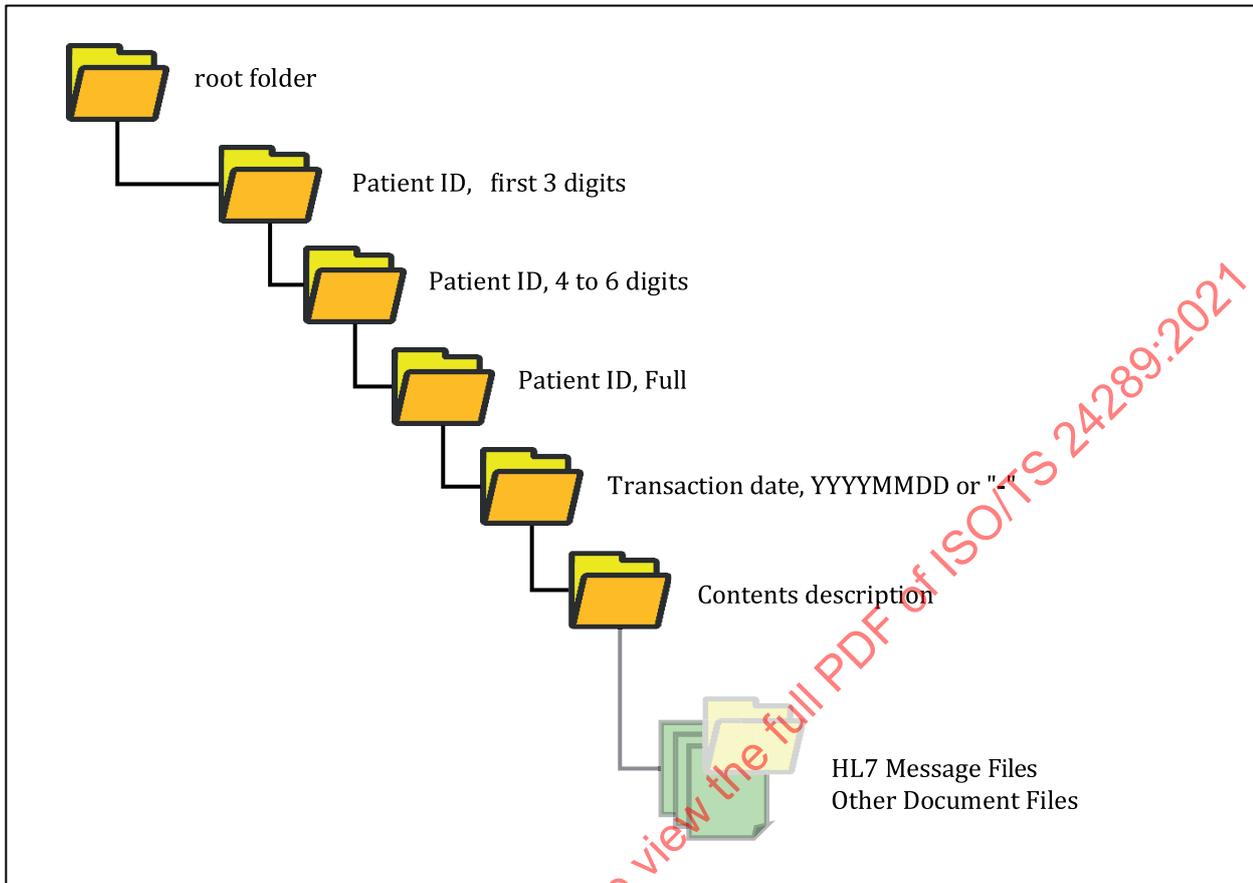


Figure 1 — The hierarchical structure of storage

4.1.3 Metadata required for storage structure

The assigned folder name within the hierarchical structure that is associated with a particular HL7 message or other document uses the following metadata generated as a transaction, as described in [Table 1](#).

Note that it is recommended that an “implementation guide” be in place when this specification is used. This guide covers operational issues (including privacy and security), and also define a base time zone (recommended UTC) to be assumed by all systems creating, accessing and modifying records.

