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# **Integrating the Healthcare Enterprise (IHE) International Principles of Governance**

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Approved for Interim Use

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## 1. Introduction

60 Integrating the Healthcare Enterprise (IHE) International is an organization that enables users  
and developers of information technology for healthcare to achieve interoperability of systems  
through the precise definition of healthcare tasks, the specification of standards-based  
communication between systems required to support those tasks and the testing of systems to  
65 determine that they conform to the specifications. The work is managed by IHE committees and  
sponsored by various national and international bodies.

This Principles of Governance document describes the organization, policies and procedures of  
IHE International. It was officially adopted by the Board of IHE International on October 5,  
2007. Currently, IHE International is an unincorporated association composed of many member  
70 organizations. The IHE International Board has expressed the intention to undertake the legal  
steps necessary to form a non-profit corporation by March 2008. The current document will  
govern IHE International activities until the process of incorporation is complete, at which time  
it will be superseded by the articles of incorporation and a policies and procedures manual for  
IHE International, Inc.

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## 2. Mission

80 The goal of IHE is to improve the ability of computer systems in healthcare to share information  
so that all information relevant to a patient's care is available to the patient and the care provider  
when required. The driving needs for this work include:

- facilitating the seamless exchange of health information among care providers both  
within the enterprise and across care settings
- providing interoperability capabilities to support the deployment of electronic health  
85 records in their various national and regional contexts
- enabling local, national and regional health information networks
- addressing needs for security and privacy
- improving the efficiency and effectiveness of healthcare workflows

- and generally removing barriers to safe and optimal patient care

90 IHE engages developers and users of healthcare IT systems in a collaborative forum for  
identifying and resolving interoperability problems facing healthcare. IHE promotes and  
accelerates the coordinated adoption of established standards by creating and maintaining  
Technical Documents, including implementation guidelines called IHE Profiles, which are  
published in a set of documents called the IHE Technical Frameworks. IHE encourages  
95 harmonization and global adoption of the guidelines by collaborating with national and regional  
groups. IHE fosters compatible implementations of the Profiles by organizing testing events and  
associated educational seminars.

Systems that conform to IHE Profiles communicate more effectively, are more easily  
implemented, and enable efficient, secure access to relevant health information, both within  
100 healthcare delivery organizations and between different care settings and administrative entities.

## 2.1. Principles

IHE operates under the following guiding principles:

1. *Transparency.* Essential information regarding governance, activities and decisions of the Committees is accessible to all parties on a timely basis.
- 105 2. *Openness.* Participation is open to all affected interests.
3. *Stakeholder Representation.* The governance and all activities include broad representation from stakeholders.
4. *Healthcare Leadership.* Leadership by organizations of clinical, administrative, engineering and IT professionals in healthcare is critical to addressing the right  
110 problems and designing clinically useful solutions.
5. *Industry Engagement.* Participation by healthcare systems and equipment vendors is critical to ensure the viability of solutions designed and the timely implementation of effective products.
6. *Impartiality and Balance.* No one interest dominates the process or is favored over  
115 another among competing interests and various stakeholders.
7. *Due Process.* Decisions are arrived at by procedures that assure all views are considered and a dispute resolution process is provided.
8. *Consensus.* Unanimous consent is sought on all decisions, with recorded votes resorted to only when the issue must be closed and no more time is available to resolve  
120 differences.
9. *Competition.* Recognizing that the membership of IHE includes business organizations that compete directly with one another, normal considerations of appropriate legal boundaries, including antitrust, will be observed.
- 125 10. *Relevance.* Developed specifications address clearly defined and widely shared healthcare needs.

11. *Effectiveness*. Activities are scoped such that each results in a practical result in one or at most two years.
12. *Interoperability-orientation*. Developed specifications focus on details essential to interoperability rather than application design details.
- 130 13. *Harmonization*. Developed specifications resolve overlaps and conflicts between selected standards.
14. *Respect local healthcare practices*. Developed specifications shall recognize and support variations in care practices in member regions and nations.

### 3. Organizational Overview

135 IHE activities fall into two categories and IHE is organized to reflect this:

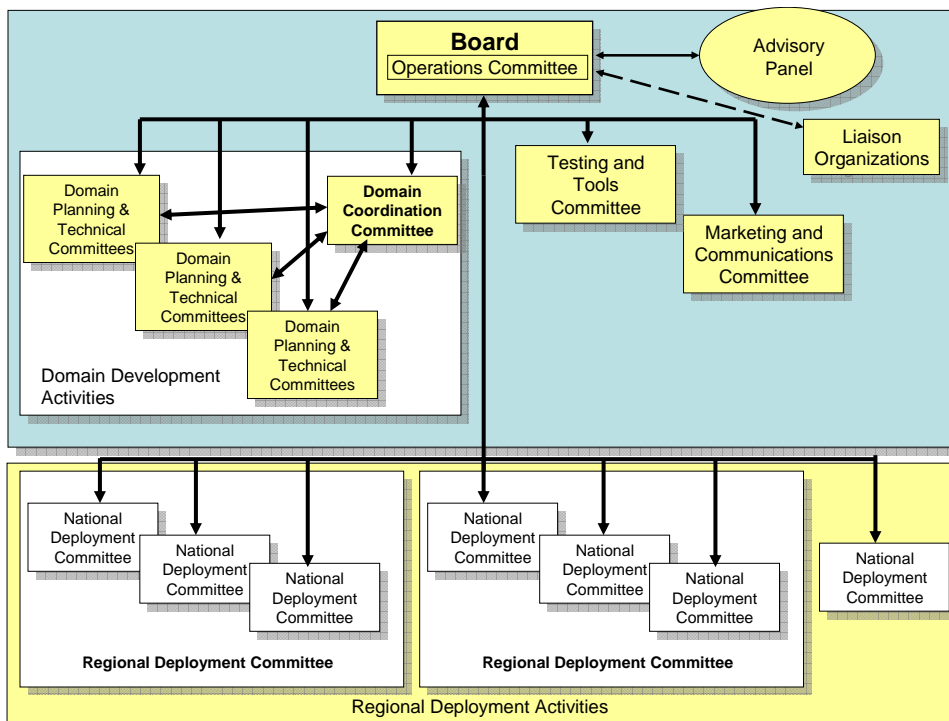
1. *Development activities*: the work that leads to publication of the IHE Technical Frameworks; international in scope; organized along clinical and operational domains. Typically within each Domain, a Planning Committee annually selects the use cases and a Technical Committee profiles the use of standards to address the use case,  
140 documenting them in Technical Framework documents and their supplements. A Domain Coordination Committee ensures that consistent processes and technical directions are followed.
2. *Deployment activities*: regional/national testing and demonstrations of the profiles contained in the Technical Frameworks and their supplements, as well as promotional and educational efforts. Testing activities include the development of testing software and related tools. Deployment activities are organized by National and Regional  
145 Deployment Committees that are separate entities with a close collaborative relationship with IHE International.

150 The sections below provide further detail on the scope of responsibilities and composition of the committees briefly described here:

- The *Board* and its *Board Operations Committee* govern the other committees of IHE International. They empower and coordinate National and Regional Deployment Committees.
- The *Testing and Tools Committee* coordinates IHE testing activities conducted by  
155 National and Regional Deployment Committees, including the development of testing software and other tools.
- The *Marketing and Communication Committee* coordinates IHE marketing and communication activities and resources.
- The *Advisory Panel* is a group of invited leaders in healthcare information technology and related fields, who agree to provide guidance to the IHE Board.
- 160 • *Domain Committees* (Planning and Technical) develop the IHE Technical Frameworks, the interoperability specifications which are the foundational work product of IHE.

- The *Domain Coordination Committee* ensures consistent processes across IHE Domains and promotes effective communication and coordination among them.
- 165 • *National and Regional Deployment Committees* are empowered by the IHE Board to conduct testing, demonstrations, educational events and other deployment activities within their geographic area. They also develop National Extensions to the IHE Technical Frameworks to address local variations in care delivery. They develop their own governance rules and business models, but adhere to the general principles expressed in this document and the guidelines outlined in Section 8 and 9 below.
- 170 • *Liaison Organizations*, including relevant Standards Development Organizations, enter into mutual agreements with IHE International to communicate on and coordinate complementary activities.

