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Integrating the Healthcare Enterprise (IHE) International, Incorporated Principles of Governance

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1. Introduction

130 Integrating the Healthcare Enterprise (IHE) International, Incorporated is a non-profit
organization incorporated under the laws of the State of Illinois, U.S.A. IHE International
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
135 determine that they conform to the specifications. The work is managed by IHE committees and
sponsored by various national and international bodies. The composition of the IHE International
Board is published at <http://www.ihe.net/governance/board.cfm>.

140 This Principles of Governance document describes the organization, policies and procedures of
IHE International, Inc. It was officially adopted by the Board of IHE International on October 5,
2007. This amended version is published following the incorporation of IHE International, Inc.
in September 2009. It was approved for use as amended by the IHE International Board on
August 11, 2010.

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2. Mission

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:

- 150 • 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 records
in their various national and regional contexts
- enabling local, national and regional health information networks
- 155 • addressing needs for security and privacy
- improving the efficiency and effectiveness of healthcare workflows
- and generally removing barriers to safe and optimal patient care

160 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

165 Technical Documents, including implementation guidelines called IHE Profiles, which are published in a set of documents called the IHE Technical Frameworks. IHE encourages 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 healthcare delivery organizations and between different care settings and administrative entities.

2.1. Principles

170 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.
2. *Openness.* Participation is open to all affected interests.
- 175 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 problems and designing clinically useful solutions.
- 180 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 another among competing interests and various stakeholders.
- 185 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 differences.
- 190 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.
10. *Relevance.* Developed specifications address clearly defined and widely shared healthcare needs.
- 195 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.

13. *Harmonization*. Developed specifications resolve overlaps and conflicts between selected standards.

200 14. *Respect local healthcare practices*. Developed specifications shall recognize and support variations in care practices in member regions and nations.

3. Organizational Overview

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

205 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, documenting them in Technical Framework documents and their supplements. A Domain Coordination Committee ensures that consistent processes and technical directions are followed.

210 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 Deployment Committees that are separate entities with a close collaborative relationship with IHE International.

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

- 220 • 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 National and Regional Deployment Committees, including the development of testing software and other tools.
- 225 • 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.
- 230 • *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.
- 235 • *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.

- The *Global Deployment Coordination Committee* facilitates consistent use of IHE profiles, processes, tools, and services across IHE regions and promotes effective communication and coordination among them.
- *Liaison Organizations*, including relevant Standards Development Organizations, enter into mutual agreements with IHE International to communicate on and coordinate complementary activities.

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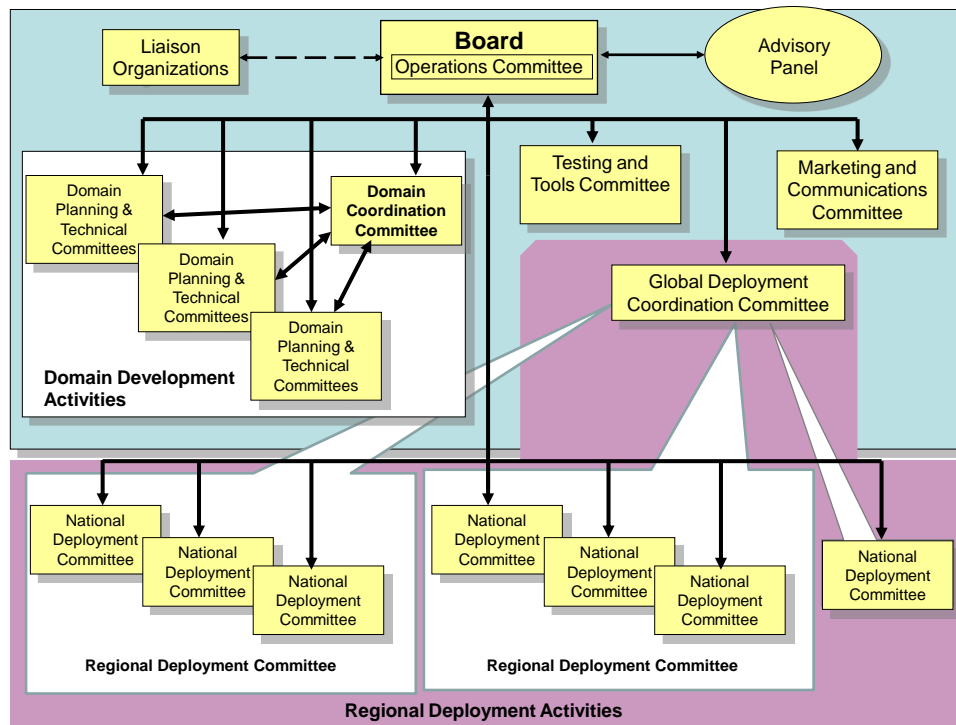


Figure 3-1: IHE International Committees and Relationships

4. Board and Board Operations Committee

4.1. Scope

250

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.

