TECHNICAL REPORT

ISO/TR 28380-1

First edition
2014-02-15

Health informatics — IHE global standards adoption —

Part 1: Process

Informatique de santé — Adoption des normes globales IHE —

Partie 1: Procédé

Reference number
ISO/TR 28380-1:2014(E)

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Published in Switzerland

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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).

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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 28380 consists of the following parts, under the general title *Health informatics — IHE global standards adoption*:

— *Part 1: Process*

— *Part 2: Integration and content profiles*

The following parts are under preparation:

— *Part 3: Deployment*

Introduction

This part of ISO/TR 28380 describes how the Integrating Healthcare Enterprise (IHE[1)]) process specifies and facilitates adoption of profiles of selected standards to support carefully defined healthcare tasks that depend on electronic information exchange. It accelerates the worldwide adoption of standards targeted to achieving the interoperability of healthcare information between software applications within healthcare enterprises and across various care settings.

IHE is an initiative designed to stimulate the integration of electronic information systems that support the delivery of modern healthcare. Its fundamental objective is to facilitate the standards-based exchange of authorized and relevant health information for citizens as consumers of health services and for healthcare professionals in the care of their patients. Integrating these systems and devices both within the healthcare enterprise, across a variety of care settings, and personal health management services will empower patients and health professionals with efficient access to necessary health information.

The information exchange between IT systems, applications, and devices in healthcare is a complex process due to the wide range of medical specialities, the rapid evolution of knowledge, use of technology in the delivery service, and the broad range of stakeholders that need to cooperate.

Stakeholders include legislative institutions, governmental entities, insurers, vendors, employers, and care providers organized in a variety of entities ranging from the small physician practice to large hospital networks. Interoperability standards have proven quite complex to develop, driven by a wide range of standard development organizations each effective at engaging a subset of these many stakeholders.

In such a complex environment, standards require flexibility to account for a variety of environments within which they can be used. Removing this flexibility would only result in further fragmentation. An agreed upon process to rationalize the implementation of combined sets of these standards is required in order to address some of the most common cases of information exchange in a defined manner that can be tested.

This part of ISO/TR 28380 summarizes the successful work done by the IHE initiative, in which several of the ISO/TC 215 member countries are engaged. This part of ISO/TR 28380 is intended to provide all ISO members with an understanding of the valuable experience gained, as well as access to the results achieved. The IHE is both a process and a forum that rationalizes at a multi-national level the adoption of interoperability standards that can be profiled and combined to meet healthcare needs.

IHE draws on established healthcare-specific standards such as those developed by ISO/TC 215, as well as general purpose IT standards, to define technical frameworks for the implementation of information exchange to further address specific healthcare improvement or clinical goals. It includes a rigorous testing process for the implementation of these technical frameworks. It also organizes educational sessions and exhibits at major meetings of healthcare professionals to demonstrate the benefits of these frameworks and encourages their adoption by the healthcare industry, the technology industry, and other stakeholders worldwide. These elements are further discussed in this part of ISO/TR 28380.

By facilitating the adoption of internationally recognized standards (e.g. ISO, HL7, DICOM, IEEE, IETF, and OASIS) in healthcare, IHE is doing what “Wi-Fi” has done in the field of wireless networking to the adoption and deployment of the IEEE 802.11 standard. The IHE process produces detailed implementation guides called “Integration Profiles or Content Profiles”.

Each profile references foundation standards from Standards Development Organizations (SDOs) and constrains them as allowed by the parent SDO.

IHE makes configuration choices where necessary in these standards to ensure that IT systems or devices commonly used in healthcare can easily exchange information in the context of the specific but broadly required use case. When clarifications or gaps are identified in the standards, IHE refers

1) Information on IHE may be found at www.ihe.net.

recommendations to the relevant standards bodies. To this end, IHE maintains liaison relationships with all major SDOs involved in healthcare (e.g. ISO, HL7, CEN, DICOM and IEEE).

The intended audience for this part of ISO/TR 28380 includes, but is not limited to, the following:

— IT departments of healthcare institutions;

— technical and marketing staff in the healthcare information technology industry;

— experts involved in standards development;

— those interested in integrating healthcare information systems and workflows;

— leadership in national and regional healthcare information exchange projects.

Health informatics — IHE global standards adoption —

Part 1: Process

1 Scope

This part of ISO/TR 28380 describes how the Integrating the Healthcare Enterprise (IHE) process specifies and facilitates profiles of selected standards to support carefully defined healthcare tasks that depend on electronic information exchange. It accelerates the worldwide adoption of standards targeted at achieving interoperability between software applications within healthcare enterprises and across healthcare settings. The Integration and Content Profiles are specified in ISO 28380-2.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
actor
functional component of a system that exchanges transactions with other actors as defined in an IHE Integration Profile

2.2
Content Profile
coordinated set of standards-based information content exchanged between the functional components of communicating healthcare IT systems and devices

Note 1 to entry: It also specifies a specific element of content (e.g. a document) that can be conveyed through the transactions of one or more associated Integration Profile(s).