The committees and their relationships are shown in the diagram below:



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## 4. Board and Board Operations Committee

### 4.1. Scope

180 The IHE International Board is the broadest oversight body of IHE and is responsible for overall management, direction, coordination and governance.

It performs this by management of IHE international development activities, oversight of the deployment activities conducted by the partner national and regional deployment organizations.

The Board's responsibilities include, but are not limited to:

1. Ensuring that the principles of governance are upheld and maintained;
- 185 2. Defining the IHE mission, goals and objectives
3. Annually reviewing the scope, duties and membership of all IHE Domains and Regions.
4. Establishing and periodically renewing international cooperation agreements with relevant organizations.
- 190 5. Providing guidance and coordination among national and regional deployment efforts
6. Incubating expansion of new national and regional committees
7. Providing guidance to domain committees
8. Incubating expansion of new domain activities and committees
9. Resolving conflicts referred to them by other Committees
- 195 10. Recruiting relevant professional societies as sponsoring and collaborating organizations
11. Recruiting stakeholders for planning and technical committee membership
12. Developing and implementing policies related to trademark and publication issues
13. Directing communications about the IHE initiative through the Marketing and Communication Committee
- 200 14. Representing IHE International in public forums and other communications venues.
15. Providing IHE Liaison with standards groups and other non-governmental organizations
16. Reviewing and approving a budget for IHE development activities to be developed and submitted annually by the Secretariat of the Board.

## 205 **4.2. Membership and Procedures**

The Board membership and procedures shall follow those described in Section 10, General Membership and Procedures, but differ from or expand on those procedures as follows:

### **4.2.1. Membership**

210 The Board shall be composed of representatives of active Member Organizations. There are six categories of Board Members with the following qualifications:

1. Each IHE International Sponsor shall designate a principal representative and an alternate, both drawn from the community represented by the sponsor. [4-6 MEMBERS EXPECTED]

- 215 2. The overall active Membership shall elect, for 2-year terms, four voting members-at-large. Half of their terms shall expire in alternate years. They shall belong to member organizations other than those already represented on the Board. [4]
- 220 3. Each Domain Planning Committee shall designate for two-year terms a principal representative and an alternate, who may be drawn from either the Domain Planning or Technical Committee active membership (Co-chairs are recommended). They shall belong to other member organizations than those already represented on the Board. [10-12 AND GROWING]
- 225 4. The Board shall elect, for 2-year terms, two voting representatives drawn from the pool of past Domain co-chairs. Their terms shall expire in alternate years. They shall belong to member organizations other than those already represented on the Board. [2]
5. Each Regional Committee shall designate a principal representative and an alternate. [3]
6. Each National Committee shall designate a principal representative and an alternate. [8-15]

[APPROXIMATE COUNT: 35 TOTAL]

#### 230 **4.2.2. Committee Structure**

The Board shall elect as co-chairs, two Board Members drawn from Member Organizations in the User category. They will serve as co-chairs for renewable two-year terms.

#### **4.2.3. Matters Requiring Formal Decision**

The following actions shall be formally approved by the Board:

- 235 1. Modification of the Charter, IHE governance documents or operating procedures;
2. Creation, changes in scope or dissolution of an IHE Domain
3. Creation, changes in scope or dissolution of an IHE Regional or National Committee.
4. Election of officers and at-large members of the Board Operations Committee;
5. Considering and acting on proposals for termination of the Board, Domain co-chairs;
- 240 6. Election of co-chairs
7. Approval of yearly budget
8. Legal decisions

#### **4.2.4. Announcements and Publications**

245 Face-to-face meetings of the IHE Board shall be announced not less than 60 days prior to the meeting. An agenda shall be published no later than 30 days prior to the meeting.

Teleconference meetings shall be announced not less than 9 days prior to the meeting. An agenda shall be published no later than 3 days prior to the meeting.

The documents published by IHE International, in particular the Technical Frameworks, will have a copyright under IHE International.

#### 250 **4.2.5. Establishing New Domains**

A proposal to establish a new IHE Domain shall be addressed to the Secretary of the IHE Board and shall indicate:

1. The organization(s) proposed to act as Domain Sponsor(s) (typically a professional society or coalition of societies associated with users in the proposed Domain)
- 255 2. The name and contact information of a nominee for the Secretary of the proposed Domain
3. The scope of interest to be addressed by the domain (preferably with an initial list of proposed problems worth addressing)
- 260 4. A list of IHE Regional/National Committees that support the creation of the new domain;
5. An initial list of developer members likely to join/participate
6. An initial list of user or general interest members likely to join/participate
7. A rationale for creating the new domain, including explanation of why the proposed work cannot be performed in one or more existing domains

265 A domain proposal shall be published to the Board membership at least 45 days prior to the meeting where the vote shall be taken to allow time for regions and existing domains to review and discuss the proposal.

The IHE International Committee shall consider the maturity of the proposal, its timeliness, international backing, its proposed sponsors and their prospective ability to lead the new domain.

270 The International Board shall take a vote to accept or reject the proposal.

When a proposal for a new domain is approved, its sponsors shall provide a plan for launching domain activities and supply contacts to begin participating in the IHE Board and other general IHE committees.

#### **4.2.6. Establishing New National and Regional Deployment Committees**

275 An application to establish a new IHE Regional or National Deployment Committee shall be addressed to the Secretary of the Board of IHE International by one or more prospective sponsoring organizations. An application form will be available from the Secretariat of the Board. The application shall identify:

- 280
1. The organizations proposed to act as sponsors for the Regional or National Committee (typically a professional society or coalition of societies associated with users or developers in the proposed Regional or National Committee)
  2. The name and contact information of a nominee for Committee Secretary
  3. An initial list of Developer category members likely to join/participate
  4. An initial list of User members likely to join/participate
- 285
5. Indication of potential areas of interest

A Regional or National Committees proposal shall be submitted for consideration to the Secretary of the Board of IHE International. The Board shall consider the maturity and timeliness of the proposal, and the prospective ability of its sponsors to lead the new Regional or National Committees. In the case of a new National Committee in a region with an existing

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Regional Committee, the Board shall also consult with that Regional Committee on the appropriateness of the application. Within 45 days from submission, the Board shall take a vote to accept or reject the proposal and inform the applying organization of its decision.

When a proposal for a new National or Regional Committee is approved, its sponsors shall provide a plan for launching domain activities and supply contacts to begin participating in the

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IHE Board and other general IHE committees. Within 6 months sponsors of the National or Regional Committee shall submit a draft governance plan to the Secretary of the Board.

#### **4.2.7. Board Operations Committee**

The Board shall form a Board Operations Committee to facilitate its operations. The responsibilities of the Board Operations Committee include:

- 300
1. Providing advice to the sponsoring organizations in the business and financial governance of the IHE International Board
  2. Development of an annual budget for Board committee activities, which it presents to the Board for approval
  3. Providing advice on, and resolution of, administrative issues as requested by the Board
- 305
4. Developing recommendations to the Board to facilitate its review and decision process.
  5. Fulfilling other responsibilities specifically delegated by the Board.

The Board Operations Committee membership consists of a subset of members of the Board:

1. The Co-chairs of the Board [2]
- 310
2. One representative from each active Region in IHE [3]
3. Three members-at-large elected by the Board from its membership. [3]
4. One staff representative from each IHE International Sponsor, as nonvoting representatives [3 or more]

315 A quorum of two-thirds of current members shall be required for all votes of the Board Operations Committee.

Board Operations Committee meeting minutes shall be distributed promptly to all Board members for information.

Any Board member may request that a Board Operations Committee decision or action be placed on the agenda of a subsequent meeting or Teleconference of the International Board.

320 At the subsequent meeting or teleconference, the Board may, through a two-thirds majority vote, reverse, negate or otherwise modify the Board Operations Committee action.

#### **4.2.8. Advisory Panel**

325 The Board may form an Advisory Panel of leaders in healthcare information technology and related fields, who agree to provide guidance to the Board. Members of the Advisory Panel serve by invitation of the Board for renewable two-year terms.

#### **4.2.9. Liaison Organizations**

Liaison Organizations are entities, including standards development organizations, with which IHE establishes working relationships to advance shared objectives in keeping with the mission of IHE.