255

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

1. Ensuring that the principles of governance are upheld and maintained;
2. Defining the IHE mission, goals and objectives

3. Annually reviewing the scope, duties and membership of all IHE Domains and Regions.
- 260 4. Establishing and periodically renewing international cooperation agreements with relevant organizations.
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
- 265 8. Incubating expansion of new domain activities and committees
9. Resolving conflicts referred to them by other Committees
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
- 270 13. Directing communications about the IHE initiative through the Marketing and Communication Committee
14. Representing IHE International in public forums and other communications venues.
15. Providing IHE Liaison with standards groups and other non-governmental organizations
- 275 16. Reviewing and approving a budget for IHE development activities to be developed and submitted annually by the Secretariat of the Board.

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:

280 4.2.1. Membership

The Board shall be composed of representatives of 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.
- 285 2. The Member Organizations 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.
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
290 Technical Committee active membership (Co-chairs are recommended). They shall belong to other member organizations than those already represented on the Board.

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.
- 295 5. Each Regional Committee shall designate a principal representative and an alternate.
6. Each National Committee shall designate a principal representative and an alternate.

300 In addition, Board Co-chairs who have completed their terms of service may be invited by the Board to serve as non-voting Emeritus Co-chair members of the Board. Only the two most recently retired Board Co-chairs shall serve at any one time. The term of the longest-serving Emeritus Co-chair shall thus expire when a newly retired Board Co-chair agrees to replace him or her.

305 If a current Board Member no longer a representative of a member organization, affected Board rep is removed and alternate replaces him/her (subject to normal procedures). If a Board rep designated by a body within IHE (such as sponsors, domains, deployment committee) moves to another organization, he/she will continue in current position until the designating body selects a replacement. For at-large Board representatives, the Board will, at its next meeting consider and vote on a motion whether to hold a new election or allow the representative to fulfill his or her term.

310 **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

315 The following actions shall be formally approved by the Board:

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;
- 320 5. Considering and acting on proposals for termination of the Board, Domain co-chairs;
6. Election of co-chairs
7. Approval of yearly budget
8. Legal decisions

4.2.4. Announcements and Publications

325 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.

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

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:

- 335 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)
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)
- 340 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
- 345 7. A rationale for creating the new domain, including explanation of why the proposed work cannot be performed in one or more existing domains

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.

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

355 When a proposal is accepted, the new domain is provisionally approved. This allows the domain to announce its formation and start holding meetings as IHE Domain Planning and Technical Committees.

The Domain champions and sponsors shall prepare a plan for advancing the domain from provisional launch to full operation. The plan shall include:

1. The name of the domain representative to the International Board
- 360 2. The results of membership recruitment for the planning and technical committees, including the names of the co-chairs of those committees and record of their attendance at Domain Coordination Committee meetings
3. Training plans (completed or upcoming) to ensure that sponsors, co-chairs and domain representative are knowledgeable of IHE procedures and profiling conventions

- 365
4. A roadmap for selecting a first profile, starting the first annual cycle and participating in a first Connectathon
 5. A budget proposal for the first 2 years of Domain operations, demonstrating sufficient funding for secretariat services, hosting committee webex/teleconferences and face-to-face meetings, etc.
 - 370 6. Outreach plans to the International users and vendors of the Domain

Following submission of the plan by the Domain Representative to the International Board, a motion may be made to make the Domain fully operational. When such a motion is approved, the domain may commence full operation including publication of Technical Framework documents for public comment and trial implementation.

375

4.2.6. Establishing New National and Regional Deployment Committees

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:

380

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
- 385 3. An initial list of Developer category members likely to join/participate
4. An initial list of User members likely to join/participate
5. Indication of potential areas of interest

390

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 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.

