### INTERNATIONAL STANDARD

ISO 13120

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# Health informatics — Syntax to represent the content of healthcare classification systems — Classification Markup Language (ClaML)

Informatique de santé — Syntaxe de représentation du contenu des systèmes de classification des soins de santé — Langage de balisage de la classification (ClaML)

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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*.

This second edition cancels and replaces the first edition (ISO 13120:2013), which has been technically revised. The main changes compared to the previous edition are as follows:

- Alignment of the Classification Markup Language (ClaML) to HTML;
  - Replacement of the format 'Document Type Definition' (DTD) by an 'XML Schema Definition' (XSD);
  - Provision of XSD files and further informative Annexes on the ISO Standards Maintenance Portal;
  - Addition of a new Annex C on 'Different ways of modification';
  - Complete editorial revision.

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

Healthcare classification systems are developed and distributed in a variety of informal formats, such as MS Word, with little consistency in approach between developers. Exchanging data from these systems or attempting to parse the informal text into a more formal structure, say for publishing purposes, presents many challenges because mistakes are easily made and difficult to detect. For example, the accidental deletion of a tab can transform a sibling rubric into a parent. Text files with comma-separated value fields are another mechanism widely used for storing and transferring data, but as a solution here are limited by insufficient formal structuring capabilities.

In the interests of safely exchanging and distributing the content and hierarchical structure of healthcare classification systems, this document presents a simple XML specification, ClaML, for exchange and distribution of healthcare classification systems. XML is the chosen format for this syntax as: a) XML provides the necessary structuring elements, and b) there are many readily available XML parsers in existence.

This document builds on EN 14463:2008 and ISO 13120:2013.

In this version of the syntax representing ClaML 3.0.0 there had been performed a lot of structural and content-related changes to solve known problems with ClaML 2.0.0 according to experiences out of practical use and to serve additional demands of classification developers and end users. Major changes are the replacement of the DTD (Document Type Definition) by an XSD (XML Schema Definition) and the alignment with HTML by inclusion of XHTML 1.1.

ClaML is intended to serve as the core representation from which all publication forms can be derived. It contains information of a depth sufficient to uniquely identify and describe the structure and relevant elements of healthcare classification systems. This document does not intend to prescribe to developers how healthcare classification systems should be structured, nor does it define or explain the meaning of the structuring elements. ClaML is not meant to be a direct format for viewing or printing the content of a healthcare classification system. Views and prints are to be derived from this representation by post processing.

ClaML is targeted at:

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- developers of first generation[1] healthcare classification systems to assist in the construction, maintenance and publication (both in paper and electronic formats) of their particular healthcare classification systems;
- b) developers of information systems to assist in the inclusion of mechanisms for unambiguous loading of healthcare classification systems into their applications;
- c) organizations responsible for updating healthcare classification systems;
- d) institutions receiving updated healthcare classification systems.

# Health informatics — Syntax to represent the content of healthcare classification systems — Classification Markup Language (ClaML)

#### 1 Scope

The main purpose of ClaML is to formally represent the content and hierarchical structure of healthcare classification systems in a markup language for the safe exchange and distribution of data and structure between organizations and dissimilar software products.

The scope of healthcare classification systems covered by this document encompasses terminologies, and is constrained to traditional paper-based systems (like ICD-10) and systems built according to categorial structures and a cross thesaurus (like ICNP)[2]. ClaML is intended for representation of healthcare classification systems in which classes have textual definitions, hierarchical ordering, named hierarchical levels (such as "chapter", "section"), inclusion and exclusion criteria, and codes. It is not intended to cover any formal representation, neither for definition or composition of concepts, nor for specification of classification rules. Systems with such formal specifications can at best be partially represented using ClaML, and are hence out of scope. Most of the notes and examples in this document relate to ICD. This is because ICD is the most common classification system in the scope of this document. As a highly complex classification system it is an inexhaustible source for examples of nearly any kind. But all these notes and examples represent also other similar classification systems, if applicable, which are usually less complex. An overview of currently known classification systems using ClaML is provided in a separate document which is electronically available (see 7.3).

This document is not intended to: CUMENT Preview

- a) provide a normative syntax on how a healthcare classification system is to be constructed;
- b) define link types between elements in a healthcare classification system (this is left to the developers of healthcare classification systems);
- c) provide a representation for direct viewing or printing.