330 A Liaison Organization relationship may be formalized in a Memorandum of Understanding that shall be approved by a vote of the International Board.

### **4.3. Sponsors and Associate Organizations**

335 Certain IHE Member Organizations shall assume the Sponsor roles described below. Each IHE Committee shall be sponsored by one or more relevant Member Organizations which together organize the Secretariat and appoint the Committee Secretary.

The specific responsibilities of committee Sponsors and Secretariat are described in the relevant Committee sections elsewhere in this document.

#### **4.3.1. IHE International Sponsors**

340 IHE International Sponsors are Member Organizations of IHE International that sponsor Domain Committees and Regional/National Deployment Committees, as well as assuming the additional responsibilities described below:

1. Acting as the Secretariat for general committees of IHE International, including the Board, Advisory Panel, Marketing and Communications Committee and Tools and Testing Committee
- 345 2. Assuming significant financial responsibility for the general committees of IHE International, including the Board and its Board Operations Committee, the Marketing and Communications Committee and the Testing and Tools Committee

3. Publishing the IHE Technical Frameworks
4. Providing legal advice, support, indemnifications and accountability to the Board
- 350 5. Supporting the development of testing tools and hosting IHE Connectathons and related events
6. Developing an annual budget for IHE International and presenting it to the Board Operations Committee and Board for approval

355 They shall adhere to the principles of IHE and promote the broad success of the initiative worldwide.

360 The Board shall have the authority to consider and, in its discretion, approve a Member Organization's participation as an IHE International Sponsor. Organizations wishing to become IHE International Sponsors may apply to the Secretariat of the Board and, if approved, shall enter into a written agreement with IHE International. Under such an agreement, a newly added IHE International Sponsor will share the expense and responsibilities of supporting the Secretariat of the International Board with the other IHE International Sponsors. Such agreements shall have an initial term of three years and may be renewed by the Board for additional three-year terms.

#### **4.3.2. Domain Sponsors**

365 Domain Sponsors shall be Member Organizations in the User Category which do not have direct or indirect responsibilities in the acquisition decision of systems implementing IHE specified capabilities. Domain Sponsors generally come from Healthcare Professional Organizations (clinical, IT, administrative, public health, etc.) or Governmental Agencies. In supporting development activities of IHE International in the domain (or domains) relevant to their membership and mission, they shall adhere to the principles of IHE and promote the broad success of the initiative worldwide.

Domain Sponsors take responsibility for development of IHE Technical Frameworks and associated documents in the domain (or domains) relevant to their membership and mission.

#### **4.3.3. National/Regional Deployment Sponsors**

375 National/Regional Sponsors shall be Member Organizations in the User, Developer or General Interest categories with no direct or indirect responsibilities in developing for sale, or making acquisition decisions about implementing, systems with IHE-specified capabilities. National/Regional Sponsors generally come from Healthcare Professional Organizations (clinical, IT, administrative, public health, etc.), Trade Associations, Health Research or Governmental Agencies (This may be further refined by each Regional/National Committee). In supporting deployment activities in a National/regional Deployment Committee in a country or group of countries relevant to their membership and mission, they shall adhere to the principles of IHE and promote the broad success of the initiative worldwide.

385 National/Regional Initiative Sponsors take responsibility for supporting IHE deployment activities, including the IHE implementation testing process, in a given nation or region. The

main role of these sponsors is directly related to National and Regional IHE Deployment Committees.

#### **4.3.4. Associate Organizations**

390 Associate Organizations are Member Organizations that have indicated their support for the  
goals of the IHE initiative and their willingness to help in communicating information about it to  
their membership and industry vendors in their environment. These organizations have no  
specific responsibilities for development or deployment activities. They agree to allow the use of  
their logo in publications describing the IHE initiative and to share communications about IHE  
395 recruit and support volunteer domain experts from among their membership to take part in  
domain committee activities.

### **5. Domain Committees**

#### **5.1. Scope**

400 Each domain shall be responsible for the development and maintenance of an IHE Technical  
Framework addressing interoperability in its particular domain of healthcare, as defined by the  
Board.

#### **5.2. Sponsorship and Secretariat**

405 The Board shall consider and ratify a Member Organization's participation as a Domain Sponsor.  
Organizations wishing to become Domain Sponsors may apply to the Secretariat of the Board  
and shall enter into a written agreement with IHE International. Under such an agreement, a  
Domain Sponsor takes responsibility for supporting the operations of the Domain Planning and  
Technical Committees in its domain. Such Agreements are granted for three years and may be  
renewed by the Board for additional three-year terms.

410 Domain Sponsors take responsibility to provide financial and other resources to support the  
activities of a domain that is relevant to their membership and mission. This includes the  
development and maintenance of an IHE Technical Framework and associated documents.

The Domain Sponsor shall appoint a Secretary to support the operation of the Domain  
Committees. The Domain Committee Secretary is responsible for:

- 415 1. Organizing and hosting domain planning and technical committees composed of  
volunteer domain experts and IHE Member representatives.
2. Coordinating with the IHE International Sponsors and Domain Coordination  
Committee to publish the work of their domain committees under IHE International  
Copyright;
- 420 3. Providing information for publication about their membership, plans, process and work  
product (e.g., via the www.ihe.net Website).

### **5.3. Committee Structure**

425 Generally each Domain has a separate Domain Planning Committee and Domain Technical Committee. This allows the use case definition, and the selection and prioritization of work items to be distinguished from the more technical work of specifying the use of the standards in supporting specific use cases.

Some Domains may chose to operate under a combined Planning and Technical Committee. In this case the procedures described below for Planning and Technical Committees shall be applied as distinct phases of the combined Committee's work.

### **5.4. Domain Planning Committees**

#### **430 5.4.1. Scope**

An IHE Domain Planning Committee prioritizes and coordinates the development activities of the domain, and the production of basic marketing and education materials for the domain.

435 Domain Planning Committees are responsible for receiving and analyzing use cases and interoperability problems faced by users, prioritization of these use cases, detailed workflow analysis and refining its scope, overseeing the specification of an implementation guide or profile ensuring interoperability among the communicating systems involved in the use case.

IHE Domain Planning Committees are responsible for:

1. Soliciting input from Regional/National Deployment Committees on current problems;
2. Developing work item proposals to address identified interoperability needs;
- 440 3. Prioritizing and selecting work items, based on global analysis of the needs for the Domain, the Domain scope, fit with existing IHE Profiles and feasibility evaluations from the Technical Committee;
4. Advising the Technical Committee;
5. Developing white papers on relevant issues;
- 445 6. Coordinating development of education and marketing materials for new Profiles; and
7. Communication and coordination of development activities across domains.

A Domain Planning Committee may elect to refer appropriate issues to the IHE Domain Coordination Committee or the Board for advice or resolution.

#### **5.4.2. Membership and Procedures**

450 The policies and procedures of Domain Planning Committees differ from or expand on those described in Section 10, below, as follows:

#### **5.4.2.1. Committee Structure**

455 The Committee may choose to establish internal Liaisons with other Domain Planning Committees or Regional/National Committees to address the need for close cooperation and communication.

It is recommended that one Domain Planning Committee co-chair be selected from the User member category and one from the Developer member category.

#### **5.4.2.2. Actions Requiring Approval**

460 The following actions shall be approved by expressed consensus or a recorded vote of the Domain Planning Committee:

1. Creation or dissolution of a subcommittee
2. Creation/removal of new internal Liaison positions
3. Selection of work items for each annual cycle
- 465 4. Approval of supplements to the IHE Technical Framework proposed for Final Text release by the Domain Technical Committee
5. Proposals to the IHE International Board for termination of the Committees of the Domain

### **5.5. Domain Technical Committees**

#### **5.5.1. Scope**

470 Each IHE Domain generally has a Technical Committee to carry out the work items identified by the Planning Committee and develop the resulting technical specifications and whitepapers.

