TECHNICAL REPORT

# ISO/TR 28380-3

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# Health informatics — IHE global standards adoption —

## Part 3: Deployment

*Informatique de santé — Adoption des normes globales IHE —*

*Partie 3: Déploiement*

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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

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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]

**3.3.1**
**electronic health record**
**EHR**
information relevant to the wellness, health and healthcare of an individual, in computer-processable form and represented according to a standardized information model

[SOURCE: ISO 18308:2011, 3.20]

**3.3.2**
**electronic health record**
**EHR**
longitudinal electronic record of an individual that contains or virtually interlinks to data in multiple EMRs and EPRs, which is to be shared and/or interoperable across healthcare settings and is patient-centric

Note 1 to entry: Adapted from the European 2011 eHealth Strategies Final Report, January 2011.

**3.4**
**health**
state of complete physical, mental and social well-being and not merely the absence of disease or infirmity

[SOURCE: WHO 1948]

**3.5**
**health information**
information about a person relevant to his or her health

[SOURCE: ISO 18308:2011, 3.28]

**3.6**
**healthcare**
activities, services, or supplies related to the health of an individual

[SOURCE: EN 13940-1:2007]

**3.7**
**healthcare activity**
activity performed for a subject of care with the intention of directly or indirectly improving or maintaining the health of that subject of care

[SOURCE: EN 13940-1:2007]

**3.8**
**healthcare professional**
person authorized to be involved in the direct provision of certain healthcare provider activities in a jurisdiction according to a mechanism recognized in that jurisdiction

Note 1 to entry: Adapted from EN 13940–1:2007.

**3.9**
**healthcare provider**
healthcare organization or healthcare professional involved in the direct provision of healthcare

[SOURCE: EN 13940-1:2007]

**3.10**
**patient**
individual who is a subject of care

[SOURCE: ISO/TR 20514:2005, 2.30]

**3.11**
**policy**
set of rules such as legal, political or organizational which can be expressed as obligations, permissions or prohibitions

Note 1 to entry: Adapted from ISO/TS 22600-1:2006, 2.13.

**3.12**
**privacy**
freedom from intrusion into the private life or affairs of an individual when that intrusion results from undue or illegal gathering and use of data about that individual

[SOURCE: ISO/IEC 2382-8:1998, 08.01.23]

**3.13**
**registry**
server capable of holding data for the systematic and continuous follow-up of information objects maintained in accordance with specific rules

[SOURCE: ISO/TR 21089:2004]

**3.14**
**semantic interoperability**
ability for data shared by systems to be understood at the level of fully defined domain concepts

[SOURCE: ISO 18308:2011, 3.45]

**3.15**
**syntactic interoperability**
capability of two or more systems to communicate and exchange data through specified data formats and communication protocols

[SOURCE: ISO 18308:2011, 3.48]

**3.16**
**use case**
methodology used in system analysis to identify, clarify, and organize system requirements

Note 1 to entry: The use case is made up of a set of possible sequences of interactions between systems and users in a particular environment and related to a particular goal. In the context of this Technical Report, a use case provides a depiction of the actors and services that addresses information exchange in the context of a set of specific tasks performed by different systems or devices

**3.17**
**vocabulary**
terminological dictionary which contains designations and definitions from one or more specific subject fields

[SOURCE: ISO 1087-1:2000]

# 4 Abbreviations

| | |
|---|---|
| ATNA | Audit Trail and Node Authentication |
| BPPC | Basic Patient Privacy Consent |
| CEN | European Standardization Committee |
| CDA | Clinical Document Architecture |
| DICOM | Digital Imaging and Communications in Medicine |
| EHR | Electronic Health Record |
| HL7 | Health Level Seven |
| IHE | Integrating the Healthcare Enterprise |
| IHTSDO | International Health Terminology Standards Development Organization |
| ISO | International Organization for Standardization |
| ISO/TC 215 | ISO Technical Committee 215 (Health Informatics) |
| IT | Information Technology |
| LOINC | Logical Observation Identifiers Names and Codes |
| MoH | Ministry of Health |
| OASIS | Advancing Open Standards for the Information Society |
| PDQ | Patient Demographics Query |
| PHR | Personal Health Record |
| SDO | Standards Development Organization |
| SNOMED CT | Systematized Nomenclature of Medicine Clinical Terms |
| W3C | World-Wide Web Consortium |
| XCA | Cross-Community Access |
| XDS | Cross-enterprise Document Sharing |
| XUA | Cross-Enterprise User Assertion |

# 5 General approach to analyse the interoperability requirements in support of an interoperability use case

## 5.1 Concept of an Interoperability Use Case

A Use Case is a concept that is widely used but often called with different terms (requirement, business scenario, etc.). In this Technical Report, we focus the use case content on interoperability defined as: “A depiction of the actors and services that address information exchange in the context of a set of specific tasks performed by different systems or devices in support of its users”.

Use Cases can be defined at various levels. An Interoperability Use Case is at a level that Part 1 of this report describes as:

"This encompasses health system objectives such as "chronic disease management" or "sharing patient summaries with a medication history." There are many ways of identifying and structuring use cases at the business level, which contributes to the challenge of accepting a certain fuzziness and flexibility. Interoperability level use cases are most successful, when they select a small – and therefore achievable and implementable scope, thus providing value while remaining achievable. This is what a number of regional and national projects around the world are often using to shape their objectives in the area of interoperability. However, as the number of use cases providing incremental interoperability requirements increases, it becomes apparent that they overlap, each potentially reusing a subset of another Interoperability Use Case (e.g. in our example above "sharing patient summaries and "patient empowerment with a medication history" have likely some overlap). This needs to be recognized, and factoring will happen at the lower levels of requirements."

