TECHNICAL REPORT

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Health informatics — IHE global standards adoption —

Part 1: Process

Informatique de santé — Adoption des normes globales IHE —

Partie 1: Procédé

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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

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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**

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 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.

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 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.

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 Abbreviations

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
IHTSDO	International Health Terminology Standards Development Organisation
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 Global standards adoption process overview

4.1 General

The IHE standards adoption process is entirely driven by the definition of requirements for interoperability, often called “use cases”. These standards are a means of addressing these interoperability problems. Therefore this section provides:

— an overview of the main steps of the IHE process

— a definition of the level of requirements at which this process operates, and

— the involvement of stakeholders and the overall structure in which the process is performed.

4.2 Development and deployment process

The IHE process comprises a development process and a deployment process as depicted in Figure 1. The development feeds the deployment-validation process, which in turn enables the deployment-production process resulting in implementation projects with successful interoperability. As additional requirements are identified during implementations, the IHE process is intended to repeat itself by expanding the information exchange capabilities year after year.

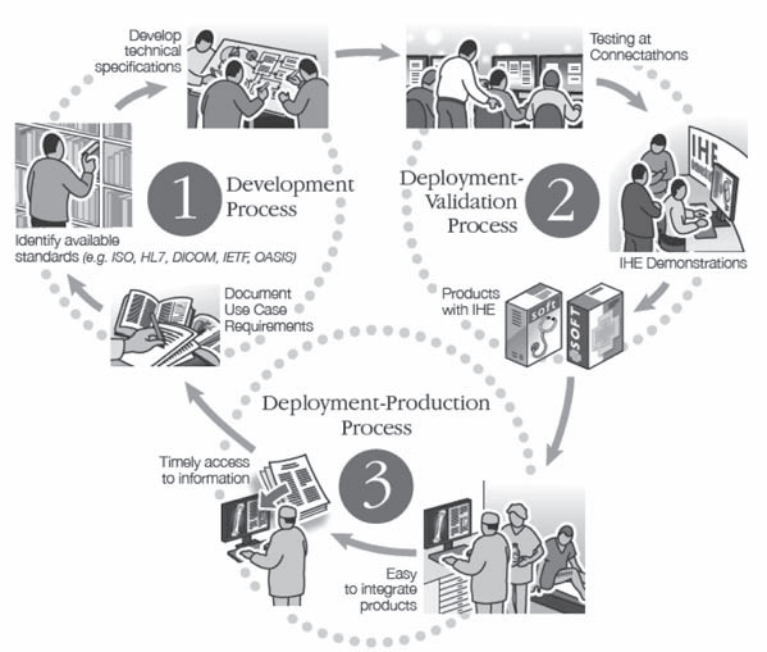

Figure 1 — IHE development and deployment process

The development process starts with a set of documented use cases; it proceeds to the selection of relevant standards that support the use case and documents in a structured manner the subset or "profile" of these base standards with a significant reduction of options. These profiles are then published in the corresponding IHE Technical Framework for the domain. As a result, the implementers of an IHE profile are ensured to achieve the intended level of interoperability within the context of the corresponding use case by receiving the necessary detailed implementation guidance for the selected standards.

The deployment process builds upon profile specifications produced by the development process. It starts with the validation process which includes the testing of working implementations of these profiles, demonstrates successful interoperability between independent implementations at various exhibitions, and concludes with the means for developers of IT products to state their compliance to one of more profiles.

The deployment into production of healthcare delivery systems leverages interoperable health IT products by integrating them in care management or delivery systems. This effective support of end users is where the benefits of standards-based interoperability are realized. Although the IHE process is not directly responsible for conducting these deployment projects in production, it expects that such projects will continuously provide feedback to the development process. It does this by supplying additional use case requirements in order to expand the richness of interoperability and by issuing Change Proposals to the profile maintenance process when implementers discover interoperability issues.

The profile development process is distinguished from the profile deployment-validation process for several reasons:

— The development process is executed at the global level in order to produce internationally agreed upon Integration and Content Profiles

— The deployment-validation process is carried out at the level of specific countries or a group of countries, which reflects the different mix of implementers and is close to the health organizations that deploy the technology and need to achieve interoperability.

— Some national extensions to the globally agreed upon profiles are often necessary and are specified by the deployment-validation process generally at the national level and are documented into a specific part of the Technical Frameworks.

— It is a good engineering quality approach to keep some balance of power between the two parts of the process, each challenging the other to improve the quality of its outcome.

4.3 Levels of requirements

One significant challenge in standards adoption is to offer an approach that balances the broad and unbounded need for interoperability and the necessity to solve specific but common interoperability problems involving different health IT systems or devices.