An IHE Domain Technical Committee is responsible for:

1. Assessing the feasibility of work item proposals from the Planning Committee
- 475 2. Selecting and harmonizing appropriate standards to address interoperability needs in selected work items
3. Developing detailed implementation documentation for selected work items
4. Documenting testing requirements in adherence with guidelines developed by the Testing and Tools Committee for Profiles they develop
5. Developing the IHE Technical Framework of the Domain
- 480 6. Maintaining the IHE Technical Framework according to a change management process
7. Reviewing and approving for publication National Extensions submitted by National Deployment Committees for the Domain Technical Framework

8. Soliciting and responding to input from National and Regional Deployment Committees on technical solutions developed

485 9. Responding to requests for interpretations of the Committee's Profiles

10. Adopting Committee policy and procedures and revisions thereof

The technical specifications documents developed by Domain Technical Committees, including the Technical Framework and Supplements, are published by the Domain Secretariat in conjunction with the IHE International Secretariat.

490 **5.5.2. Membership and Procedures**

The policies and procedures of the Domain Technical Committees differ from or expand on those described in Section 10, below, as follows:

**5.5.2.1. Committee Structure**

495 The Committee may choose to establish internal Liaisons with other Domain Technical Committees or Regional/National Committees to address the need for close cooperation and communication.

**5.5.2.2. Actions Requiring Approval**

The following actions shall be approved by expressed consensus or a recorded vote of the IHE Domain Technical Committee:

500 1. Creation or dissolution of a subcommittee

2. Creation/removal of new internal Liaison positions

3. Evaluation of work items for each annual cycle

4. Release of supplements to the IHE Technical Framework for public comment

5. Release of supplements to the IHE Technical Framework for trial implementation

505 6. Release of each revision of the Domain Technical Framework

7. Inclusion of change proposals in trial implementation supplements or in final text of the Domain Technical Framework.

8. Proposals to the IHE International Board for termination of the Committees of the Domain

510 **5.5.3. Announcements and Publications**

Domain Technical Committees shall adhere to procedures described in the Policies and Procedures document for the review and publication of the Technical Framework and related documents, including the development of supplements through public comment and trial implementation and final text revisions and associated Committee decision points.

## 515 **6. Domain Coordination Committee**

### **6.1. Scope**

The Domain Coordination Committee is responsible for ensuring consistent processes across IHE Domains and promoting effective communication and coordination among them. Domain Coordination Committee activities include:

- 520 1. Sharing experience and advice on best practices, including mentoring of newly created Domains
2. Discussing and collecting input on Profiles that may cross Domain boundaries
3. Coordinating Domain development and publication schedules
- 525 4. Develop, in conjunction with the Testing and Tools Committee, a consistent approach to ensuring testability of Profiles
5. Developing common operational procedures (change proposal handling, profile standards selection, etc.)
6. Developing common infrastructure for efficient committee work
- 530 7. Ensuring consistency in content and format among Technical Frameworks and related documents published by all IHE Domains
8. Review and approval of IHE Profiles prior to their publications as final text

### **6.2. Membership and Procedures**

#### **6.2.1. Membership**

535 The Domain Coordination Committee is composed of the current co-chairs of all Domain Planning and Technical Committees.

#### **6.2.2. Secretariat**

The IHE International Sponsors shall jointly provide the Secretariat for the Domain Coordination Committee.

## **7. Testing and Tools Committee**

### 540 **7.1. Scope**

The Testing and Tools Committee is responsible for supervising and coordinating the testing activities conducted by National and Regional Deployment Committees and the development of testing software and other tools used in the testing process. Its responsibilities include:

- 545 1. Developing and maintaining quality procedures for testing processes and events, including IHE Connectathons
2. Coordinating the requirements gathering process for test specifications and test assertions for the IHE Profiles developed in the IHE Domain committees
3. Develop, in conjunction with the Domain Coordination Committee, a consistent approach to ensuring testability of Profiles
- 550 4. Coordinating budget and resources contributed to technical project management of testing activities by National and Regional Deployment Committees
5. Securing funding for the development of testing software and related tools
6. Managing and coordinating budget and resources, including funding, voluntary manpower and software libraries, contributed to development of testing software and related tools by National and Regional Deployment Committees, and other organizations
- 555 7. Making recommendations to the Board with respect to intellectual property issues including licensing and use of testing software and related tools
8. Providing guidance to the Technical Management Group (TMG) in its oversight of testing activities and development of testing software and related tools
- 560 9. Coordinating development and maintenance of infrastructure used in testing process, including Websites

The Testing and Tools Committee reports to the Board of IHE International. It submits to the Board for its approval an annual report, which includes a plan and schedule for testing activities worldwide and a plan and budget for development of testing software and related tools to support these activities.

## **7.2. Membership and Procedures**

The Testing and Tools Committee is composed of one representative from each organization contributing resources, including funding, voluntary manpower and software libraries, to the technical project management of testing processes and development of testing software and related tools. This will include a representative from each National and Regional Deployment Committee engaged in sponsoring Connectathons and related testing activities in its area.

## **7.3. Technical Management Group**

### **7.3.1. Scope**

575 The Technical Management Group (TMG) is a subcommittee of the Testing and Tools Committee. It is responsible for technical management of testing activities and development of testing software and related tools. It is responsible for the design, production and delivery of

testing software and related tools and has authority to make design decisions concerning architecture, tools and implementation languages and strategy.

580 The TMG regularly reports to the Testing and Tools Committee on the status of its activities and participates in the development of the Testing and Tools Committee's annual report to the Board.

### **7.3.2. Membership and Procedures**

585 The TMG will be appointed by the Testing and Tools Committee. It will be composed of representatives of the professional technical project management team retained by National and Regional Deployment Committees to oversee testing and development of testing software and related tools and representatives of organizations providing significant engineering support on a volunteer basis to the development of testing tools.

## **8. Deployment Committees**

### **8.1. National Deployment Committees**

590 IHE National Deployment Committees are affiliates of IHE International, empowered by the IHE Board to conduct testing, demonstrations and other deployment activities within their geographic areas. National Deployment Committees operate as distinct organizations, developing their own governance rules and business models, but report to and participate in the IHE Board as described herein and adhere to the general principles expressed in Section 2 and  
595 below. Organizations participating in National Deployment Committees must be Member Organizations of IHE International and, like all IHE Member Organizations, are subject to the relevant provisions of this document, including the Intellectual Property Agreement.

#### **8.1.1. Scope**

600 National Deployment Committees are responsible for promoting the appropriate use of specifications defined in the IHE Technical Framework in their respective countries. IHE National Deployment Committees represent the needs and requirements of their respective healthcare systems and promote, support and implement IHE activities at the national level. They recruit users and developers at the national level to participate in IHE Domain Committees and in testing activities organized nationally or regionally. They organize educational forums  
605 and interact with relevant governmental and non-governmental organizations.

The deployment activities of national IHE initiatives include the following:

1. Recruiting national IHE initiative participants, sponsors and contributors
2. Developing governance documents and submitting them for review and approval by the Board of IHE International and to Regional Deployment Committees where such  
610 committees are established
3. Establishing liaison relationships with other organizations in order to further communication and cooperation on shared objects

4. Planning national demonstrations and educational and promotional events
- 615 5. Developing, publishing and disseminating educational and marketing materials in conformance with guidelines of regional initiatives
6. Organizing official translations of terms and sections in the Technical Frameworks as necessary.
7. Developing National Extensions to the Technical Frameworks to address specific needs due to national policies and traditions of care.
- 620 8. Submitting National Extensions to the relevant Domain Technical Committees for review and publication
9. Participating in a Regional Deployment Committee when applicable
- 625 10. Supporting regional Connectathons and interoperability testing processes in conformance with the IHE Technical Frameworks, including approved National Extensions
11. Contributing to the development of testing software and related tools and participating in the Testing and Tools Committee, which oversees the development process

A National Deployment Committee interacts with the Board by:

1. Participating in and contributing to Board activities
- 630 2. Communicating regularly with other National and Regional Deployment Committees

A National Deployment Committee interacts with Domain Committees by:

1. Communicating national requirements relevant to work under development
2. Contributing new work item proposals
3. Reviewing and providing feedback on work item proposals and technical documents

#### 635 **8.1.1.1. National Extensions**

National Extensions are documents integral to the IHE Technical Frameworks that address unique national requirements for healthcare information and workflow.

Such extensions shall be based on final text IHE Profiles as published in the international IHE Technical Frameworks. They may extend, but shall not contradict, Profile requirements.

