Integrating the Healthcare Enterprise

IHE International

Conformity Assessment Scheme
Part 1: Requirements for IHE Authorized Testing Laboratories
(CAS-1)

Revision 1.0

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CONTENTS

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1 General Information

1.1 Scope

This document describes the management and technical requirements necessary for a Testing Laboratory involved in the IHE Conformity Assessment Program (CAP).

This document (IHE-CAS-1) is part of the Conformity Assessment Scheme administered by IHE International.

- Section 1 describes the general scope of the program and roles of entities that are participating in the implementation of the IHE Conformity Assessment process.
- Section 2 describes how the IHE International Conformity Assessment Scheme is established and maintained.
- Section 3 defines the process that a candidate Testing Laboratory retained by an IHE Deployment Committee shall follow to obtain accreditation and authorization from IHE International.
- Section 4 defines management requirements for accreditation of a Testing Laboratory.
- Section 5 describes technical requirements for accreditation of a Testing Laboratory.

The document: *Conformity Assessment Scheme Part 2* (IHE-CAS-2) describes the baseline set of IHE profiles and procedures to be used for Conformity Assessment and Testing Laboratory accreditation.

Note: Regional IHE Deployment Committees can enhance or add to this set of IHE profiles and procedures and incorporate those changes in a certification scheme that expands the scope of this program. Those Deployment Committees could then deliver a complementary certification mark or symbol to reflect regional markets or national initiatives. Such expanded programs are considered out of scope for this Conformity Assessment Scheme.

The IHE Conformity Assessment Scheme is based upon ISO/IEC 17025 and ISO/IEC 17067.

Conformance testing sessions adhering to this IHE International Conformity Assessment Scheme shall result in:

a) Publication of the Test Report Summary (see Section 5.10.10) result of the testing by an Authorized Testing Laboratory accredited to ISO/IEC 17025 and the IHE International Conformity Assessment Scheme.

In a future version of this testing scheme:

b) Award of an IHE International “Testing mark” as specified in Appendix D representing the testing by an Authorized Testing Laboratory accredited to ISO/IEC 17025 and the IHE International Conformity Assessment Scheme.

In addition, it may also result in:

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c) Award of a formal certification by an accredited certification body selected by the IHE Deployment Committee and operating under ISO 17065 or ISO/IEC Guide 65 evaluating test results provided by an ISO/IEC 17025 accredited Testing Laboratory following the IHE International Conformity Assessment Scheme.

1.2 Purpose

The purpose of this document is to set forth the procedures and general requirements under which a Test Testing Laboratory can be accredited and authorized by IHE International to perform IHE Conformity Assessment under the IHE-CAS. This document is for use by testing laboratories developing management and technical systems to govern their operations. IHE Deployment Committees, Testing Laboratory customers, regulatory authorities, and accreditation bodies may also use it as a basis upon which to judge the competence of testing laboratories.

By fulfilling the requirements set forth in this document, a Testing Laboratory will meet both the technical competence requirements and management system requirements necessary to deliver consistent, technically valid test results. The management system requirements in this document (Section 4) are relevant to Testing Laboratory operations and meet the principles of ISO 17025:2005 *General requirements for the competence of testing laboratories* that applies the principles of the more generic ISO 9001:2000 *Quality management systems – Requirements*, directly to testing laboratory environments, systems and practices.

IHE International administers this scheme so that accreditation of Testing Laboratories performed according to its requirements will receive international recognition.

This document does not specifically address compliance with regional or national regulatory and safety requirements or additional regional testing criteria.

1.2.1 Accreditation Program

IHE International authorizes testing laboratories that are accredited by internationally recognized accrediting bodies that have found them competent to perform specific tests to ensure conformance with IHE profiles. This recognition of Testing Laboratories is based on internationally accepted standards. It facilitates the selection by IHE Deployment Committees of competent laboratories for use in product Conformity assessment while promoting the acceptance of test results across the world and thereby encouraging adoption of IHE profiles for interoperability worldwide

The IHE International Conformity Assessment Scheme (IHE-CAS) establishes base requirements for all IHE Conformity assessment programs. Each IHE National/Regional Deployment Committees will determine the detailed scope of its program based on a selection of IHE profiles, and actors relevant to the region and market. The list of current profiles and actors eligible for inclusion is provided in Volume 2 of the Conformity Assessment Scheme (IHE-CAS-2).

Both public and private Testing Laboratories are eligible for accreditation, including commercial laboratories, university laboratories, and local government laboratories. Accreditation of an IHE

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Testing Laboratories is based on evaluation of the Testing Laboratory's management and technical qualifications and competence for following specific test methods. An accredited Testing Laboratories is required to have adequate safeguards to ensure that its management and personnel are free from conflicts of interest and other business pressures that may adversely affect the quality, impartiality, and independence of their work.

At this time, the IHE-CAS does not allow manufacturers' in-house laboratories performing the testing on their own products.

The scope of accreditation for each Testing Laboratory will detail the specific test methods, measurements, and services for which a Testing Laboratory has been accredited for the complete IHE-CAS-2 or a subset.

1.2.2 Accreditation Program Information

As Conformity Assessment Scheme owner, IHE International makes the following information publicly available through its website:

a) A description of the Conformity Assessment Program (international level), including the scope of accreditation offered

b) Information about the accreditation process and the requirements for conformity assessment (assessment checklists, and other guidance materials)

c) Test methods and tools information required to be used for conformity assessment by the accredited Testing Laboratories

d) Directory of accredited Testing laboratories retained by IHE Deployment Committees and authorized by IHE International which includes the name and address, accreditation effective and expiration dates, and scope of accreditation (available subset of IHE-CAS-2) for each lab

e) Information about international recognition of the IHE Testing Mark

f) Various publications and forms for the use and benefit of accredited labs, assessors, technical experts, and other interested parties

1.2.3 Confidentiality

To the extent permitted by laws applicable to Testing Laboratories and IHE Deployment Committees in their place of incorporation and business activity, IHE International and all entities involved in the Conformity Assessment Program will protect the confidentiality of all information obtained relating to the application, on-site assessment, proficiency testing, evaluation, and accreditation of laboratories beyond the information publicly released as specified in the IHE-CAS (see Section 1.2, 5.10 and Appendix D).

