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An American National Standard

# Standard Specification for Guideline Elements Model (GEM)—Document Model for Clinical Practice Guidelines<sup>1</sup>

This standard is issued under the fixed designation E 2210; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 This specification covers a document type definition (DTD) that specifies a standard representation for storing and organizing the heterogeneous information contained in clinical practice guidelines. This specification is intended to facilitate translation of natural-language guideline documents into a format that can be processed by computers. It can be used to represent document content throughout the entire guideline life cycle. Information at both high and low levels of abstraction can be accommodated. This specification is based on the guideline elements model (GEM) created at the Yale Center for Medical Informatics and designed to serve as a comprehensive XML-based guideline document representation.

1.2 This specification refers to and makes use of recommendations from the World Wide Web consortium, the W3C.<sup>2</sup>

1.3 *Standard Guideline DTD*—This specification defines a standard DTD for clinical practice guidelines. The DTD is included in **Annex A1**.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory requirements prior to use.*

## 2. Referenced Documents

### 2.1 ASTM Standards:

- E 1239 Guide for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Automated Patient Care Information Systems<sup>3</sup>
- E 1384 Guide for Content and Structure of the Electronic Health Record (EHR)<sup>3</sup>
- E 1633 Specification for Coded Values Used in the Electronic Health Record<sup>3</sup>
- E 2182 Specification for Clinical XML DTDs in Healthcare<sup>3</sup>

**E 2183** Guide for XML DTD Design, Architecture and Implementation<sup>3</sup>

2.2 *W3C World Wide Web Consortium:*

XML 1.0 Recommendation<sup>4</sup>

XHTML Basic Recommendation<sup>5</sup>

XLINK<sup>6</sup>

Namespaces Recommendation<sup>7</sup>

XSL/XSLT<sup>8</sup>

Schemas<sup>9</sup>

2.3 *HL7 Standards:*<sup>10</sup>

Informative Document: Using XML as an Alternative Message Syntax for HL7, Version 2.3.x

Clinical Document Architecture

## 3. Terminology

### 3.1 Definitions:

3.1.1 *document type definition (DTD)*—the formal definition of the elements, structures, and rules for enabling platform-independent data access via XML, or for marking up a given type of SGML document.

3.1.2 *extensible markup language (XML)*—standard from the World Wide Web Consortium (W3C) that provides for tagging of information content within documents, offering a means of representation of content in a format that is both human and machine readable. Through the use of customizable style sheets and schemas, information can be represented in a uniform way, allowing for interchange of both content (data) and format (metadata).

3.1.3 *health level 7 (HL7)*—a standards organization traditionally focused on standards for healthcare information interchange. HL7 messages are the dominant standard for peer-to-peer exchange of clinical text-based information. More recently, HL7 has developed a comprehensive object model of

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<sup>2</sup> <http://www.w3.org>

<sup>3</sup> *Annual Book of ASTM Standards*, Vol 14.01.

<sup>4</sup> <http://www.w3.org/XML/>

<sup>5</sup> <http://www.w3.org/TR/2000/REC-xhtml-basic-20001219>

<sup>6</sup> <http://www.w3.org/XML/Linking>

<sup>7</sup> <http://www.w3.org/TR/REC-xml-names/>

<sup>8</sup> <http://www.w3.org/Style/XSL/>

<sup>9</sup> <http://www.w3.org/XML/Schema>

<sup>10</sup> <http://www.HL7.org>

the healthcare enterprise and the first level of an XML clinical document architecture.

3.1.4 *HL7 clinical document architecture (CDA)*—a document markup standard for the structure and semantics of exchanged clinical documents. A clinical document is a documentation of observations and other services with the following characteristics: persistence, stewardship, potential for authentication, wholeness, and human readability. A CDA document is a defined and complete information object that can exist outside of a message and can include text, sounds, and other multimedia content.

3.1.5 *hypertext markup language (HTML)*—the language used in creating a web page. Its origin is an implementation of SGML DTD. It provides tags regarding the way a document should be displayed in the text of an HTML document, which act as commands that a browser interprets when downloading an HTML file.

