TECHNICAL REPORT

**ISO/TR 14639-2**

First edition

# Health informatics — Capacity-based eHealth architecture roadmap —

## Part 2: Architectural components and maturity model

*Informatique de santé — Feuille de route de l'architecture de santé électronique fondée sur la capacité —*

*Partie 2: Composants architecturaux et modèle de maturité*

**PROOF/ÉPREUVE**

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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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health informatics*.

ISO/TR 14639 consists of the following parts, under the general title *Health informatics — Capacity-based eHealth architecture roadmap*:

— *Part 1: Overview of national eHealth initiatives*

— *Part 2: Architectural components and maturity model*

 

# Introduction

ISO/TC 215 has identified that there is an urgent need to provide International Standards for health information architectures that includes requirements tailored also to low- and middle-income countries with relatively immature resources available. A Public Health Task Force of international experts, established by TC 215, has developed a report outlining the challenges these countries face and some of the relevant standardization strategies.

This part of ISO/TR 14639 provides a guide to best practice business requirements and principles for planning the use of information and communications technology (ICT) to support the development, coordination, and delivery of healthcare services by countries and subordinate health authorities within a country.

One of the activities motivating this work originates from a meeting in March 2010, in Bellagio, Italy to explore how the "digital divide" between high-income and low-income countries could be addressed.[10]

The following observations were noted.

a) There is a surge of interest in the development of eHealth infostructure to support effective Health Information Systems (HIS) in low-income countries, including responding to disease outbreaks, monitoring the health status of the population, and improving both public and individual health.

b) Health informatics International Standards help countries to make the proper decisions regarding their eHealth architecture such that they can strengthen their health systems. HIS architectures that are non-proprietary and based on International Standards are likely to be more robust and future-proof.

c) The use of health informatics International Standards in low-income countries is hampered due to lack of knowledge and awareness about appropriate standards, affordable access to standards and implementation guides, and little participation in Standards Development Organization (SDO) activities due to little or no funding to support such engagement.

d) Existing international health informatics International Standards insufficiently address the needs of low-income countries (LICs) for developing their monitoring, public health, and patient care systems. An example of this is mobile computing and the use of SMS for transmitting patient information, reminders, and alerts. Thus, the participation of LICs in the International Standards development process is essential.

e) Participation in ISO activities requires a national standards organization or government department as an official member of ISO.

f) Development of International Standards has a cost. A significant amount of money and time needs to be invested in preparation of documents, commenting on proposals, and participation in SDO meetings and for adopting, adapting, and localization of standards. These costs represent a genuine barrier to the participation of low-income countries.

g) Access to International Standards also comes with a cost that is often prohibitive for people and organizations in low-income countries.

h) There is recognition that the business model of some SDOs is based on the sale of International Standards to support the standards development process and operating expenses.

i) HIS strengthening can be promoted by using commonly shared International Standards to carry out Monitoring and Evaluation (M & E) activities for government bodies, international organizations, donors, and other interested parties.

j) There are duplications and overlaps in health informatics International Standards across multiple SDOs. Low-income countries require a single set of usable International Standards based on the work of ISO/TC 215, HL7, and CEN/TC 251 Joint Initiative Council (JIC) to harmonize International

Standards and facilitate the global, international adoption, and adaption of organizational and regional standards based on the ISO standards process.

k) Promotion of International Standards worldwide is consistent with the ISO mission yet barriers exist to the achievement of this objective.

While not all of these observations are addressed within the scope of this Technical Teport, the report is an attempt to respond to some of these observations, providing a robust framework for low-income countries for their eHealth architecture planning and health system development. The other items are intended to be addressed in due course.

This part of ISO/TR 14639 examines various activities and associated criteria for the effective use of information and communication technology (ICT) in support of health service delivery, planning, and coordination. It aims to provide relevant guidance on uses of information, based on model criteria by which development of eHealth capability can be planned and progress toward its mature use can be assessed.

In preparing this part of ISO/TR 14639, the original aim was to provide guidance for developing and emerging countries and for the many international groups that conduct health programs in the developing and emerging world. As the work proceeded, it became clear that the work is more widely applicable to all health services and that there are potential lessons for all as they examine the way in which information is produced, managed, and used in various aspects of their work. The identification of relevant health informatics standards and the role of international standardization in support of eHealth were also important drivers.