The definition of interoperability requirements can be performed at different level of granularity. In order to clarify the level at which the IHE Global Standards Adoption Process operates, four levels of requirements initially proposed by the United States EHR Vendor Association in its Interoperability Roadmap provide an effective breakdown:

a) **Business Use Case Level** — This level corresponds to the business view of IT systems such as "chronic disease management system" or "patient empowerment with a medication history system". There are many ways of identifying and structuring use cases at the Business Level Use Case, which contributes to the challenge of accepting a certain fuzziness and flexibility. Business Level Use Cases are most successful when they select a small and therefore achievable scope for implementing requirements, each providing value while remaining achievable. This is increasingly occurring in a number of regional and national projects around the world. However, as the number of use cases providing incremental interoperability requirements increases, it becomes apparent that they overlap, each potentially reusing a subset of an earlier one (e.g. in our example below, "chronic disease management" would have significant overlap with a "patient empowerment with a medication history" use case. This needs to be accepted, and factoring will happen at the lower requirements levels.

b) **Interoperability Service Level** — An interoperability service defines 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 interoperability services that are most likely to be needed to support a broad range of business level use cases. This is a use case driven approach at an intermediate level, which facilitates the support of business requirements with specific purpose, data, and exchange requirements. The range of services is large but can be more easily organized and bounded than at the business use case level. An example of this further refinement is in the terms used to describe the services themselves: "electronic drug prescribing", "sharing of patient's medical summaries", and "access to a patient's current immunization list".

c) **Integration and Content Profile Level** — This level is more granular than the interoperability service level in order to provide maximum flexibility in terms of implementation architectures. This architecture independence is achieved by combining actors from multiple Integration Profiles. Integration Profiles are common interoperability building blocks, easily implemented in various software architectures [e.g. can be mapped to components in a service-oriented architecture (SOA)] that can be effectively factored in order to maximize reuse of specification and implementation methods, as well as allowing for evolutionary growth. Standards generally operate at a domain-focused level in that multiple standards are generally needed to define an Integration Profile. The Integration and Content Profile level is the level at which it is most practical to perform interoperability conformance testing. It is the level at which IHE manages its requirements.

d) **Base Standard Level** — Base standards are in some cases healthcare specific, and in other cases used across a wide range of industries to achieve fundamental IT communication or security management. Base standards are foundations that enable the creation of elementary services,

messages, and documents to support any possible use case in their domain. Like the other three levels, base standards development is also use-case driven, but is faced with the significant challenge of anticipating a greater variety of needs and market evolution. The large number of SDOs working on base standards means there is the risk of overlaps and inconsistencies between approved standards. Since these standards are not necessarily specific to healthcare, their use in this setting requires a number of constraints that are provided at the profile level (e.g., selection among competing standards to identify healthcare suitable options). The required flexibility of base standards makes their development a long-term activity with often unpredictable delivery schedules. For this reason, standards development and profile development are generally separate activities that operate on different schedules and consensus processes but with strong two-way collaboration that allows for approved standards to be updated with newly identified content as these standards make their way into profiles.

Figure 2 illustrates how these four levels support each other by adding specific technical depth as one moves from the level of business use cases (at the left side of the diagram) to the middle levels where it is possible to accomplish effective, testable, and robust interoperability (at the IHE Level), all the way to the most granular details provided by the base standards (at the right).

Business level use cases (furthest to the left) are many, varied, and naturally overlapping. Base standards (furthest to the right) are also varied and complex foundational specifications delicate to combine. The middle two layers are where a critical rationalization and the definition of common "solutions building blocks" are best conducted. These four levels are not intended to propose a systems requirement analysis process but simply a high-level identification of the granularity and scope of interoperability requirements. Applying these four levels to an example is illustrated in Table 1.

Figure 2 — Example of four levels of requirements

Table 1 — Business use case level

Business Use Case Level: Chronic Disease Management system

- Interoperability Service: Patient Identification Service
  - Profile: Patient ID Cross-referencing (PIX)
    - Standard: HL7 V2.5
  - Profile: Patient Demographics Query (PDQ)
    - Standard: HL7 V3
- Interoperability Service: Secured Channel between Trusted Nodes
  - Profile: Audit Trail and Node Authentication
    - Standard: DICOM- HL7-ASTM-IETF-RFC 3881
  - Profile: Consistent Time (CT)
    - Standard: IETF-NTP
- Interoperability Service: Sharing of Care Summaries
  - Profile: Cross-Enterprise Document Sharing (XDS)
    - Standard: ISO 15000, OASIS
    - Standard: CEN 13606
    - Standard: HL7 V2.5, HL7 CDA
  - Profile: Medical Summary (XDS-MS)
    - Standard: HL7 CDA
    - Standard: HL7-ASTM CCD
    - Standard: SNOMED
- Interoperability Service: Laboratory Orders and Test Results Workflow
  - Profile: Lab Scheduled Workflow
    - Standard: HL7 V2.5
    - Standard: LOINC

4.4 Stakeholder participation and overall structure

This section introduces the main organization roles that support the process that will be described in Clauses 6 and 7.

IHE is not organized as a typical SDO. This is due to its objective: address commonly needed specific information exchange related use cases by leveraging widely recognized standards for interoperability. It is focused at bridging the gap between the development of standards and the effective and efficient deployment of standards-based information exchange in healthcare.

But like an SDO, IHE needs to bring together many organizations and individuals who are stakeholders. It offers an open forum to participate in the initiative and contributes to achieving its objective. This section describes the different modes of participation and is not intended to describe the governance process used to make decisions but to focus on the roles that support the process.

Planning Committee – Each IHE Domain has a Planning Committee open to all stakeholders' representatives (end users, vendors, clinicians, etc.) interested in that domain. The Planning Committee is responsible for setting the development priorities for the domain on a yearly cycle and maintains a multi-year roadmap on a longer term basis. The Planning Committee in a domain regularly surveys its environment and considers what interoperability problems should be addressed in a given cycle, ensure that adoption barriers are reasonably low, and that a range of policy constraints are identified.