3.1.6 *namespaces*—provide a simple method for qualifying element and attribute names used in XML documents. This is accomplished by associating a particular tag set by associating a prefix with a URI reference. XML namespaces provides a mechanism for authoring compound documents (documents consisting of elements and attributes from multiple DTDs or schemas) in such a way that will provide global identification without collisions of names that are the same but are used differently.

3.1.7 *parser*—a specialized software program that recognizes markup in a document and differentiates the content from the markup. A parser that reads a DTD and checks and reports on markup errors is a validating XML parser. A parser can be built into an XML editor to prevent incorrect tagging and to check whether a document contains all the required elements.

3.1.8 *schema*—defines the elements that can appear within the document and the attributes that can be associated with an element. It also defines the structure of the document: which elements are child elements of others, the sequence in which the child elements can appear, and the number of child elements. It defines whether an element is empty or can include text. The schema can also define default values for attributes. Schema is a W3C term for the next generation of DTDs.

3.1.9 *stylesheet*—the XSL transformations (XSLT) describes a vocabulary recognized by an XSLT processor to transform information from an organization in the source file into a different organization suitable for continued downstream processing. The extensible stylesheet language (XSL) describes a vocabulary recognized by a rendering agent to reify abstract expressions of format into a particular medium of presentation.

3.1.10 *valid XML document*—a document that is well-formed, with internal or DOCTYPE reference to element definition of tags within the document.

3.1.11 *well-formed XML document*—an XML document that conforms to the syntax as specified by the W3C XML 1.0 recommendation.

3.1.12 *World Wide Web Consortium (W3C)*—develops interoperable technologies (specifications, guidelines, software,

and tools) to lead the Web to its full potential as a forum for information, commerce, communication, and collective understanding.

3.1.13 *XHTML*—HTML documents that are well formed and can be processed by an XML parser.

3.1.14 *XLL/XLINK/XPOINTER*—XLL, the extensible linking language, is divided into two parts, XLinks and XPointers. XLink, the XML linking language, defines how one document links to another document. XPointer, the XML pointer language, defines how individual parts of a document are addressed. XLinks point to a URI (in practice, a URL) that specifies a particular resource. The URL may include an XPointer part that more specifically identifies the desired part or section of the targeted resource or document. XPointer, the XML pointer language, defines an addressing scheme for individual parts of an XML document. XLinks point to a URI (in practice, a URL) that specifies a particular resource. The URI may include an XPointer part that more specifically identifies the desired part or element of the targeted resource or document. XPointers use the same XPath syntax as XSL transformations to identify the parts of the document they point to, along with a few additional pieces.

### 3.2 Definitions of Terms Specific to This Standard:

3.2.1 *clinical practice guidelines*—systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.<sup>11</sup>

3.2.2 *guideline elements model (GEM)*—an XML-based guideline document model that promotes translation of natural language guideline documents into a format that can be processed by computers. Developed at the Yale Center for Medical Informatics, GEM serves as the basis for this specification.<sup>12</sup>

3.2.3 *guidelines interchange format (GLIF)*—a proposed representation for guideline logic created by the INTERMED Collaboratory.<sup>13</sup>

3.2.4 *national guidelines clearinghouse (NGC)*—a website sponsored by the U.S. Agency for Healthcare Quality and Research that disseminates information about qualifying guidelines. It includes a structured vocabulary for describing several aspects of guidelines.<sup>14</sup>

### 3.3 GEM Definitions:

3.3.1 See Table A1.1 in Annex A1.

## 4. Significance and Use

4.1 *GEM Representation*—The guideline elements model (GEM) was created to unify representations created by health services researchers and by informatics specialists. Specification E 2210 DTD is based on the GEM knowledge representation. It is intended to be:

<sup>11</sup> *Guidelines for Clinical Practice: From Development to Use*, Institute of Medicine, National Academy Press, Washington, DC, 1992.

<sup>12</sup> <http://ycmi.med.yale.edu>

<sup>13</sup> <http://www.glif.org>.

<sup>14</sup> <http://www.guideline.gov>