#### 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3166-1, Codes for the representation of names of countries and their subdivisions — Part 1: Country codes

ISO 639-1, Codes for the representation of names of languages — Part 1: Alpha-2 code

#### 3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological 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="http://www.electropedia.org/">http://www.electropedia.org/</a>

#### 4 Abbreviated terms

ClaML Classification Markup Language

DTD Document Type Definition

HTML HyperText Markup Language[4][5][6]

ICD International Classification of Diseases

ICF International Classification of Functioning, Disability and Health

ICNP International Classification for Nursing Practice

OPS "Operationen und Prozedurenschlüssel", the German procedure classification

WHO World Health Organization

XHTML Extensible HyperText Markup Language [4][5][7]

XML Extensible Markup Language 1.0[3]

XSD XML Schema Definition

#### 5 Conformance

The normative part of this document is written in the form of an XML Schema Definition (XSD). Many commercially available XML tools provide facilities to test the conformance of an XML document with an XSD. Users of ClaML are encouraged to perform such a test before distributing their healthcare classification systems in the format of this document.

#### 6 Conventions

The font Courier New is used to denote XSD or XML content of ClaML. XML examples in this document are only a partial representation of a ClaML file. For reasons of readability parts are left out at "...".

In descriptive parts of this document **bold** text is used to denote elements and attributes defined in the XSD. For names of elements Upper CamelCase is used (i.e. a single string, consisting of multiple words without spaces, each starting with a capital); for names of attributes lowercase is used. Italic text in quotation marks is used to denote attribute values.

NOTE Names of externally defined XHTML 1.1 elements are in lowercase.

#### 7 Classification markup language

#### 7.1 Basis of the syntax

The basis of the syntax is to represent the content of healthcare classification systems. The syntax defined in this document is called Classification Markup Language. It is defined here in the form of an XSD. The reference to this syntax will be headed to ClaML in this document. The version of ClaML described in this document is version 3.0.0.

#### 7.2 HTML inclusion

In the previous ClaML 2.0.0 version internally defined elements were used for representation of textual content of a healthcare classification system. These elements originated from the DocBook standard. Experiences with this version raised the wish to align ClaML to HTML for various reasons (e.g. HTML

is more common, it enables easier transformation between different formats and it contains in ClaML so far missing features for accessibility demands). Therefore for this version these elements have been removed and replaced by inclusion of externally defined equivalent content of HTML. The module-based XHTML 1.1 definition<sup>[5][7]</sup> appeared to be the most suitable candidate for integration as it allows the inclusion of the model (xhtml11-model-1.xsd) and modules (xhtml11-modules-1.xsd) schema files into the same namespace of ClaML. This enables the use of these elements in a ClaML file without a prefix. Extensions by redefinition of XHTML modules allow keeping ClaML specific functions. This XHTML 1.1 inclusion should as well cover functionality of the HTML 5 specification<sup>[6]</sup> in its basics, which is not available as XML Schema Definition file. However, this partial inclusion does not meet the official criteria for XHTML Host Language Document Type Conformance or XHTML Integration Set Conformance. ClaML may therefore not be called "XHTML Host Language Conforming" or "XHTML Integration Set Conforming" [7].

For further information on the specific use of XHTML 1.1 elements in ClaML refer to the notes on the **Label** element in <u>7.7.25.1</u> and the extended XHTML anchor element (a) in <u>7.7.26</u>.

#### 7.3 Electronic inserts

The following electronic inserts are located in the ISO Standards Maintenance Portal 13120 folder: <a href="http://standards.iso.org/iso/13120/ed-2/en">http://standards.iso.org/iso/13120/ed-2/en</a>.

In the versions of ClaML published so far (EN 11463:2008, ISO 13120:2013), the DTD was only a regular part of the text document. In this version 3.0.0 of the syntax, the XML Schema Definition as given in 7.6 is also provided as electronic insert. The ClaML3.0.0.xsd file has been uploaded to the ISO database and is electronically available.

Direct link: <a href="http://standards.iso.org/iso/13120/ed-2/en/ClaML3.0.0.xsd">http://standards.iso.org/iso/13120/ed-2/en/ClaML3.0.0.xsd</a>

Also a DTD and an XSD file of the previous version 2.0.0 have been generated to support users upgrading to the new version. In the versions of ClaML published so far (EN 11463:2008, ISO 13120:2013), the specification was only defined as DTD. So for this revision the old DTD needed to be translated into an XSD first as basis for any further changes. Changes are much more comprehensible when comparing the new ClaML 3.0.0 XSD to this file instead of the old DTD. This XSD file might as well be used as replacement for the old DTD when dealing with ClaML 2.0.0-based healthcare classification systems. The files are stored in the ed-1-en.zip file. File names: ClaML2.0.0.dtd and ClaML2.0.0.xsd.