An Interoperability Use Case can be summarized in one sentence and described in a few pages of text that any stakeholder in health, including non IT professionals would understand along with the necessary underlying exchange of health information.

An Interoperability Use Case is described by a flow of health information between Actors, where Actors are a representation of health information systems supporting users such as healthcare professionals in specific roles as well as the patients, but also extend to include the organizations they support and benefit from the real world information interchange defined by an Interoperability Use Case.

Examples of Interoperability Use cases:

— Patient summaries for regional/national information sharing;

— Prescriptions for regional/national information sharing;

— Request and results distribution for radiology enterprise workflow (e.g. within a hospital);

— Flow of device measurements from mobile and/or home-based monitoring devices to care management services.

These examples of Interoperability Use case cover a diverse range of information exchange environments: cross-border, national/regional, intra-hospital; and citizens on the move or at home. They come from the European eHealth Interoperability Framework (http://ec.europa.eu/digital-agenda/en/news/ehealth-interoperability-framework-study) and the eHealth Interoperability Standards Mandate (www.ehealth-interop.eu).

## 5.2 Decomposition of an Interoperability Use Case into Technical Use Cases

A set of Technical Use Cases may be derived from an Interoperability Use Case by taking the requirements at a service/content/semantic level, where the flows of health information are more specific and described between specific software entities, or Technical Actors that support the Actors engaged into the Interoperability Use Case. This results in a decomposition of an Interoperability Use Case into Technical Use Cases of different types, such as:

a) Specific flows of health information between Technical Actors abstracting the part of software applications, which are engaged in one or more specific transactions or services to support a specific aspect of a real world health information interchange.

b) Specific health information content and semantics associated with each flow between the Technical Actors identified in 1) above.

c) Specific security and privacy requirements attached to the above specific flows identified in 1) above.

The isolation of these Technical Use Cases is important because it modularizes the specification process around Profiles, or a reusable communication service which is defined in Part 1 of this technical report as:

"A communication service defining 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 communication services that are most likely to be needed to support a broad range of interoperability use cases".

These Technical Use Cases may be defined at different levels of granularity, but their main characteristics are that the interoperability requirements are sufficiently focused so that each Technical Use Case forms a building block of requirements which is reusable across multiple Interoperability Use Cases. This encourages and supports modularity as well as facilitating evolution by substitution.

It is at the level of Technical Use Cases that the IHE development process operates, by associating a detailed selection of supporting standards. This is where the processes discussed in Part 1 are engaged and result in the specification of profiles that each support a well-defined Technical Use Case.

