TECHNICAL REPORT

ISO/TR 28380-2

First edition
2014-02-15

Health informatics — IHE global standards adoption —

Part 2: Integration and content profiles

Informatique de santé — Adoption des normes globales IHE -- — Partie 2: Intégration et profils de contenu

Reference number
ISO/TR 28380-2:2014(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).

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 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 the most recent Integrating the Healthcare Enterprise (IHE) Profiles developed by IHE. IHE specifies and facilitates adoption of profiles of selected standards to support carefully defined healthcare-related tasks that depend on information exchange. Use of IHE processes and of the resulting profiles accelerates the worldwide adoption of standards targeted to achieving the interoperability of health information between software applications within 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/TC215 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 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 2:
Integration and content profiles

1 Scope

This part of ISO/TR 28380 describes the most recent Integrating the Healthcare Enterprise (IHE) Profiles developed by IHE. These profiles of selected standards support carefully defined healthcare-related tasks that depend on information exchange. It accelerates the worldwide adoption of standards targeted to achieving the interoperability of health information between software applications within enterprises and across various care settings. Each available Integration or Content Profile is described with reference to the specification provided.

ISO/TR 28380-1 is a companion to this part of ISO/TR 28380. The reader is encouraged to be familiar with the process followed by IHE in developing the Integration and Content Profiles described in this part of ISO/TR 28380.

2 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/TR 28380-1 and the following 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 Symbols and abbreviated terms

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
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 Overview of IHE Profiles

A Profile identifies a subset of the functional components of communicating IT systems within a real-world healthcare information system environment. These functional components are called IHE Actors. An IHE Integration Profile specifies their interactions in terms of a set of coordinated, standards-based transactions. An IHE Content Profile specifies a specific element of content (e.g. a clinical document) that can be conveyed through the transactions of one or more associated Integration Profile(s).

In the following sections, each IHE Domain is introduced, its scope is defined, and a reference to the most current list of Profiles is provided. Only profiles having reached the Final Text or Trial Implementation status are listed. A definition of the approval of these statuses is provided in ISO/TR 28380.

A broad range of Profiles is currently available. These Profiles cover the following:

— Integration Profiles and Content Profiles. Each Profile is identified by an abbreviation or acronym of a few letters, unique within IHE.

— Interoperability within the enterprise and across enterprises or organizations.

— Profiles specific to speciality workflow or information content, as well as profiles more generic that serve a range of health environment and care delivery.

— The need for interoperability in the context of a well-defined use case (generally documented in Volume 1 of a Domain Technical Framework).

— The detailed profile specifications combine a set of referenced base standards. They address the requirements that ensure interoperable transactions and/or content that can be exchanged among the actors taking part in a series of interoperability scenarios supporting the use case.

— The high-level technical specification is documented in Volume 1 of the Domain Technical Framework, whereas the detail specifications for the transactions and content is specified in other volumes of the Domain Technical Framework.

The completed and approved Technical Frameworks and Supplements can be found at: http://www.ihe.net/Technical_Frameworks/.

Figure 1 depicts the overall structure of the IHE Profiles. These specifications are published as Technical Frameworks, one per IHE Domain. However, Trial Implementation Supplements are published independently until sufficient implementation feedback has been gathered and they are approved as Final Text, at which point they are merged in subsequent yearly revision of the Domain Technical Framework (see ISO/TR 28380).