395

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 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

400

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

1. Providing advice to the sponsoring organizations in the business and financial governance of the IHE International Board
- 405 2. In collaboration with the Treasurer of the Board, develop an annual budget for IHE International activities, which it presents to the Board for approval
3. Providing advice on, and resolution of, administrative issues as requested by the Board Secretariat
4. Developing and presenting proposals to the Board regarding operational, financial and strategic planning matters
- 410 5. Maintaining and overseeing implementation of the IHE International Strategic Plan, as developed and periodically updated by the IHE International Board
6. Fulfilling other responsibilities specifically delegated by the Board.

Whenever possible, the BOC shall make decisions 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.

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

The membership of the BOC shall consist of nine current Board members selected by the Board. In selecting the membership of the BOC, the Board shall, as far as possible, adhere to the following guidelines for distribution of membership:

- 420 1. The Co-chairs of the Board [2]
2. One representative from different regions with active IHE deployment committees[3]
3. Members representing a cross-section of different IHE domains and other Board membership categories [4]
- 425 4. The Secretary of the Board and one or more staff representatives of IHE International participating, as nonvoting members

In evaluating candidates, the Co-chairs, Secretary and Board shall consider the candidates' experience in operation, financial and strategic planning issues and ensure the necessary expertise to facilitate maintenance of strategic plan.

430 The BOC shall designate a Strategic Planning Leader with primary responsibility for ensuring that matters pertaining to the Strategic Plan are identified, tracked and executed in a timely manner. The BOC shall select the Strategic Planning Leader by soliciting candidates from among BOC members. The Strategic Planning Leader will be selected by consensus of BOC members where possible. If more than one candidate is identified, the BOC may hold a vote of its members to select the Strategic Planning Leader.

435 To select BOC members, the Board shall solicit candidates from among current Board members. The Co-chairs and Secretary will propose a slate of candidates that reflects as closely as possible the foregoing distribution guidelines. A majority vote of current Board members shall be required to confirm each individual member of the slate. In case any member of the slate fails to

440 attain a majority vote of Board members, the Co-chairs and Secretary shall solicit a replacement candidate for that individual and present the replacement candidate for a vote of the Board.

BOC members will serve for two-year terms and may serve multiple terms (subject to the selection process described above). If the tenure on the Board of a BOC member ends before the conclusion of their scheduled term on the BOC, the Board shall select a replacement following the process and guidelines above.

445 **4.2.8. Advisory Panel**

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

450 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.

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

455 **4.3. Sponsors and Associate Organizations**

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. Member Organizations shall apply to the IHE International Board for its approval to assume sponsorship of specific IHE
460 committees, and the Board shall have the authority to consider and, at its discretion, approve such applications. In exercising its approval authority, the Board shall consider the applicant organization's ability to perform the sponsorship duties required and its commitment to observe and promote the principles defined in section 2.1 above.

465 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

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:

- 470 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
2. Assuming significant financial responsibility for the general committees of IHE International, including the Board and its Board Operations Committee, the Marketing
475 and Communications Committee and the Testing and Tools Committee

3. Providing legal advice, support, indemnifications and accountability to the Board
4. Developing an annual budget for IHE International and presenting it to the Board Operations Committee and Board for approval

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

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
485 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.

4.3.1.1. IHE International Secretariat

490 The secretariat of the IHE International Board and associated committees is provided by the IHE International Sponsors, currently the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). These committees include the Board, Advisory Panel, Domain Coordination Committee, Global Deployment Coordination
495 Committee, Domain Secretaries Committee, Marketing and Communications Committee, and Testing and Tools Committee. The secretariat is responsible for organizing these committees, recording and maintaining their rosters, scheduling and hosting their meetings and teleconferences, attending all such meetings and teleconferences and recording minutes of these meetings and maintaining infrastructure for committee communication and collaboration such as Websites, Wikis and Web/teleconference facilities. The IHE International Board Secretariat also
500 works with Domain Committee secretaries and technical committee co-chairs in publishing the IHE Technical Frameworks.

4.3.2. Domain Sponsors

Domain Sponsors shall be Member Organizations in the User Category. Domain Sponsors generally come from Healthcare Professional Organizations (clinical, IT, administrative, public
505 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

510 National/Regional Sponsors shall be Member Organizations in the User, Developer or General Interest categories. 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

515 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.

