PD ISO/TR 28380-3:2014

BSI Standards Publication

Health informatics — IHE global standards adoption

Part 3: Deployment

bsi.

...making excellence a habit.™

Document Sharing Hub

Full document details: PD ISO/TR 28380-3:2014

National foreword

This Published Document is the UK implementation of ISO/TR 28380-3:2014.

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 2015. Published by BSI Standards Limited 2015

ISBN 978 0 580 83288 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 31 January 2015.

Amendments issued since publication

Date	Text affected

Documents
Document Sharing Hub

Full document details: PD ISO/TR 28380-3:2014

TECHNICAL REPORT

ISO/TR 28380-3

First edition
2014-12-15

Health informatics — IHE global standards adoption —

Part 3: Deployment

Informatique de santé — Adoption des normes globales IHE —

Partie 3: Déploiement

Reference number
ISO/TR 28380-3:2014(E)

Documents
Document Sharing Hub
© ISO 2014

Full document details: PD ISO/TR 28380-3:2014

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

© ISO 2014 – All rights reserved

Documents
Document Sharing Hub

Full document details: PD ISO/TR 28380-3:2014

Contents

Page

Foreword ..... **iv**

Introduction ..... **v**

1 Scope **1**

2 Normative References **1**

3 Terms and definitions **1**

4 Abbreviations **4**

5 General approach to analyse the interoperability requirements in support of an interoperability use case **4**
- 5.1 Concept of an Interoperability Use Case 4
- 5.2 Decomposition of an Interoperability Use Case into Technical Use Cases 5

6 Project Interoperability Specification **7**
- 6.1 Scope of Interoperability 7
- 6.2 Selection and combination of the appropriate Profiles 7
- 6.3 Establishing a Jurisdictional Interoperability Framework 10
- 6.4 Examples to illustrate the application of the above methodology to specific Interoperability Use Cases 10

7 Deployment benefits of profile-based interoperability specifications **11**
- 7.1 Alternatives and Deployment benefits 11

8 Approach to testing for interoperability **14**
- 8.1 Four phases of Testing for Interoperability 14
- 8.2 Responsibilities and Entrance/Exit Criteria 15
- 8.3 Test Management Processes and Certification 16

Bibliography **18**

© ISO 2014 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TR 28380-3:2014

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. 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. 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*, WG 2, *Systems and Device Interoperability*.

ISO 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*

— *Part 3: Deployment*

Part 1 and 2 have been approved by the TC 215 and have been published.

This technical report will complement and support the general requirements for the adoption of global standards towards increasing the efficiency of deploying interoperability in health.

© ISO 2014 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TR 28380-3:2014

Introduction

The purpose of this Technical Report is to structure and facilitate adoption and deployment of health interoperability standards in a broad range of eHealth projects, including regional and national programs.

A solid standards adoption process is a critical element that complements standards development and ensures that timely and effective implementation of standards is realized for health information exchange.

This technical report is intended to help and guide eHealth projects in the way to specify their use of interoperability standards in health information exchange by reusing IHE Profiles to support specific business use cases chosen by the project.

This technical report is the third part of a multi-part Technical Report on IHE Global Standards Adoption. It builds upon:

— TR 28380-1, *Health Informatics — IHE Global Standards Adoption — Part 1: Process*

— TR 28380-2, *Health Informatics — IHE Global Standards Adoption — Part 2: Integration and Content Profiles*.

This Technical Report uses the term Profile as defined by TR 28380. A Profile is intended to guide implementers in a detailed manner and to ensure that implementations may be tested for compliance. For each use case, a Profile selects from a number of interoperability standards specific to healthcare (ISO TC215, HL7, DICOM, CEN, etc.) as well as general IT standards from ISO, or Internet related standards bodies (e.g. W3C, IETF, OASIS).

Such Profiles are intended to guide implementers in a detailed manner and ensure that implementation may be tested for compliance and interoperability among implementations of like profiles achieved.

For each standard it profiles, i.e. defines a specific and proper subset of each selected standard; IHE leverages implementation guides produced by the source standard development organizations (SDO), if they exist, and specifies the integration of these standards. This coordinated process has been developed by Integrating the Healthcare Enterprise (IHE) and has been in effective use since 1998 to address a rapidly increasing number of healthcare interoperability problems for citizens as consumers of health services and for health professionals in the care of their patients.