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1.2.4 Referencing Testing Laboratory Accreditation

IHE International will grant permission to use the designation IHE International Authorized Testing Laboratory (IHE International ATL) term and symbol (see Appendix A) to accredited Testing Laboratories that it authorizes. This designation and seal are to be used solely for the purpose of announcing their authorized status, and for use on reports that describe testing within the scope of this IHE-CAS.

IHE International controls the use of this designation and seal in order to ensure that accredited Testing Laboratories express their accredited and authorized status clearly and accurately, and not misleading.

1.2.5 Mutual Recognition

IHE International promotes the acceptance worldwide of test reports from IHE International Testing Laboratories that have been accredited.

IHE International considers Authorized Testing Laboratories that meet the requirements of ISO/IEC 17025 and those requirements of this IHE-CAS, to be equivalent in their testing process and results. Purchasers and users of systems tested in these laboratories can confidently accept test reports issued by any Authorized IHE International Testing laboratories and the outcome of the validation of test reports (see Appendix D).

Note: Regional or national deployment committees may impose additional requirements on an IHE International Authorized Testing Laboratory beyond those specified in this Conformity Assessment Scheme in order to meet specific local needs. If so, they are required to publish documents for accreditation defining these additional requirements. This is beyond the scope of this IHE-CAS scheme and such principles for extensions are discussed in Annex C.

1.2.6 Choice of a suitable Accreditation Body

Deployment Committees may choose for their Testing Laboratories an accreditation body that can assess them to the requirements of this scheme. These bodies shall meet the ISO/IEC 17011 requirements and be a member of ILAC (International Testing Laboratory Accreditation Cooperation. If an accreditation body does not meet these requirements, its choice will have to be approved by the *Conformity Assessment Coordination Committee* of IHE International.

1.3 References

The following ISO Standards are referenced or used in the IHE-CAS:

- ISO 9000:2000, Quality management systems – Fundamentals and vocabulary
- ISO 9001:2000, Quality management systems – Requirements
- ISO/IEC 17000:2004, Conformity assessment – Vocabulary and general principles
- ISO/IEC 17011:2004, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

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- ISO/IEC 17020:1998, General criteria for the operation of various types of bodies performing inspection
- ISO/IEC ISO/IEC 17025:2005, General requirements for the competence of Testing laboratories
- ISO/IEC Guide 65:1996, General requirements for bodies operating product certification systems
- ISO/IEC 17065:2012, Conformity assessment – Requirements for bodies certifying products, processes and services
- ISO/IEC 17067:2012, Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes

1.4 Definitions

CAP

The Conformity Assessment Program established and administered by IHE International, consists of Test Methods used by an authorized IHE International Testing Laboratories to test IHE profiles and actors as defined by the IHE Conformity Assessment Scheme (IHE-CAS-1 and IHE-CAS-2).

Authorized IHE International Testing Laboratory

A Testing Laboratory retained by an IHE National or Regional Deployment Committee that has been accredited by an ISO/IEC 17025 accrediting body and has been authorized by IHE International to perform testing based on the IHE Conformity Assessment Scheme (IHE-CAS-1 and IHE-CAS-2).

Accreditation

Formal recognition by an accreditation body that a Testing Laboratory is competent to carry out specific tests methodology, as outlined in this document and the IHE Conformity Assessment Scheme Part 2 Document (IHE-CAS-2).

Approved Signatory

An individual designated by a Testing Laboratory and deemed competent and authorized to sign accredited Conformity Assessment test reports and assume responsibility for the results they contain. An Approved Signatory is responsible for the technical content of the report and is the contact person for questions or problems with the report.

Assessment (on-site assessment)

Systematic, independent, and documented process for determining Testing Laboratory competence and for obtaining records, statements of fact and other relevant information by assessors at the Testing Laboratory facilities and other places where test services are provided

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with the objective of determining the extent to which requirements are fulfilled. Note from ISO/IEC 17000:2004: While "audit" applies to management systems, "assessment" applies to conformity assessment bodies.

Authorized Representative

An individual authorized by a Testing Laboratory top management to commit the organization to fulfill the conditions for accreditation. The Authorized Representative reports to IHE International or the regional/national deployment committee's authorized accreditor any changes that may affect the Testing Laboratory's capability, scope of accreditation, or compliance with accreditation requirements, including any changes in key personnel.

Certificate of Accreditation - IHE Testing Laboratory

Document granted to a Testing Laboratory issued by an accreditation body approved by IHE International. A Certificate of Accreditation is always issued with a Scope of Accreditation (see Scope of Accreditation).

Certificate of IHE International Authorized Testing Laboratory

Document issued by IHE International to an accredited Testing Laboratory confirming that it is an IHE International Authorized Testing Laboratory.

Customer

Any person or organization that engages the services of a Testing Laboratory to perform testing of a customer's product or service.

Competence

Ability of a Testing Laboratory to conduct tests in accordance with the specified standards and profiles to produce accurate, proper, fit for purpose, technically valid data and test results.

Inter-Testing Laboratory comparisons

Organization, performance and evaluation of tests on the same or similar systems by two or more laboratories in accordance with predetermined conditions. (See also proficiency Testing Laboratory.)

Measuring and test equipment (M & TE)

All of the instruments, standards, reference materials, auxiliary apparatus and instructions that are necessary to perform a measurement.

Nonconformity

Nonfulfillment of IHE International requirements for accreditation; may also be referred to as a Deficiency.

Proficiency testing (Testing Laboratory proficiency testing)

Understood broadly to include items such as:

a) Qualitative schemes: laboratories are required to identify a component of a test item.

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b) Data transformation exercises: laboratories are furnished with sets of data and are required to manipulate the data to provide further information.

c) Inter- Testing Laboratory comparisons: Single item testing where one item is sent to a number of laboratories sequentially and returned to the organizer at intervals.

d) One-off exercises: laboratories are provided with a test item on a single occasion.

e) Continuous schemes: laboratories are provided with test items at regular intervals on a continuing basis.