This part of ISO/TR 14639 builds on lessons from many countries, including those whose activities are summarized in ISO/TR 14639-1 and was, in large part, inspired by experience with the Health Metrics Network (WHO/HMN Framework) activities sponsored by the World Health Organization (WHO). The particular focus of this part of ISO/TR 14639 is the potential for ICT to assist in the collection, communication, storage, processing, and use of information to support the delivery, planning, and coordination of health services; however, it also recognizes the importance of initial measures that involve paper-based collection and the need for a migration path from manual to semi-automated to fully automated information management systems.

The enterprise-wide business reference architecture described in this part of ISO/TR 14639 represents a starting point for the enterprise viewpoint or business layer of a comprehensive enterprise architecture, which would include other layers or viewpoints, such as the information/data, computational/function, engineering, and technology perspectives. This model would serve, for example, to assist in identifying initiatives and exploring the attributes of the components that would form a national eHealth strategy.

A comprehensive enterprise architecture is typically set up and maintained using a structured process that involves the following:

l) an organized approach to ensuring that investments in ICT technology and information systems meet overall priorities for effective operation and delivery of healthcare services and the information needed for their planning, development, and continuous improvement;

m) identifying and describing the main attributes of the eHealth information services, components, activities, and policies needed to support the operational requirements for health services within a jurisdiction (or organization);

n) development of structured requirements for more detailed planning and investment in health information systems and for the development and dissemination of health information policies.

Where relevant, this part of ISO/TR 14639 takes advantage of and makes reference to the principles, policies, and specifications set out in relevant International Standards and existing architectural frameworks commonly used in the health sector including: ISO 12967, Health Informatics Service Architecture (HISA),[1][2][3] the vision and principles of the World Economic Forum (WEF) Global Health Data Charter[4] as seen in Annex A, and the Health Enterprise Architecture Framework (HEAF).[5] A layered approach to structuring of information architectures and models is proposed in this part of ISO/TR 14639, based on similar approaches such as the General Component Model introduced in

 

Annex B,[6] the WHO Health Metrics Network Framework,[7] TOGAF,[8] and the Zachman framework.[9] In particular, HISA and the HEAF have been developed specifically to assist in the process of defining eHealth architectures for use in health services. See Annex C for more information on HISA. A short list of selected health informatics International Standards upon which the architectural components are based is found in Annex D. See 6.1.4 regarding governance and national ownership of eHealth standards adoption and implementation.

In May 2012, WHO and ITU published a National eHealth Strategy Toolkit[93] that embodies most of the concepts relevant to an Enterprise Architecture, tailored to the creation of a National eHealth Strategy. This resulted in a process that is exhaustive yet streamlined and easier to understand and apply. The Toolkit presents a thorough step-by-step set of methods, checklists, and examples to be used by country or region-level managers when developing an eHealth Strategic Vision, an eHealth Action Plan, and a Monitoring and Evaluation Plan. The WHO-ITU National eHealth Strategy Toolkit and ISO/TR 14639-1 and this part of ISO/TR 14639 form a complementary set of tools for the design and deployment of an eHealth architecture.

The architectural components and their characteristics as described in this part of ISO/TR 14639 are designed to be reviewed and, where appropriate, adopted by countries and subordinate health authorities at a level relevant to their specific needs. In particular:

o) The components and characteristics may be used as model requirements in developing enterprise architectures or as a means of assessing and improving eHealth maturity.

p) Each component is configurable to meet local needs by describing characteristics indicative of a range of capability from the most basic through to the highly advanced.

q) The characteristics of various capacity levels for each component form the basis of the underlying maturity model.

r) Typical starting points for the development of capability are provided for each of the components at the lowest maturity level, together with the basic principles the architecture should adhere to.

s) There is an emphasis on developing appropriately layered, well-structured eHealth architectures with well-defined and preferably standardized interfaces between the various components and layers.

t) There is a particular focus on potential eHealth requirements relevant to low- and middle-income (LMIC) countries.

# Annex D
(informative)

# Candidate standards supporting eHealth Architecture Model and Maturity Models

The candidate standards have been provided in two groups – Candidate Group 1 and Candidate Group 2. This division is based on expert opinion but does not reflect a full consensus agreement. Individuals may see the need to choose standards from either group to meet their specific implementation needs.

