PD ISO/TR 28380-1:2014



BSI Standards Publication

Health informatics — IHE global standards adoption

Part 1: Process

bsi.

...making excellence a habit.™

National foreword

This Published Document is the UK implementation of ISO/TR 28380-1:2014.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2014. Published by BSI Standards Limited 2014

ISBN 978 0 580 81873 8

ICS 35.240.80

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 28 February 2014.

Amendments issued since publication

Date	Text affected

PD ISO/TR 28380-1:2014

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)

© ISO 2014



COPYRIGHT PROTECTED DOCUMENT

© ISO 2014

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword ..... **iv**

Introduction ..... **v**

1 Scope **1**

2 Terms and definitions **1**

3 Abbreviations **3**

4 Global standards adoption process overview **3**
4.1 General 3
4.2 Development and deployment process 4
4.3 Levels of requirements 5
4.4 Stakeholder participation and overall structure 7

5 Development process **8**

6 Deployment-validation process **10**

7 Principle and policies **12**

8 Overview of the Technical Framework **12**
8.1 Relationship to real-world architectures 12
8.2 Structure of the Technical Frameworks 13
8.3 Relationship to base standards 13
8.4 IHE Technical Framework development and maintenance process 14
8.5 Implementation of the Technical Framework 14

Annex A (informative) **IHE Integration Statement template** **15**

Annex B (informative) **IHE sponsoring organizations** **17**

© ISO 2014 – All rights reserved

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*

© ISO 2014 – All rights reserved

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.

© ISO 2014 – All rights reserved

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.

© ISO 2014 – All rights reserved

TECHNICAL REPORT **ISO/TR 28380-1:2014(E)**

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.

© ISO 2014 – All rights reserved