Quality Management System

A system to establish a quality policy and quality objectives and to achieve those objectives. [ISO 9000:2000, 2.2.3]

Quality manual

A document specifying the quality management system of an organization. [ISO 9000:2000, 2.7.4]

Requirement

A provision that conveys criteria that must be fulfilled to achieve and maintain accreditation. [ISO/IEC Guide 2:2004, 7.5]

Revocation

The removal of the accredited status of a Testing Laboratory if found to have violated the conditions for accreditation.

Scope of Accreditation

The Scope of Accreditation lists the test methods or services, for which the Testing Laboratory is accredited. (See also Certificate of Accreditation.) Shall be documented with the accreditation granted to a Testing Laboratory.

Suspension

Temporary removal of the accredited status of a Testing Laboratory for all or part of its scope of Accreditation when it is determined (by the IHE Deployment Committee, Accreditor or IHE International) that the Testing Laboratory does not meet the conditions for accreditation.

Test method

Defined technical procedure, test cases, test tools and processes to determine one or more specified characteristics of a product.

Traceability

Property of the result of a measurement or the value of a standard whereby it can be related to a specific requirement, usually in IHE Profiles or international standards, through an unbroken chain of comparisons (called a traceability chain), each of which has stated uncertainties.

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2 Processes for the establishment and implementation of the IHE International CAS

2.1 Basis for Establishment

2.1.1 General

As part of its Conformity Assessment Program, IHE International and its Deployment Committees have developed this IHE-CAS as the overarching scheme for the implementation of accredited testing services.

Note: IHE Deployment Committees may expand the scope of the IHE-CAS-2 in response to Regional or national government legislative or administrative actions or to requests by private sector entities. Such extensions are possible but are out of scope of this IHE International Conformity Assessment Scheme.

2.1.2 Establishment of a Testing Laboratory

A request to establish a Testing Laboratory must be made by an active IHE Deployment Committee to IHE International. Each request must include, among other requirements, the initial set of IHE profiles targeted for testing, one or more retained Testing Laboratory and the accreditation body chosen.

Note: Other requirements such as administrative and business requirements are not defined in the IHE-CAS.

2.2 Development of technical requirements

IHE International develops the technical requirements in the form of profiles specifications documented in its technical frameworks (in the status of final text-See 4.2.2). This is an open process, involving relevant and impartial expert advice, ensuring that all interested parties have the opportunity for effective involvement. This advice is obtained directly through Development Committees organized by IHE International. It includes Planning and Technical Committees or other suitable means, such as its profile maintenance process and outcome of collaborative testing events (or Connectathons).

IHE International organizes Technical Committee meetings or other means of collecting input, with an opportunity for all interested parties to attend and/or respond. A summary of each meeting is prepared and made available upon request.

Technical requirements for accreditation are specified:

- in IHE-CAS-1, Section 5 of this document, as general requirements such as the process to select profiles and test methods.
- in IHE-CAS-2, with the selected IHE Profiles, the test methods and test results templates.

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2.3 Announcing the establishment of the IHE International CAS

This IHE-CAS becomes effective upon announcement by IHE International. The announcement notice identifies the scope of the CAS and advises laboratories how to apply for accreditation.

2.4 Adding to or modifying the IHE International CAS

The Conformity Assessment Coordination Committee of IHE International is responsible to maintain the IHE-CAS. In particular, any entity, including regional or national Deployment Committee, wishing to add specific test methods, or IHE profiles may propose such an extension.

The Conformity Assessment Coordination Committee is responsible to manage additions or modifications to the IHE-CAS when:

- the additional test methods, or IHE profiles requested are of interest to the IHE Deployment Committees overseeing Testing Laboratories;
- it is feasible and practical to accredit Testing laboratories for the additional test methods, or profiles/standards, (for example according to the scope of the accreditation;
- it is feasible and practical to accredit Testing laboratories for the additional test methods, or profiles/standards, (for example according to the scope of the accreditation; and
- it is likely that most or all laboratories will seek accreditation for the additional test methods, or profiles/standards.

The Relevant Committee manages the maintenance and publication process for the CAS. The process for modifying the IHE-CAS depends on the nature of the modification. Significant changes to the CAS may be subject to a process similar to that described in Section 2.4. Minor changes (e.g., addition of methods for technologies already included in a CAS-2) may be handled in a less formal manner.

2.5 Termination of the IHE-CAS

IHE International may terminate its CAS when it is determined that a need no longer exists to accredit laboratories for the services covered under the scope of the CAS. If IHE International determines that input from interested parties is necessary prior to making the determination to terminate the CAS, IHE Deployment Committees with Testing Laboratory(ies) will provide comments on the proposed termination. In the event that IHE International decides to terminate its CAS, a 90-day notice will be published setting forth the basis for that determination.

When the IHE-CAS is terminated, IHE International will cease to grant or renew authorizations following the effective date of termination. Authorizations previously granted remain effective until their expiration date unless terminated voluntarily by Testing Laboratory or revoked by IHE

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International. Technical expertise will be maintained by IHE International while any authorization remains effective.

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3 Testing Laboratory Accreditation process

3.1 Application for initial accreditation

Accreditation is the result of a successful assessment by an accreditation body.

Testing Laboratories apply for accreditation by submitting a completed application and any required fees to the accrediting body retained by their partner IHE Deployment Committee along with any additional materials required, such as a quality manual, and associated documentation. (See Section 3.7 for renewal of accreditation.)

By signing the application, the Testing Laboratory's Authorized Representative commits the Testing Laboratory to follow the process for accreditation documented in the IHE CAS and the Authorization process documented in Section 3.6 (See Appendix B of this document for an overview).

3.2 Activities prior to on-site assessment

The activities prior to on-site assessment by the accrediting body and the Testing Laboratory follow ISO ISO/IEC ISO/IEC 17025. They relate to both the initial accreditation and the renewal of accreditation.

3.3 On-site assessment

3.3.1 On-site assessment process

The on-site assessment activities by the accrediting body and the Testing Laboratory follow ISO ISO/IEC ISO/IEC 17025. They relate to both the initial accreditation and the renewal of accreditation.