- 640 National Deployment Committees are responsible for initiating the development of such extensions, and shall submit their draft national extensions to the Domain Committee responsible for the IHE Profile(s) affected. National Extensions shall be submitted in English, but may include national language translations. They will be reviewed by the Domain Technical Committee, which may return comments and suggestions to the submitting National Deployment
- 645 Committee. Once agreed, National Extensions are published as part of the Domain Technical Framework.

## 8.2. Regional Deployment Committees

IHE Regional Deployment Committees are affiliates of IHE International, empowered by the IHE Board to conduct testing, demonstrations and other deployment activities within their respective geographic areas. They operate as distinct organizations, developing their own governance rules and business models, but report to and participate in the IHE Board as described herein and adhere to the general principles expressed in Section 2 and below. Organizations participating in Regional Deployment Committees must be Member Organizations of IHE International and, like all IHE Member Organizations, are subject to the relevant provisions of this document, including the Intellectual Property Agreement.

### 8.2.1. Scope

Each National and Regional Deployment Committee is sponsored by one or more relevant IHE Member Organizations. Sponsors of National and Regional Deployment Committees provide the Secretariat for such committees and support their communication and infrastructure needs as appropriate.

Each National and Regional Deployment Committees shall notify the Board of any change in its current sponsors.

These groups may rely on funding from other organizations, including governmental bodies and non-governmental organizations and, if so, are responsible for securing and managing any such funds. Sponsoring organizations of National and Regional Deployment Committees may also sponsor domain development activities, though they are not required to do so. Their activities include:

1. Recruiting regional IHE initiative participants, sponsors and contributors.
2. Establishing liaison relationships with other organizations in order to further communication and cooperation on shared objectives
3. Planning regional activities and coordinating national activities
4. Planning and supporting interoperability testing including Connectathons
5. Planning regional demonstrations and educational and promotional events
6. Retaining a technical project manager or management team to coordinate interoperability testing, Connectathons and demonstrations
7. Developing, publishing and disseminating educational and marketing materials in conformance with guidelines of IHE International
8. Organizing and holding regional Connectathons and interoperability testing processes in conformance with the IHE Technical Frameworks, including approved National Extensions
9. Contributing to the development of testing software and related tools and participating in the Testing and Tools Committee, which oversees the development process

Regional Deployment Committees interact with the Board by:

1. Participating in and contributing to IHE International Board activities
- 685 2. Communicating regularly with other IHE National and Regional Deployment Committees

A Regional Committee interacts with IHE Domain Committees by:

1. Providing regional requirements
2. Contributing work item proposals
- 690 3. Reviewing and providing feedback on work item proposals and technical documents

### **8.3. Deployment Committee Membership and Procedures**

#### **8.3.1. Membership**

695 Membership is open to stakeholder organizations in the region or nation covered by the committee having a material interest in topics covered by IHE International. Members may include healthcare professional societies, provider groups, public health organizations, patient representatives, payers, healthcare IT users' associations, healthcare IT vendors' associations, academic institutions, research organizations, and standard development organizations.

#### **8.3.2. Committee Structure**

700 National and Regional Deployment Committees may create subcommittees as needed to address their needs and interests. They may establish working groups to address tasks such as:

1. Reviewing IHE Technical Frameworks and proposing National Extensions to meet local needs;
2. Planning and coordinating national and regional demonstrations, workshops and other forms of education and marketing;
- 705 3. Planning and coordinating regional Connectathons
4. Gathering experts to prepare and provide national requirements documents to relevant IHE Domains

710 They may also form Review Committees, composed of executive staff and senior membership of their sponsoring organizations, to mediate issues that may have implications for commercial competition and to act as final authority on issues related to testing in their nation or region.

## **9. General Membership Procedures**

### **9.1. IHE Organizational Membership and Committee Participation**

IHE International is composed of Member Organizations interested in improving the interoperability of healthcare information systems. An organization that becomes a member of

715 IHE International may designate representatives to participate in Domain Committees and National/Regional Deployment Committees relevant to its interests.

A Member Organization shall designate a principal voting representative to each Committee on which it wishes to be represented, by notifying the Secretary of that Committee. One or more alternate representatives may also be designated.

720 Where two or more Member Organizations have Parent/Subsidiary relationships with one another, they will be allowed only one voting representative collectively for each Committee on which one or more of the Member Organizations is represented.

725 Committees are generally open to all interested parties. Specific committees may choose to establish additional participation procedures, subject to review by the Board, so long as they do not contradict the principles expressed in this document (see Section 2).

### **9.1.1. Application for Membership in IHE**

Interested stakeholder organizations may apply to become Members of IHE by submitting an application for membership to the Secretary of the IHE International Board (on a form to be available from the Secretary) indicating the applicant's:

- 730 • Direct and material interest in the work of IHE
- Qualifications and willingness to participate actively
- Membership category
- Initial list of Committees of interest
- Indication of any Parent/Subsidiary relationships with other IHE Member Organizations
- 735 • Principal Representatives for those Committees (and alternate[s], if desired).

*Combined Interest:* When appropriate, the Secretary may recommend that the applicant seek representation through an organization that is already a member and represents the same or similar interest.

740 The Board shall acknowledge each organization submitting a complete and satisfactory application as a Member of IHE.

Each prospective member organization shall submit a committee participation agreement to the Board Secretary acknowledging its acceptance of IHE intellectual property and other committee policies. This agreement shall be signed by duly authorized officers of the member organization.

### **9.1.2. Membership Interest Categories**

Any stakeholder with interests that might be directly and materially affected by the activity of an IHE development or deployment committee shall have the opportunity for fair and equitable participation without dominance by any single interest.

750 Each IHE International member shall propose its own membership interest category: User, Developer and General Interest. Several types of organizations and their category are shown below.

Organizations that could fall into more than one category must choose a single affiliation for membership and voting purposes. Committees may choose to establish membership rules or voting procedures based on interest categories.

755

Organization Type	Interest Category			Description
	User	Developer	General Interest	
Healthcare Professional Organizations	X	X		Organizations for healthcare professionals (such as clinicians, IT, administrators, providers, and public health practitioners)
Provider Organizations	X	X		Organizations that provide healthcare
Provider Developers	X	X		Organizations such as hospitals that develop IHE-related software for their own use.
Open Source Developers		X		Organizations developing software with freely available source code
Vendors		X		Organizations that commercially develop, market, install, service or support IT products in healthcare
Consultants	X	X		Professional consultants to users, developers and government agencies.
Trade Associations		X		Trade associations that represent the collective interests of a category of vendors.
Government Agencies	X		X	Government agencies with responsibilities for and/or a relationship to healthcare information technology used in the public sector
Consumer Organizations			X	Organizations representing consumers with an interest in health information technology standards
Standards-Developing Organizations			X	Any standards-developing organization with a relevant interest. These groups may also enter into liaison relationships with IHE International and its committees.

Healthcare Services Purchasers or Employers			X	Healthcare services purchasers or employers
Health IT Promotion Organizations			X	Organizations with a broad representation of stakeholders with an interest in healthcare information technology standards
Health Research Organizations			X	Organizations performing clinical, technology or health-services research

## 9.2. Committee Procedures

All committees, including the Board, shall adhere to the principles identified in Section 2.

760 All committees, including the Board, shall adhere to the procedures defined in this section unless otherwise documented in the committee-specific sections of this document.

A committee may form subcommittees reporting to it. These subcommittees are required to adhere to the same procedures as other IHE committees. The parent committee retains responsibility for the oversight and output of those subcommittees.

765 On questions of parliamentary procedures not covered in this document, Robert's Rules of Order (latest edition) or an equivalent manual of parliamentary procedures may be used to expedite due process.

A committee and its co-chair may select a parliamentarian to interpret procedural rules and advise the committee on procedural issues; the Secretary may fill this responsibility.

770 At all meetings of the IHE International Board and its committees, including Domain Committees, business will be conducted in English.

### 9.2.1. Open Meetings and Notice

775 Meetings shall be announced by email notice to membership and posting on the IHE Calendar. Notice shall include the date and time of the meeting, the location (for a face-to-face meeting), telephonic access information (for a teleconference) and an agenda indicating the subject(s) to be addressed.

Face-to-face meetings shall be announced not less than 60 days prior to the meeting. In order to facilitate participation by committee Representatives worldwide, whenever possible the committee's sponsoring organizations should consider rotating a committee's meetings to different locations.