The Planning Committee will work with its peer Technical Committee and ultimately decide which interoperability problems should be formally documented and solved during each yearly cycle.

Technical Committee – Each IHE Domain has a Technical Committee open to all stakeholders' representatives (end users, vendors, clinicians, etc.) interested in that domain. The primary responsibility of a Technical Committee is the development of the IHE Technical Framework for that domain and the subsequent maintenance of that documentation. The Technical Committee advises the Planning Committee on the adequacy of the scope of work proposed for any given cycle and takes direction from the Planning Committee as to which problems to solve. This balance of roles between the Planning Committee and the Technical Committee ensures that the right problem is addressed at the right time in a technically viable way that can be immediately implemented and achieve the desired interoperability solution.

Deployment Committees – A regional or national IHE organization sponsors a Deployment Committee that organizes IHE deployment activities in a specific region or country (e.g. organizing implementation testing, public demonstrations). Often, IHE Deployment Committees cooperate to organize joint activities in a larger region or continent (e.g. IHE Europe includes IHE Germany, IHE France, IHE Italy, IHE UK, IHE Netherlands, IHE Denmark, IHE Norway, and IHE Spain who together organize a joint European-wide Connectathon).

5 Development process

The IHE development process is performed within each IHE Domain and is driven by both a Domain Planning Committee and its peer Technical Committee. The development process repeats on overlapping annual cycles, each lasting about 18 months. This overlap with the previous cycle is spent at planning the next cycle and the overlap with the following cycle spent at finalizing the supplements to the Domain Technical Framework. This development process has three major characteristics:

- Requirements driven: One has to define the use case that drives the need for interoperability before solutions and standards are assessed and selected.
- Global: Input is encouraged from a broad range of countries or realms. Such input is used to identify the global requirements and the need for realm-specific extensions. Although the realm-specific extensions will not be addressed in the development process but rather in the Deployment Process, the solution needs to anticipate the impact of these additional requirements.
- Executed on a fixed calendar: This ensures predictable time windows for requirements input, public comments, and implementation, and equally important focus of a broad number of contributors, supporters, and developers all around the world.

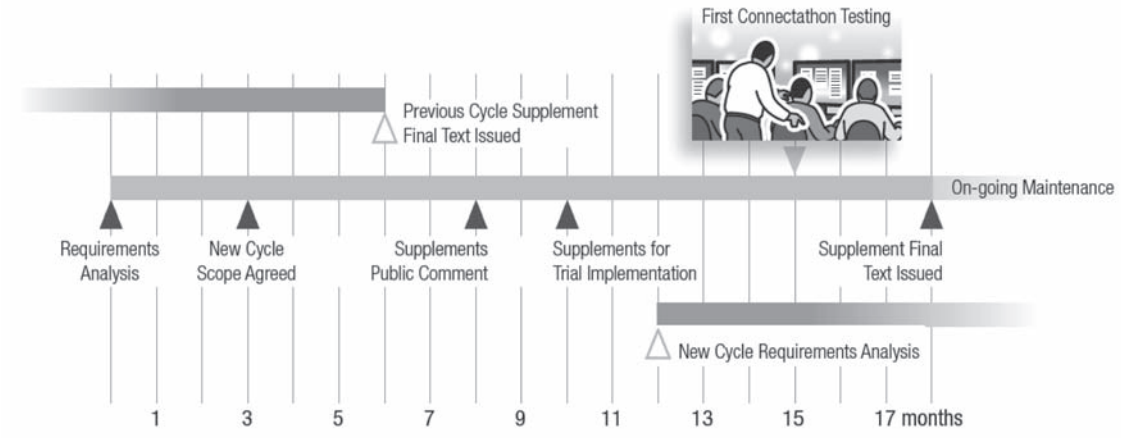

Figure 3 — IHE development process yearly cycle

Figure 3 depicts the major milestones of the annual cycle of the development process. Each domain follows this process, within its own scope. The five major milestones of the profile development process are:

1. **Requirements Analysis** - The Planning Committee obtains a list of interoperability problems that are most relevant to that domain from end users, market research, and non-resolved issues from prior cycles. During this phase of the cycle, the Planning Committee restricts its work to identifying the main areas that need development without proposing solutions. Typically during this time, the Planning Committee can identify more issues for development than can be resolved during the coming development cycle. The Planning Committee will then prioritize the problems list based on several factors: most commonly encountered globally, logical next step based on previously addressed problems, size of effort, consensus level among the end users and implementers (market readiness), experience and understanding of the issues, policy barriers, etc. A short list of 6 to 12 problems is typically the result of this first phase along with a brief two- or three-page scope description of each issue.