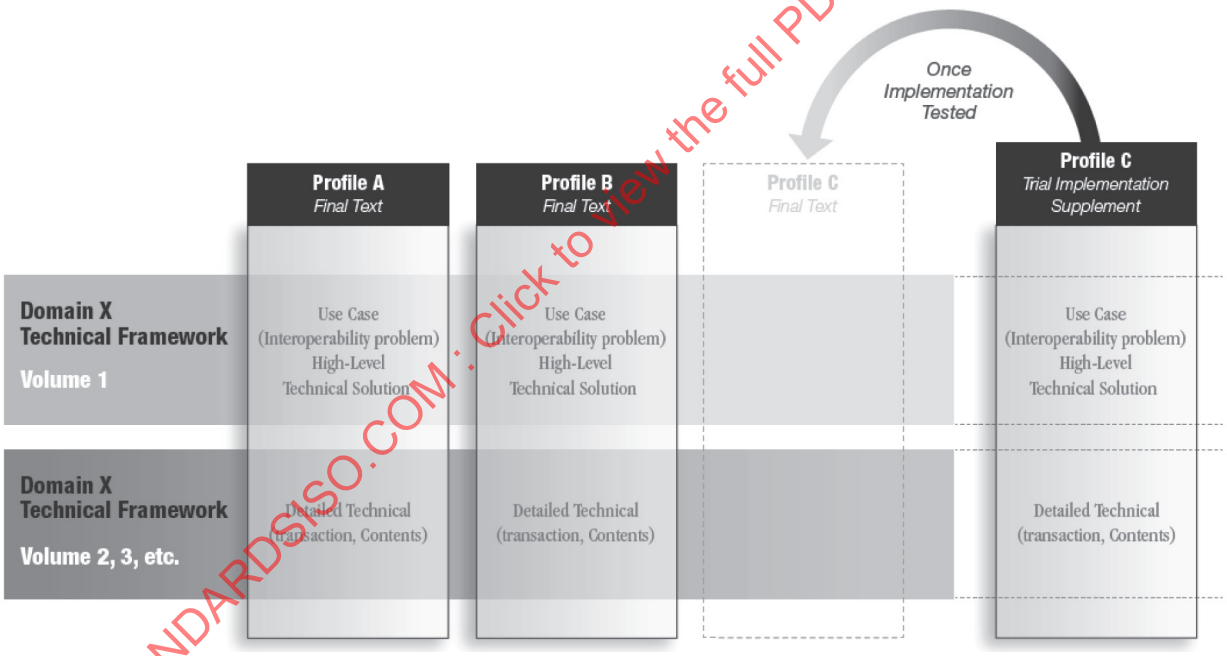

Figure 1 — Organization of the IHE Technical Frameworks and Supplements

Existing IHE Domains are described within the following sections of this part of ISO/TR 28380. These will be expanded as existing and new Domains complete Profile specifications.

5 Anatomic Pathology (AP) Domain

5.1 AP Domain Scope

The aim of the Anatomic Pathology Domain activities is to anatomic support pathology laboratories, their information, automation, imaging systems, and equipment. The scope of the anatomic pathology

includes surgical pathology, biopsies pathology, cytopathology, autopsies, and related techniques (such as immunohistochemistry and molecular pathology).

Information systems in anatomic pathology laboratories gather medical data (text, images, etc.) throughout specimen management from specimen reception to report editing. The diagnostic process in anatomical pathology (Figure 1) differs from that in the clinical laboratory since it relies on image interpretation. It also differs from that in radiology since it is specimen-driven, and when digital imaging is performed, many types of imaging equipments (gross imaging, microscopic still imaging, whole slide imaging, multispectral imaging, etc.) can be involved for a single examination. Moreover, images of the same study can be related to different specimen (parts and/or slides) from one or even different patients (e.g Tissue Micro Array). Finally, slides are always available to acquire more images if needed. In radiology, the diagnostic process is patient-driven, an examination (study) usually involves a single image acquisition modality, and all images of the study are related to one and only one patient

5.2 AP Infrastructure and Content Profiles

The Integration and Content Profiles specifications can be found at: http://www.ihe.net/Technical_Frameworks/#pathology.

A summary description of each profile along with its status is available at: http://wiki.ihe.net/index.php?title=Profiles#IHE_Anatomic_Pathology_Profiles.

Each profile is described in Reference [2] with a scope statement, its benefits, high-level technical details, the type of systems affected, and the precise references to the specifications of these profiles in the IHE IT Infrastructure Technical Frameworks.[3]

6 Cardiology (CARD) Domain

6.1 CARD Domain Scope

The Cardiology Domain addresses information sharing, workflow, and patient care in cardiology, including electrophysiology and nuclear medicine.