Table 1 — Metadata required for storage structure

#	Item	Description
1	Patient ID	<p>An ID that uniquely identifies the patient within a particular healthcare facility.</p> <p>The first 3 digits of the patient ID, 4-6 digits of the patient ID, and the entire patient ID are used as the storage (search) key for load balancing without requiring the use of a database engine.</p> <p>This set a hierarchy of access keys and prevents the creation of many subfolders under one folder.</p> <p>If the patient ID is less than 6 characters, add characters so that it has 6 or more digits. The character to add is "0" added to the front of the patient ID, or any character is embedded after it.</p> <p>However, the patient ID is not actually changed and the original patient ID is stored separately.</p> <p>The patient ID shall consist of an alphanumeric character.</p> <p>It shall not contain "_" (underscore).</p>
2	Transaction date	<p>Transaction date is the date when medical information including medical treatment, laboratory test, hospitalization, and discharge, etc. is documented in EMR.</p> <p>If transaction date is available, then use the ISO 8601 date and time representation basic format YYYYMMDD.</p> <p>If transaction date and time data is available, then use the ISO 8601 date and time representation basic format YYYYMMDDhhmmss.</p> <p>If the date is not available, then use a "-" (hyphen).</p> <p>Also use "-" (hyphen) when the transaction date of patient attribute, disease name or allergy is different from the concept of medical treatment day.</p>
3	Contents description	<p>An identifier to distinguish the contents.</p> <p>For HL7 Message Files, refer to Table 2.</p> <p>For Document Files, refer to Table 3.</p>

4.1.4 Folder name rules

Folders are configured based on the following rules.

a) First level folder (root)

The root folder of the storage. The folder name may be an arbitrary name.

b) Second level folder (Patient ID)

The first folder used to identify patient IDs. This folder name shall be set with the first three characters of the patient ID. The characters for patient ID count from left to right.

c) Third level folder (Patient ID)

The second folder that identifies patient IDs. The folder name shall be set to the 4th to 6th characters of the patient ID. The characters for patient ID count from left to right.

d) Forth level folder (Patient ID)

The folder that identifies patient IDs. The folder name shall be set with the entire patient ID (6 characters or more).

e) Fifth level folder (Transaction date)

The folder that identifies the transaction date. If transaction date is available, then use the full 8-character date format: YYYYMMDD. If transaction date and time data is available, then use the format YYYYMMDDHHMMSS. If the date is not available, then use a "-" (hyphen).

f) Sixth level folder (Contents description)

The folder that identifies contents. For HL7 Message Files, refer to [Table 2](#). For Document Files, refer to [Table 3](#).

Example of data storage in each folder is shown in [Figure 2](#).