2. **Scope Agreement** - The Domain Technical Committee is given this short list of issues to evaluate and starts the Supplement Proposal phase. During this time, the Technical Committee prepares a three- to five-page profile proposal describing the interoperability issues and proposes approaches or candidate standards that can be used to address the issue. At this point, each proposed supplement is typically associated with one potential profile. The Technical Committee scores each profile proposal to guide the Planning Committee about the degree of difficulty and standards availability or other risks. The Technical Committee also advises the Planning Committee on the amount of resources needed for each proposed supplement, as well as an overall assessment of the total work effort the Domain Technical Committee can accomplish during the upcoming cycle. The Planning Committee takes the profile proposals from the Technical Committee and the advice on work effort and makes a final decision on those profiles or supplements that should be addressed in the current annual cycle. Any proposals that are not addressed are postponed for consideration in future cycles.

3. **Draft Supplements for Public Comment** - The Technical Committee then begins the process of selecting appropriate standards and producing the profile technical specification in the form of a supplement to the Domain Technical Framework, describing how the existing IHE Technical Framework will be extended to accommodate this new profile (e.g. reuse of some existing constructs). By placing each new profile specification in a separate supplement, the reviewer's task is greatly simplified. The Technical Committee produces the Draft Supplements for a 30-day Public Comment. During this time, the supplements are available for review by the general public (developers, end users, system integrators) worldwide.

4. **Supplements for Trial Implementation** - At the conclusion of the Public Comment period, the Domain Technical Committee resolves all of the comments entered from the public comment, including comments generated by committee members. The outputs of this activity are the Supplements for Trial Implementation. These supplements are now ready for developers to implement and test in a trial mode.

   A number of subsequent steps in the deployment-validation process, presented in Clause 7, relate to the implementation of the Draft Supplements for Trial Implementation and its associated testing activities. This testing has two objectives: (1) test actual implementations for effective interoperability, as well as (2) validate the Integration Profile specification. In the course of implementation and during the Connectathon testing, developers will discover different interpretations of the framework and thus the need for further clarifications or possible corrections. The resulting modification suggestion(s) can then be submitted to the Technical Committee in the form of Change Proposals.

5. **Supplements Final Text** - The Technical Committee reviews any Change Proposals submitted on Trial Implementation Supplements within a few weeks. Approved changes are published for implementers' benefit. When both the Technical and Planning Committee judge that sufficient implementation experience has been gained and that the intended use case interoperability is achieved, all approved Change Proposals are applied to the Trial Implementation Supplement to produce a Supplement Final Text. These Final Text Supplements are now ready to be used for

implementation by product developers. They are guaranteed to be stable and implementers are encouraged to claim compliance in their product Integration Statement (see Annex A). These Final Text Supplements will also be folded into the subsequent release of the Technical Framework (See 8.4 for the Technical Framework maintenance).

This concludes the primary part of the development process. Only profiles in final text and national extensions when accepted are published in the corresponding Technical Frameworks. The maintenance process of these Technical Frameworks is also part of the development process and is described in 8.4. Any party can submit a Change Proposal to the relevant IHE Technical Committee for any Integration Profile in Trial Implementation or Final Text for which an incompatibility issue is uncovered in an implementation project. Resolution ensures that further implementations are facilitated.

The Quality Management rules applied by IHE ensure constant evolution in interoperability capabilities and provide solutions for a pragmatic path to reaching the desirable plug-and-play vision.

6 Deployment-validation process

The deployment-validation process delivers tangible implementation experience feedback, education, and test results. Unlike the development process, which is globally coordinated by IHE International, several instances of deployment-validation process operate in parallel, on a national basis (e.g. Japan) or on a regional basis, often on the basis of large parts of the world that regroup several IHE Countries (e.g. Europe or North America). Such Deployment Processes can be initiated at any time in the year by each IHE Regional Deployment Committee and as many times as desired (simply needs to ensure that there is a critical mass of participants). Yearly Connectathon by regions is the minimum interval to avoid excluding any interested participant, but more frequent Connectathon events in a specific region have been conducted and are expected to become common as the number of participants further expands.

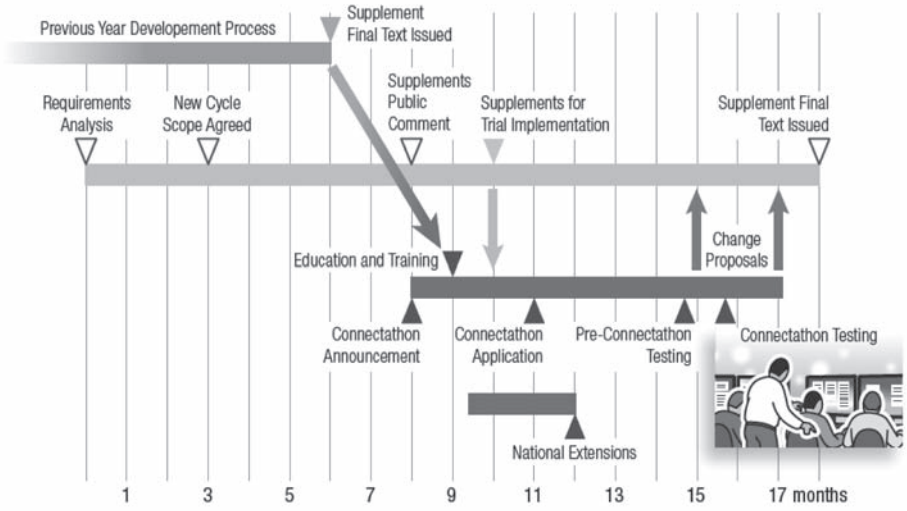

Figure 4 — Deployment-validation process in synchronization with the development process

Figure 4 represents a regional deployment-validation, which closely follows the development cycle, as well as the specification of a national extension. The deployment-validation process applies to both Final Text Profiles (ready for market deployment) and Trial Implementation Profiles (not yet ready for market deployment). This process has five major milestones:

1. **Connectathon Announcement —** Regional IHE Deployment Committees will issue an open call for developers (commercial or not) to participate in a Regional or National Connectathon. Participants will be offered to choose from: (1) new Trial Implementation Profiles, (2) existing Final Text Profiles, (3) National Extensions associated to one or more of the previous profiles.