6.2 CARD Domain Integration and Content Profiles

The Integration and Content Profiles specifications can be found at: http://www.ihe.net/Technical_Frameworks/#cardiology.

A summary description of each profile along with its status is available at: http://wiki.ihe.net/index.php?title=Profiles#_IHE_Cardiology_Profiles.

Each profile is described in Reference [4] with a scope statement, its benefits, high-level technical details, the type of systems affected, and the precise references to the specifications of these profiles in the IHE Cardiology Technical Frameworks.[5]

7 Eye Care Domain

7.1 Eye Care Domain Scope

The Eye Care Domain addresses the interoperability needed for IHE conformant instruments from different vendors to work together, sending images and measurements to any IHE conformant electronic medical record or patient management software. IHE Profiles address the problems of connectivity and communication to have all the patient data in one place: patient record information from the electronic health record, billing information from the practice management system, images from a fundus camera, optical coherence tomography, refractive instruments, etc.

7.2 Eye Care Domain Integration and Content Profiles

The Integration and Content Profiles specifications can be found at: http://www.ihe.net/Technical_Frameworks/#eye.

A summary description of each profile along with its status is available at: http://wiki.ihe.net/index.php?title=Profiles#_IHE_Eyecare_Profiles.

Each profile is described in Reference [6] with a scope statement, its benefits, high-level technical details, the type of systems affected, and the precise references to the specifications of these profiles in the IHE Eye Care Technical Frameworks.[7]

8 Information Technology Infrastructure (ITI) Domain

8.1 ITI Domain Scope

The IT Infrastructure Domain supplies infrastructure interoperability for sharing healthcare information. An infrastructure-related Profile represents a common IT function that is used as an interoperability building block for a variety of use cases (a necessary ingredient but rarely visible to the end user). These profiles can be embedded in an application but are often deployed as a shared resource within a health enterprise or regional/national health IT infrastructure.

8.2 IT Infrastructure Integration and Content Profiles

The Integration and Content Profiles specifications can be found at: http://www.ihe.net/Technical_Frameworks/#IT.

A summary description of each profile along with its status is available at: http://wiki.ihe.net/index.php?title=Profiles#IHE_IT_Infrastructure_Profiles.

Each profile is described in Reference [8] with a scope statement, its benefits, high-level technical details, the type of systems affected, and the precise references to the specifications of these profiles in the IHE IT Infrastructure Technical Frameworks.[9][10][11][12]

9 Laboratory (LAB) Domain

9.1 LAB Domain Scope

The Laboratory Domain addresses information sharing and workflow related to *in vitro* diagnostic testing in clinical laboratories, as well as *in vivo* at the point of care.

IHE Laboratory Domain addresses information sharing and workflow related to *in vitro* diagnostic testing in clinical laboratories, as well as point of care testing. The IHE Laboratory Domain was established in 2003 and manages the Laboratory Profiles and the Laboratory Technical Framework.

9.2 LAB Integration and Content Profiles

The Integration and Content Profiles specifications can be found at: http://ihe.net/Technical_Framework/index.cfm#laboratory.

A summary description of each profile along with its status is available at: http://wiki.ihe.net/index.php?title=Profiles#IHE_Laboratory_Profiles.

Each profile is described in Reference [13] with a scope statement, its benefits, high-level technical details, the type of systems affected, and the precise references to the specifications of these profiles in the IHE Laboratory Technical Frameworks.[14][15][16][17]

10 Patient Care Coordination (PCC) Domain

10.1 PCC Domain Scope

The Patient Care Coordination Domain was established in July 2005 to deal with integration issues that cross providers, patient problems, or time. It deals with general clinical care aspects such as document exchange, order processing, and coordination with other speciality domains. PCC also addresses workflows that are common to multiple speciality areas and the integration needs of speciality areas that do not have a separate domain within IHE.