3.3.2 On-site assessment report

The assessor from the accreditation body submits a written report on the compliance of the Testing Laboratory with the IHE CAS requirements. The report shall include as a minimum:

a) date(s) of assessment;

b) the names of the assessor(s) responsible for the report;

c) the names and address of the Testing Laboratory site (or sites, if multiple) that have been assessed;

d) the assessed scope of accreditation;

A copy of the accreditation report or certificate shall be provided by the IHE Deployment Committee to IHE International. Further details may be requested as appropriate.

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3.3.3 Notification and resolution of nonconformities

IHE Deployment Committees are required to report any unresolved nonconformities resulting from the assessment or changes in accreditation status of the Testing Laboratory within 10 days to IHE International. Testing activities by the Testing Laboratory shall be suspended and IHE International may revoke its authorization.

3.4 Proficiency testing

3.4.1 General

Proficiency testing is an integral part of the accreditation process. The performance of tests and reporting of results requires competence from the Testing Laboratory. The accrediting body shall determine the competence of the testing staff and the effectiveness of the Testing Laboratory's management system.

IHE International requires each Testing Laboratory to:

a) Have every staff member (Test Manager and Testing Team members) participate at least once every four years in proficiency testing training organized by IHE International related to each set of profiles from those in the IHE-CAS for which it is (or plans to become) accredited. This should be performed by half of the staff, before gaining initial accreditation.

b) The Test Manager, or designate, plus at least one Test Team member shall have participated as a Monitor in one of the IHE Connectathons (other than the one organized by their retained Testing Laboratory). Initially this should be performed before gaining initial accreditation.

c) At any point in time, after one year following initial accreditation, the Testing Laboratory shall maintain the levels of qualification defined by a) and b) above for the testing staff (Test Manager and Test Team).

Additional applicable requirements and information about proficiency testing programs, service providers, and frequency of participation is given in IHE-CAS Part 2, when applicable. This may include proficiency testing requirements, proficiency testing methods varying depending on the nature of the test item and use inter- Testing Laboratory comparisons with known test data and expected results.

3.4.2 Analysis and reporting

The accreditation body analyzes proficiency testing data and reports each Testing Laboratory's results only to that organization.

3.4.3 Proficiency testing nonconformities

Unsatisfactory participation in any proficiency testing program is a nonconformity that must be resolved in order to obtain or maintain accreditation.

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Proficiency testing nonconformities are defined as, but not limited to, one or more of the following:

a) failure to meet specified proficiency testing participation or performance requirements prescribed by IHE International;

b) failure to produce acceptable test results when using standard reference materials defined in IHE-CAS-2.

The accrediting body will notify the Testing Laboratory of proficiency testing nonconformities and actions to be taken to resolve them.

3.5 Granting accreditation

Accreditation is granted by the accreditation body when a Testing Laboratory has met all IHE International CAS-1 and CAS-2 requirements relevant to its scope.

The accreditation body provides to the Testing Laboratory a Certificate of Accreditation which includes:

a) The name and address of the Testing Laboratory that has been accredited;

b) The scope of the accreditation, including (1) the test methods, or types of tests, for which accreditation has been granted, and (2) for tests, the IHE International profiles and actors tested, the methods used, and the tests performed as defined in IHE-CAS-2.

c) The Testing Laboratory's Authorized Representative;

d) The effective and the expiration dates of the accreditation;

The certificate of accreditation shall have a term not longer than four years.

Renewal dates may be reassigned by no more than three months to the benefits of the Testing Laboratory and/or IHE International. If a renewal date is changed, the Testing Laboratory will be notified by the accreditation body in writing of the change and any resulting impact.

In addition, following initial accreditation:

a) An on-site assessment by the accreditation body shall be conducted at a minimum every four years thereafter.

b) Yearly remote assessments by the accreditation body shall be conducted for changes in CAS-2.

Delay of assessments beyond these frequencies may affect a Testing Laboratory's accreditation status.

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3.6 Authorization of a Testing Laboratory

3.6.1 IHE International Authorization Overview

The Conformity Assessment Coordination (CAC) Committee grants authorization to a Testing Laboratory to perform Conformity Assessment Testing according to the IHE-CAS upon:

a) Review of the accreditation report submitted by the Deployment Committee that has retained the Testing Laboratory to take note of its successful accreditation.

b) Recording the commitment of a Deployment Committee to contribute its share of resources to support test tooling development and management of the conformity assessment program.

c) Recording the commitment and readiness of the Testing Laboratory to conduct testing according to the IHE-CAS and to be referred to as an IHE International Authorized Testing Laboratory

d) Establishment a collaborative agreement between the Conformity Assessment Coordination Committee of IHE International, the supervising IHE Deployment Committee and its retained Testing Laboratory.

IHE International and the IHE Deployment Committee jointly acknowledge this Authorization in writing.

3.6.2 Authorization following IHE-CAS accreditation

The Conformity Assessment Coordination (CAC) Committee of IHE International is responsible for authorizing, renewing, suspending, and revoking an IHE International Authorized Testing Laboratory to perform IHE testing per the IHE-CAS.

The Decision to authorize a Testing Laboratory is based on the Testing Laboratory's record, including:

a) Information provided on the authorization application

b) Accreditation granted by a suitable accreditation body (see Section 1.2.6)

c) Is retained by an IHE Deployment Committee committed to engage in the Conformity Assessment Coordination Committee's activities

d) The requested scope of accreditation (subset of CAS-2)[1]

e) A general description of the Testing Laboratory, including its facilities and scope of operation

[1] Scope: A Testing Laboratory may choose to request its accreditation to include other IHE profiles that are not in CAS-2. Although such an accreditation will exceed the scope of the IHE-CAS, IHE International authorization only applies to the part that is related to the subset of the CAS-2.

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f) Additional business requirements specified outside of IHE-CAS

Authorization is granted for the same duration as certification has been granted.

3.7 Renewal of accreditation and of IHE International authorization

It is the responsibility of the IHE International Authorized Testing Laboratory to renew its accreditation, if so desired, to allow sufficient time to complete the Accreditation renewal process.

The IHE Deployment Committee that has a retained a Testing Laboratory should communicate to the Conformity Assessment Coordination (CAC) Committee the reports of accreditation renewal of the Testing Laboratory within 10 days to avoid a lapse in authorization.