2. **Education and Training —** Regional or National IHE Deployment Committees will typically organize workshops to educate end users and developers about the new and existing Integration Profiles in order to plan for a testing event or Connectathon, as well as demonstrations at local exhibitions.

3. **Connectathon Application —** Participating developers can register for the event called the Connectathon (further described below) with one or more implementation claimed to support one or more of the profiles proposed.

4. **Connectathon Pre-tests —** Each Connectathon has entrance criteria consisting of completion of a set of unit tests to be executed against IHE required test tools. These pre-Connectathon tests are supervised by the Sponsor-selected regional technical manager. The test tools (with a new generation tool called GAZELLE) are designed to test basic adherence to the profiles and to assist participants in their preparation for the Connectathon. Participants who do not successfully complete the software pre-tests are denied admission to the Connectathon to minimize disruption to those participants who are prepared.

5. **Connectathon Testing —** During the Connectathon event, developers bring their hardware/software implementations of one or more profiles together in one location (or virtual setting) for Sponsor-supervised testing. The Sponsors are responsible for procuring the test setting with network support and hiring a technical manager who administers those tests. Each participating system is tested for each registered combination of IHE Actor and IHE Integration or Content Profile. To successfully complete Connectathon testing, each system must test with at least three other peer systems as designated by the project manager. It is possible for one system to successfully test one basket of actor/profile combinations while not completing the testing for one or more other combinations. The recorded output of the Connectathon is a result matrix that lists by participant those combinations of IHE Actors, and Integration Profiles that have been successfully tested.

6. **National/Regional Extensions —** The national or regional extensions to the globally agreed profiles are specified by the deployment process as necessary. These are submitted to the relevant Domain Technical Committee, which review, approve, and publish them in a specific part of their Technical Framework.

The second output of the Connectathon is the list of issues discovered during implementation of the profiles by participating implementers (e.g. different interpretations of the Technical Framework or other errors). This information is fed back to the Technical Committee in the form of Change Proposals (See Development process, Clause 5, Milestone 5). The Technical Committee of each of the domains processes these correction proposals, resolves them, and incorporates them in the trial implementation version in order to produce the final text version. The final text version is then published and is the version that should be used for deployment and conformance (IHE Integration Statements. See Annex A).

An overview of the IHE Testing Process is presented in Figure 5.

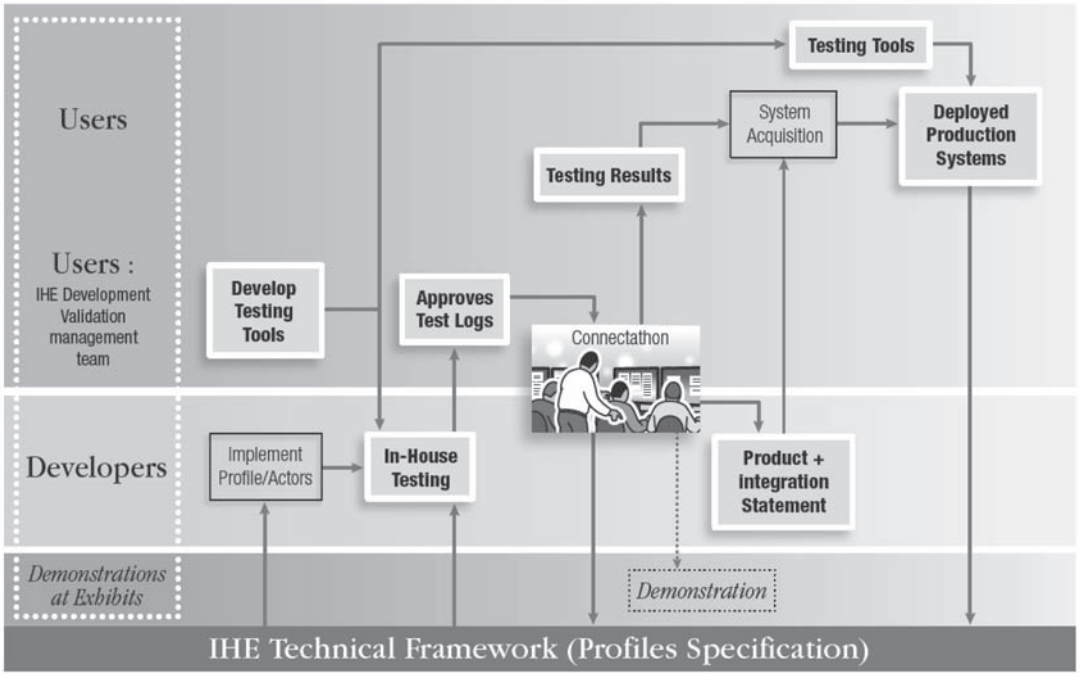

Figure 5 — Overview of the IHE testing process

7 Principle and policies

The IHE process is lead by Sponsors who primarily represent users of health IT technology, thus providing the necessary independence from the developers of health IT technology. Developers of technology solutions or products implementing IHE Profiles are engaged and welcomed into the IHE process. This ensures their buy-in and accelerates adoption in commercially available products, without allowing control of the overall standards adoption process, including the conformance testing process.