10.2 PCC Integration and Content Profiles

The Integration and Content Profiles specifications can be found at: http://www.ihe.net/Technical_Frameworks/#pcc.

The PCC Integration and Content Profiles are listed at: http://wiki.ihe.net/index.php?title=Profiles#IHE_Patient_Care_Coordination_Profiles.

Each profile is described in Reference [18] with a scope statement, its benefits, high-level technical details, the type of systems affected, and the precise references to the specifications of these profiles in the IHE Patient Care Coordination Technical Frameworks.[19]

11 Patient Care Device (PCD) Domain

11.1 PCD Scope

The Patient Care Device Domain is concerned with use cases in which at least one actor is a regulated patient-centric point-of-care medical device that communicates with at least one other actor such as a medical device or information system.

The PCD domain coordinates with and supports other domains, such as Radiology (medical imaging), Laboratory, and Cardiology to ensure consistency in use cases involving regulated medical devices as they occur throughout the Enterprise.

11.2 PCD Integration and Content Profiles

The Integration and Content Profiles specifications can be found at: http://ihe.net/Technical_Framework/index.cfm#pcd.

The PCD Integration and Content Profiles are listed at: http://wiki.ihe.net/index.php?title=Profiles#IHE_Patient_Care_Device_Profiles.

Each profile is described in Reference [20] with a scope statement, its benefits, high-level technical details, the type of systems affected, and the precise references to the specifications of these profiles in the IHE Patient Care Devices Technical Frameworks.[21][22]

12 Pharmacy (PHARM) Domain

12.1 PHARM Scope

The Pharmacy Domain addresses information sharing, workflow, and patient care in both community and hospital pharmacies.

12.2 PHARM Integration and Content Profiles

The Integration and Content Profiles specifications can be found at: http://www.ihe.net/Technical_Frameworks/#pharmacy.

The PHARM Integration and Content Profiles are listed at: http://wiki.ihe.net/index.php?title=Profiles#IHE_Pharmacy_Profiles.

Each profile is described in Reference [31].

13 Quality, Research, and Public Health (QRPH) Domain

13.1 QRPH Domain Scope

The Quality, Research, and Public Health Domain address the infrastructure and content necessary to:

- share information relevant to quality improvement,
- improve the liaison between the primary care system and clinical research, and
- provide population base health surveillance.

The three distinct components of the QRPH Domain are all reliant on the secondary use of data gathered in clinical care.

The work of QRPH enables the stakeholders to focus on the workflow cycle of queries for data and selection of population cohorts from within the clinical record. In addition, QRPH incorporates the output from the query specification within the clinical system workflow to enable clinical decision support and defines profiles for adverse event reporting, especially with reference to medication-related adverse outcomes.

13.2 QRPH Integration and Content profiles

The Integration and Content Profiles specifications can be found at: http://www.ihe.net/Technical_Frameworks/#quality.

The QRPH Integration and Content Profiles are listed at: http://wiki.ihe.net/index.php?title=Quality,_Research_and_Public_Health.

Each profile is described in Reference [23] with a scope statement, its benefits, high-level technical details, the type of systems affected, and the precise references to the specifications of these profiles in the IHE Quality Research and Public Health Technical Frameworks.[24]

14 Radiation Oncology (RO) Domain

14.1 RO Domain Scope

The Radiation Oncology Domain addresses information sharing, workflow, and patient care in Radiation Oncology.

14.2 RO Domain Integration and Content Profiles

The Integration and Content Profiles specifications can be found at: http://www.ihe.net/Technical_Frameworks/#rad_onc.

The RO Integration and Content Profiles are listed at: http://wiki.ihe.net/index.php?title=Radiation_Oncology.

Each profile is described in Reference [25] with a scope statement, its benefits, high-level technical details, the type of systems affected, and the precise references to the specifications of these profiles in the IHE Radiation Oncology Technical Frameworks.[26]