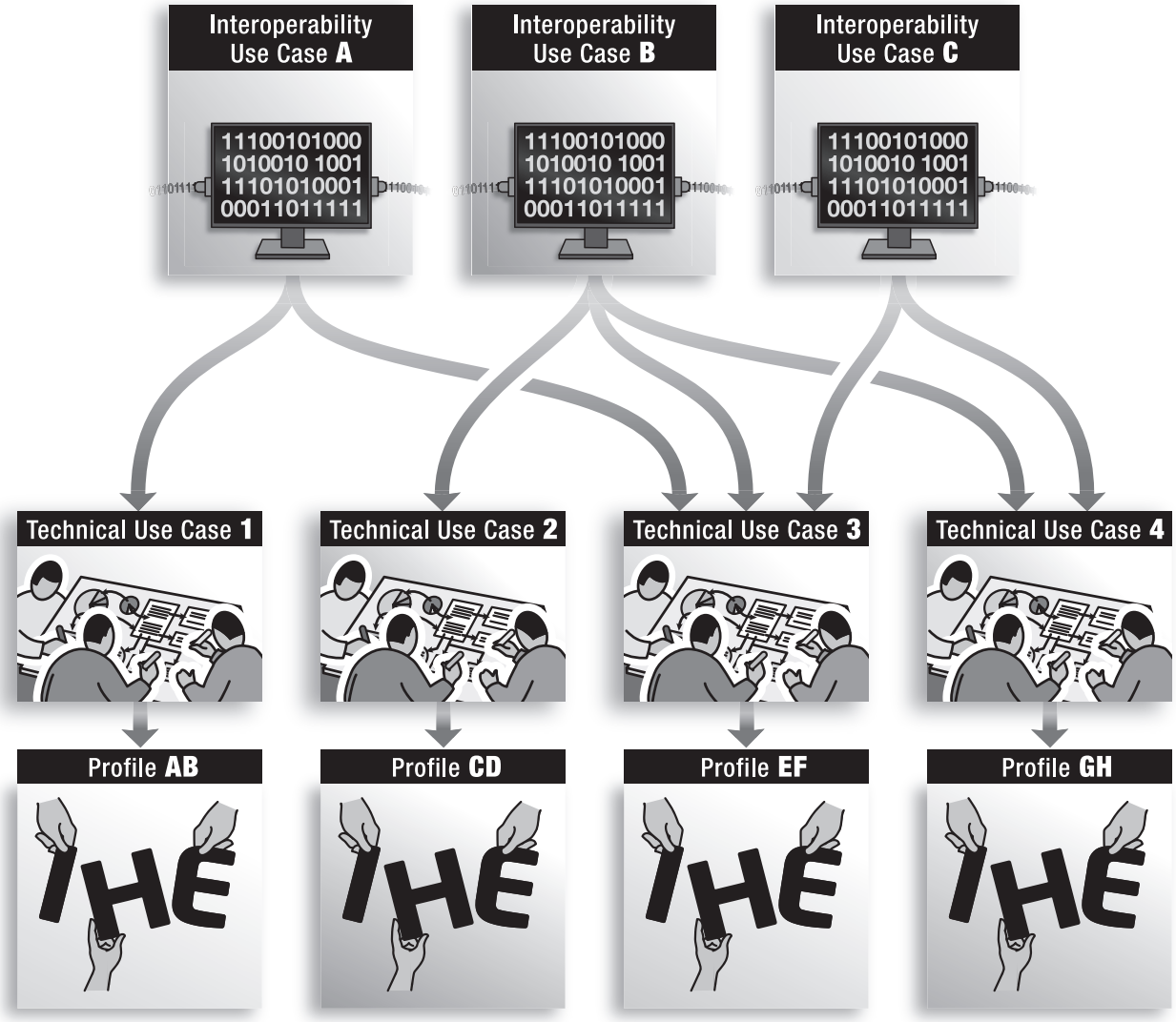


**Figure 1 — Decomposition of Interoperability Use Cases into Profiles/Technical Use Cases**

A breakdown of an Interoperability Use Case such as *Patient summaries for regional/national information sharing* may for example include the following Technical Use Cases:

a) Patient summary document content data structure;

b) Coded entries terminology value sets (diagnosis, medications, allergies, procedures, etc.);

c) Patient identity demographics query;

d) Sharing of documents within a region (publish, query and retrieve to a document registry and repositories);

e) Access to documents across regions (peer-to-peer query/retrieve);

f) User authentication, audit trail feed, system authentication and transport encryption;

g) Patient privacy consent content data structure.

Examples of specific Profiles associated with each one of these Technical Use Cases are discussed in 6.4.

# 6 Project Interoperability Specification

## 6.1 Scope of Interoperability

A simplified abstraction that represents the two dimensional scope of interoperability in an eHealth project is shown in Figure 2 below.

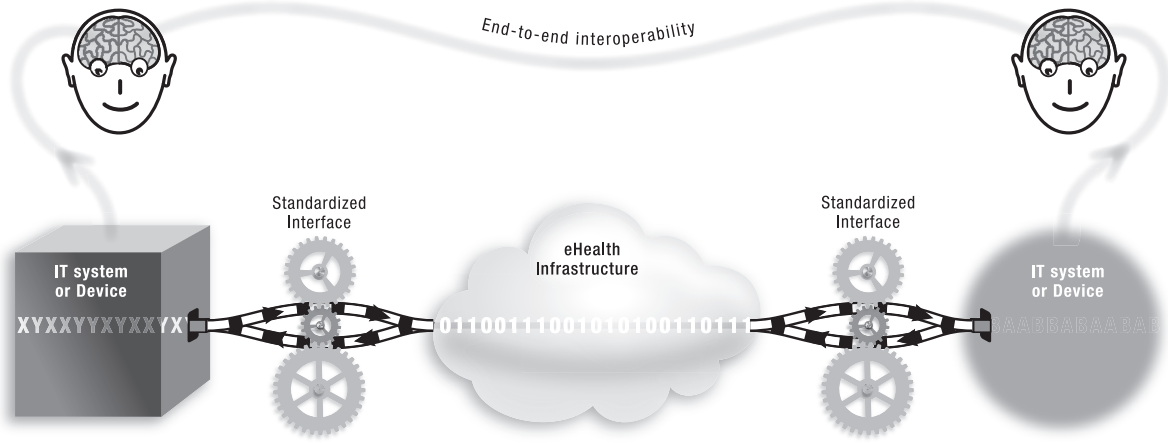


**Figure 2 — Two dimensional scope of interoperability**

One generally distinguishes between a set of IT systems that provide an infrastructure to which are interfaced the IT systems and devices used by the health workers and patients. This depiction is simply intended to position:

— the need for a “standardized interface“ between the infrastructure and the various IT systems and devices it interconnects (the vertical system-to-system interfaces as shown by the vertical arrows in Figure 2)

— the end-to-end interoperability requirements (the end-to-end user perception of interoperability as shown by the horizontal arrow in Figure 2.

The role of the Interoperability Specification in an eHealth project is to specify the interfacing of the various IT systems and devices to the eHealth infrastructure. This interfacing covers not only the specification of the information that may flow back and forth across the interface, but also the policies that control the behaviour of the systems and users to ensure end-to-end interoperability (e.g. semantics, security, privacy, service level agreements). Although these policies are not discussed here, they are critical to interoperability and only their technical support is addressed by the Profiles that seek to be, as much as possible, policy neutral.

## 6.2 Selection and combination of the appropriate Profiles

Applying the above methodology to a typical eHealth project is where the benefits should be realized.