8 Overview of the Technical Framework

Each IHE Domain (Cardiology, Laboratory, IT Infrastructure, Patient Care Coordination, Patient Care Devices, etc.) publishes its own IHE Technical Framework. It is a document containing a set of Integration and Content Profiles supporting interoperability for a specific domain of clinical practice or technology infrastructure.

These Domain Technical Frameworks share many common structural and conceptual principles. A number of those principles are presented in this section:

— relationship to real-world architectures;

— general structure;

— relationship to base standards;

— manner in which implementations can conform.

8.1 Relationship to real-world architectures

Each Integration Profile, documented in a Domain Technical Framework, identifies a subset of the functional components of communicating IT systems within a real-world healthcare information system environment, called IHE actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions.

For each actor, the IHE Technical Framework defines only those functions associated with interoperability between information systems. The IHE definition of such a technical actor should therefore not be taken as the complete definition of any product that might implement it nor should the framework itself be taken to comprehensively describe the architecture of a healthcare information system or of a network of systems.

While some of the transactions are traditionally performed by specific product categories (e.g. HIS, Clinical Data Repository, Radiology Information Systems, Clinical Information Systems, or Cardiology Information Systems), the abstraction of actors

— avoids forcing the association with such product categories, allowing new product combinations to emerge and

— provides a basis for defining the interactions among functional components of the healthcare information system environment. In situations where a single physical product implements multiple functions, only the interfaces between the product and external functions in the environment are considered to be significant.

Therefore, IHE takes no position as to the relative merits of an integrated environment based on a single, all-encompassing information system versus one based on multiple systems that together achieve the same end. IHE facilitates the integration of multiple vendors' systems based on the IHE Technical Framework.

8.2 Structure of the Technical Frameworks

Each IHE Technical Framework is organized into several volumes.

Volume 1 of each Domain IHE Technical Framework provides a high-level view of the supported interoperability use case, identifying the actors that interact via transactions or content for each Integration or Content Profile.

Other volumes of the IHE Technical Framework provides detailed technical descriptions of each IHE transaction or content modules used in the Integration or Content Profiles of that domain. Some transactions or content modules can be re-used by Integration or Content Profiles of other IHE Domains.

A specific volume defines national or regional extensions to Integration or Content Profiles for that domain. National or regional practices or laws can require extensions to the baseline definitions for profiles in a domain.

8.3 Relationship to base standards

The IHE Technical Frameworks identify functional components of a distributed healthcare environment (referred to as IHE actors), solely from the point of view of their interactions. At its current level of development, it defines a coordinated set of transactions based on standards from various bodies (e.g. ASTM, CEN, CDISC, DICOM, HL7, IETF, ISO, LOINC, OASIS, IHTSDO, and W3C). As the scope expands, transactions based on other standards can be included as required.

The IHE Technical Framework does not duplicate but references the base standards. As necessary, IHE recommends selection of specific options supported by these standards; however, IHE does not introduce technical choices that contradict conformance to these standards. If errors in or extensions to existing standards are identified, the policy of IHE is to report them to the appropriate standards bodies for resolution within their conformance and standards evolution strategy.

IHE is therefore an implementation framework, not a foundation or base standard. IHE Integration Profiles are standardizing the way approved standards are implemented and clearly contribute to standardization of health information exchange [e.g. the U.S. ANSI-sponsored Healthcare Information Technology Standards Panel (HITSP) calls these profiles "Composite Standards"]. Conformance claims for implementations must still be made in direct reference to specific base standards. Implementation and conformance to IHE Profiles is discussed in Annex A.

8.4 IHE Technical Framework development and maintenance process

Each IHE Technical Framework is continuously maintained and expanded on an annual basis by the Technical Committee for that domain. The development and maintenance process of the Framework follows a number of principles to ensure stability of the specification so that both vendors and users can use it reliably in specifying, developing, and acquiring systems with IHE interoperability capabilities.

The first of these principles is that any extensions, clarifications, and corrections to a profile within a Technical Framework must maintain backward compatibility with previous releases of the profile in order to maintain interoperability with systems that have implemented IHE Actors and Transactions defined by that profile.

The IHE Technical Framework is developed and re-published annually with two types of input:

a) **Add new supplements that have been approved for final text.** As the Technical Committee develops supplements (public comments, trial implementation, and final text as explained in Clause 6), they are added to the current stable release of the Technical Framework when they reach final text.

b) **Maintain existing profiles.** The Technical Committee regularly considers change proposals to the profiles from the current stable release of the Technical Framework. The set of changes that have been approved since the last release of the Technical Framework are folded into a new release.

Vendors and other developers of software applications should use the latest published release of a Technical Framework.