National/Regional Initiative Sponsors take responsibility for supporting IHE deployment
activities, including the IHE implementation testing process, in a given nation or region. The
520 main role of these sponsors is directly related to National and Regional IHE Deployment
Committees.

4.3.4. Associate Organizations

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
525 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
with their membership through periodic email updates and selected printed mailings. They may
recruit and support volunteer domain experts from among their membership to take part in
530 domain committee activities.

5. Domain Committees

5.1. Scope

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
535 Board.

5.2. Sponsorship and Secretariat

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
540 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.

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
545 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:

1. Organizing and hosting domain planning and technical committees composed of
volunteer domain experts and IHE Member representatives.

- 550 2. Coordinating with the IHE International Sponsors and Domain Coordination
 Committee to publish the work of their domain committees under IHE International
 Copyright;
3. Providing information for publication about their membership, plans, process and work
 product (e.g., via the www.ihe.net Website).
- 555 4. Maintain the committee roster, record the participation in the minutes of all committee
 meetings and notify the co-chairs of the membership or observer status of each
 participant in the meeting.

5.3. Committee Structure

560 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.

565 Some Domains may choose 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

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.

570 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:

- 575 1. Soliciting input from Regional/National Deployment Committees on current problems;
2. Developing work item proposals to address identified interoperability needs;
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;
- 580 4. Advising the Technical Committee;
5. Developing white papers on relevant issues;
6. Coordinating development of education and marketing materials for new Profiles; and
7. Communication and coordination of development activities across domains.

585 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

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

590 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

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
- 600 3. Selection of work items for each annual cycle
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

5.4.2.3. Frequency of Meetings

605 Domain Planning Committees shall hold an official meeting, either via face-to-face or telecom, at least four times per year in at least three calendar quarters.

5.5. Domain Technical Committees

5.5.1. Scope

610 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
- 615 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
- 620 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
- 625 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.

630 **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

635 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:

- 640 1. Creation or dissolution of a subcommittee
2. Creation/removal of new internal Liaison positions
3. Evaluation of work item proposals 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
- 645 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

650 **5.5.2.3. Frequency of Meetings**

Domain Technical Committees shall hold official meetings, either via face-to-face or telecom, at least four times per year in at least three calendar quarters.

5.5.3. Announcements and Publications

655 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.

6. Domain Coordination Committee

6.1. Scope

660 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:

1. Sharing experience and advice on best practices, including mentoring of newly created Domains
- 665 2. Discussing and collecting input on Profiles that may cross Domain boundaries
3. Coordinating Domain development and publication schedules
4. Develop, in conjunction with the Testing and Tools Committee, a consistent approach to ensuring testability of Profiles
- 670 5. Developing common operational procedures (change proposal handling, profile standards selection, etc.)
6. Developing common infrastructure for efficient committee work
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

675 **6.2. Membership and Procedures**

6.2.1. Membership

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

6.2.2. Secretariat

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

7. Testing and Tools Committee

7.1. Scope

685 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:

1. Developing and maintaining quality procedures for testing processes and events, including IHE Connectathons
- 690 2. Coordinating the requirements gathering process for test specifications and test assertions for the IHE Profiles developed in the IHE Domain committees
3. Developing, in conjunction with the Domain Coordination Committee, a consistent approach to ensuring testability of Profiles
4. Coordinating budget and resources contributed to technical project management of testing activities by National and Regional Deployment Committees
- 695 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
- 700 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
- 705 9. Coordinating development and maintenance of infrastructure used in testing process, including Websites

The Testing and Tools Committee reports to the IHE International Board. 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.

710 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.

715

7.3. Technical Management Group

7.3.1. Scope

720 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.

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

725 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
730 volunteer basis to the development of testing tools.

8. Deployment Committees

8.1. National Deployment Committees

735 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
below. Organizations participating in National Deployment Committees must be Member
Organizations of IHE International and, like all IHE Member Organizations, are subject to the
740 relevant provisions of this document, including the Intellectual Property Agreement.

8.1.1. Scope

745 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
and interact with relevant governmental and non-governmental organizations.