Candidate Group 1 are those deemed of high importance and relevance with respect to facilitating the development, design, and implementation of national-level health information system (HIS) initiatives, particularly in LMICs. The list includes standards pertaining to core areas such as data, messaging, architecture, and security.

Candidate Group 2 are those deemed useful and may be of high value relevant to a particular country's national HIS initiative but may not be deemed essential (core) to moving forward with implementation in LMICs.

The majority of the standards listed are ISO standards but other key standards of importance, e.g. HL7, SNOMED CT, are also included.

**Table D.1 — Candidate Standards — Group 1**

| Recommended | | | |
|---|---|---|---|
| **#** | **Standard** | **Reference** | **Available at:** |
| 1 | Business requirements for health summary records — Part 1: Requirements | TR 12773–1 | ISO/TR 12773-1:2009 |
| 2 | Business requirements for health summary records — Part 2: Environmental scan | TR 12773–2 | ISO/TR 12773-2:2009 |
| 3 | Capacity-based eHealth architecture roadmap — Part 1: Overview of national eHealth initiatives | TR 14639–1 | ISO/TR 14639-1:2012 |
| 4 | Classification of purposes for processing personal health information | TS 14265 | ISO/ TS 14265:2011 |
| 5 | Deployment of a clinical data warehouse | TS 29585 | ISO/ TS 29585:2010 |
| 6 | Directory services for healthcare providers, subjects of care and other entities (renamed 2007 - Brisbane) | ISO 21091 | ISO 21091:2013 |
| 7 | EHR communication — Part 1: Reference model | ISO 13606-1 | ISO 13606-1:2009 |
| 8 | EHR communication — Part 2: Archetype interchange specifications | ISO 13606-2 | ISO 13606-2:2008 |
| 9 | EHR communication Part 3 — Archetypes and term list interchange specifications | ISO 13606-3 | ISO 13606-3:2008 |
| 10 | EHR communication — Part 4: Security | ISO 13606-4 | ISO/TS 13606-4:2009 |
| 11 | EHR communication — Part 5: Interface specification | ISO 13606-5 | ISO 13606-5:2010 |
| 12 | EHR definition, scope and context | TR 20514 | ISO/ TR 20514:2005 |
| 13 | EHR system functional model | ISO 10781 | ISO/ HL7 10781:2009 |
| 14 | Functional and structural roles | TS 21298 | ISO/ TS 21298:2008 |

**Table D.1** *(continued)*

| Recommended | | | |
|---|---|---|---|
| 15 | Good principles and practices for a clinical data warehouse | TR 22221 | ISO/ TR 22221:2006 |
| 16 | Guidelines for terminology development organizations | TR 12309 | ISO/ TR 12309:2009 |
| 17 | Harmonized data types for information interchange (name change 2007) | ISO 21090 | ISO 21090:2011 |
| 18 | Health indicators conceptual framework | ISO 21667 | ISO 21667:2010 |
| 19 | Health Informatics — Service architecture — Enterprise viewpoint | ISO 12967-1 | ISO 12967-1:2009 |
| 20 | Health Informatics — Service architecture — Information viewpoint | ISO 12967-2 | ISO 12967-2:2009 |
| 21 | Health Informatics — Service architecture — Computational viewpoint | ISO 12967-3 | ISO 12967-3:2009 |
| 22 | Clinical document architecture (Release 2) | ISO 27932 | ISO/ HL7 27932:2009 |
| 23 | HL7v 2.5 — An application protocol for electronic data exchange in health-care environments | ISO 27931 | ISO/ HL7 27931:2009 |
| 24 | HL7 v3 — Reference information model | ISO 21731 | ISO/ HL7 21731:2006 |
| 25 | Identification of subjects of healthcare | TS 22220 | ISO/ TS 22220:2011 |
| 26 | IHE Integrating the Healthcare Enterprise | | www.ihe.net |
| 27 | Information security management in health using ISO/IEC 27002 | ISO 27799 | ISO 27799:2008 |
| 28 | Interoperability of telehealth systems and networks — Part 1: Introduction and definitions | TR 16056 | ISO/TR 16056-1:2004 |
| 29 | Knowledge management of health information standards | TR 13054 | ISO/ TR 13054:2012 |
| 30 | Logical Observation Identifiers Names and Codes (LOINC) | | http://loinc.org |
| 31 | Personal health records: definition, scope and context | TR 14292 | ISO/ TR 14292:2012 |
| 32 | Privilege management and access control — Part 1: Overview and policy management | TS 22600–1 | ISO/TS 22600-1:2006 |
| 33 | Privilege management and access control — Part 2: Formal models | TS 22600–2 | ISO/TS 22600-2:2006 |
| 34 | Privilege management and access control — Part 3: Implementations | TS 22600–3 | ISO/TS 22600-3:2009 |
| 35 | Pseudonymization | TS 25237 | ISO/ TS 25237:2008 |
| 36 | Requirements for an electronic health record architecture | TS 18308 | ISO 18308:2011 |
| 37 | Secure archiving of electronic health records — Part1: Principles and requirements | TS 21547 | ISO/ TS 21547:2010 |
| 38 | Secure archiving of electronic health records — Part 2: Guidelines | TR 21548 | ISO/ TR 21548:2010 |
| 39 | System of concepts to support continuity of care | ISO 13940 | ISO/IS 13940 |
| 40 | SDMX-HD | | http://www.sdmx-hd.org/ |
| 41 | SNOMED-CT | | http://www.ihtsdo.org/ |
| 42 | WHO ICD-10 | | http://www.who.int/classifications/icd/en/ |