2.3
Connectathon
testing event at which developers have registered their system implementations for supervised interoperability testing with other systems implementations

Note 1 to entry: Each participating system is tested for each registered combination of an IHE Actor and IHE Integration or Content Profile.

2.4
deployment-production process
part of the IHE process that deploys into production healthcare delivery systems that effectively support end users with standards-based interoperability as specified by IHE

Note 1 to entry: Although the IHE process is not directly responsible to conduct these deployment projects in production, it expects that such projects will continuously provide feedback to the development process.

2.5
deployment-validation process
part of the IHE process that builds upon IHE Profile specifications produced by the development process

Note 1 to entry: The process starts with the testing of working implementations of these profiles, demonstrates successful interoperability between independent implementations, and concludes with the means for developers of IT products to state their compliance to one or more profiles.

2.6
development process
part of the IHE process that identifies and prioritizes use cases, selects interoperability standards, defines the necessary constraints and documents these specifications in the form of either an Integration Profile or a Content Profile

2.7
Domain
field of clinical or healthcare technology-related activities

2.8
draft supplement for public comment
specification candidate for addition to an IHE Domain Technical Framework (e.g. a new profile) that is issued for comment by any interested party

2.9
Integration Profile
IHE Integration Profile specifies the information exchanges to support a specific business process

Note 1 to entry: It is a coordinated set of interactions exchanged between the functional components of communicating healthcare IT systems and devices. These functional components are called IHE Actors. An IHE Integration Profile specifies their interactions in terms of a set of coordinated, standards-based transactions.

2.10
Technical Framework
collection of profile specifications related to an IHE Domain and its specific clinical or technological focus

Note 1 to entry: Profiles within a Technical Framework and across Technical Frameworks can be combined.

2.11
transaction
specification for a set of messages exchanged between pairs of actors in support of an Integration Profile

2.12
Trial Implementation Supplement
specification candidate for addition to an IHE Domain Technical Framework (e.g. a new profile) that is issued for early implementation by any interested party

Note 1 to entry: The authoring Technical Committee expects developers' feedback.

2.13
use case
textual and graphical depiction of the actors and operations that address information exchange in the context of a set of specific tasks for a workflow performed by different systems or devices

3 Abbreviations

ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
CDA	Clinical Document Architecture
CDISC	Clinical Data Interchange Standards Consortium
CEN	European Committee for Standardization
DICOM	Digital and Imaging Communications in Medicine
EHR	Electronic Health Record
HIS	Hospital Information System
HL7	Health Level Seven
IETF	Internet Engineering Task Force
IEEE	Institute of Electrical and Electronics Engineers
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standards Development Organisation
LOINC	Logical Observation Identifiers Names and Codes
OASIS	Organization for the Advancement of Structured Information Standards
PDQ	Patient Demographics Query
PIX	Patient Identifier Cross-Referencing
RIS	Radiology Information System
SDO	Standard Development Organization
SNOMED	Systematized NOmenclature of MEDicine
XDS	Cross-Enterprise Document Sharing
W3C	World Wide Web Consortium

4 Global standards adoption process overview

4.1 General

The IHE standards adoption process is entirely driven by the definition of requirements for interoperability, often called “use cases”. These standards are a means of addressing these interoperability problems. Therefore this section provides:

— an overview of the main steps of the IHE process

— a definition of the level of requirements at which this process operates, and

— the involvement of stakeholders and the overall structure in which the process is performed.

4.2 Development and deployment process

The IHE process comprises a development process and a deployment process as depicted in Figure 1. The development feeds the deployment-validation process, which in turn enables the deployment-production process resulting in implementation projects with successful interoperability. As additional requirements are identified during implementations, the IHE process is intended to repeat itself by expanding the information exchange capabilities year after year.