Integrating the information systems and devices within healthcare institutions, across a variety of care settings, and personal health management services will empower patients and healthcare professionals with a more efficient access to accurate information. IHE has a formal Type-A Liaison relationship with ISO TC215. It is sponsored by a large number of healthcare user organizations world-wide and has engaged over 300 vendors in healthcare IT (www.ihe.net). 16 countries are directly engaged in IHE at the time of writing this Technical Report.

The information exchange among IT systems, applications and devices in healthcare is a complex challenge. In particular, it needs to account for the wide range of medical specialities, for the rapid evolution of knowledge and for the use of technology in the delivery services, among the broad range of stakeholders that need to cooperate ranging from democratic institutions, governmental entities, insurers and employers, to care providers organized in a variety of entities of all sizes (single doctors' practice to large hospital networks).

Interoperability standards have proven quite complex to develop and are driven by a wide range of standard development organizations (SDO) each effective at engaging a subset of these many stakeholders. In such a complex environment, standards have to incorporate much flexibility and optionality to account for a variety of environments in which they could be used. Removing the need for flexibility and optionality in these standards would only result in further fragmentation. An agreed upon process to rationalize and constrain 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 definite manner that can be tested.

© ISO 2014 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TR 28380-3:2014

This Technical Report is based on the valuable work done by the IHE initiatives in which several of the ISO/TC 215 member countries are engaged. This Technical Report is intended to provide all ISO members with an understanding of the practical experience gained as well as access to the results achieved.

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 and HL7, as well as general purpose IT standards, in order to define a technical framework for the implementation of information exchange to address specific health improvement or clinical goals. It includes a rigorous interoperability testing process for the implementation of this technical framework.

IHE also organizes educational sessions and exhibits at major meetings of health professionals to demonstrate the benefits of this framework and encourage its adoption by the healthcare industry, the technology industry, and other stakeholders worldwide. These elements are further discussed in Part 1 of this technical report.

The intended audience of this ISO Technical Report is:

— IT departments of healthcare institutions;

— Technical and marketing staff in the healthcare technology industry;

— Experts involved in standards development;

— Health Professionals interested in integrating healthcare information systems and workflows;

— National and regional healthcare information exchange projects leadership.

© ISO 2014 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TR 28380-3:2014

Health informatics — IHE global standards adoption —

Part 3: Deployment

1 Scope

This part of this Technical Report describes the general methodology to analyse interoperability requirements in support of a use case to produce the selection and combination of the relevant Profiles specified in TR 28380-2. It is illustrated by applying this methodology to a small number of examples. It also identifies and proposes a high-level quantification of the benefits gained by the use of a profile based specification of interoperability. Finally this technical report will discuss the approach to effectively test interoperability from the specific of the standards and profiles, up to the level of business use cases.

ISO/TR 28380-1 is a companion to this part of this Technical Report. ISO/TR 28380-1 describes how the IHE process identifies technical use cases for interoperability and specifies profiles of selected standards to support these carefully defined healthcare tasks that depend on electronic information exchange. The reader is encouraged to be familiar with this process followed by IHE in developing its Profiles.

A wide portfolio of such profiles for Integration, Security, and Semantic Content is now available across various domains of healthcare clinical specialities and technologies, as described in ISO/TR 28380-2.

The reader of this part of this Technical Report is encouraged to be familiar with this process followed by IHE in developing its Profiles as it builds upon ISO/TR 28380-1 and ISO/TR 28380-2 by addressing a number of key issues to support eHealth projects across all sectors of health to more effectively deploy standards-based interoperability between software applications and devices, including within healthcare organizations and across healthcare and home settings.

2 Normative References

ISO/TR 28380-1, *Health informatics — IHE global standards adoption — Part 1: Process*

ISO/TR 28380-2, *Health informatics — IHE global standards adoption — Part 2: Integration and content profiles*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purposes of this document, the terms and definitions of ISO/TR 28380-1 and the following apply.

3.1
actors
actors are information systems or components of information systems that produce, transmit or act on health information exchanged to support operational activities

3.2
eHealth
refers to the combined use of electronic communication and information technology in the health sector to enable better health and healthcare

[SOURCE: WHO]

© ISO 2014 – All rights reserved

Documents
Document Sharing Hub

Full document details: PD ISO/TR 28380-3:2014