3.8 Changes to scope of accreditation and of IHE International authorization

A Testing Laboratory may request in writing changes to its scope of accreditation to its accreditation body:

a) The Testing Laboratory must meet all IHE International CAS-1 and in scope CAS-2 requirements for the requested additions to its scope. Additional on-site assessment and/or proficiency testing may be required, as determined by the accrediting body.

b) A Testing Laboratory may also request deletions from it scope of accreditation. The deletions may be temporary or permanent.

The IHE Deployment Committee that has a retained a Testing Laboratory should communicate to the Conformity Assessment Coordination (CAC) Committee the change of scope in accreditation of the Testing Laboratory within 10 days of the change being recorded by the accreditation body to ensure an update of the authorization record.

3.9 Suspension of Accreditation and Authorization

If a Testing Laboratory's accreditation is suspended by its accreditation body, the IHE Deployment Committee shall notify IHE International of that action, within 10 days, stating the reasons for and conditions of the suspension and specifying the action(s) the Testing Laboratory must take to have its accreditation reinstated. A reassessment of the Testing Laboratory may also be required by the accreditation body for reinstatement.

Given the conditions of suspension (failure to meet one or more of the requirements stated in Section 3.6.2), IHE International may decide to prohibit the Testing Laboratory from performing any test based on the IHE International CAS, use of IHE logo in its communication and advertising during the suspension period. IHE International will identify this suspended Testing Laboratory in its public list of authorized Testing Laboratories.

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When accreditation is reinstated by the accrediting body, IHE International shall be notified by the IHE Deployment Committee and will have one month to authorize the Testing Laboratory to resume testing activities as an IHE International Authorized Testing Laboratory.

3.10 Denial and revocation of authorization

If the Conformity Assessment Coordination (CAC) Committee denies or revokes authorization of a Testing Laboratory on the basis of failure to meet one or more of the requirements stated in Section 3.6.2 (e.g., suspended Testing Laboratory has not reinstated its accreditation after long period), it informs the IHE Deployment Committee and the Testing Laboratory of the reasons for the denial or revocation and the procedure for appealing the decision. Revocation of authorization can apply to all or part of a Testing Laboratory's scope of accreditation.

The Testing Laboratory or the IHE Deployment Committee has 30 days from the date of receipt of the denial or revocation letter to appeal the decision to the IHE International Board. If the appeal is made of the decision, the denial or revocation will be stayed pending the outcome of the appeal. The proposed denial or revocation will become final either (1) through the issuance of a written decision to the Testing Laboratory and the IHE Deployment Committee or (2) within the 30-day period from the date of receipt in the event that no appeal is made.

If authorization is revoked, the Testing Laboratory may decide to voluntarily terminate its accreditation (see Section 3.11).

Test reports issued by the Testing Laboratory prior to revocation of its authorization remain valid.

A Testing Laboratory whose authorization has been denied or revoked, may reapply (see Section 3.6).

3.11 Voluntary termination of authorization

A Testing Laboratory with a 30 days prior notice may terminate its participation and responsibilities as an IHE International Authorized Testing Laboratory by advising its supervising IHE Deployment Committee and the IHE International Conformity Assessment Coordination (CAC) Committee in writing of its desire to do so.

Upon receipt of a request for termination, IHE International will terminate the Testing Laboratory's authorization, notify the Testing Laboratory that its authorization has been terminated, and instruct the Testing Laboratory to no longer use the IHE International CAS symbol from all new test reports, correspondence, and advertising.

A Testing Laboratory whose authorization has been voluntarily terminated may reapply (see Section 3.6).

3.12 Other Appeals

A Testing Laboratory may appeal any adverse decision made by the IHE International Conformity Assessment Coordination (CAC) Committee, including refusal to accept an

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application; requests for corrective actions; decisions on changes in scope of authorization; decision to deny, suspend, or revoke authorization; and any other action affecting a Testing Laboratory's authorization.

a) Appeals of decisions made initially by the IHE International Conformity Assessment Coordination (CAC) Committee (e.g., denial of authorization, revocation of authorization) are handled by the IHE International Board (see Section 3.10).

b) Other appeals are handled by the IHE International Conformity Assessment Coordination (CAC) Committee that may designate an advisory panel of experts to address such appeals. The disposition of such appeals shall be communicated to the IHE International Board.

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4 Management requirements

4.1 Organizational context

IHE International is comprised of several organizations or entities operating at the international and the regional/national levels. This section describes activities by these organizations ranging from profile specifications development to fostering adoption of profiles throughout the world that are involved directly or indirectly in conformity assessment:

- IHE International approves and publishes the IHE International Conformity Assessment Scheme (IHE-CAS). The scheme owner administers the scheme per Section 4.3.1 through 4.3.3.
- IHE Domain Development Committees define the specifications of the IHE Profiles and their interoperability requirements. These profiles are used as the basis for IHE-CAS-2.
- IHE Deployment Committees that organize the adoption of IHE profiles including the use of conformity assessment testing results in regions of the world and nations. A number of IHE Deployment Committees chose to organize IHE Connectathons and/or IHE Conformity Assessment testing activities by retaining Testing Laboratories.
- Conformity Assessment Coordination Committee of IHE International maintains the IHE International Conformity Assessment Scheme (IHE-CAS) and is the forum where IHE Deployment Committee members coordinate the availability of test methods (including test tools, test scripts and test cases). To that end it provides consistent and quality direction to the different testing development teams collaborating in the IHE International Test Tool Development Committee.
- IHE International Authorized Testing Laboratories perform testing based on the processes defined in IHE-CAS-2 and provide testing reports from the execution of the test methods specified by IHE-CAS-2.
- Validation Entity validates and publishes the testing report summary provided by the IHE International Authorized Testing Laboratories.
- Accreditation Bodies audit and assess the activities of the Testing Laboratories for conformance to the IHE-CAS and the underlying ISO/IEC 17025 standards.

4.2 Management of the IHE-CAS

This section covers the document control for both IHE-CAS-1 and IHE-CAS-2 by IHE International.