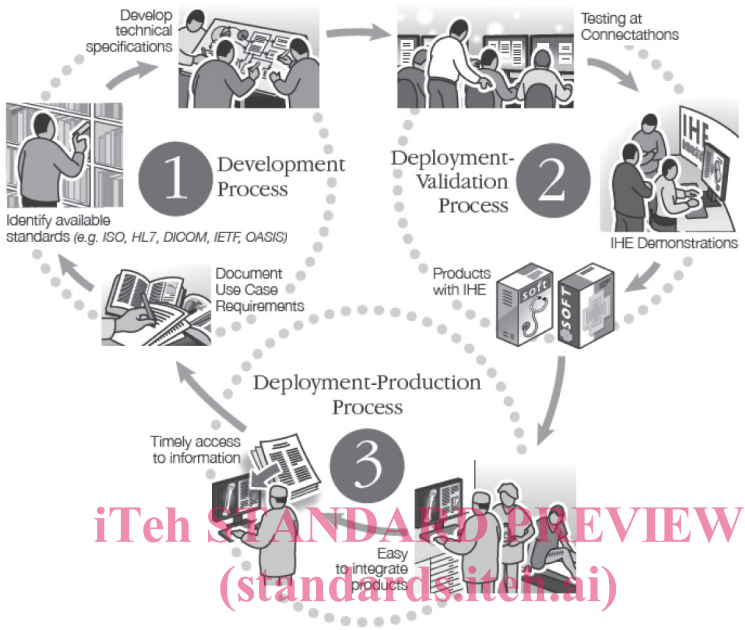

Figure 1 — IHE development and deployment process

The development process starts with a set of documented use cases; it proceeds to the selection of relevant standards that support the use case and documents in a structured manner the subset or "profile" of these base standards with a significant reduction of options. These profiles are then published in the corresponding IHE Technical Framework for the domain. As a result, the implementers of an IHE profile are ensured to achieve the intended level of interoperability within the context of the corresponding use case by receiving the necessary detailed implementation guidance for the selected standards.

The deployment process builds upon profile specifications produced by the development process. It starts with the validation process which includes the testing of working implementations of these profiles, demonstrates successful interoperability between independent implementations at various exhibitions, and concludes with the means for developers of IT products to state their compliance to one of more profiles.

The deployment into production of healthcare delivery systems leverages interoperable health IT products by integrating them in care management or delivery systems. This effective support of end users is where the benefits of standards-based interoperability are realized. Although the IHE process is not directly responsible for conducting these deployment projects in production, it expects that such projects will continuously provide feedback to the development process. It does this by supplying additional use case requirements in order to expand the richness of interoperability and by issuing Change Proposals to the profile maintenance process when implementers discover interoperability issues.

The profile development process is distinguished from the profile deployment-validation process for several reasons:

— The development process is executed at the global level in order to produce internationally agreed upon Integration and Content Profiles

— The deployment-validation process is carried out at the level of specific countries or a group of countries, which reflects the different mix of implementers and is close to the health organizations that deploy the technology and need to achieve interoperability.

— Some national extensions to the globally agreed upon profiles are often necessary and are specified by the deployment-validation process generally at the national level and are documented into a specific part of the Technical Frameworks.

— It is a good engineering quality approach to keep some balance of power between the two parts of the process, each challenging the other to improve the quality of its outcome.

4.3 Levels of requirements

One significant challenge in standards adoption is to offer an approach that balances the broad and unbounded need for interoperability and the necessity to solve specific but common interoperability problems involving different health IT systems or devices.

The definition of interoperability requirements can be performed at different level of granularity. In order to clarify the level at which the IHE Global Standards Adoption Process operates, four levels of requirements initially proposed by the United States EHR Vendor Association in its Interoperability Roadmap provide an effective breakdown:

a) **Business Use Case Level** — This level corresponds to the business view of IT systems such as "chronic disease management system" or "patient empowerment with a medication history system". There are many ways of identifying and structuring use cases at the Business Level Use Case, which contributes to the challenge of accepting a certain fuzziness and flexibility. Business Level Use Cases are most successful when they select a small and therefore achievable scope for implementing requirements, each providing value while remaining achievable. This is increasingly occurring in a number of regional and national projects around the world. However, as the number of use cases providing incremental interoperability requirements increases, it becomes apparent that they overlap, each potentially reusing a subset of an earlier one (e.g. in our example below, "chronic disease management" would have significant overlap with a "patient empowerment with a medication history" use case. This needs to be accepted, and factoring will happen at the lower requirements levels.

b) **Interoperability Service Level** — An interoperability service defines a number of related means and constraints to exchange specific types of health information for the purpose of communicating this information from one or more systems to another or accessing it in remote systems. One defines at this level core interoperability services that are most likely to be needed to support a broad range of business level use cases. This is a use case driven approach at an intermediate level, which facilitates the support of business requirements with specific purpose, data, and exchange requirements. The range of services is large but can be more easily organized and bounded than at the business use case level. An example of this further refinement is in the terms used to describe the services themselves: "electronic drug prescribing", "sharing of patient's medical summaries", and "access to a patient's current immunization list".

c) **Integration and Content Profile Level** — This level is more granular than the interoperability service level in order to provide maximum flexibility in terms of implementation architectures. This architecture independence is achieved by combining actors from multiple Integration Profiles. Integration Profiles are common interoperability building blocks, easily implemented in various software architectures [e.g. can be mapped to components in a service-oriented architecture (SOA)] that can be effectively factored in order to maximize reuse of specification and implementation methods, as well as allowing for evolutionary growth. Standards generally operate at a domain-focused level in that multiple standards are generally needed to define an Integration Profile. The Integration and Content Profile level is the level at which it is most practical to perform interoperability conformance testing. It is the level at which IHE manages its requirements.

d) **Base Standard Level** — Base standards are in some cases healthcare specific, and in other cases used across a wide range of industries to achieve fundamental IT communication or security management. Base standards are foundations that enable the creation of elementary services,

