



## COCIR Position Paper

### COCIR\* position on the certification of Healthcare IT product interoperability

**The objective of this position paper is to contribute to ensuring an interoperability conformance testing process which is trustworthy and helps avoid costly retesting and duplicate development of testing and validation tools in multiple jurisdictions over Europe.**

#### **0. Introduction**

COCIR and its members are committed to the development of Healthcare IT as being crucial for improving safety, quality, accessibility and efficiency of healthcare in Europe.

COCIR and its members are committed to the continuous effort of all stakeholders addressing the challenges in the area of interoperability between healthcare systems for realistic applications and to leverage the long experience of the industry applying self-certification.

Proven solutions for interoperability in the healthcare domain exist already for many years, thanks to internationally operating organisations such as HL7, DICOM and IHE. In close collaboration between industry and healthcare providers, standards and profiles for interoperability have been developed in many clinical areas, thus allowing communication of medical data, including the semantic level, between healthcare providers, whether national or cross-border.

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*\* COCIR is the voice of the European Radiological, Electromedical and Healthcare IT Industry. COCIR is a non-profit trade association, founded in 1959, representing the medical technology industry in Europe. COCIR's members commit themselves to play a driving role in developing the future of healthcare in Europe and worldwide.*

*COCIR Company Members: Agfa HealthCare, Canon Europe, Carestream Health, Dräger Medical, Elekta, FujiFilm, GE Healthcare, Hitachi Medical Systems Europe, IBA Ion Beam Applications, IBM, ICW, Intel, iSoft, Philips Medical Systems, Quovadx, Siemens Medical Solutions, Toshiba Medical Systems Europe. COCIR National Associations Members: AGORIA (Belgium), ANIE (Italy), SNITEM (France), ZVEI (Germany), SPECTARIS (Germany), Holland Healthcare Technology Association (Netherlands), FENIN (Spain), Swedish Medtech (Sweden), AXREM (UK), FIHTA (Finland).*

New challenges arise for national governments from the expansion of national healthcare IT infrastructures. The long and successful experience of organisations like IHE, DICOM and HL7 can help to contribute to solutions for interoperability.

By clarifying the position of COCIR and its members supplying Healthcare IT (HIT) products, the objective of this position paper is to contribute to ensuring an interoperability conformance testing process which is trustworthy, and encourages regional or national health infrastructure and care delivery organizations projects to benefit from a simpler deployment without having to create a multitude of ad-hoc testing processes over Europe.

**The scope of this position paper comprises**

- ***interoperability conformance testing***
- ***and certification processes for healthcare IT products such as electronic medical records, department IT systems, personal health record systems.\****

This position paper exclusively addresses the interoperability aspect. The two following aspects and validation processes are **outside of its scope**:

1. Some categories of products are required to be developed under an accredited quality assurance process to ensure its products comply with external Medical Device regulations.
2. Functional HIT product certification may be needed for some products and markets in order to build the required market trust. Functionality is related to the capabilities offered by the product to its primary user. It is now widely accepted that functionality testing and interoperability conformance testing are two complementary, but separate dimensions that each needs to be addressed.

### **1. Stakeholders' objectives regarding interoperability certification for healthcare IT products**

COCIR believes that current and future challenges in eHealth can only be tackled on the basis of a continuous dialogue among all stakeholders.

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\* *The underlying definitions of both terms can be found below in paragraph 2.1. .*

Therefore, the following brief analysis gives an overview of the primary and secondary stakeholders, and their respective expectations and objectives in the field of interoperability certification for HIT products.

- ❖ Healthcare Authorities:
  - Improve the quality and reduce the cost of patient care by pro-actively promoting the adoption of HIT products or by means of regulation.
  - Assure that the expected benefits are obtained.
  - Introduce incentive programs.
  - Define and benchmark the required functionality.
- ❖ Patients:
  - Have safety concerns and expect high quality of care.
  - Have privacy and security concerns for health data.
- ❖ Care Providers:
  - Require quality labeling, want to receive the product with the interoperability capabilities that were promised.
  - Want to be comfortable with the introduction of HIT products in their care delivery process.
- ❖ Vendors:
  - Need a harmonized and stable market and easy, cost efficient market access in order to provide affordable and high quality solutions.
  - Promote the adoption of HIT products in the care delivery process by means of incentives related to certification.
- ❖ Standard Development Organizations:
  - Foster the development and deployment of standards.

## **2. Current practice of HIT product interoperability conformance testing**

The stakeholders' objectives identified in the previous section need to be supported by the means of an effective and efficient interoperability conformance testing (the technical evaluation part), and a reliable certification process (the policy and trust management).