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4.2.1 Role of IHE-CAS-2

The IHE-CAS-2 describes the set of profiles and associated test methods to be used for accredited testing. The IHE-CAS-2 document is continuously maintained and revised typically on an annual basis. The maintenance follows principles described below:

a) The IHE-CAS-2 document is an integral part of the IHE International Conformity Assessment Scheme and describes requirements consistently with the ISO/IEC 17025;

b) Accredited Testing Laboratories shall update their own test process within a period of six months from the effective date of each new version of the IHE-CAS-2.

4.2.2 Document approval and issue

IHE-International delegates to the Conformity Assessment Coordination Committee to update the current version of IHE-CAS-1 and IHE-CAS-2 by correcting identified issues and updating the set of profiles and test scripts it references.

The Conformity Assessment Coordination Committee oversees the development of new versions of the CAS addressing all comments received or any other defects identified (e.g., from complaints to IHE Testing Laboratories for example).

Each major new version of IHE-CAS-1 is published and submitted for public comments for a period of 45 days. After resolution of the received comments by the Conformity Assessment Coordination Committee, the new version is submitted for approval to the IHE International Board with a proposed effective date. After approval the new version is published on IHE International's website.

Each major version of IHE-CAS-2 is published and submitted for public comments for a period of one month. After resolution of the received comments by the Conformity Assessment Coordination Committee, the new version is approved by the Conformity Assessment Coordination Committee with an effective date. After approval, the new version is published on IHE International's website. IHE-CAS-2 is typically updated each year.

IHE-CAS-2 references IHE Profiles that have gone through the process of public comment and trial implementation testing and have been advanced to the status of final text.

4.3 Testing Laboratory management system

IHE International Authorized Testing Laboratory must comply with ISO/IEC 17025 for the requirements that are relevant to testing activities.

Note: If an IHE International Authorized Testing Laboratory services offers other services than testing within the IHE-CAS scope of accreditation, this Testing Laboratory shall have a policy and procedures for maintaining a clear separation of those other testing services from its IHE CAS testing services.

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4.3.1 Quality system

The Testing Laboratory shall take precaution to secure the integrity and the traceability of the test results generated by the testing activities per ISO/IEC 17025. Testing Laboratories are required to produce documentation of technical procedures in addition to establishing a quality manual.

Note: An example of Quality Management System is offered by the Antilope (European Union Funded project): *Quality Management System for Interoperability Testing (http://www.antilope-project.eu/resources).*

4.3.2 Document control

The Testing Laboratory shall implement all relevant documents, test methods (test plans, test cases or test procedures and test tools) specified by IHE-CAS-2 for each of the profiles offered for testing.

The Testing Laboratory is authorized to develop additional documentation, specifications, procedures, methods and tools to facilitate the testing activities as long as these supplemental materials meets the requirements described in Section 5.4.3.

The Testing Laboratory shall establish procedures and mechanisms to control the compliance of its own deliverables to the IHE-CAS of IHE International by keeping them up to date. Testing Laboratories shall conduct periodic quality review (typically once a year).

4.3.3 Subcontracting of testing

The Testing Laboratory shall maintain a register of all subcontractors that it uses for tests and a record of evidence of compliance with the IHE-CAS. The Testing Laboratory has the responsibility to verify that the sub-contractor has:

a) Policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results

b) Arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.

4.3.4 Service to the Customer

A Testing Laboratory is retained by an IHE Deployment Committee and operates under its direction.

Customers of the Testing Laboratory are IT systems implementers that submit their products for the testing defined in IHE-CAS.

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4.3.5 Complaints

The Testing Laboratory shall have a policy and procedures for resolution of complaints received from Customers or other parties. The Testing Laboratory shall maintain records of all complaints, their investigations and resolutions, including any corrective actions.

Testing Laboratory, taking into account confidentiality constraints, shall prepare an annual complaint report to the IHE Deployment Committee with copy to IHE-International. This report will contain the list of major complaints and their resolution.

Complaints specifically addressing the IHE-CAS shall be analyzed by IHE International's Accredited Conformity Assessment Coordination Committee for traceability as a valuable source of feedback to improve the quality of the global process.

4.3.6 Corrective action

Testing Laboratories shall take corrective actions whenever quality system, management, or technical non-conformities are identified either through a complaint or an internal source. The Testing Laboratory shall establish necessary policies and procedures and designate appropriate authorities for implementing corrective actions.

Corrective actions should be designed to eliminate and prevent recurrence of the problem.

Testing Laboratory shall document and monitor the results to ensure of corrective actions to ensure they have been effective.

The Testing Laboratory shall communicate its annual report of corrective actions to the IHE Deployment Committee with copy to IHE International for improvement of the global process.

4.4 Implementation of a certification program by IHE Deployment Committee

When an IHE Deployment Committee choses to administer a certification program in its region/nation related to profiles included in IHE-CAS-2, it is required to base its certification on results produced by an IHE International authorized Testing Laboratory accredited against ISO/IEC 17025 and the IHE International CAS.

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5 Technical requirements

5.1 General

Many factors determine the correctness and reliability of the tests performed by a Testing Laboratory.

5.2 Personnel

The Testing Laboratory will designate at least the following personnel:

Top Level Management

Coordinates all activities. Receives reports from the Quality Manager and the Test Manager.

Quality Manager

Manages the Quality Assurance process, reports to Top Level Management. Shall be a person distinct from Top level Management.

Test Manager

Manages and organizes the testing activities, reports to Top Level Management. Follows rules from the Quality Management System to ensure the overall quality of the process. Shall be a person distinct from Top Level Management and the Quality Manager.

Testing Team

Performs tests under the supervision of the Test Manager.

System Under Test (SUT) Operators

Execute the test steps required by the test scripts.

5.3 Accommodation and environmental conditions

See ISO/IEC 17025.

5.4 Test methods and method validation

5.4.1 General

The Testing Laboratory shall use appropriate test methods and procedures for all tests within its scope as specified in the IHE-CAS-2 document. Deviation from test methods shall occur only if the Testing Laboratory has documented the deviation in the test report, provided technical justification, received the authorization from QA Manager, and the affected customer have indicated their acceptance of the deviation and the Testing Laboratory has notified the Conformity Assessment Coordination Committee of IHE International and the IHE Deployment Committee.