780 Teleconference meetings at which committee votes may be taken shall be announced not less than 7 days prior to the meeting.

Observers from Member Organizations are welcome at all committee meetings, but will have no voting privileges. Observers who do not represent IHE Member Organizations may be invited at the discretion of the Committee Co-chairs.

785 Minutes shall be published and made available to the public within a reasonable period, normally not more than 7 days from the time of the meeting.

### **9.2.2. Committee Structure**

A committee shall consist of its Secretariat, members and two co-chairs.

790 There shall be a Secretary who is appointed by the committee's Sponsoring Organization(s).  
The Sponsors of a committee are responsible for establishing and maintaining the Committee's Secretariat.

At least one designated committee Co-chair shall convene and preside over each committee meeting and along with the committee Secretary be responsible for ensuring conformance with the governance rules established in this document.

### **9.2.3. Voting and Quorum**

795 Decisions taken by a committee, whether at a face-to-face meeting, by teleconference or by letter ballot, and whether reached by consensus or vote, shall require a quorum of 50% of the Members that have voting privileges.

800 Decisions shall be recorded by the Secretary in the minutes. In the event that more than one position receives substantial votes, the Chair may request the details of the majority and minority positions also be recorded in the minutes.

Whenever possible, committee decisions shall be achieved by consensus. When a matter is put to a recorded vote, approval is determined by no less than a 66% affirmative vote of those voting.

805 Each Member Organization shall have one vote to be cast by the principal representative (or by an alternate if the principal is not available to vote).

All committee votes shall be open, and the results of the voting shall be recorded in the minutes.

Whenever possible, in order to enable fair participation by committee Representatives regardless of location, matters to be voted on will be announced in advance and voting via email or teleconference will be permitted.

### **9.2.4. Letter Ballots**

810 For letter (or email) ballots on matters other than Co-chair elections, each member shall vote one of the following positions:

1. Affirmative;
2. Affirmative, with comment;

- 815        3.    Negative, with reasons (the reasons for a negative vote shall be given and if possible should include specific wording or actions that would resolve the objection); or
4.    Abstain.

The voting period for letter ballots shall end 30 days from the date of issue or as soon as all ballots are returned, whichever comes earlier.

- 820    A follow-up e-mail requesting immediate return of the ballot shall be sent by the Secretary, as appropriate, to members and alternate members whose votes have not been received within ten working days before the ballot closes.

### **9.2.5. Matters Requiring a Vote**

825    The following actions shall require a recorded vote (at a face-to-face meeting or teleconference) or a letter ballot:

1.    Adoption of committee procedures or revisions thereof
2.    Approval of change of committee scope
3.    Approval of termination of the committee
4.    Recall of officers
- 830    5.    Approval of minutes

Votes on these matters may be taken at a committee meeting only if the meeting agenda published 30 days in advance of the meeting, announces that such a vote is expected.

The following actions require approval by a quorum of committee members present at a face-to-face meeting:

- 835        1.    Formation of a subcommittee, including its procedures, scope, and duties
2.    Disbanding of a subcommittee

At the discretion of the co-chairs and the Secretary, action on items not published in the meeting agenda, may be postponed until a future meeting or addressed in a letter ballot.

### **9.2.6. Attendance, Absence and Voting Privileges**

- 840    Each committee shall maintain a roster that identifies committee Representatives with voting rights and may also list non-voting committee Representatives.

The Secretary shall not be considered a Representative with voting rights.

- 845    Attendance at committee meetings is an obligation of membership. “Meetings” include face-to-face meetings, teleconferences and letter ballots. The “attendance” date for a letter ballot is considered to be the final date when responses are due.

The Secretary shall record the presence of the Principal or designated Alternate Representative of each Member represented at each committee meeting at which a decision is taken.

It shall be the responsibility of Committee Representatives to make their attendance known to the Secretary.

850 A new Member Organization shall be entitled to vote and count towards a quorum of each committee it has joined, upon attendance by a designated Representative beginning at the second committee meeting after the Member Organization joins.

855 A Member Organization is considered present at a committee meeting if its Principal Representative or Alternate(s), if any, is present. A Member Organization that is not present at three consecutive meetings at which votes are taken is considered lapsed and forfeits the privilege of voting on any Committee matter. At that time, Committee Representatives of such a Member Organization will be considered non-voting Representatives and will not be counted towards a quorum for voting purposes. The Secretary shall notify the Committee Co-chair(s) and the Member's Principal and Alternate Representatives in writing of this status change.

860 A lapsed Member Organization shall have its voting privilege restored upon and at the attendance of one or more of its Representatives at two successive committee meetings, and that Member Organization will be allowed to vote at that second successive meeting.

865 A Member Organization that does not participate in the activities of a Committee for a full year may be removed from the roster of that Committee. To be subsequently reinstated on the roster of a committee, the Member Organization shall submit to the Secretary of that committee a letter indicating its intention to renew participation in the committee's activities and including the name and contact information of its designated Principal Representative and any Alternates.

### **9.2.7. Co-chair Elections**

870 Each co-chair shall serve a two-year term and may serve no more than two consecutive terms. The terms of the co-chairs shall expire in alternating years.

The Secretary shall announce elections to be held for the position of Co-chair to the committee membership and invite nominations (including self-nominations). Nominees shall be drawn from the current voting members of the committee at the time of the announcement.

875 Following the closure of nominations the Secretary shall conduct a 15-day ballot period via email. If a quorum of votes is not attained, the nomination and election process shall be re-run. A candidate must obtain a majority of the votes to be elected. If no candidate exceeds 50% of the cast votes, a run-off election between the top two candidates shall be conducted. The person elected shall be announced at the next meeting (typically the last meeting of the year) and they shall assume office immediately following the meeting.

### **9.2.8. Co-chair Responsibilities**

The responsibilities of Committee Co-chairs include:

1. Organizing the committee.
2. Conducting Committee meetings and conference calls
3. Preparing and announcing agendas for Committee meetings and conference calls

- 885
4. Supporting the Secretary in documenting and disseminating meeting minutes
  5. Be a consistent and active participant in Domain Coordination Committee.

### **9.2.9. Secretariat of a Committee**

The sponsors of a Committee are responsible for appointing the Secretary for the Committee.

The Secretary shall:

- 890
1. Oversee the Committee's compliance with IHE policies and procedures.
  2. Update materials relevant to the Committee on the ihe.net web site, ftp site and Wiki
  3. Maintain a current and accurate roster of the Committee and distribute it to the members at least annually and, otherwise, on request. The roster shall include the following:

895

    - Title of the Committee;
    - Scope of the Committee;
    - Name and address of the Secretariat and Secretary;
    - Officers;
    - Members -- including the name of the organization, company or agency; its voting representative and alternate(s) with their addresses and other contact information;
    - Type and category of each member and the tally of classifications: total of voting members, subtotals for each interest category and voting quorum requirements.

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  - 4. Provide appropriate administrative personnel and resources to perform administrative work including:

905

    - Arranging meetings;
    - Maintaining adequate records, including recording and transcribing meeting minutes.
    - Distributing meeting notices, agendas, minutes, ballots and draft documents in a timely manner, and
    - Supporting on-line access to relevant information by the Committee's members and the public.
    - Arranging for the publication of Committee documents, revisions, and addenda;
    - Maintaining a list of ongoing projects and their status and
    - Performing other administrative functions as required.

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### **9.2.10. Meeting Conduct**

915 All meetings shall be conducted under the following guidelines and any additional ones that the Board may prescribe to avoid any violation of antitrust laws. The Committee Secretary shall be responsible for monitoring adherence to these guidelines.

No commercial topics shall be acted upon or considered. Specifically excluded is discussion of:

- 920
1. Current or future prices or components thereof, including discounts, rebates, and credit terms;
  2. Price list or procedures for coordinating price changes;
  3. Sales or production quotas;
  4. Allocation or division of territories of customers among manufacturers, distributors, or retailers;

925

  5. Boycotting any party or denying any party access to markets, products, product inputs, or information;
  6. Identified individual company statistics, market shares, inventories or merchandising methods;

930

  7. Commercial practices, warranties, guarantees, or the particular terms and conditions of sales, including credit, shipping and transportation arrangements, or
  8. Trade abuses, or excluding or controlling competition

Meetings shall be conducted in such a manner that all members are afforded an adequate opportunity to present their views. All opinions shall be considered before actions are voted upon. The co-chairs shall undertake this responsibility with the assistance of the Secretary.