### **2.1 Interoperability conformance testing and certification process - definition**

Certification is a labeling process, either under a quality system or by a third party. This labeling must not be confused with the technical conformance testing process used for product validation. Both elements need to be addressed, but need to meet a series of criteria of very different nature.

This position paper uses the term *interoperability conformance testing* for the technical process that evaluates whether an implementation meets the requirements of an *interoperability specification* (e.g. an IHE Profile along with the set of referenced standards). The term *certification process* designates the labeling and the requirements associated with obtaining, maintaining, challenging the "label".

The Healthcare IT Industry has extensive experience with interoperability conformance testing that validates products for use in successful interoperable healthcare IT implementations, from basic connection level to semantic interoperability at the application level. Probably the most complex applications in the industry today comprise: clinical workflow, decision support, care coordination, image analysis, quality management, and public health, just to name a few.

## **2.2 The role of Integrating the Healthcare Enterprise - IHE\* - in HIT product interoperability conformance testing**

In a highly innovative field like Healthcare IT only the fast-moving organizations can play a significant role. Interoperability being the goal, standardization, conformance testing and certification are only means to an end. They need to be placed in a broader context to be effective, and this is what IHE has done, and therefore why we would like to analyze their best practice.

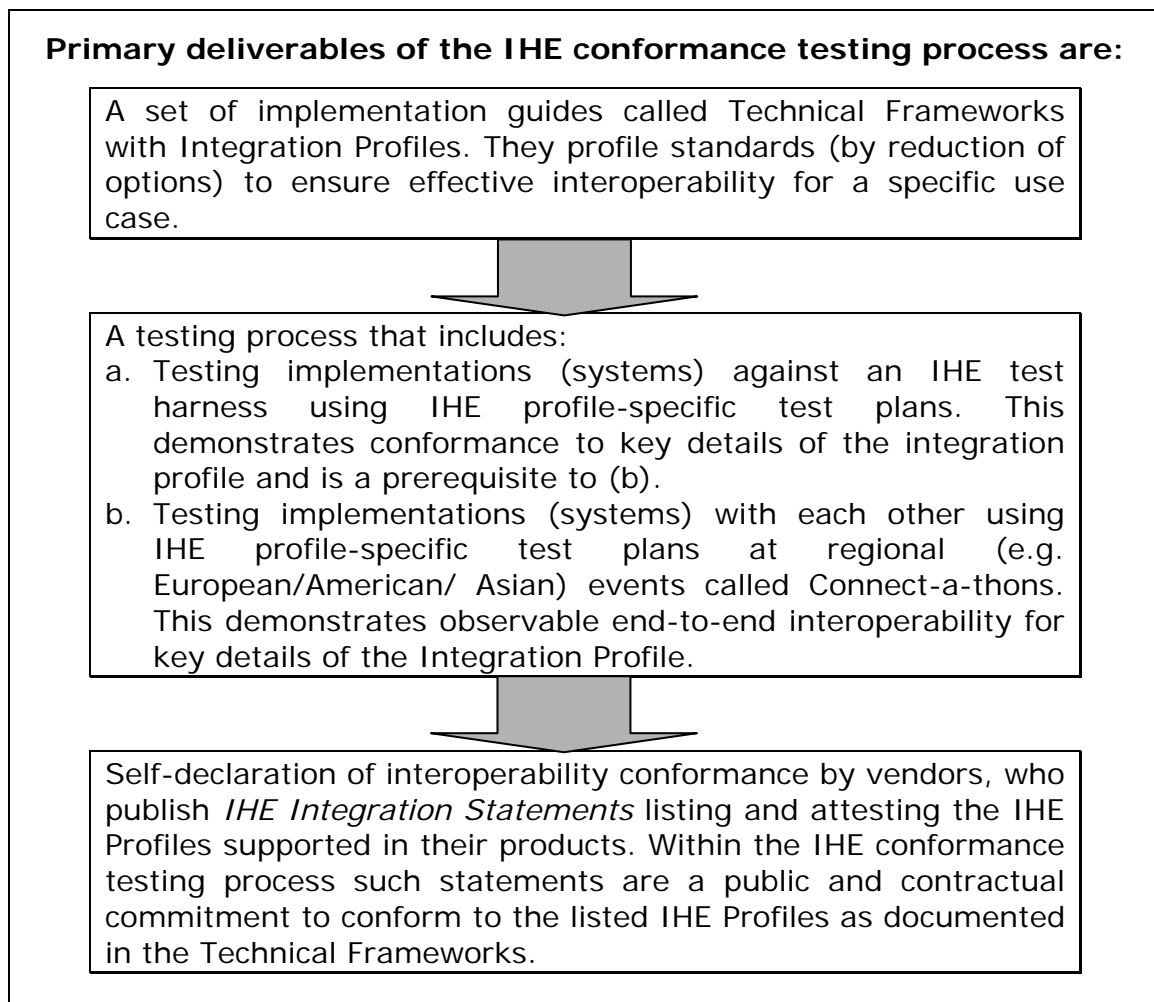
The strengths of IHE are its user orientation and its ability to quickly react in defining detailed *Integration Profiles* (unambiguous detailed standards-based implementation guides) addressing interoperability issues in response to provided use cases.