The deployment activities of national IHE initiatives include the following:

- 750 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 committees are established
- 755 3. Engaging with provider community in region and establish liaison relationships with other national organizations in order to further communication and cooperation on shared objectives
4. Planning national demonstrations and educational and promotional events
5. Developing, publishing and disseminating educational and marketing materials in conformance with guidelines of regional initiatives
- 760 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
- 765 8. Submitting National Extensions to the relevant Domain Technical Committees for review and publication.
9. Participating in a Regional Deployment Committee when applicable
10. Supporting regional Connectathons and interoperability testing processes in conformance with the IHE Technical Frameworks, including approved National Extensions
- 770 11. Participating in national product validation and certification activities when appropriate
12. 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
- 775 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

780 **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.

785 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
790 Committee, which may return comments and suggestions to the submitting National Deployment
Committee. Once approved by both the Domain Technical Committee and the National
Deployment Committee, National Extensions are published as part of the Domain Technical
Framework.

8.2. Regional Deployment Committees

795 IHE Regional Deployment Committees are affiliates of IHE International, empowered by the
IHE Board to conduct testing, demonstrations and other deployment activities spanning a well-
defined collection of nations. Regional Deployment Committees are open to participation by any
National Deployment Committee within that region. They operate as distinct organizations,
developing their own governance rules and business models, but report to and participate in the
800 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

805 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.

810 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:

- 815 1. Recruiting regional IHE initiative participants, sponsors and contributors.
2. Recruit local experts to join Domain Planning and Technical Committees.
3. Establishing liaison relationships with other organizations in order to further
communication and cooperation on shared objectives
4. Planning regional activities and coordinating national activities
- 820 5. Planning and supporting interoperability testing including Connectathons
6. Planning regional demonstrations and educational and promotional events

7. Retaining a technical project manager or management team to coordinate interoperability testing, Connectathons and demonstrations
- 825 8. Developing, publishing and disseminating educational and marketing materials in conformance with guidelines of IHE International
9. Organizing and holding regional Connectathons and interoperability testing processes in conformance with the IHE Technical Frameworks, including approved National Extensions
- 830 10. 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
2. Communicating regularly with other IHE National and Regional Deployment Committees
- 835 3. Participating in and contributing to IHE Global Deployment Coordination Committee activities

A Regional Committee interacts with IHE Domain Committees by:

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

8.3. Deployment Committee Membership and Procedures

8.3.1. Membership

845 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 standards development organizations.

8.3.2. Committee Structure

850 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;
- 855 2. Planning and coordinating national and regional demonstrations, workshops and other forms of education and marketing;
3. Planning and coordinating regional Connectathons

4. Gathering experts to prepare and provide national requirements documents to relevant IHE Domains

860 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. Global Deployment Coordination Committee

9.1. Scope

865 The Global Deployment Coordination Committee (GDC) facilitates consistent use and adoption of IHE profiles, processes, tools, and services throughout the world.

Global Deployment Coordination Committee activities include:

1. Develop new services and use existing services to facilitate and accelerate deployment
2. Engage developers in the IT vendor and research communities
- 870 3. Identify pilot projects for profiles that fill an agreed-upon need and expedite implementation
4. Develop concise value statements and operational descriptions for decision makers in the vendor IT and research communities
5. Gather and disseminate information on deployment projects
- 875 6. Obtain market needs to guide development work in IHE domain committees
7. Provide support to deployment committees so they can learn from one another.
8. Align international agenda
9. Facilitate sharing of best practices, including organizational and business models
10. Increase focus and follow-up on deployment committee reports
- 880 11. Develop a domain / deployment strategy that provides a conduit for the exchange of useful knowledge and resources, resulting in relevant, high-quality solutions.

9.2. Membership and Procedures

885 The policies and procedures of the Global Deployment Coordination Committee differ from or expand on those described in Section 10, below, as follows:

9.2.1. Membership

The GDC is composed of representatives from regional and national deployment committees.

1. Each Regional Deployment Committee may designate one user representative and one vendor representative

- 890 2. Each National Deployment Committee may designate one representative (from any interest category).

9.2.2. Committee Structure

The Committee may choose to establish internal Liaisons to other Committees

9.2.3. Frequency of Meetings

- 895 The Global Deployment Coordination Committee shall hold official meetings, either face-to-face or via teleconference, at least four times per year in at least three calendar quarters.

Teleconferences will be held at rotating times designed to allow for fair participation across all timezones where voting members reside. For the same purpose, locations of face-to-face meetings will be varied across all regions where voting members reside.