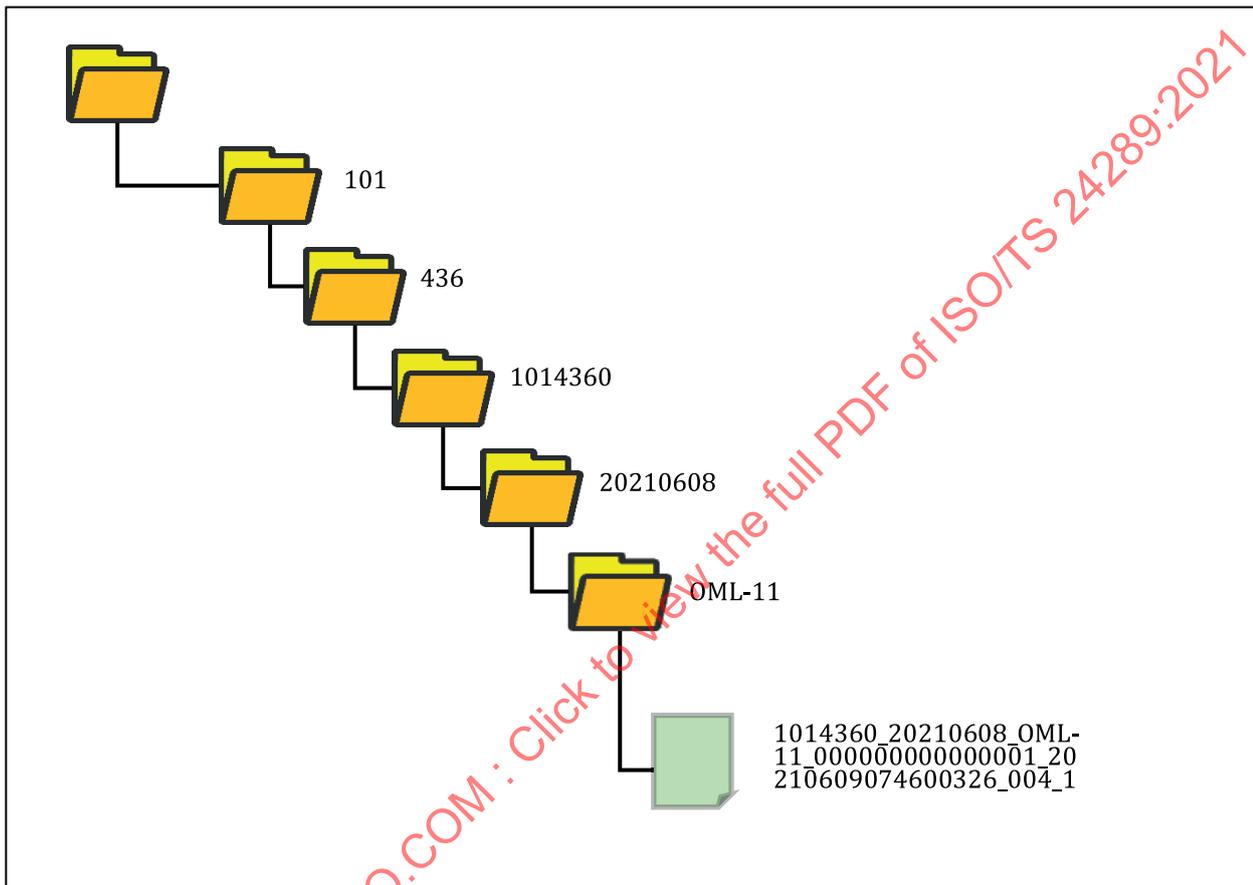


Figure 2 — Example of data storage in each folder

4.2 Configuration rules for HL7 Message Files

4.2.1 General

This subclause defines the configuration rules of HL7 Message Files.

HL7 Ver2.5 messages are generated as transactions, captured as message files, and multiple HL7 Ver2.5 message files are stored in the lowest-level folder.

It is assumed that each HL7 Ver2.5 message is only associated with a single “patient ID”, such that no redundancy occurs. All HL7 V2.5 transactions shall be included in the extract, and where corrections are made in the electronic medical record, these will be represented in the extract by further HL7 V2.5 transactions with later transaction timestamps. In this case, a new file is always created for corrections. In the case where multiple HL7 Ver2.5 messages are generated for the same patient on the same day, multiple files can exist under the same folder. In this case, a rule is set so that each file name is unique.

4.2.2 Hierarchical structure of HL7 Message Files

The folder structure representing the hierarchical structure of HL7 Message Files is shown in [Figure 1](#).

4.2.3 Items required for storage configuration

The folder name in the hierarchical structure of storage uses the following attribute information in HL7 Ver2.5 messages generated as transactions.

Table 2 — Items required for configuring HL7 Message Files

#	Item	Description
1	Patient ID	Refer to Table 1 .
2	Transaction date	Refer to Table 1 .
3	Contents description	It has an identifier to distinguish content type. It shall define and use content according to HL7 message type, or alternatively an implementation-specific classification rule. Refer to Annex A . Table A.1 may be used but is not required. The contents description shall not contain an “_” (underscore).
4	Order No.	An identification number that identifies the doctor's orders and practices. For HL7 message with an order number, the ORC-2 Placer Order Number (or equivalent) shall be used. If there is no order number available, create a user-assigned number that can identify the order of transaction within the same “patient ID” and “content description”, or else a fixed “9999999999999999” shall be used. While the order number may include a version number and the number of trials indicated by the message, the hierarchy shall use the order number obtained after removing the version number and any trials affected by correction/deletion.
5	Transaction date and time	If transaction date and time data is available, then use the ISO 8601 date and time representation basic format YYYYMMDDhhmmssff.
6	Department Code	The code of the identified department of the healthcare organization responsible for the data source. if the department code does not exist, an implementation-assigned fixed default value such as “-” or “000” shall be used. An “_” (underscore) shall not be contained in the department code.
7	Condition flag	A flag that identifies whether the file is valid or invalid. 1: Valid 0: Invalid (cancelled) This value is determined from the value of the ORC-1 Order Control of the HL7 message and the existing file storage status.

4.2.4 Rules for configuring storage

4.2.4.1 Folder name rules

Configure folders based on the following rules:

- a) The first level folder (root) to fifth level folder (Transaction date)

Refer to “[4.1.4 Folder name rule](#).”

- b) Sixth level folder (Contents description)

This represents a folder that distinguishes message contents. The folder name shall define and use content according to HL7 message type, or alternatively an implementation-specific classification rule.

4.2.4.2 HL7 Ver2.5 message file name rule

- a) Each item value defined in “[Table 2](#) Items required for configuring HL7 Message Files” combined with “_” (underscore) shall be set.