Interoperability Use Cases are often dependent on the specifics of the health system in which they will be deployed. Each one of these Interoperability Use Cases that a project has chosen to address can be decomposed into a coherent set of Technical Use Cases along with the associated supporting Profiles, where they exist. Of course, some Technical Use Cases may be found to lack the associated supporting Profiles, or that certain extensions may be required. The Profile development process is organized to be reactive, and address these newly identified gaps (new profile or extension to an existing profile). Gaps can be submitted to IHE and addressed in most cases within a year, unless there is also a gap in the base standards. In some cases, projects may have to specify an interim profile to meet their timeline and proceed in parallel, while the base standards and new profile are developed.

Experience has shown that Technical Use Cases and associated Profiles can be specified to be sufficiently generic and be adapted to health system specificities either by minor extensions, or by being combined with other existing profiles in a project specific way.

When an eHealth project uses this Use Case driven methodology and as result has performed the specification of the interoperability needed to interconnect the set of IT systems and devices and their supported applications, it has produced what is called in this Technical Report a project-specific Interoperability Specification.

When such an Interoperability Specification is created by referencing existing Profiles (IHE and other), the Interoperability Specification is greatly simplified. It is modular, and because it re-uses these internationally defined profiles, much of the documentation work can be avoided. The Interoperability Specification added-value means that the major focus can be on the project specifics:

— First on the orchestration among the Profiles,

— Second on filling some of the profile gaps and extensions, if needed.

This results in a specification significantly reduced in size, much easier to develop and maintain, as well as simpler to navigate and test for anyone familiar with the referenced profiles.

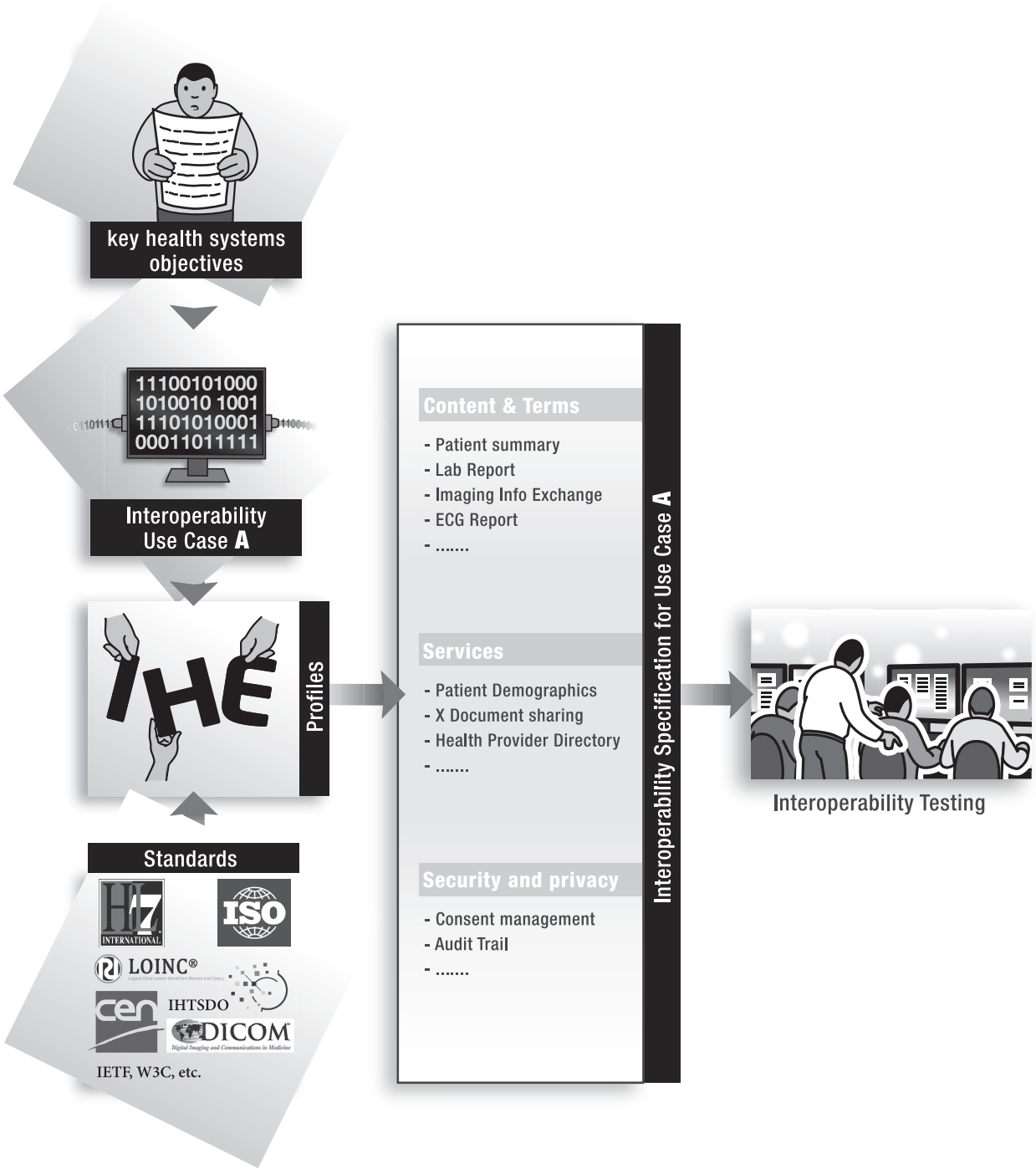


**Figure 3 — From Use Case to Profiles to deliver an Interoperability Specification**

The use of reusable "prefabricated building blocks" to address a complex problem is a classical engineering strategy and has proven successful in eHealth interoperability. It provides a good balance between the necessary flexibility to address project specific requirements, and the ability to reuse common building blocks (Profiles) across Interoperability Specifications. This strategy has far greater benefits than simply reusing building blocks of specification as discussed in Clause 7.