Direct link: http://standards.iso.org/iso/13120/ed-2/en/ed-1-en.zip

#### 7.4 Informative addenda

The following informative addenda are located in the ISO Standards Maintenance Portal 13120 folder: <a href="http://standards.iso.org/iso/13120/ed-2/en">http://standards.iso.org/iso/13120/ed-2/en</a>.

According to the substantial changes from the previous ClaML version 2.0.0 to this version 3.0.0 some informative documents have been generated. These documents will help to better understand the changes and facilitate the transfer of healthcare classification systems to the new version.

The "ClaML\_XSD\_2.0.0\_TO\_3.0.0" document illustrates the changes of the specification in detail and shall help users to better understand them and facilitate an update to the new version. All changes based on the ClaML 2.0.0 XSD are yellow highlighted. Insertions are displayed as red and underlined text. Deletions are displayed as blue and striked-through text. The ClaML\_XSD\_2.0.0\_TO\_3.0.0.pdf file has been uploaded to the ISO database and is electronically available.

Direct link: http://standards.iso.org/iso/13120/ed-2/en/ClaML\_XSD\_2.0.0\_TO\_3.0.0.pdf

The "Inventory of classification systems using ClaML" document gives an overview of currently known healthcare classification systems using ClaML. These might serve as example healthcare classification systems when considering representing a new healthcare classification system in ClaML and gives a better understanding of the scope of the syntax. The file is stored in the ed-1-en.zip file. File name: Inventory\_of\_classification\_systems\_using\_ClaML\_2016-02-15.pdf.

Direct link: <a href="http://standards.iso.org/iso/13120/ed-2/en/ed-1-en.zip">http://standards.iso.org/iso/13120/ed-2/en/ed-1-en.zip</a>

The "ClaML 2.0.0 structure" document displays the ClaML 2.0.0 structure in a diagram. The file is stored in the ed-1-en.zip file. File name: ClaML2.0.0\_structure.pdf.

Direct link: <a href="http://standards.iso.org/iso/13120/ed-2/en/ed-1-en.zip">http://standards.iso.org/iso/13120/ed-2/en/ed-1-en.zip</a>

The "ClaML 3.0.0 structure" document displays the ClaML 3.0.0 structure in a diagram. The ClaML3.0.0\_ structure.pdf file has been uploaded to the ISO database and is electronically available.

Direct link: http://standards.iso.org/iso/13120/ed-2/en/ClaML3.0.0\_structure.pdf

#### 7.5 ClaML implementation profile

ClaML offers a wide range of possibilities for the representation of classification content. The defined XML structure partially allows tree structures of endless depth. This generates serious problems for end users when importing ClaML files. As healthcare classification systems nowadays contain a huge amount of data, so do the resulting ClaML files. Therefore it is difficult for end users to oversee what needs to be addressed in their import routines so that no important information of the files is overlooked.

Hence classification system developers are highly encouraged to provide an implementation profile with their ClaML files. Such an implementation profile should at a minimum address the following questions:

- which elements and attributes are used in the current ClaML file;
- maximum expectable depth of the tree structure regarding potentially endless branches;
- subclassificiation structure (e.g. maximum level, use of multiple modifiers);
- notes on further necessary post-processing for generation of output formats.

#### 7.6 XML Schema Definition

```
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```

```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>

<!--ClaML ver 3.0.0 -->
<xs:schema xmlns:xs="http://www.w3.org/2001/XMLSchema"</pre>
 xmlns:xml="http://www.w3.org/XML/1998/namespace"
 elementFormDefault="qualified" attributeFormDefault="unqualified">
   <xs:import namespace="http://www.w3.org/XML/1998/namespace"</pre>
    schemaLocation="http://www.w3.org/2001/xml.xsd"/>
   <xs:include schemaLocation="http://www.w3.org/MarkUp/SCHEMA/xhtml11-model-1.xsd"/>
   <xs:redefine schemaLocation="http://www.w3.org/MarkUp/SCHEMA/xhtml11-modules-1.xsd">
      <xs:attributeGroup name="xhtml.a.attlist">
         <xs:attributeGroup ref="xhtml.a.attlist"/>
         <xs:attribute name="modifier" type="xs:string" use="optional"/>
         <xs:attribute name="code" type="xs:string" use="optional"/>
         <xs:attribute name="variants" type="xs:NMTOKEN"</pre>
         use="optional"/>
      </xs:attributeGroup>
      <xs:group name="xhtml.a.content">
         <xs:choice>
            <xs:group ref="xhtml.a.content"/>
            <xs:element ref="Usage"/>
         </xs:choice>
      </xs:group>
   </xs:redefine>
   <xs:group name="rubric.simple">
      <xs:choice>
         <xs:group ref="xhtml.Anchor.class"/>
         <xs:group ref="xhtml.InlPres.class"/>
         <xs:group ref="xhtml.InlPhras.class"/>
```