- 935
- The Secretary shall ensure that minutes of all meetings are clear, complete, and accurate with regard to the actions that were taken and the justification for those actions.

There shall be no conversations "off the record" at meetings. If comments are not appropriate for recording, they shall not be brought up at meetings.

- 940
- Meetings shall be adjourned when all business has been completed. No committee business shall be conducted in informal meetings of committee subgroups.

## **10. Ratification of this Governance Document**

This Governance document is to be ratified by the current IHE Strategic Development Committee. The membership of this Committee includes:

1. One Representative of each IHE International Sponsor and Domain Sponsor

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2. Domain Technical and Planning Committee co-chairs, present and past
3. One representative per National and Regional Deployment Committee

### **10.1. Implementation Period**

950

Once this Governance document is approved, the IHE Strategic Development Committee, with its current membership, will become the Interim Board of IHE International pending election of new Board members and incorporation of IHE International. During this interim period:

1. The current Strategic Development Committee Co-chairs will continue to serve in the role of IHE International Board Co-chairs to ensure stability during the transition.

2. Current IHE International, Domain, National and Regional Sponsors will apply to IHE International as Members and Sponsors.
- 955 3. Organizations with Domain Planning or Technical Committee representatives will apply to IHE International as Member Organizations.
4. Other organizations may apply to IHE International to become Member Organizations
5. The Interim IHE International Board will conduct a review of IHE Domains, and decide those that will be deemed as established Domains, and those that will be deemed  
960 “in formation”.
6. National and Regional Deployment Committees will need to submit their application to IHE International

Within 9 months of ratification of this Governance document, the Board and relevant IHE Committees will:

- 965 1. The Board will hold elections and establish new membership.
2. Domain Planning and Technical Committees will elect Board representatives under the new governance.
3. National and Regional Deployment Committees will elect their Board representatives.

## **10.2. Amendments**

970 Amendment of this Governance document shall be accomplished by a vote of the Board. Proposed amendments shall be published to the Board membership by email and posted on the website. An agenda listing the proposed amendment shall be published at least 30 days prior to the meeting where the vote shall be taken.

975 Individual committee charters for all IHE committees will be approved by the IHE International Board.

## **10.3. Transition to Self-supporting Organization**

980 The model of operation defined in this document formalizes current practices of IHE and its committees. Operation of the organization relies on voluntary commitment of resources by Member Organizations. In particular, committee operations depend on in-kind contributions of staff time and resources, as well as direct financial contributions, by the sponsoring organizations. The governance principles described herein are based on a continuation of that practice. It is the understood intent of the IHE Strategic Development Committee, which has overseen the drafting of this document and is responsible for ratifying it, that IHE International should move toward a business and operational model that encourages increasing self-  
985 sufficiency and broader-based support for its activities. The IHE International Sponsors and the incipient IHE International Board agree to work toward these goals and to consider amendments to the current governance principles to foster such developments.

## 11. Selected Definitions

990        *Adopter:* A commercial entity or other organization making use of the Technical Documents published by IHE International, for the purpose of conforming to the technical specifications defined therein.

995        *Affiliate:* A corporation, company or other entity that, directly or indirectly, shares a common Parent with the Member Organization.

1000       *Connectathon:* A testing process organized and held regularly by IHE National and Regional Deployment Committees, where healthcare IT vendors and other stakeholder organizations can validate the conformance of health information systems with the IHE Technical Frameworks and related standards and the interoperability of such systems with complementary systems.

1005       *Contribution:* Any written submission to an IHE Domain Committee by a representative of a Member Organization, and any other statement made within the context of an Domain Committee activity, including oral statements in Domain Committee sessions, as well as written and electronic communications made at any time or place, which are addressed to the Domain Committee mailing list, intended by the Representative for publication or use as all or part of an IHE Profile or other Technical Document.

1010       *Control:* Control of a corporation, company or other entity shall mean: a) to have more than fifty percent (50%) of the outstanding shares or securities representing the right to vote for the election of the board of directors or a similar managing authority or supervisory board or b) with regard to an entity which does not have outstanding shares or securities, as may be the case for a partnership, joint venture,  
1015       unincorporated association, or not-for-profit corporation, to have more than fifty percent (50%) of the ownership or voting interests representing the right to elect the governing body or otherwise make decisions for said corporation, company or other entity.

1020       *Developer:* A Member Organization that is actively involved in the development of healthcare information technology systems.

1025       *Domain:* An organizational unit of IHE International, based around a distinct area of clinical and/or operational activity and interest in healthcare. Each IHE Domain organizes and runs its own Domain Committees, typically including a Domain Planning and Domain Technical Committee. IHE Domains operate under the sponsorship of one or more Member Organizations whose constituents have expertise and interests in the

1030 clinical and/or operational area of the Domain. Each Domain is responsible for developing its own Technical Documents, in coordination with other IHE Domains wherever appropriate.

1035 *Domain Committee:* A committee of IHE International dedicated to developing Technical Documents and/or fostering their use in healthcare IT systems pursuant to the goals of IHE International. Domain Committees are composed of voluntary representatives of IHE Member Organizations and operate under the rules defined in this document. Each IHE Domain typically includes a Domain Planning Committee and a Domain Technical Committee.

1040 *Domain Planning Committee:* A committee within an IHE Domain whose responsibilities include prioritizing and coordinating the development activities of the Domain, and the production of basic marketing and education materials for the Domain.

1045 *Domain Technical Committee:* A committee within an IHE Domain whose responsibilities include carrying out work items identified by the Planning Committee of that Domain and developing technical specifications and whitepapers.

*General Interest Member:* A Member Organization that has a significant interest in learning about healthcare information technology systems.

1050 *Interoperability:* The ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities.

1055 *Liaison Organization:* An organization such as a standards development organization or other non-governmental organization, with which IHE establishes a working relationship to advance shared objectives in keeping with the mission of IHE. A relationship with a Liaison Organization may be formalized in a Memorandum of Understanding.

1060 *Member Organization:* An organization that provides representatives to participate in IHE committees and/or acts as a sponsor of IHE activities. Any organization that is a stakeholder in healthcare information technology may become a member organization of IHE. Member organizations are required to agree to abide by the policies and procedures of IHE International, including stipulations regarding intellectual property and anti-competitive activities. Member organizations can designate appropriate representatives to certain IHE committees and/or nominate them for elected positions in other IHE committees, as described herein.

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1070        *Parent:* A corporation, company or other entity that, directly or indirectly, Controls the  
Member Organization, but such corporation, company or other entity shall be deemed  
to be a Parent only so long as such Control exists.

1075        *Profile:* Standards-based interoperability specifications developed by IHE International and  
its committees that are collected and published in the IHE Technical Frameworks and  
their supplements.

1080        *Representative:* An individual who serves on one or more IHE committees on behalf of a  
Member Organization. A Member Organization may designate a Primary  
Representative and one or more Alternate Representatives to any IHE Domain  
Committee to whose work it has an interest in contributing. Representatives to  
Domain Committees achieve and maintain privileges to contribute to committee  
Technical Documents and vote on committee matters as described in the sections  
setting forth the Membership and Procedures of these committees herein. Criteria for  
1085 participation in other IHE committees are likewise described in the Membership and  
Procedures sections pertaining to each committee.

1090        *Subsidiary:* A corporation, company or other entity that, directly or indirectly, is controlled  
by the Member Organization, but such corporation, company or other entity shall be  
deemed to be a Subsidiary only so long as such Control exists.

1095        *Technical Documents:* The work product created and published by IHE Domain Committees.  
IHE Technical Documents include, but are not limited to, the IHE Technical  
Frameworks and their supplements (in the various drafts and final text form) and  
white papers published by Domain Committees, as well as National Extensions to the  
Technical Framework (including sections translated from other IHE Technical  
Documents).

*User:* A Member Organization that is (and/or whose members are) actively involved in using  
healthcare information technology systems.