## 6.3 Establishing a Jurisdictional Interoperability Framework

Policy makers realize the complexity of eHealth interoperability, especially when they are responsible for guiding the deployment of a large number of eHealth projects in their jurisdiction (a hospital, a region, a nation, or a union of nations). They are faced with the challenge of leaving sufficient flexibility for each of the projects that fall under the responsibility of different stakeholders (e.g. public hospitals, private hospitals, community pharmacies and laboratories, clinics and general practitioners, various public health entities and research agencies). Such policy makers are faced with the challenge to establish an interoperability framework that drives the necessary consistency towards a culture of interoperability while leaving enough flexibility for each one of the many eHealth projects in their jurisdiction. Indeed such projects will develop, according to their specific constraints and often across long periods of time.

A profile-based approach to interoperability is well positioned to offer a solution to this complex policy setting problem. By simply recognizing a set of profiles aligned with the need of the class of Interoperability Use Cases that have been identified as priorities within the policy maker‘s jurisdiction, it becomes possible to allow the eHealth projects to develop their own Interoperability Specifications and procure their own infrastructure as well as implement the corresponding compliant interfaces for the IT systems and devices to be interconnected, while also maintaining a good level of consistency. Although perfect consistency may not be achieved, the bulk of the content of the project-specific Interoperability Specifications will be consistent as it references and reuses the same set of recognized profiles. Further federation of these distinct eHealth projects into a jurisdiction-wide interconnected system remains possible with reasonable efforts.

This approach is being considered by the European Commission and a number of countries (e.g. France, Austria, States of the USA, Switzerland) have found it to be effective.

## 6.4 Examples to illustrate the application of the above methodology to specific Interoperability Use Cases

Continuing with the example of an Interoperability Use Case such as Patient summaries for regional / national information sharing, introduced in Clause 5, it is possible to further refine the example by identifying a choice of specific profiles that supports each of these Technical Use Cases identified in 5.3:

a) Patient summary document content data structure → Cross-Enterprise Personal Health Record Profile (IHE XPHR);

b) Coded entries terminology value Sets (diagnosis, medication active ingredients, allergies, procedures, etc.) → Profile documenting national appropriate Value Sets from SNOMED CT, HL7 and LOINC;

c) Patient identity demographics query → Patient Demographics Query (IHE PDQ V3);

d) Sharing of Documents within a region (publish, query and retrieve to a document registry and repositories) → Cross-Enterprise Document Sharing Profile (IHE XDS);

e) Access to documents across regions (peer-to-peer query/retrieve) → Cross Community Access (IHE XCA);

f) User Authentication, audit trail feed, system authentication and transport encryption → Cross-Enterprise User Assertion (IHE XUA), Audit Trail and Node Authentication (IHE ATNA);

g) Patient Privacy Consent Content Data Structure → Basic Patient Privacy Consent (IHE BPPC);

The above example is not intended to be exhaustive in terms of listing the Technical Use Cases and corresponding Profiles, but provides a concrete example to illustrate the approach.

Examples of IHE Profiles supporting each Technical Use Case are shown between brackets. These are covered by TR28380 Part 2 and further information about each of these IHE profiles may be found at http://wiki.ihe.net/index.php?title=Profiles. IHE Profiles are based on International Standards with rare exceptions. Indeed some of CDA Templates leveraged by the IHE Patient Care Coordination have been initially defined by US or EU realm guidelines, but before adoption in an IHE profile those have been screened for international applicability.

# 7 Deployment benefits of profile-based interoperability specifications

When an eHealth project chooses to build its Interoperability Specification by referencing Profiles, it introduces a good level of modularity, with a design that has been agreed by a world-wide community of experts and users. It takes advantage of an appropriate level of flexibility to address the project specific requirements, without having to face the complexity to develop such an Interoperability Specification from the ground up, by starting from the base standards. This strategy for developing a project specific Interoperability Specification has far greater benefits than simply reusing building blocks of specification. These include:

— responsiveness in the maintenance of the profile specification and of the underlying base standards.

— reduced costs to develop applications that conform to the Profile across a large number of products that are needed to serve the many niche market segments that compose health systems.

— defragmentation of the eHealth market, where project specific interoperability - be it at the country, regional, hospital or community levels - is typically one of the most significant barriers to rapid adoption.

— ease of access to pre-existing testing tools and processes to ensure quality interoperability, as well as associated certification processes to assist market transparency.

— reduced cost of software development and increased speed of development and deployment. Possibility of "off the shelf" products which already implement IHE profiles, being used

— training and deployment skills needed to deploy the above software applications, systems and devices, with their constraints (cost, regulatory, continuity of service, etc.). A supportive IHE Community providing vendor education and development support

— availability of existing pool of companies and IT professionals skilled in IHE profile implementation

— simplifying the specifications of the various policies needed to support interoperability (e.g. security, privacy) through reuse of policies across projects, when possible.