```
</xs:choice>
       </xs:group>
       <xs:group name="rubric.complex">
          <xs:choice>
             <xs:group ref="rubric.simple"/>
             <xs:group ref="xhtml.BlkStruct.class"/>
             <xs:element ref="Include"/>
             <xs:element ref="IncludeDescendants"/>
             <xs:element ref="Fragment"/>
             <xs:group ref="xhtml.List.class"/>
             <xs:group ref="xhtml.Table.class"/>
          </xs:choice>
       </xs:aroup>
       <xs:element name="ClaML">
          <xs:complexType mixed="false">
             <xs:sequence>
                <xs:element ref="Classification" minOccurs="1"</pre>
                 maxOccurs="unbounded"/>
             </xs:sequence>
             <xs:attribute name="version" type="xs:string" use="required"/>
          </xs:complexType>
       </xs:element>
       <xs:element name="Classification">
          <xs:complexType mixed="false">
             <xs:sequence>
                <xs:element ref="Meta" minOccurs="0" maxOccurs="unbounded"/>
                <xs:element ref="Identifier" minOccurs="0"</pre>
                 maxOccurs="unbounded"/>
                <xs:element ref="Title" minOccurs="1"</pre>
                 maxOccurs="unbounded"/>
                <xs:element ref="Authors" minOccurs="0" maxOccurs="1"/>
                <xs:element ref="Variants" minOccurs="0" maxOccurs="1"/>
                <xs:element ref="ClassKinds" minOccurs="1" maxOccurs="1"/>
                <xs:element ref="UsageKinds" minOccurs="0" maxOccurs="1"/>
                <xs:element ref="RubricKinds" minOccurs="1" maxOccurs="1"/>
                <xs:element ref="Modifier" minOccurs="0"</pre>
                 maxOccurs="unbounded"/>
https://standards.ii<xs:element/ref="ModifierClass"/minOccurs="0"87b2-e61e57ea6d7c/iso-13120-2019
                 maxOccurs="unbounded"/>
                <xs:element ref="Class" minOccurs="0"</pre>
                 maxOccurs="unbounded"/>
             </xs:sequence>
             <xs:attribute ref="xml:lang" use="required"/>
             <xs:attribute ref="xml:space" use="optional"</pre>
              default="default"/>
          </xs:complexType>
          <xs:key name="Class-code-key">
             <xs:selector xpath="./Class"/>
             <xs:field xpath="@code"/>
          </xs:key>
          <xs:keyref name="SubClass-code-keyref" refer="Class-code-key">
             <xs:selector xpath="./Class/SubClass"/>
             <xs:field xpath="@code"/>
          </xs:keyref>
          <xs:keyref name="SuperClass-code-keyref" refer="Class-code-key">
             <xs:selector xpath="./Class/SuperClass"/>
              <xs:field xpath="@code"/>
          </xs:keyref>
          <xs:keyref name="IncludeDescendants-code-keyref"</pre>
           refer="Class-code-key">
             <xs:selector xpath=".//IncludeDescendants"/>
             <xs:field xpath="@code"/>
          </xs:keyref>
```