900 9.3. Reporting and Budget

The GDC will submit an annual report and annual budget proposal to the IHE International Board for its review and approval.

- IHE International will provide funding to support convening regular teleconferences and meetings of the GDC. The annual budget proposal developed by the GDC will specify and provide rationale for all other proposed expenses for consideration and approval by the IHE International Board.
- 905

10. Conformity Assessment Coordination Committee

10.1. Scope

- The Conformity Assessment Coordination Committee (CAsC) is responsible for coordinating, overseeing and managing all activities and duties pertaining to the IHE International Conformity Assessment program, as defined by the IHE Conformity Assessment Scheme. This will include:
- 910

1. Maintaining, including additions and modification, to the IHE International Conformity Assessment Scheme (IHE-CAS)
- 915 2. authorizing, suspending (temporary suspension), revoking (permanent termination) and surveying the activity of testing labs worldwide, which intend to or have been authorized to test products for conformity under the IHE-CAS
3. Coordinating the availability of test methods (including test tools, test scripts and test cases), including the terms of its licensing to authorized testing labs worldwide.
- 920 4. Providing direction to the different testing development teams that collaborate in the IHE International Testing and Tools Committee.
5. Maintaining an open dialogue with National/Regional Deployment Committees, IHE International Domain Committees, and IHE stakeholders in order to evaluate, assess and incorporate modifications and additions to the IHE-CAS and/or to the test methods.
- 925 6. Addressing, investigating and resolving disputes and complaints about content of IHE-CAS or its interpretation

7. Defining reciprocity agreements and memorandums with other partner testing organizations that leverage or will leverage IHE-CAS

10.2. Membership

930 The Conformity Assessment Coordination Committee is composed of IHE International members representing either IHE International National/Regional Deployment Committees, IHE Benefactors and/or IHE Partner organizations engaged in IHE Conformity Assessment testing or supporting (in-kind or financially) development of IHE Conformity Assessment testing tools and methods. Request for admission to membership is submitted directly to the Conformity Assessment Coordination Committee Co-Chairs together with a presentation of the rationale for admission. The request for admission is then discussed and voted on in the Conformity Assessment Coordination Committee. Participation in CAsC meetings is reserved to representatives of member organizations. Each member has one vote regardless of the number of representatives.

10.2.1. Membership Tiers and Roles

Tier	Category	Annual Fee
A	Founding Members (IHE-USA, IHE-Europe, IHE-Japan)	Yes
B	Members (supporting CA tool development and have an operational CA program)	Yes
C1	Members (supporting CA tools development, without CA program running)	Yes
C2	Members (supporting CA tools maintenance, may run a CA program)	Yes
D	General Interest	No

940 10.2.2. Voting Matrix: Topics and Tiers

Committee members in some Membership Tiers are prohibited from voting on certain committee topics as outlined in the following table.

Tier	CA Governance and CAS-1, Lab Authorization, Dispute Resolution	CAS-2 and Profile selection and prioritization	CA Tool Maintenance and support and membership fees	CA Tools development prioritization and management	Financial commitments to support CA Tools development (funding plan)	Committee work (minutes, agenda, work/input on documents, etc.)	Legal matters (MOUs, licensing agreements, etc.)
A
B
C1
C2
D

10.2.3. Membership Fees

945 To support the specific tasks and activities that entail running the IHE International Conformity Assessment program, general cost for documentation publication, legal fees, controversies and

disputes resolution, meeting rooms, etc. is split evenly among the members of tier A, B, and C1/C2.

These fees are set by the CAsC Committee on a yearly basis.

950

11. Education Committee

11.1. Scope

The Education Committee is responsible for directing and overseeing educational activities of IHE International and IHE National Deployment Committees. The responsibilities of the Education Committee include:

955

1. Monitor and support the organization of educational activities such as informative webinars conducted by IHE International Domain Committees.
2. Coordinating educational activities and materials developed and disseminated by IHE National Deployment Committees by providing a forum for planning, developing guidelines and facilitating sharing of materials.
3. Reviewing, commenting on and approving for use the Certification Scheme (syllabus and exam materials, processes, certification mark, etc.) developed for the IHE Certified Professional (ICP) program as well as the promotion of training events and certification exams.