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## **Appendix A: Intellectual Property Agreement**

### **A.1 Ownership and Licenses**

#### **A.1.1 Ownership Of Copyrights**

1105 The Member Organizations agree that IHE International shall own, notwithstanding the retention by each Member Organization of its ownership interest in any parts it has contributed, the copyright in all IHE Technical Documents.

##### **A.1.1.1 Copyright Licenses**

1110 IHE International hereby grants to each Member Organization, and to any other user of these documents, an irrevocable, worldwide, perpetual, royalty-free, nontransferable, nonexclusive, non-sublicensable license under its copyrights in any IHE Profiles and Technical Framework documents, as well as any additional copyrighted materials that will be owned by IHE International and will be made available for use by Member Organizations, to reproduce and distribute (in any and all print, electronic or other means of reproduction, storage or transmission) such IHE Technical Documents. The licenses covered by Section A.1.1.1 are only  
1115 to those copyrights owned or controlled by IHE International itself. If parts of the Technical Framework are included in products that also include materials owned or controlled by other parties, licenses to use those products are beyond the scope of this IHE document and would have to be obtained from that other party.

##### **A.1.1.2 Copyright of Base Standards**

1120 IHE Technical Documents refer to and make use of a number of standards developed and published by several standards development organizations. All rights for their respective base standards are reserved by these organizations. This agreement does not supercede any copyright provisions applicable to such base standards.

### **A.2 Trademark**

1125 IHE® and the IHE logo are trademarks of the Healthcare Information Management Systems Society in the United States and trademarks of IHE-Europe in the European Community. They may only be used with the written consent of the Secretariat of the IHE Board, which may be given to a Member Organization in broad terms for any use that is consistent with the IHE mission and operating principles.

### **A.3 Patent Disclosure**

#### **A.3.1 Introduction**

1135 An important purpose of IHE International is the development and dissemination for broad adoption of standards-based interoperability specifications known as IHE Profiles that are collected and published in the IHE Technical Frameworks. Since part of the intent in publishing these documents is to offer an open and abstract architecture that can be adopted by developers to increase the level of interoperability across healthcare information systems, it is important for the committees developing the Technical Frameworks to know if they incorporate any technologies that are or may be considered proprietary intellectual property.

### **A.3.2 Duty to Disclose Patents and Patent Applications**

1140 Each Member Organization has an affirmative duty of good faith through its Committee Representatives to bring to the attention of IHE International any claims of a patent or patent application anywhere in the world (excluding design patents and design registrations) owned, controlled or that can be sublicensed by the Member Organization (or a Parent Company, Subsidiary or Affiliate of the Member Organization) now or at any future time of which the  
1145 Committee Representative is aware and which the Representative believes would necessarily be infringed by implementation of IHE Technical Documents developed by any Committee on which the Member Organization participates. No Member Organization or Committee Representative shall knowingly conceal from IHE International any patents or patent applications owned, controlled or sublicensable by the Member Organization (or any Parent  
1150 Company, Subsidiary or Affiliate) which would be necessarily infringed by a user of the IHE Technical Frameworks in order to conform to Profiles specified in the IHE Technical Frameworks or any revision thereof that is proposed for adoption. However, the preceding provisions notwithstanding, no Member Organization shall be obligated to disclose any information about a patent application which has not been published other than to identify the  
1155 existence of the patent application and the affected IHE Technical Document(s).

### **A.3.3 Necessary Claims**

A claim is necessarily infringed for purposes of this Agreement (a “Necessary Claim”) only when it is not possible to avoid infringing it because there is no plausible non-infringing alternative for implementing the relevant portions of an IHE Technical Document.

### **1160 A.3.4 No Duty to Search Patent Portfolios**

IHE Member Organizations and their Committee Representatives do not have an affirmative duty to search patent portfolios to determine whether a Member Organization owns a patent or patent application involving Necessary Claims.

### **A.3.5 Limitation of Duty to Disclose to Active Committee Representatives**

1165 The affirmative duty of a Member Organization's Committee Representative(s) to disclose known patents applies only as to Committees on which they serve as Representatives (whether voting or non-voting) or to whose IHE Technical Documents they make any Contribution.

### **A.3.6 Timing of Disclosure**

1170 The duty of good faith described in Section A.3.2 includes a requirement that the disclosure be made as expeditiously as possible after the Member Organization or Committee Representative recognizes the obligation of disclosure and not less than 10 days prior to the date that the affected IHE Technical Document is scheduled for initial publication for public comment.

### **A.3.7 Method of Disclosure**

1175 Disclosures should be made in writing and submitted to the IHE Board Secretariat who shall make them immediately available to the Board and any affected committees.

### **A.3.8 Obligation to License**

1180 Each Member Organization commits to license to all Adopters on reasonable and non-discriminatory terms any Necessary Claims which the Member Organization (or a Parent Company, Subsidiary or Affiliate of the Member Organization) has the power to license, subject to a condition of reciprocity. As used herein, “reciprocity” means that with respect to any Adopter that has a patent or patent application required in the use of IHE Technical Documents, the Member Organization (or Parent Company, Subsidiary or Affiliate of the Member Organization) shall be required to license to such an Adopter only if that Adopter also is willing to license its patent or patent applications on reasonable and non-discriminatory terms.

### **A.3.9 No Effect on Obligations Related to Base Standards**

1185 IHE Technical Documents refer to and make use of a number of standards developed and published by several standards development organizations. IHE Member Organizations may also participate in the standards development organizations responsible for base standards used in IHE Technical Documents and may thus be subject to obligations with respect to intellectual property imposed by these organizations. The obligations of IHE Member Organizations under this IHE Intellectual Property Agreement do not in any way alter their obligations under the intellectual property policies of any other standards development organization, nor do the obligations of IHE Member Organizations under the intellectual property policies of any other standards organizations alter their obligations under this IHE Intellectual Property Agreement.

### **A.3.10 Confidentiality Provision**

1195 Each Member Organization that receives, as a result of disclosure under this Section A.3.2, confidential information about a patent application of another party shall take all reasonable steps to prevent further disclosure of such information to any individuals or organizations other than those involved in the IHE activities out of which the disclosure under this Section A.3.2 arose.

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## **A.4 Withdrawal**

A Member Organization may withdraw from this Agreement only by terminating its status as a Member Organization. A Member Organization wishing to withdraw from this Agreement must do so by submitting notice of its intent to withdraw to the IHE Board Secretariat, and the

1205 effective date of termination will be the date of receipt by the IHE Board Secretariat of such notice of intent to withdraw. The IHE Board Secretariat will promptly notify the IHE Board and any affected committees of any such notice received.

#### **A.4.1 Effect of Expiration, Termination and Withdrawal**

1210 Termination of a Member Organization's participation in this Agreement shall not affect the existence or enforceability of the terms of this Agreement as to the remaining Member Organizations. In the event of termination of a Member Organization's participation in this Agreement, the provisions of this Intellectual Property Agreement shall survive with respect to any Contributions previously made by that Member Organization even if not incorporated into IHE Technical Documents as of the notice date. When used in this section, the "notice date" is  
1215 the date on which the Member Organization has provided notice of intent to withdraw to the IHE Board Secretariat.

#### **A.5 Non-Compliance**

1220 In the event that a Member Organization materially violates the duty of good faith described in Section A.3.2, above, the violating Member Organization shall be required, to the full extent of its power to do so, to license to all Adopters on reasonable and non-discriminatory terms any Necessary Claims relating to the patents or patent applications giving rise to the violation. In addition, at the discretion of the IHE International Board, any Member Organizations violating the duty of good faith described in Section A.3.2 may be excluded from future IHE committee activities.

#### **A.6 Requirement to Execute a Declaration**

1225 Each IHE Member Organization shall confirm its commitment to this IHE Intellectual Property Agreement by executing a Declaration in the form set forth below.

## A.7 Declaration

1230 \_\_\_\_\_ ("Member Organization") agrees that as a condition  
of participation of its Committee Representatives in IHE International, its Committees or  
Subcommittees, that it (the Member Organization) will abide by the policies and procedures  
described in the foregoing Principles of Governance. Moreover, Member Organization agrees to  
abide by the duty of good faith set forth in the foregoing Intellectual Property Agreement.

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**Signed by** \_\_\_\_\_ **Title** \_\_\_\_\_

Authorized Signature

**Print Name** \_\_\_\_\_ **Date** \_\_\_\_\_

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