8.5 Implementation of the Technical Framework

Developers have a number of choices in implementing IHE Profiles in systems and devices. These decisions cover three classes of narrowly defined choices:

a) For a system, select which profile(s) it needs to support.

b) For each profile, select one or more actors available in this profile under which it will participate. (Multiple Actors per system or device are acceptable.)

c) For each actor and profile pair, select the profile options to be implemented. Very few profile options exist in IHE Integration and Content Profiles.

All required transactions for a specific actor must be implemented for the profile to be supported.

Implementers shall provide a statement describing which IHE Actors, IHE Integration, or Content Profiles are incorporated in a given product. The form for such a statement is defined in Annex A of this part of ISO/TR 28380. By comparing the IHE Integration Statements from different products, a user familiar with the IHE concepts of actors and Integration Profiles can determine the level of integration between them. Vendors publishing IHE Integration Statements accept full responsibility for their content.

In general, a product implementation can incorporate any single actor or combination of actors. When two or more actors are grouped together, internal communication between actors is assumed to be sufficient to allow the necessary information flow to support their functionality. The exact mechanisms of such internal communication are outside the scope of the IHE Technical Framework.

When multiple actors are grouped in a single-product implementation, all transactions originating or terminating with each of the supported actors shall be supported (i.e. the IHE transactions shall be offered on an external product interface), except when exceptions are explicitly allowed in the profile.

Annex A
(informative)

IHE Integration Statement template

A.1 General

IHE Integration Statements are documents prepared and published by developers, especially vendors, to describe the conformance of their products with the IHE Technical Framework. They identify the specific IHE capabilities a given product supports in terms of IHE Actors and Profiles.

Users familiar with these concepts can use Integration Statements to determine what level of integration a vendor asserts a product supports with complementary systems and what clinical and operational benefits such integration might provide. Integration Statements are intended to be used in conjunction with statements of conformance to specific standards (e.g. ISO, HL7, IETF, DICOM, W3C).

IHE provides a process for developers to test their implementations of IHE Actors and Profiles. The IHE testing process, culminating in a multi-party interactive testing event called the Connectathon, provides developers with valuable feedback and provides a baseline indication of the conformance of their implementations. The process is not intended to independently evaluate, or ensure, product compliance. In publishing the results of the Connectathon and facilitating access to developers' IHE Integration Statements, IHE and its sponsoring organizations are in no way attesting to the accuracy or validity of any developer's IHE Integration Statements or any other claims by vendors regarding their products.

NOTE Developers have sole responsibility for the accuracy and validity of their IHE Integration Statements. Developers' Integration Statements are made available through IHE for consideration by parties seeking information about the integration capabilities of particular products. IHE and its sponsoring organizations have not evaluated or approved any IHE Integration Statement or any related product, and IHE and its sponsoring organizations shall have no liability or responsibility to any party for any claims or damages, whether direct, indirect, incidental, or consequential, including, but not limited to, business interruption and loss of revenue, arising from any use of, or reliance upon, any IHE Integration Statement.

A.2 Structure and content of an IHE Integration Statement

An IHE Integration Statement for a product shall include

a) the vendor or developer Name,

b) the Product Name (as used in the commercial context) to which the IHE Integration Statement applies,

c) the Product Version to which the IHE Integration Statement applies,

d) a publication date and optionally a revision designation for the IHE Integration Statement,

e) the following statement: "This product implements all transactions and content required in the IHE Technical Framework to support the IHE Integration and Content Profiles, Actors and Options listed below:", and

f) a list of IHE Profiles supported by the product and, for each profile, a list of IHE Actors supported. For each Integration or Content Profile/Actor combination, one or more of the options defined in the IHE Technical Framework can also be stated. Profiles, Actors, and Options shall use the names defined by the IHE Technical Framework Volume 1.

NOTE 1 The vendor can also elect to indicate the release number of the Technical Framework referenced for each profile.

NOTE 2 Implementation of the profile implies implementation of all required transactions for an actor, as well as selected options.

The statement shall also include references and/or Internet links to the following information:

— specific Internet address (or universal resource locator [URL]) where the vendor's Integration Statements are posted;

— URL where the vendor's standards conformance statements (e.g. HL7, DICOM) relevant to the IHE transactions implemented by the product are posted;

— URL of the IHE Initiative's web page for general IHE information (www.ihe.net).

An IHE Integration Statement is not intended to promote or advertise aspects of a product not directly related to its implementation of IHE capabilities.

A.3 Format of an IHE Integration Statement

Each Integration Statement shall follow the format shown below. Vendors can add a cover page and any necessary additional information in accordance with their product documentation policies.

IHE Integration Statement		**Date**	**12 Oct 2012**
Developer	**Product Name**	**Version**	
Any Medical Systems Co.	Integrate Record	V2.3	
This product implements all transactions and content required in the IHE Technical Framework to support the IHE Integration and Content Profiles, Actors and Options listed below:			
Integration and Content Profiles Implemented	**Actors Implemented**	**Options Implemented**	
Cross-Enterprise Document Sharing	Document Source	None	
Cross-Enterprise Document Sharing	Document Consumer	None	
Cross-Enterprise Sharing of Lab Reports	Content Consumer	None	
Audit Trail and Node Authentication	Secured Node	None	
Patient Identity Cross-referencing	Patient Identifier Cross-reference Consumer	PIX Update Notification	
Internet address for vendor's IHE information: www.anymedicalsystemsco.com/ihe			
Links to Standards Conformance Statements for the Implementation			
HL7	www.anymedicalsystemsco.com/hl7		
Links to general information on IHE			
In North America: www.ihe.net	In Europe: www.ihe-europe.org	In Japan: http://www.ihe-j.org/	

Figure A.1 — IHE Integration Statement

Annex B
(informative)

IHE sponsoring organizations

NOTE This annex may not be complete.