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5.4.2 Development and Selection of Standards Methods

The Testing Laboratory shall use test methods, which follow IHE International guidelines (Profiles) as specified in the IHE-CAS-2.

The Conformity Assessment Coordination Committee in IHE International coordinates the development of test methods and engages qualified test tool development teams.

5.4.3 Testing Laboratory-developed methods

The introduction of test methods developed by the Testing Laboratory for its own use is allowed as long as the Testing Laboratory has been accredited by demonstrating that its own developed methods are materially equivalent to those specified by IHE-CAS-2 and achieve equivalent results.

5.4.4 Non-standard methods

Non-standards methods (See ISO/IEC 17025) are methods that the Testing Laboratory shall validate to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. Non-Standard methods shall be used.

5.4.5 Validation of methods

Standard methods (test cases, procedures, reference test data and test tools) included in IHE-CAS-2 are validated through use by Test Teams from Testing laboratories and SUT Operators in at least three IHE Connectathons. Validation reports are reviewed by the Conformity Assessment Coordination Committee of IHE International which approves the validation process.

The Testing Laboratory shall validate any Testing Laboratory-developed methods (e.g., standard methods used outside their intended scope, and modifications of standard methods) to confirm that the methods are fit for the intended use, are materially equivalent to those specified by IHE-CAS-2 and achieve equivalent results.

5.4.6 Estimation of uncertainty of measurement

Developers of Test Methods perform the estimation of uncertainty of measurement (test coverage) of the standard methods (test cases and test tools) included in IHE-CAS. The Conformity Assessment Coordination Committee of IHE International reviews the estimation of uncertainty of measurement report for approval.

5.4.7 Control of data

The acquisition, processing, recording, reporting, storage or retrieval of test data by Testing Laboratory computerized equipment shall be controlled according to ISO/IEC 17025 requirements.

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5.5 Test Equipment and Test Methods

See ISO/IEC 17025.

IHE International provides, to authorized Testing Laboratories, software for the standard test methods (test cases, procedures, test data references, and test tools) and associated documentation (e.g., operator manuals) under a controlled update process.

5.6 Measurement traceability

5.6.1 General

The Testing Laboratory shall validate all equipment used for testing that may have a significant effect on the accuracy or validity of test results before being put it into service using an established program and procedure.

Note: Such a program should include a system for selecting, using, validating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests.

5.6.2 Specific requirements

For calibration, see ISO/IEC 17025.

5.6.3 Testing

IHE-CAS-2 references sample test data that shall be used by each Testing Laboratory to validate the accuracy of its test methods before they are put into service.

The Testing laboratories shall maintain a local record of their periodic accuracy validation of test methods.

5.6.4 Reference standards and reference materials

IHE Specifications. See IHE-CAS-2 for details on the tested IHE specifications.

Sample test data shall be traceable to IHE Profiles. See IHE-CAS-2 for details on the tested IHE Specifications.

5.7 Sampling

Not applicable.

5.8 Handling of test items

See ISO/IEC 17025.

5.9 Ensuring the quality of test results

See ISO/IEC 17025.

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5.10 Reporting the results

5.10.1 General

The Testing Laboratory shall accurately and clearly report the results of each test or series of tests carried out in accordance with any specific instructions in the test scripts. The results shall be reported in a test report, and shall include all information necessary for the interpretation of the test results and all information required by the script used. This information is normally what is required by Sections 5.10.2 and 5.10.3.

Any information listed in Sections 5.10.2 and 5.10.3 which is not reported to the customer shall be readily available from the Testing Laboratory which carried out the tests.

5.10.2 Test reports

Each test report shall include at least the information recommended by ISO ISO/IEC 17025. Test reports shall follow the template provided in IHE-CAS-2.

5.10.3 Test reports – Additional Requirements

In addition to the requirements listed in Section 5.10.2, test reports shall, where necessary for the interpretation of the test results, include information about deviations from, additions to, or exclusions from the test methods, and information on specific test conditions, any opinions and any interpretations (see Section 5.10.5).

The name of at least one Approved Signatory shall appear on a test report that displays the *IHE International Conformity Assessment Program* (CAP) symbol and references the Authorized Testing Laboratory authorization and accreditation. A computer-generated report may have the Approved Signatory's name printed along with the test results, as long as there is evidence that there is a system in place to ensure that the report cannot be generated without the review and consent of the Approved Signatory. There may be legal or contractual requirements for original signatures to appear on the report.

A test report that contains both data covered by the accreditation and data not covered by the accreditation shall clearly identify the data that are not covered by the IHE-CAS accreditation and must prominently display the following statement at the beginning of the report: "This report contains data that are not covered by the IHE-CAS accreditation."

A test report that contains both data covered under the accreditation and data provided by a subcontractor shall clearly identify the data that were provided by the subcontractor. The report must prominently display the following statement at the beginning of the report: "This report contains data that were produced under subcontract by Testing Laboratory X." If the subcontracted Testing Laboratory is accredited through the IHE-CAS, then this should also be stated. It shall also be stated if the subcontracted Testing Laboratory is not accredited (for conditions, see Sections 4.3.3 and 5.10.6).

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Each test report shall include a statement that the report must not be used by the Customer to claim product certification, approval, or endorsement by IHE International or regional/national Deployment Committee, or any applicable government agency.

5.10.4 Calibration certificates

Not applicable.

5.10.5 Opinions and interpretations

See ISO/IEC 17025.

5.10.6 Testing results obtained from subcontractors

The use of subcontractors by a Testing Laboratory is allowed and shall follow ISO/IEC 17025.

5.10.7 Electronic transmission of results

See ISO/IEC 17025.

5.10.8 Format of reports

The Test Reports shall distinguish:

a) The Test Report Summary. A template for test reports provided in IHE-CAS-2 shall be used.

b) The Test Report Details.

5.10.9 Amendments to test reports

See ISO/IEC 17025.

5.10.10 Publication of Test reports

The Test Report Summary (see Section 5.10.8), once validated by the Validation Entity will be published.

The test Report Summary shall contain a statement specifying that it may only be reproduced in full and publication of excerpts is forbidden.