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965

11.2. Membership and Procedures

The Education Committee is composed of IHE International members representing IHE International Domain and/or National Deployment Committees who volunteer to serve two-year renewable terms. Partner organizations engaged in IHE-related educational activities may participate in committee activities as deemed appropriate by the committee chair or co-chairs.

970

The members of the committee will select at least one committee member to serve as chair of the committee. It is recommended that two committee members be selected to serve as co-chairs. The chair or co-chairs will serve two-year renewable terms.

12. General Membership Procedures

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12.1. 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 IHE International may designate representatives to participate in Domain Committees relevant to its interest. A member organization may also apply to relevant National/Regional Deployment Committees.

980

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.

985 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.

990 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).

12.1.1. 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:

- 995
- 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
- 1000
- 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.

1005 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.

1010 Membership shall not commence until any applicable membership fees have been paid in full.

12.1.2. Termination of Membership

Member Organizations may terminate their membership in IHE International at any time by notifying the IHE International Board through its secretary (secretary@ihe.net) of their intent to do so.

1015 The IHE International Board may terminate the Membership of any Member Organization by a vote of its members, upon judgment that it has acted in violation of the Principles of IHE International and rules for participation, including failure to make payment in full of any applicable membership fees within 90 days of receiving notice of the fees due.

12.1.3. Membership Interest Categories

1020 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.

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
1025 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.

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

Organization Type	Interest Category			Description
	User	Developer	General Interest	
Health Research Organizations			X	Organizations performing clinical, technology or health-services research

1030

12.2. Committee Procedures

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

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.

1035 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.

1040 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.

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

1045 12.2.1. Open Meetings and Notice

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 meeting in-person attendance), telephonic access information (for a teleconference) and an agenda indicating the subject(s) to be addressed.

1050 Meetings allowing in-person attendance 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.

1055 Teleconference-only meetings at which committee votes may be taken shall be announced not less than 7 days prior to the meeting.

Additional representatives from Member Organizations are welcome at all committee meetings, but each organization shall have no more than one vote on any voting matter. .

The participation of individuals who do not represent an IHE Member Organization, referred to as Observers, shall be explicitly approved by the co-chairs at each meeting in which they

1060 participate. The presence of all attendees, including Observers, shall be recorded in the minutes of each meeting. Observers shall be occasional and not regular committee participants and are not entitled to participate as authors of technical documents. .

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.

1065 **12.2.2. Committee Structure**

A committee shall consist of its Secretariat, members and two co-chairs. In exceptional cases, a committee may have one or three co-chairs.

1070 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.

12.2.3. Voting and Quorum

1075 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.

1080 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.

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).

1085 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.

12.2.4. Letter Ballots

1090 For letter (or email) ballots on matters other than Co-chair elections, each member shall vote one of the following positions:

1. Affirmative;
2. Negative; the reasons for a negative vote shall be given and if possible should include specific wording or actions that would resolve the objection; or
- 1095 3. 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.

1100 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.

12.2.5. Matters Requiring a Vote

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
- 1105 2. Approval of change of committee scope
3. Approval of termination of the committee
4. Recall of officers
5. Approval of minutes

1110 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:

1. Formation of a subcommittee, including its procedures, scope, and duties
 2. Disbanding of a subcommittee
- 1115 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. In accordance with the Principles listed in Section 2, this is strongly recommended for significant issues.

12.2.6. Attendance, Absence and Voting Privileges

1120 Each committee shall maintain a roster that identifies member Representatives with voting rights and may also list member Representatives who do not currently have voting rights (non-voting representatives).

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

1125 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.

1130 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.

1135 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.

1140 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.

1145 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.

12.2.7. Co-chair Elections

1150 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.

1155 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. If appropriate candidates are not available within the voting membership of the committee, the committee may expand its pool of candidates by including as eligible nominees specific candidates who are not voting members.

1160 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.

1165 If a current Domain Co-chair is no longer a representative of a member organization, affected co-chair is removed and election for new co-chair held. If affected Co-chair moves to another member organization, he/she will continue in position as co-chair until domain secretary presents a motion on whether to hold an election to replace the affected Co-chair or have him/her remain in the position for remainder of term.

The IHE International Board may appoint one committee member to serve as an interim chair of the committee in order to initiate committee activity or if the committee is otherwise unable to

1170 select a chair. Alternatively, a committee with no co-chairs may identify an interim co-chair while a co-chair election is being held.