B.1 List of development sponsoring organizations

This section contains a list of sponsoring organizations and the domains they manage.

- American Academy of Ophthalmology (AAO) – Eye Care
- American College of Cardiology (ACC) – Cardiology
- Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH) – Laboratory
- Healthcare Information and Management Systems Society (HIMSS) – IT Infrastructure, Patient Care Coordination
- Japan Association of Healthcare Information Systems Industry (JAHIS) – Laboratory
- Radiological Society of North America (RSNA) – Radiology
- Société Française d'Informatique de Laboratoire (SFIL) – Laboratory
- American College of Clinical Engineers – Patient Care Devices
- Association pour le Développement de l'Informatique en Cytologie et en Anatomie Pathologiques (ADICAP) – Pathology

B.2 Asia - List of regional sponsoring and supporting organizations

B.2.1 Japan

This section contains a list of regional sponsoring and supporting organizations.

- Ministry of Economy, Trade and Industry (METI)
- Ministry of Health, Labour and Welfare (MHLW)
- Medical Information Systems Development Centre (MEDIS-DC)
- Japan Industries Association of Radiological Systems (JIRA)
- Japan Association of Healthcare Information Systems Industry (JAHIS)
- Japan Radiological Society (JRS)
- Japan Society of Radiological Technology (JSRT)
- Japan Association of Medical Informatics (JAMI)

B.2.2 Taiwan

- See http://wiki.ihe.net/index.php?title=Taiwan'.

B.2.3 Korea

- See http://wiki.ihe.net/index.php?title=Korea.

B.3 Europe - List of regional sponsoring and supporting organizations

IHE-Europe is an umbrella organization that federates several IHE National Chapters in Europe. At the European level it includes:

- European Society of Radiology (ESR)
- European Coordination Committee of the Radiological Electromedical and Medical Informatics Industries (COCIR)
- European Society of Cardiology (ESC)

B.3.1 France

- Groupement d'Intérêt Public – Groupement pour la Modernisation du Système d'Information Hospitalier (GIP GMSIH)
- Société Française de Radiologie (SFR)
- Société Française d'Informatique de laboratoire (SFIL)
- Association pour le Développement de l'Informatique en Cytologie et en Anatomie Pathologiques (ADICAP)
- Groupement d'Intérêt Public – Carte de Professionnel de Santé (GIP CPS)
- Groupement d'Intérêt Public – Dossier Médical Personnel (GIP DMP)

B.3.2 Germany

- Deutsche Roentgengesellschaft (DRG)
- Zentralverband Elektrotechnik- und Elektronikindustrie (ZVEI)

B.3.3 Italy

- Società Italiana di Radiologia Medica (SIRM)
- Ministry of Health

B.3.4 Norway

- KITH – Norwegian Centre for Informatics in Health and Social Care

B.3.5 Spain

- HL-7 ESPAÑA (HL7-SP)
- Sociedad Española de Informática de la Salud (SEIS)
- Sociedad Espanola de Radiologia Medica (SERAM)

B.3.6 The Netherlands

- Amphia Ziekenhuis (Amphia)
- De Orde Van Medisch Specialisten (OMS)

- HL7 Netherlands (HL7)
- Nationaal ICT Instituut in de Zorg (NICTIZ)
- Nederlandse Vereniging voor Radiologie (NVvR)
- TNO Prevention and Health (TNO)

B.3.7 United Kingdom

- British Institute of Radiology (BIR)
- Institute of Physics and Engineering in Medicine (IPEM)
- Connecting for Health Agency (CfH)
- Royal College of Radiologist (RCR)
- The Society of Radiographers (SOR)
- Picture Archiving and Communication Systems National Evaluation Team (PACSnet)

B.3.8 Denmark

- http://www.ihe-dk.dk/

B.3.9 Austria

- http://www.ihe-austria.at/

B.4 North America - List of regional sponsoring and supporting organizations

B.4.1 Canada

- Canada Health Infoway-Inforoute Santé du Canada (Infoway)
- Canadian Healthcare Information Technology Trade Association (CHITTA)
- Information Technology Association of Canada (ITAC)
- Ontario Hospital Association (OHA)
- HIMSS-Ontario (HIMSS)
- Université du Québec, École de Technologie Supérieure (ETS)
- Canadian Association of Radiologist (CAR)

B.4.2 United States of America

- American Academy of Ophthalmology (AAO)
- American Association of Physicists in Medicine (AAPM)
- American College of Cardiology (ACC)
- American College of Clinical Engineering (ACCE)
- American Society for Therapeutic Radiology and Oncology (ASTRO)
- Healthcare Information and Management Systems Society (HIMSS)

- Radiological Society of North America (RSNA)
- American College of Physicians (ACP)

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