# Preamble

The IHE International Certification Working Group (WG) has been tasked by the IHE International Board to explore the certification topic, and make recommendations as to how it should apply to IHE International.

To ensure input on this discussion, the WG conducted a survey among IHE International members (general membership and National/Regional Deployment Committees). The survey asked specific questions to solicit input, and responses were used to shape the recommendations in this document.

In addition, a report from the IHE USA Pilot Certification provided vital input to this discussion.

Based on WG deliberations, the following criteria were identified as key elements of an IHE Conformity Assessment Program:

1. **Rigor**. An increase in the current level of rigor should be incorporated into the IHE testing process in order to enhance the users’ trust in the implementation of IHE profiles.
2. **Connectathon**. Maintain and reaffirm the value of Connectathon, ensuring additional testing programs are linked to the Connectathon(s) whenever possible
3. **Outcomes**. Clarity, trustworthiness and transparency of testing outcomes should be improved.
4. **Product Focus**. An accredited testing program should focus on products in addition to vendor capability which is what the current Connectathon program validates. Vendors should be required to declare product names/details and versions when registering for this additional testing.
5. **Cost.** Accredited testing shall only add costs that are commensurate with the additional benefits gained by the testing program.
6. **Alignment**. National/Regional Deployment Committees are encouraged to establish IHE testing programs that add value to other testing/certification programs established in that jurisdiction, to ensure efficiency and reduce vendor burden.

# Certification WG Recommendations to IHE International Board

The IHE International Certification WG recommends that “baseline” criteria be established for a Conformity Assessment program sponsored by IHE International, as follows:

1. Testing programs (in addition to Connectathon testing) will be established using the ISO 17025 standards, and performed by Testing Lab(s) accredited under these standards
2. IHE international will be the scheme[[1]](#footnote-1) holder for accreditation purposes.
3. The IHE International Scheme will include all or part of the Technical Framework documents, limited to Integration Profiles that are published in final text (e.g. no Supplements).
4. IHE National/Regional Deployment Committees may elect to have the IHE accredited testing programs operate in conjunction with an IHE Connectathon, or separate from a Connectathon.
5. IHE National/Regional Deployment Committees shall adhere to the IHE International scheme (see footnote 1) in their testing programs, but will have the responsibility for operationalizing the testing effort. In addition, IHE National/Regional Deployment Committees may elect to add an appropriate form of Certification as a further step in the rigor chain, for use within their jurisdiction.
6. IHE International neither requires nor forbids National/Regional Deployment Committees from adding an accredited Certification program (e.g. under ISO 17065).

IHE International recognizes four incremental levels of conformity assessment for IHE Profile/Actor pairs, as follows:

1. **Connectathon**. A Connectathon provides recognition of vendor capability of conformity to one or more IHE Profile/Actor pairs.
2. **Integration Statement** represents a vendor’s self-attestation of product capability.
3. **Testing Mark**. Represents a 3rd-party attestation of an accredited testing program under the ISO 17025 standard, with international recognition among IHE National/Regional Deployment Committees worldwide.
4. **Certification Mark**. Represents an accredited 3rd-party certification of a product having successfully passed an accredited testing program as defined by the above accredited testing scheme. A national or regional recognized certification process such as the one defined by ISO 17065 may be used. This is an optional step that can be added as required by National/Regional Deployment Committees.

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1. IHE International can be the Scheme Owner for establishing an accredited ISO 17025 Testing Program.  As a scheme owner, IHE International would need to provide accreditation bodies with the Scheme by which a testing lab would be accredited per ISO 17025 for proficiency against the scheme. A Scheme is composed of:

   Criteria – which are the requirements the product has to meet.  The IHE Technical Framework could serve as a basis to create a baseline criteria.

   Testing Process and/or Procedures – Testing Process is general objectives of the testing without the specifics of how to test.  Testing Procedures are composed of test plans and test methods.

   If a deployment committee wishes to add requirements to the “baseline criteria” provided in the IHE International Scheme, then it would create a second scheme by which accreditation bodies would accredit the testing lab per ISO 17025 for proficiency in the deployment committee specific scheme.

   .  [↑](#footnote-ref-1)