— improved clarity of documentation

— reduced cost of software maintenance

## 7.1 Alternatives and Deployment benefits

Considering a number of eHealth projects around the world, it appears that three types of implementation strategies are used for the design of interoperability (interfacing to an health infrastructure and end-to-end interoperability-See 6.1):

a) Profile based: Set the overall eHealth project functional requirements (Interoperability Use Cases) and have the project develop its Interoperability Specification by drawing upon Profiles. Tender an eHealth infrastructure on one hand and on the other, the interfacing of the numerous IT system/devices to be connected (adapting existing systems or deploying new systems)

b) Customized standards: Set the overall eHealth project functional requirements (Interoperability Use Cases) and have the project develop it's Interoperability Specifications by using base standards directly (not mediated by profiles). Tender on the basis of this Interoperability Specification of an eHealth infrastructure on one hand and on the other, the interfacing of the many IT system/devices to be connected (adapting existing systems or deploying new systems).

c) Infrastructure vendor: Set the overall ehealth project functional requirements (Interoperability Use Cases). Tender the eHealth infrastructure on the basis of these Interoperability Use Cases and make the infrastructure vendor(s) responsible for setting the project Interoperability Specifications. Tender the interfacing of IT system/Devices to be connected (adapting existing systems or deploying new systems) on the basis of the Infrastructure vendor provided Interoperability Specification.

The impact of the choice of one of the above three deployment strategies can be analysed at a high level across the major implementation and support activities as presented in Table 1 below.

Assumption: For each one of the three broad implementation strategies, a number of areas of impact are identified in Table 1. These specific areas of impact are grouped into three categories: technology, process and people. Each area of impact is evaluated at a coarse level using a scale with three levels of relative value:

⇨ *Small*: Small impact which implies limited cost and efforts;

⇨ *Medium*: Medium impact which implies a significant cost and efforts;

⇨ *Large*: Large Impact which implies higher cost and efforts.

No attempt is made to quantify the actual costs or the relative importance of the various areas of impact. These are expected to vary significantly in value across different projects, due to many factors such as the Use Cases chosen, the environment of the deployment, and the scale of the project. However, their relative impact should remain valid across projects.

Note that in each one of the three deployment strategies, gaps in base standards or profiles may have to be addressed. Although different strategies may be used, this issue exists for each one of the strategies. In some cases, projects may have to specify an interim profile to meet their timeline and proceed in parallel, while the base standards and new profile are developed (See 6.2).

**Table 1 — Example of three potential deployment strategies**

| Implementation Strategies | 1 Profile Based | | 2 Customized Standards | 3 Infra-structure vendor |
|---|---|---|---|---|
| **Areas of Impact associated with the interoperability pathway to adoption** | Initial Cost | Life Cycle Cost | Initial Cost = > Life Cycle Costs | Initial Cost = > Life Cycle Costs |
| **Technology** | | | | |
| Determine and Document Interoperability Use Cases | *Medium* | | *Medium* | *Medium* |
| Development of Interoperability Specification | *Medium* | *Small* | *Large* | *Large* |
| Maintenance of Interoperability Specification | *Small* | | *Large* | *Large* |
| Connect new IT systems and devices to Infrastructure | *Medium* | *Small* | *Large* | *Large* |
| Connect existing IT systems/devices to Infrastructure | *Medium* | | *Large* | *Large* |
| Compliance Testing | *Medium* | *Small* | *Large* | *Large* |
| Build eHealth Infrastructure | *Small* | | *Large* | *Medium* |
| Change eHealth infrastructure | *Small* | | *Large* | *Large* |
| **Process** | | | | |
| Engage/educate key stakeholders | *Medium* | | *Medium* | *Large* |
| Interoperability Specification Development Schedule Risks | *Small* | *N/A* | *Large* | *Medium* |
| Develop implementation and testing schedule | *Medium* | *Small* | *Large* | *Medium* |
| Change management | *Medium* | *Small* | *Medium* | *Large* |
| Policy development | *Medium* | | *Large* | *Medium* |
| Opportunities for change | *Large* | | *Medium* | *Medium* |
| Environmental analysis | *Large* | *Small* | *Large* | *Large* |
| **People** | | | | |
| Recruitment of skilled staff - Domain knowledge | *Small* | | *Medium* | *Large* |
| Cost of adding support for new Interoperability use cases | *Small* | | *Medium* | *Large* |
| Awareness and education training | *Medium* | *Small* | *Medium* | *Medium* |

# 8 Approach to testing for interoperability

Testing for interoperability is a challenge that requires specific attention. The testing has to be sufficient to ensure that IT systems and devices that need to be connected to the eHealth Infrastructure are compliant, meet the information quality requirement of the eHealth project and will not disrupt existing information exchange. The testing effort needs to be of reasonable size, to avoid unnecessary high costs and delays to the overall eHealth project. To strike a good balance between these opposing constraints is a challenge that will benefit from the use of profile-based Interoperability Specifications.

## 8.1 Four phases of Testing for Interoperability

A classical approach to interoperability testing is to distinguish separate phases of testing each driven by a business objective, with clear hand-offs between each one of these phases in order to isolate defects and reduce the risks of compounding the detection and resolution of defects. This is especially critical in major eHealth projects where a large number of systems need to be deployed across periods measured in years rather than months.

It is also important to take a holistic approach to implementation verification, from the early phases of software development until the setting into operation of IT systems exchanging actual health information reliably.