12.2.8. Co-chair Responsibilities

The responsibilities of Committee Co-chairs include:

1. Organizing the committee.
- 1175 2. Conducting Committee meetings and conference calls
3. Preparing and announcing agendas for Committee meetings and conference calls
4. Supporting the Secretary in documenting and disseminating meeting minutes
5. Be a consistent and active participant in Domain Coordination Committee.

12.2.9. Secretariat of a Committee

1180 The sponsors of a Committee are responsible for appointing the Secretary for the Committee.

The Secretary shall:

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
- 1185 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:
 - Title of the Committee;
 - Scope of the Committee;
 - Name and address of the Secretariat and Secretary;
 - 1190 • 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.
- 1195 4. Provide appropriate administrative personnel and resources to perform administrative work including:
 - Arranging meetings;
 - Maintaining adequate records, including recording and transcribing meeting minutes.
 - 1200 • 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

- 1205 • Performing other administrative functions as required.

12.2.10. Meeting Conduct

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.

- 1210 No commercial topics shall be acted upon or considered. Specifically excluded is discussion of:
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;
 - 1215 4. Allocation or division of territories of customers among manufacturers, distributors, or retailers;
 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;
 - 1220 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

1225 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.

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.

1230 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.

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

13. Ratification of this Governance Document

1235 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
 2. Domain Technical and Planning Committee co-chairs, present and past
 3. One representative per National and Regional Deployment Committee
-

13.1. Implementation Period

- 1240 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.
 - 1245 2. Current IHE International, Domain, National and Regional Sponsors will apply to IHE International as Members and Sponsors.
 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
 - 1250 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 “in formation”.
 6. National and Regional Deployment Committees will need to submit their application to IHE International
- 1255 Within 9 months of ratification of this Governance document, the Board and relevant IHE Committees will:
1. The Board will hold elections and establish new membership.
 2. Domain Planning and Technical Committees will elect Board representatives under the new governance.
 - 1260 3. National and Regional Deployment Committees will elect their Board representatives.

13.2. Amendments

- 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.
- 1265
- Individual committee charters for all IHE committees will be approved by the IHE International Board.

13.3. Transition to Self-supporting Organization

- 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
- 1270
- 1275

should move toward a business and operational model that encourages increasing self-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.

1280 **14. Selected Definitions**

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.

1285 *Affiliate:* A corporation, company or other entity that, directly or indirectly, shares a common Parent with the Member Organization.

1290 *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.

1295 *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
1300 Technical Document.

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, 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
1305 entity.
1310

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

1315 *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

1320 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 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.

1325 *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.

1330 *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.

1335 *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.

1340 *General Interest Member:* A Member Organization that has a significant interest in learning about healthcare information technology systems.

1345 *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.

1350 *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.

1355 *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.

1360

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.

1365

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.

1370

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 participation in other IHE committees are likewise described in the Membership and Procedures sections pertaining to each committee.

1375

1380

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.

1385

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).

1390

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

Appendix A: Intellectual Property Agreement

A.1 Ownership and Licenses

1395 A.1.1 Ownership Of Copyrights

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

1400 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
1405 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 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
1410 the scope of this IHE document and would have to be obtained from that other party.

A.1.1.2 Copyright of Base Standards

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 supersede any copyright
1415 provisions applicable to such base standards.

A.2 Trademark

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 IHE International Board Operations
1420 Committee, 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

1425 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

1430 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

1435 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 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 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 existence of the patent application and the affected IHE Technical Document(s).

A.3.3 Necessary Claims

1450 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.

A.3.4 No Duty to Search Patent Portfolios

1455 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

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

1460 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

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

1470 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
1475 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

1480 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
1485 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

1490 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.

A.4 Withdrawal

1495 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
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

1500 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

1505 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 the date on which the Member Organization has provided notice of intent to withdraw to the IHE Board Secretariat.

A.5 Non-Compliance

1510 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
1515 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

Each IHE Member Organization shall confirm its commitment to this IHE Intellectual Property Agreement by executing a Declaration in the form set forth below.
1520

A.7 Declaration

1525 _____ ("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.

Signed by _____ **Title** _____

Authorized Signature

1530

Print Name _____ **Date** _____