The Test Report Details will be archived by the Testing Laboratory, and may be accessed upon request by the IHE Deployment Committee and the Conformity Assessment Coordination Committee of IHE International.

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Appendix A – Referencing Authorization based on IHE International Conformity Assessment Scheme

A.1 Conditions for referencing the term, logo, and symbol of the IHE International CAS

The terms *IHE International, IHE International Authorized Testing Laboratory*, and *IHE International Conformity Assessment Program* (CAP) and the IHE-CAP logo are registered marks of IHE International, Inc, which retains exclusive rights to control their use.

Permission to use the terms and symbol (IHE-CAP logo with approved caption) is granted to IHE International Authorized Testing Laboratories for the limited purpose of announcing their IHE International Authorized status, and for use on reports that describe only testing within the scope of the IHE-CAS accreditation.

IHE International reserves the right to control the quality of the use of the IHE-CAP logo, terms, and symbol.

a) An applicant Testing Laboratory that has not yet achieved accreditation and received authorization may make reference to its applicant status. An applicant Testing Laboratory shall not use the IHE-CAP logo, terms or symbol in a manner that implies authorization.

b) The Testing Laboratory shall have a policy and procedure for controlling the use of the terms *IHE International, IHE International Authorized Testing Laboratory* and the *IHE International Conformity Assessment Program* (CAP) term, logo and symbol.

c) The term and/or symbol shall not be used in a manner that brings IHE International into disrepute or misrepresents a Testing Laboratory's scope of accreditation or authorized status.

d) When the IHE-CAP symbol is used to reference a Testing Laboratory's authorized status, it shall be comprised of the IHE-CAP logo in an approved caption. The caption shall appear below and in close proximity to the logo.

e) When the *IHE International Conformity Assessment Program* (CAP) symbol is used, the form of the IHE CAP logo must conform to the guidelines provided by IHE International.

f) When used in a contract or proposal, the *IHE International Conformity Assessment Program* (CAP) term and/or symbol shall be accompanied by a description of the Testing Laboratory's scope of accreditation and current accreditation status.

g) Laboratories shall not use the terms *certified* or *registered* when referencing their IHE CAS accreditation or conformance to ISO/IEC 17025 requirements. The correct term is IHE International *Authorized Testing Laboratory*.

A.2 Approved symbols

TBD

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Appendix B – General process for establishing IHE authorized Testing Laboratories

An overview of the main steps for establishing IHE International Authorized Testing Laboratories is provided below. This Appendix is informative and is not intended to replace the requirements specified in the body of IHE-CAS-1:

1. An IHE Deployment Committee submits to the *Conformity Assessment Coordination Committee* of IHE International its intention to perform IHE-CAS accreditation, listing a proposed ISO/IEC 17025 Accreditation Body and one or more Testing Laboratories that have expressed interest and are capable of meeting the IHE-CAS Accreditation requirements.
2. The IHE *Conformity Assessment Coordination Committee* of IHE International reviews the plan and either approves the proposed Accreditation Body or requests further information.
3. The Testing Laboratory seeks IHE-CAS Accreditation from the selected ISO ISO/IEC 17025 Accreditation Body.
4. The IHE Deployment Committee submits evidence of Testing Laboratory accreditation to the *Conformity Assessment Coordination Committee* of IHE International.
5. The *Conformity Assessment Coordination Committee* of IHE International authorizes the Testing Laboratory under supervision from the IHE Deployment Committee to perform IHE-CAS Conformity Assessment Testing.
6. The IHE Deployment Committee communicates to the *Conformity Assessment Coordination Committee* of IHE International any change, renewal or suspension of the IHE-CAS Accreditation of the IHE International Authorized Testing Laboratories under their responsibility. The *Conformity Assessment Coordination Committee* of IHE International may suspend or revoke the Authorization to perform IHE CAS Conformity Assessment Testing.

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Appendix C – Regional or National Extensions to the IHE International CAS

IHE Deployment Committees or Testing Laboratories may wish to leverage elements of the IHE CAS for performing Conformity Assessment of interoperability specifications based on IHE Profiles that are not part of IHE CAS-2.

This Appendix is informative.

Such testing and any associated testing mark or certification is outside the scope of the *IHE International Conformity Assessment Program*.

This appendix provides guidance on how the *IHE International Conformity Assessment* may be leveraged for:

1. **Testing IHE profiles that are not yet part of IHE-CAS-2.** This may be for a variety of reasons such as: the profile has not yet reached final text status, the test methods have not yet been sufficiently developed or validated, or there is not sufficient demand for accredited testing for this profile. These profiles should be tested in a manner that allows planning for an easier transition of this profile testing in a future version of the IHE-CAS-2, taking into consideration the following:
    a) The quality elements of CAS-1 are applied
    b) The Test Scripts use the IHE CAS-2 Template
    c) The Test Tools operate in a consistent environment to reduce duplication of efforts
    d) The validation of these scripts and tools is conducted in a way that is easily presentable to the Conformity Assessment Coordination Committee for future acceptance.
2. **Testing an Interoperability Specification that references one or more IHE Profiles and possibly extends them.** The extensions to such a combination of IHE Profiles with specific requirements (e.g., national or project specific needs) creates a more complex specification to test. These interoperability specifications combining and extending IHE profiles should be tested in a manner that allows such a level of testing (sometimes called a Projectathon) to leverage the profile level testing provided by the IHE-CAS taking into consideration the following:
    a) IHE at this time does not define an Interop Specification Template.
    b) The Test Tools operate in a consistent environment to reduce duplication of efforts (e.g., reuse validators and simulators with added orchestration elements)
    c) The test processes may reuse elements from IHE-CAS-1, except the elements specific to IHE Governance and except references to CAS-2.

    Note: If an Interoperability Specification template becomes available, the level of reuse should be further improved (recommended by the IHE International Summit-April 2013).

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Appendix D – Test Report Summary Validation

Test Report Summaries issued by IHE International Authorized Testing Laboratories under the IHE-CAS are validated by a Validation Entity before they are published.

This Appendix is intended to be developed in a future version of the IHE-CAS-1 to define the validation process, its outcome (e.g., issuing a testing mark) and the organization of such a Validation Entity.

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