 

**Table D.2 — Candidate Standards — Group 2**

| Optional | | | |
|---|---|---|---|
| # | Standard | Number | Source |
| 1 | Classification of safety risks from health software | TS 25238 | ISO/ TS 25238:2007 |
| 2 | Clinical analyser interfaces to laboratory information systems — Use profiles | ISO 18812 | ISO 18812:2003 |
| 3 | Controlled health terminology — Structure and high-level indicators | TS 17117 | ISO/ TS 17117:2002 |
| 4 | Format of length limited globally unique string identifiers | ISO 18232 | ISO 18232:2006 |
| 5 | Health Cards — General characteristics | ISO 20301 | ISO 20301:2006 |
| 6 | Health cards — Numbering system and registration procedure for issuer identifiers | ISO 20302 | ISO 20302:2006 |
| 7 | Health informatics profiling framework | TR 17119 | ISO/ TR 17119:2005 |
| 8 | Integration of a reference term model for nursing | ISO 18104 | ISO 18104:2003 |
| 9 | Medical waveform format — Part 92001: Encoding rules | TS 11073–92001 | ISO/TS 11073-92001:2007 |
| 10 | National Council for Prescription Drug Programs (NCPDP) Standards | | www.ncpdp.org |
| 11 | Patient healthcard data — Part 1: General structure | ISO 21549-1 | ISO 21549-1:2004 |
| 12 | Patient healthcard data — Part 2: Common objects | ISO 21549-2 | ISO 21549-2:2004 |
| 13 | Patient healthcard data — Part 3: Limited clinical data | ISO 21549-3 | ISO 21549-3:2004 |
| 14 | Patient healthcard data — Part 4: Extended clinical data | ISO 21549-4 | ISO 21549-4:2006 |
| 15 | Patient healthcard data — Part 5: Identification data | ISO 21549-6 | ISO 21549-5:2008 |
| 16 | Patient healthcard data — Part 5: Administrative data | ISO 21549-5 | ISO 21549-6:2008 |
| 17 | Patient healthcard data — Part 7: Medication data | ISO 21549-7 | ISO 21549-7:2007 |
| 18 | Patient healthcard data — Part 8: Links | ISO 21549-8 | ISO 21549-8:2010 |
| 19 | Personal health device communication — Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG) | ISO/ IEEE 11073-10406 | ISO/IEEE 11073-10406:2012 |
| 20 | Public key infrastructure — Part 1: Overview of digital certificate services | TS 17090–1 | ISO 17090-1:2008 |
| 21 | Public Key Infrastructure — Part 2: Certificate profile | TS 17090–2 | ISO 17090-2:2008 |
| 22 | Public key infrastructure — Part 3: Policy management of certification authority | TS 17090–3 | ISO 17090-3:2008 |
| 23 | Vocabulary for terminological systems | ISO 17115 | ISO 17115:2007 |