```
<xs:key name="Modifier-code-key">
  <xs:selector xpath="./Modifier"/>
   <xs:field xpath="@code"/>
</xs:kev>
<xs:keyref name="ModifierClass-modifier-keyref"</pre>
refer="Modifier-code-key">
   <xs:selector xpath="./ModifierClass"/>
   <xs:field xpath="@modifier"/>
</xs:keyref>
<xs:keyref name="ModifiedBy-code-keyref"</pre>
refer="Modifier-code-key">
  <xs:selector xpath=".//ModifiedBy"/>
  <xs:field xpath="@code"/>
</xs:keyref>
<xs:keyref name="ExcludeModifier-code-keyref"</pre>
refer="Modifier-code-key">
   <xs:selector xpath=".//ExcludeModifier"/>
   <xs:field xpath="@code"/>
</xs:keyref>
<xs:key name="Variant-name-key">
   <xs:selector xpath="./Variants/Variant"/>
   <xs:field xpath="@name"/>
</xs:key>
<xs:keyref name="variants-keyref" refer="Variant-name-key">
   <xs:selector xpath=".//*"/>
   </xs:keyref>
<xs:key name="ClassKind-name-key">
  <xs:selector xpath="./ClassKinds/ClassKind"/>
   <xs:field xpath="@name"/>
</xs:key>
<xs:keyref name="Class-kind-keyref" refer="ClassKind-name-key">
  <xs:selector xpath="./Class"/>
  s<xs:field xpath="@kind"/>|dards/iso/869f8709-da06-4656-87b2-e6fe57ea6d7c/iso-13120-2019
</xs:keyref>
<xs:keyref name="IncludeDescendants-kind-keyref"</pre>
refer="ClassKind-name-key">
   <xs:selector xpath=".//IncludeDescendants"/>
   <xs:field xpath="@kind"/>
</xs:keyref>
<xs:key name="UsageKind-name-key">
   <xs:selector xpath="./UsageKinds/UsageKind"/>
   <xs:field xpath="@name"/>
</xs:key>
<xs:keyref name="Usage-kind-keyref" refer="UsageKind-name-key">
  <xs:selector xpath=".//Usage"/>
   <xs:field xpath="@kind"/>
</xs:keyref>
<xs:key name="RubricKind-name-key">
  <xs:selector xpath="./RubricKinds/RubricKind"/>
   <xs:field xpath="@name"/>
</xs:key>
<xs:keyref name="Rubric-kind-keyref" refer="RubricKind-name-key">
   <xs:selector xpath="./*/Rubric"/>
   <xs:field xpath="@kind"/>
</xs:keyref>
<xs:key name="Author-name-key">
  <xs:selector xpath="./Authors/Author"/>
```

```
<xs:field xpath="@name"/>
          </xs:key>
          <xs:keyref name="History-author-keyref" refer="Author-name-key">
             <xs:selector xpath=".//History"/>
             <xs:field xpath="@author"/>
          </xs:keyref>
       </xs:element>
       <xs:element name="Variants">
          <xs:complexType mixed="false">
             <xs:sequence>
                <xs:element ref="Variant" minOccurs="1"</pre>
                 maxOccurs="unbounded"/>
             </xs:sequence>
          </xs:complexType>
       </xs:element>
       <xs:element name="Variant">
          <xs:complexType mixed="true">
             <xs:attribute name="name" type="xs:NMTOKEN" use="required"/>
          </xs:complexType>
       </xs:element>
       <xs:element name="Meta">
          <xs:complexType mixed="false">
             <xs:attribute name="name" type="xs:string" use="required"/>
             <xs:attribute name="value" type="xs:string" use="required"/>
             <xs:attribute name="variants" type="xs:NMTOKEN"</pre>
              use="optional"/>
             <xs:attribute name="kind" type="xs:NMTOKEN" use="optional"/>
          </xs:complexType>
       </xs:element>
       <xs:attribute name="authority" type="xs:NMTOKEN"</pre>
              use="optional"/>
             <xs:attribute name="uid" type="xs:string" use="required"/>
https://standarc<xs:attribute name="variants" type="xs:NMTOKEN" 7b2-e61e57ea6d7c/iso-13120-2019
              use="optional"/>
             <xs:attribute name="date" type="xs:dateTime" use="optional"/>
             <xs:attribute name="effectivedate" type="xs:dateTime"</pre>
              use="optional"/>
             <xs:attribute name="expirationdate" type="xs:dateTime"</pre>
              use="optional"/>
             <xs:attribute name="status" type="xs:string" use="optional"/>
          </xs:complexType>
       </xs:element>
       <xs:element name="Title">
          <xs:complexType mixed="true">
             <xs:attribute name="name" type="xs:NMTOKEN" use="required"/>
             <xs:attribute name="version" type="xs:string" use="optional"/>
             <xs:attribute name="variants" type="xs:NMTOKEN"</pre>
              use="optional"/>
          </xs:complexType>
       </xs:element>
       <xs:element name="Authors">
          <xs:complexType mixed="false">
             <xs:sequence>
                <xs:element ref="Author" minOccurs="1"</pre>
                 maxOccurs="unbounded"/>
             </xs:sequence>
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