Three main categories of testing need to be considered in the context of interoperability:

— Conformity Assessment: verifying that an implementation meets the requirements set by a specification (in our case a project interoperability specification and its underlying profiles and standards)

— Interoperability Testing: verifying that the end to end flows of information are performed in a way that meets the need of the users of the communicating systems (generally health professionals and patients). This verification needs to en sure consistency with the semantic requirements and the technical aspects of the interoperability specifications

— Performance Testing: verifying that the speed at which information is being processed, and exchanged meets the project requirements. This last type of testing is important but is not within the scope of this Technical Report, as it is largely project specific.

Conformity Assessment (or testing) and Interoperability Testing are both critical in eHealth, as they each address complementary and critical elements of interoperability as discussed in 6.1.

Given the above principles, it is beneficial to distinguish 4 phases in the testing of interoperability:

a) Profile-level testing: Testing an implementation by a *technology developer* for conformance to one or more specific profiles and its interoperability with other implementations. This is the first level where standards conformance may be effectively tested, as the profile provides the necessary implementation guidance that removes optionality that is not required from the base standards. This needs to include testing for interoperability with implementations from other technology developers to ensure end-to-end interoperability (See 6.1).

b) Interoperability Specification level testing-project specific implementation: Testing an implementation *by a technology developer* for conformance to an Interoperability Specification (combination of profiles) specific to an interoperability use case selected by an eHealth project. This needs to include testing for interoperability with implementations from other technology developers to ensure end-to-end interoperability (See 6.1).

c) Interoperability Specification level testing-pre-production: Site specific testing of an implementation for conformance *by a technology user* to an Interoperability Specification (combination of profiles) specific to an eHealth project. This includes mostly the testing of interoperability for a site where a product tested in Phase b), above, is installed and configured before it is placed in interoperability production. It is often focused on regression testing as well as testing with other implementations that have already been tested at that level for production use.

d) Interoperability Specification level testing-operational: Testing an implementation conformance by a technology user to an Interoperability Specification (combination of profiles) specific to an eHealth project and its interoperability with other implementations when this implementation is deployed in one or more production sites and is found defective while in operation.

These four phases of testing and their relationships are depicted in Figure 4. Each has an organizer, a performer and explicit entrance/exit criteria which are discussed in 8.2.

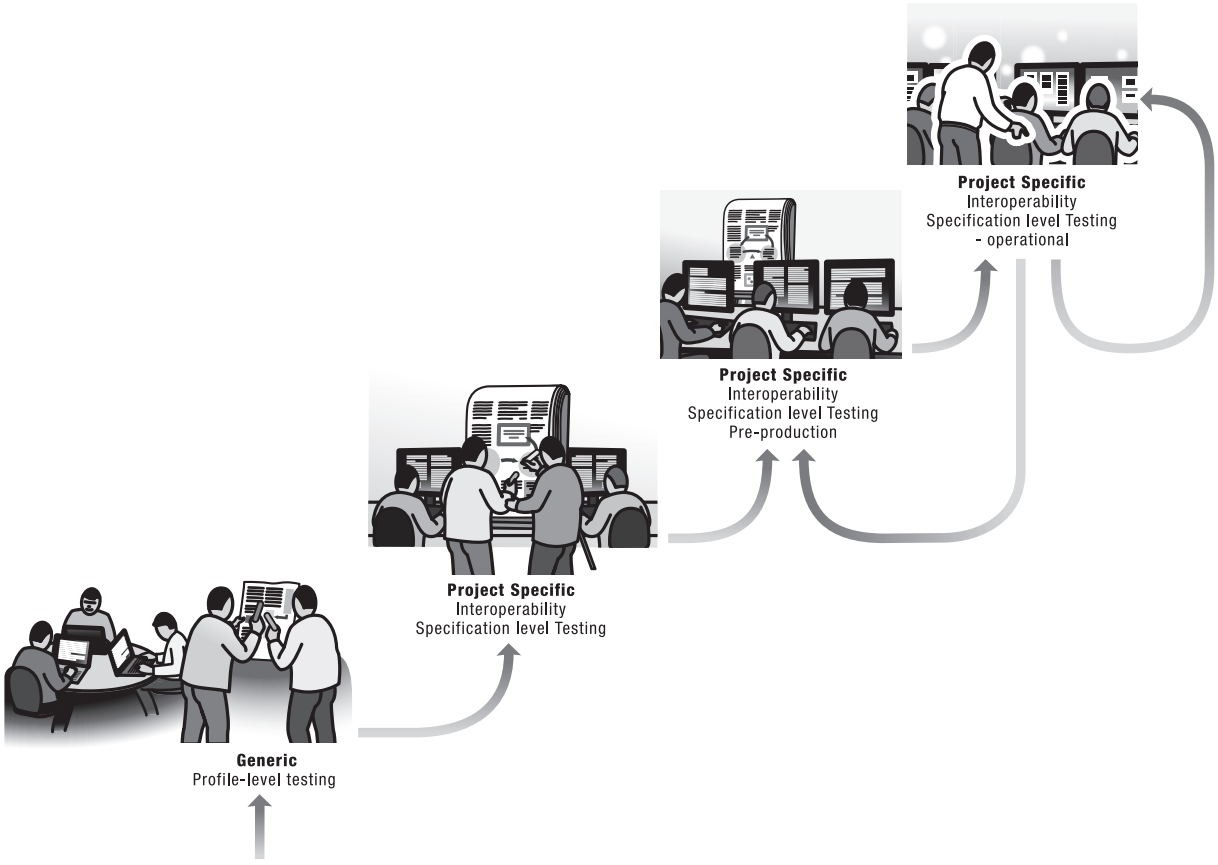


**Figure 4 — Four phases of testing and their relationships**

## 8.2 Responsibilities and Entrance/Exit Criteria

The table below highlights that the above four phases are significantly different in terms of who is the primary stakeholder and the specifics of the entrance/exit criteria. Several projects have experienced the burden associated with the failure to clearly separate these phases and the benefits from these phases being distinguished given the different entities responsible for organizing each phase of testing (organizer) and those responsible for performing the testing (performer).