"Patient ID" _ "Transaction date" _ "Contents description" _ "Order No." _ "Transaction date and time" _ "Department code" _ "Condition flag"
--

- b) The file extension shall not be set.
- c) Set the condition flag of the valid HL7 Ver2.5 message files to “1”. Cancelled HL7 Ver2.5 Message files can be left with the condition flag set to “0”.

4.3 Configuration rules for document files

4.3.1 General

This subclause defines the configuration rules of document files.

The folder hierarchical structure consists of the attributes of “Patient ID”, “Transaction date”, “Contents description”, and “Contents identifier” in documents generated as transactions, and document files and related files are stored in the lowest folder. Not only document files but also subfolders with arbitrary names can be used. In the lowest folder, document files are always unique to an individual patient.

4.3.2 Hierarchical structure of document files

The folder structure representing the hierarchical structure of document files is shown in [Figure 3](#). Any folders or files can store multiple subfolders and related document files.

One could group subfolders for each event, such as, various types of documents, including preoperative, intraoperative, and postoperative laboratory results and letters of introduction to other medical institutions.

Note that it is not always necessary to create a subfolder, but one could create further subfolders under the subfolder. Although there are no restrictions on this hierarchy, it is not recommended to make it too complicated.

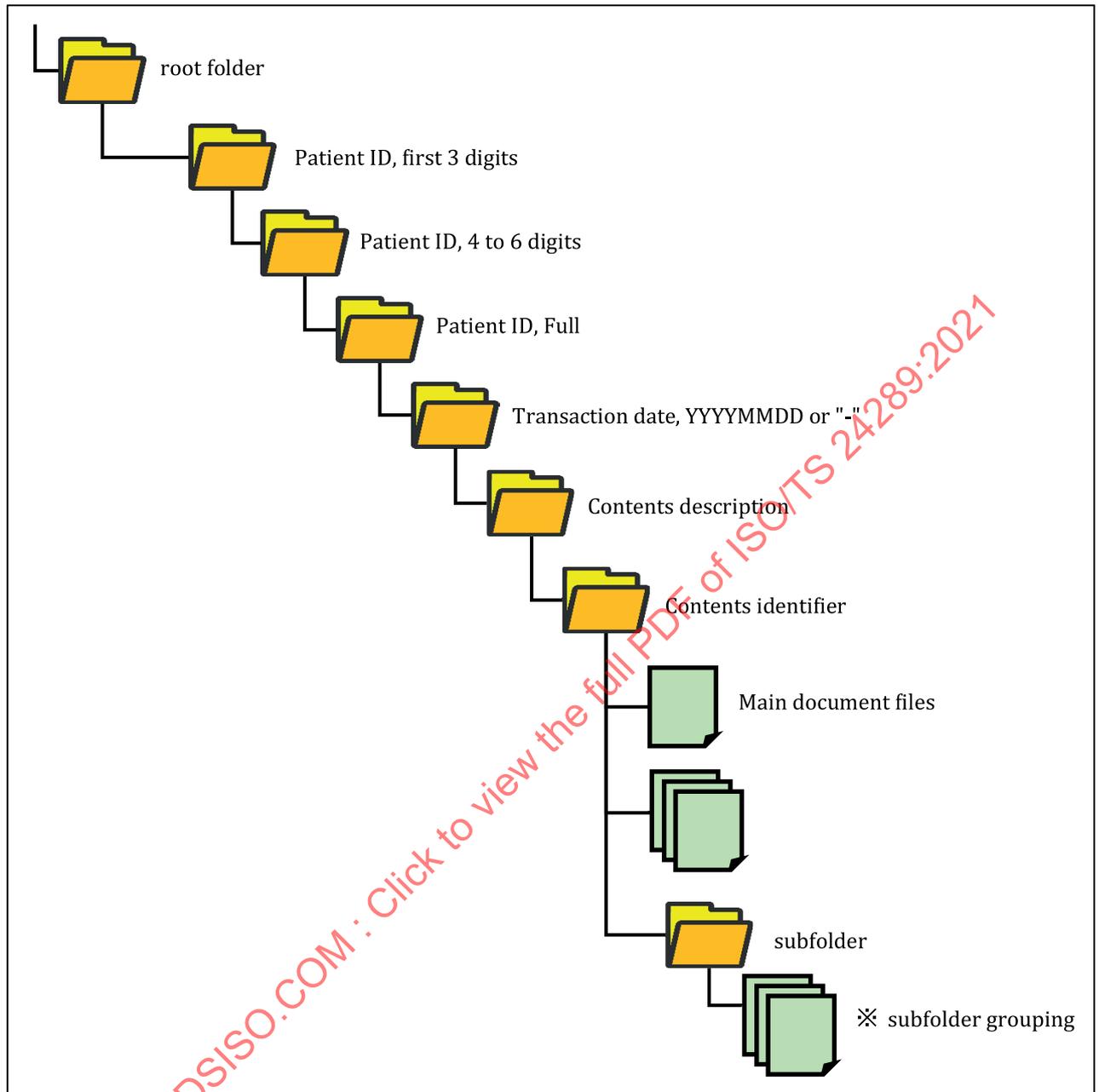


Figure 3 — Hierarchical structure of document files

4.3.3 Items required for storage configuration

The folder names for the hierarchical structure of storage use the following attribute information in documents generated as transactions.

Table 3 — Items required for configuring Document Files

#	Item	Description
1	Patient ID	Refer to Table 1 .
2	Transaction date	Refer to Table 1 .
3	Contents description	An Identifying character to distinguish contents. It shall use the code system defined by the terminology used to classify documents and shall be used in CWE (Coded with Exceptions) data type format in HL7 Ver2.5. For example, LOINC can be used as the terminology. The contents description shall not contain an “_” (underscore).
4	Contents identifier	It includes an identifier for documents. The contents identifier is an ID that makes a document unique. It is a single-use ID that identifies the same document after revisions. It corresponds to “Order No”. which is a configuration item of HL7 Message Files. Contents identifier shall not contain an “_” (underscore).
5	Transaction date and time	If transaction date and time data is available, then use the ISO 8601 date and time representation basic format YYYYMMDDhhmmssff.
6	Department Code	The code of the identified department of the healthcare organization responsible for the data source. if the department code does not exist, an implementation-assigned fixed default value such as “-” or “000” shall be used. An “_” (underscore) shall not be contained in the department code.