COCIR has been carefully monitoring the extension of IHE in many clinical domains for which it has delivered Integration Profiles. Proven experience with the IHE conformance testing process before and during IHE test sessions (the Connect-a-thons) makes IHE an important best practice to consider and leverage.

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\* *IHE-Europe (IHE-EUR) is the European organization of the international IHE organization. 'Integrating the Healthcare Enterprise' (IHE) is a joint initiative of healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM, XML and HL7 to address specific clinical needs in support of optimal patient care. Systems developed in accordance with IHE specifications communicate with one another better, are easier to implement, and enable care providers to use information more effectively.*

IHE has successfully used this interoperability conformance testing process with distributed lab testing and cross-product test sessions called Connect-a-thons for early interoperability conformance testing in the product release process.



The IHE test tools are available to all stakeholders in healthcare. These test tools are continuously enhanced and expanded when new Integration Profiles are added to the IHE Technical Frameworks.

It remains the responsibility of each implementer or vendor to publish a product specific Integration Statement attesting publicly that a named product version conforms to a specific component of an IHE Profile; and to do any additional testing in their quality assurance process they feel necessary in order to make that claim. Any liability from such a claim or failure to interoperate is entirely the responsibility of the party issuing the Integration Statement.

This IHE interoperability conformance testing process as briefly described above is a clear and simple boundary from where a certification process could be added. The following chapter of the position paper discusses ways in which this could be realized for the advantage of all stakeholders.

### **3. Interoperability conformance testing and certification in national EHR projects and IHE extensibility**

Recognizing that some markets in some countries may find additional independent 3rd party compliance verification and certification of HIT products to be valuable in order to ensure the fit of the product in the country specific health infrastructure, the IHE Testing Process has been designed to be extensible and easy to combine with legal and administrative processes offered by a variety of certification programs (public or private) that are recognized in different jurisdictions or by different organizations around the world.

It is important to be aware of the fact that the same interoperability conformance testing may be used by certification programs that operate in very different ways.

For example:

1. Some certification program may be based on a neutral third party (need not be a governmental entity) to manage the program and require that a sample of a product/implementation be tested for conformance. The weakness of this approach is that it assumes that the sample IT software being tested is consistent with the products being shipped.
2. Other certification programs are based on auditing the quality system of the vendor, including the process followed by the vendor to test each instance of the products shipped. This is the process that certification experts in other domains (e.g. food quality, security, medical devices, nuclear energy) favor for its robustness and cost effectiveness when dealing with complex and adaptable systems where standards compliance is critical.

COCIR recognizes that both models and mixed approaches among these models will persist. Experience will lead to understanding what will turn out to be the most effective approach. COCIR experience with mature certification programs in other areas such as device safety is that the audited quality system may be eventually recognized in the long-term as the most effective model for interoperability.

COCIR is convinced that public and private stakeholders can benefit from IHE's openness and from encouraging public or private certification entities - as they become established in various countries, regions, hospitals - to leverage the advantages of the IHE conformance testing process as it allows

performing the technical or conformance testing under the policies and by the various certification processes. IHE already engages jurors (or testing monitors) from impartial entities and welcomes jurors designated by certification entities.

By relying on a global testing process, as provided by IHE, the same interoperability conformance testing result can be used to meet the technical requirements of several certification programs (one test, multiple certificates).

COCIR recommends considering this flexible and proven solution as it is critical to avoid costly retesting and duplicate development of comprehensive testing and validation tools in multiple jurisdictions.

#### **4. Conclusions – COCIR Recommendations**

Therefore, COCIR recommends

1. leveraging the long experience of the industry applying self-declaration of interoperability conformance by vendors based on the proven IHE experience and conformance testing processes for realistic use cases;
2. to encourage public or private certification entities to make use of the openness of IHE's flexible and proven solution allowing the technical or conformance testing under the policies and by the various certification processes thus to join COCIR members and the user community already engaged in IHE.

COCIR also recommends to consider in this context that

3. interoperability conformance testing and certification processes be developed as independent yet related activities;
4. certification processes carefully consider audit programs of the quality system of the vendor based certification as a superior alternative to third party certification;
5. if third party certification entities are created, those should not be regulated entities, but market driven voluntary programs;
6. in order to preserve market dynamics and to ensure innovation the governmental focus lies on involvement in becoming a partner in the public/private certification process linked to interoperability conformance testing activities.