**Table 2 — Phase of testing for interoperability**

| Phase of testing for Interoperability | Organized by | Performed by | Entrance criteria | Exit criteria |
|---|---|---|---|---|
| **a - Profile-level testing** | Vendor neutral host (e.g. IHE Connectathon and Accredted Testing) | Technology developer | Lab testing passed as determined by testing scheme | Interop Testing OK<br>or Test Lab Report |
| **b - Interoperability Specification level testing - project specific implementation testing** | eHealth Project | Technology developer | All Profiles in Interop Spec OK | Project Interop Spec Ready |
| **c - Interoperability Specification level testing - project specific pre-production testing** | eHealth Project | Technology user | Project Interop Spec Ready | Pre-production Test (on-site) Patients OK |
| **d - Interoperability Specification level testing- operational testing** | eHealth Project | Technology user | Test Site/Test Patients OK | Production Test (on-site) Patients OK |

Although, there are significant responsibilities placed on the eHealth Project (3 out of the four phases of testing), it is critical to understand that the first phase, profile-level testing is outside the governance of eHealth projects and the most important in term of establishing a large ecosystem of profile-level tested products for the success of these eHealth projects. Reuse by a large number of eHealth projects will also be an important factor in the emergence of such an ecosystem at the international and national level.

Another important success factor in the testing of interoperability is the use of consistent test tools across all Phases of testing, thus resulting in a significant economy of scale for the implementers and improved consistency and repeatability of results. The benefits of using the same platform and set of open source test tools for phase a (e.g. IHE Gazelle[4]: gazelle.ihe.net) and for the testing of Phase b/c by specific projects are becoming more apparent as demonstrated by the multi-country European epSOS project.

## 8.3 Test Management Processes and Certification

The maturity of testing processes for interoperability in sectors other than health, in the context of large scale interoperability has developed primarily around the Internet and the banking sector. However, in both types of sectors, the services and application level protocols are far from the complexity needed to support most health information exchange. It is important to note however that there are two standards that are directly applicable to eHealth:

The quality criteria for interoperability test beds have been specified by the publication in 2012[5] of the CEN Workshop Agreement (CWA 16408:2012 - Testing Framework for Global eBusiness Interoperability Test Beds (GITB). It is applicable to test tools to be used for ehealth interoperability testing (www.ebusiness-testbed.eu).

ISO/IEC 17025 “General requirements for the competence of testing and calibration laboratories” is the main ISO standard used by testing and calibration laboratories. There are many commonalities with the ISO 9000 standard, but ISO/IEC 17025 is more specific in requirements for competence. It applies directly to those organizations that produce testing and calibration results. The two main sections in ISO/IEC 17025 are Management Requirements and Technical Requirements. Management requirements are primarily related to the operation and effectiveness of the quality management system within the laboratory. Technical requirements include factors which determine the correctness and reliability of the tests and calibrations performed in a laboratory.

ISO/IEC 17025 is also the basis for accreditation of conformity assessment laboratories by an accreditation body. Accreditation is simply a formal recognition by an independent third party of a demonstration of competence. An example of a conformity assessment scheme based on ISO/IEC 17025 is the IHE Conformity Assessment Scheme (IHE-CAS: www.ihe.net/Resources) that establishes requirements for IHE Authorized Testing Laboratories performing IHE Profile conformity assessment.

Specific to the area of eHealth, the Healthcare Interoperability Testing and Conformance Harmonization[6] (HITCH: www.hitch-project.eu) and ANTILOPE[7] (www.antilope-project.eu) made recommendations to the EU Commission on how to proceed with eHealth interoperability testing and certification/ in Europe. These projects propose a way forward to balance the urgency to defragment the current approach by eHealth projects, while reducing the cost of testing, raising the level of quality, and still remaining sufficiently flexible to account for local needs.

HITCH and ANTILOPE reinforces that testing and certification as related but distinct processes. While testing represents the way one assesses/measures the level of interoperability, certification is a process where a certifying entity uses the positive test results to deliver an attestation of conformity.

In the area of testing, these projects stressed the need to continue and amplify the progress accomplished in the last few years, with initiatives such as IHE Connectathons. They identified two areas that need further improvement and a more formalized approach. First, there is a need for a widely accepted quality guide for interoperability testing in health based on existing quality standards such as ISO 9001 and ISO 17025. Second, an organized collaboration is needed to reduce the fragmentation and lack of maturity in interoperability test tools and test plans in specific areas.

In the area of certification, HITCH surveyed various certification strategies and concluded that different variants would need to coexist and evolve along with profile specification stability and market maturity.

Defined elements of an effective and practical framework for testing and quality management in eHealth Interoperability have been introduced in Clause 8. At the time of writing of this Technical Report, a number of elements are still in evolution and continued efforts with feedback from eHealth projects is expected to further refine this framework.

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