7	Condition flag	A flag that identifies whether the file is valid or invalid. 1: Valid 0: Invalid (cancelled) 2: Recorded previously

4.3.4 Rules for configuring storage

4.3.4.1 Folder name rules

Configure folders based on the following rules (see also [4.1.4](#)).

- a) The first level folder (root) to fifth level folder (Transaction date).
- b) Sixth level folder (Contents description).

A folder that distinguishes content. For the folder name, it shall use the code system defined by the terminology used to classify documents, and shall be used it in the CWE type format in HL7 Ver2.5. For example, the Contents description using the local code system and the LOINC code system is as follows.

L010234^Traction therapy Note^99H16^28579-1^Physical therapy Note^LN

- c) The seventh level folder (Contents identifier).

A folder that uniquely identifies Documents. For the folder name, the value obtained by combining each item value defined in "[Table 3](#) Items required for configuration Document Files" with “_” (underscore) shall be set.

"Patient ID" _ "Transaction date" _ "Contents description" _ "Contents identifier" _ "Transaction date and time" _ "Department Code" _ "Condition flag"

- d) Set the condition flag of the valid Contents identifier folder to “1”. Cancelled Contents identifier folder can be left with the condition flag set to “0”.

4.3.4.2 Document files file name rules

- a) The document file to be stored may be of any file-type except a binary or program-executable file. This includes the file types shown in [Annex B](#).
- b) There shall be one document file under the Contents identifier folder.
- c) A subfolder may be created under the Contents identifier folder. Also, sub-subfolders can be created under subfolders, and the hierarchy is not limited. However, not limiting or complicating the operating system's file system should be taken into consideration.
- d) The names of the document files and subfolders stored under the Contents identifier folder may be arbitrary names unless contrary to the restrictions on the file system in operating system.

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Annex A (informative)

Content description corresponding to HL7 message files

In the contents description, which is a configuration item of HL7 Message Files, the applicable value corresponding to the HL7 message files is shown in [Table A.1](#).

Table A.1 — Content description corresponding to HL7 message files

#	HL7 message type	HL7 message Name	Contents description
1	ADT^A08	Update patient information	ADT-00
2	ADT^A23	Delete a patient record	ADT-00
3	ADT^A60	Registration/Update allergy information	ADT-61
4	PPR^ZD1	Registration/Update of diagnosis history	PPR-01
5	RDE^O11	Prescription order	OMP-01
6	RAS^O17	Prescription administration	OMP-11
7	RDE^O11	Injection order	OMP-02
8	RAS^O17	Injection administration	OMP-12
9	OUL^R22	Specimen observation result	OML-11