First edition
2006-08-01

Health informatics — HL7 version 3 — Reference information model — Release 1

Informatique de santé — HL7 version 3 — Modèle d'information de référence — Version 1

Reference number
ISO/HL7 21731:2006(E)

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Published in Switzerland

HEALTH LEVEL SEVEN REFERENCE INFORMATION MODEL, RELEASE 1

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

A pilot project between ISO and Health Level Seven Inc. (HL7) has been formed to develop and maintain a group of ISO/HL7 standards in the field of medical devices as approved by Council resolution 7/2002. Under this pilot project, HL7 is responsible for the development and maintenance of these standards with participation and input from ISO member bodies.

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.

ISO/HL7 21731 was prepared by HL7 and Technical Committee ISO/TC 215, *Health informatics*.

0 Introduction

This introduction is confined to discussion of the requirement for a Reference Information Model in standardization. Further information on the development of this model and the rational for advancing it as a standard can be found in Annex A.

0.1 Uses of a Reference Information Model (RIM) in Health Informatics

0.1.1 Use of the RIM in ISO TC215

ISO TC215 – Health Informatics has previously advanced ISO 17113, a specification for a framweork for developing health data interchange standards. This framework specification calls for messaging standards to be based on a single, comprehensive model of health information. The RIM presented in the current specification provides one such model. Further, the RIM may provide a reference document that can facilitate the harmonization of the health informatics standards and relaterd specifications within ISO TC 215.

0.1.2 Use of the RIM by HL7

The HL7 RIM is a critical component of the V3 development process. It is the root of all information models and structures developed as part of the V3 development process.

The HL7 V3 standard development process is a model-driven methodology in which a network of inter-related models are developed that depict the static and behavioral aspects of the requirements and design of HL7 standards, as well as the underlying semantics and business rules that govern them.

0 INTRODUCTION

The RIM provides a static view of the information needs of HL7 V3 standards. It includes class and state-machine diagrams and is accompanied by use case models, interaction models, data type models, terminology models, and other types of models to provide a complete view of the requirements and design of HL7 standards. The classes, attributes, state-machines, and relationships in the RIM are used to derive domain-specific information models that are then transformed through a series of constraining refinement processes to eventually yield a static model of the information content of an HL7 standard.

The HL7 V3 standard development process defines the rules governing the derivation of domain information models from the RIM and the refinement of those models into HL7 standard specifications. The rules require that all information structures in derived models be traceable back to the RIM and that their semantic and related business rules not conflict with those specified in the RIM. The RIM therefore is the ultimate source for all information content in HL7 V3 standards.

The RIM is used by HL7 international affiliates to extend HL7 V3 standards to meet local needs. Through a process known as localization, V3 standard specifications are extended using the RIM as the source for new information content. This new information is derived from the RIM and refined in the same manner used to create the original specification.

0.1.3 Uses of the RIM Outside of HL7

The RIM is primarily for use by HL7 and its international affiliates. However, others outside of HL7 have also found the RIM useful. Although HL7 maintains a copyright on the expression of this standard, HL7 does not seek to license or otherwise control the use of information structures or programs that implement this specification. Early adopters of the V3 standards development process have used the RIM to develop HL7-like message specifications in their own environments. These early adopters include vendors, large integrated delivery networks, and government agencies within the United States and internationally. These same early adopters are extremely active in HL7 and provide practical input to the RIM and other aspects of V3 the development process.

Some HL7 member organizations have reported using the RIM as a source of input to their enterprise information architectures or as a starting place for systems analysis and design. The RIM may indeed be useful for such purposes; however, HL7 provides no assurance that the RIM is useful for anything other than as a reference model for HL7 standards development.

The RIM is only one model of healthcare information needs. The abstract style of the RIM and the ability to extend the RIM through vocabulary specifications make the RIM applicable to any conceivable healthcare system information interchange scenario. In fact, it is conceptually applicable to any information domain involving entities playing roles and participating in acts.

The universal applicability of the RIM makes it particularly useful for an organization like HL7 that has to consider the needs of a large and diverse membership. The style of the RIM makes it extremely stable, which is another important characteristic for HL7. The HL7 standards development process calls for the creation of domain specific models derived from the RIM and the incremental refinement of those models into design models that are specific to the problem area. These problem area specific design models narrow the abstractness of the RIM and include constraints on attribute values and class relationships that are use case specific. External organizations considering using the HL7 RIM are advised to adopt a similar process of deriving design models as a transformation of the RIM.

0.2 Further information

Questions or comments about the content of the standard may be addressed to HL7 at (www.hl7.org), to one of the HL7 International Affiliate organizations, or to the Secretariat of ISO TC215 – Health Informatics.