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BSI Standards Publication

Health informatics — IHE global standards adoption

Part 3: Deployment

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National foreword

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

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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. 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

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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.

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.

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.

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]

