



# Healthcare Interoperability Testing and Conformance Harmonisation

WP3: Testing Process and Evaluation

D3.3 Feedback to the improvement of overall  
approaches described in WP1 (QMS)  
and WP2 (Testing Tools Strategy)



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ABSTRACT
This document presents the feedback to the overall approaches described in WP1 (QMS) and WP2 (Testing Tools Strategy) with the intention to improve the treatment of QMS processes (WP1) or the treatment of the tools in WP2 deliverables.
KEYWORDS
Interoperability, requirements, conformance testing, roadmap.

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## INTRODUCTION

This deliverable presents the feedback to overall approaches described in WP1 (QMS) and WP2 (Testing Tools Strategy). The intention is to improve the QMS processes defined in WP1 deliverable D1.2 [3] and improve the treatment of tools as presented in WP2 deliverables D2.1 [4] and D2.2 [5]. As those deliverables are already closed, there was never an intention to reopen them and update those deliverables with the feedback contained in this document.

In preparation as well as during the Connectathon 2011 in Pisa, Italy, a number of activities were carried out with the intention to collect as much feedback as possible on HITCH results.

Before the Connectathon 2011, a questionnaire related to QMS change-readiness was prepared and filled out by Connectathon monitors as one of the key groups that could be affected by the introduction of a QMS. In an IHE Connectathon monitors have the tasks to verify and validate the tests performed by the Systems in accordance with the test cases described in the Gazelle management tool. Monitors act under the responsibility and guidance of the Technical Project Manager. At the Connectathon in Pisa 45 monitors were active.

During the Connectathon a mini-workshop was also held, followed by a focus group interview. Everything related to the questionnaire, the mini-workshop and the focus group interview, including the analysis of the results obtained, is presented in D3.2 [7].

During the Connectathon, a HITCH workshop was organised with the intention to present the work of HITCH but with same importance, collect feedback and discuss with stakeholders from industry, authorities and research.

Last but not least, during the pre-Connectathon testing as well as during the Connectathon testing sessions available tools were in heavy use. The feedback on tools was collected throughout discussions with vendors and monitors. Part of the feedback is also coming from the IHE Connectathon 2011 final report [10]. In that document the results of the event evaluation survey are presented. From HITCH perspective, particularly insightful information on testing tools is coming from that material.

It should be noted that some of the findings coming out of WP3 work, in particular in relation to testing tools were not identified for the first time here, many were in some form present in WP2 or WP1 deliverables. However, the team felt that for completeness it is better to repeat them in this document.

## 1 REFERENCES

- [1] IHE: <http://www.ihe.net>
- [2] European FP7 Project HITCH: <http://www.hitch-project.eu/>
- [3] European FP7 Project HITCH Deliverable D1.2: Profile QMS Description
- [4] European FP7 Project HITCH Deliverable D2.1: Tools selection
- [5] European FP7 Project HITCH Deliverable D2.2: Tools of the future
- [6] European FP7 Project HITCH Deliverable D3.1: Set of test plans defined to experiment the overall approaches (QMS for IHE Connectathon)
- [7] European FP7 Project HITCH Deliverable D3.2: Evaluation results of the test plans implemented during real events
- [8] ISO 90xx: Quality Management Systems (9001-9004)
- [9] ISO 17025: General requirements for the competence of testing and calibration laboratories
- [10] IHE Connectathon 2011 – Final Report – internal IHE document

## 2 FEEDBACK TO WP1

### 2.1 General WP1 feedback from HITCH workshop, questionnaire and focus interview

From the findings coming out of the activities described in D3.2 [7], the following feedback could be extracted:

- The introduction and further implementation of a Quality Management System will probably not change much in the organisational structure, even though that some changes in the current interoperability testing procedures could be foreseen.
- Based on the view of the monitors, it could be concluded that IHE does have the required organisation to handle the needed changes when implementing a Quality Management System.
- IHE seems to have the critical mass of monitors that are ready for changes when implementing a Quality Management System.
- The success and continued expansion of IHE Connectathon requires professionalism, which can be largely improved by a Quality Management Systems.
- It will be important to engage not only the monitors as key persons but also all other persons that have a role in the IHE interoperability testing as defined in deliverable D3.1.
- Some comments received show that training of monitors and Connectathon participants could be improved.
- The questionnaire and the focus interview demonstrated that monitors are aware that goals and objectives of the Connectathon do exist but are in fact not aware of what they are. This indicates that there are various improvements to be made, such as documentation and access to it as well as training and communication within the organisation. Further elaboration of QMS processes needs to take into account these findings so that in future we see a significantly improved awareness of the goals and objectives.
- During the first day of Connectathon in Pisa, problems with network and IP addresses were experienced. This seriously affected the progress of the testing. While this was a technical problem, improved processes of ensuring stability of the testing environment are required such that problems are minimised in future events. This problem is also identified and well documented in the Pisa final report [10].

The discussion in the HITCH workshop confirmed these views, perhaps not in detail but in spirit.

### 2.2 ISO 17025 standard

During the HITCH workshop in Pisa the question of ISO 17025 [11] was raised. At the time the answer was that HITCH had not used ISO 17025 during the work on deliverable D1.2 [3].

In response to the question an initial analysis was performed and the results are presented here.

ISO 17025 [12] is an international standard setting the general requirements for the competence of testing and calibration laboratories. IHE testing of eHealth systems could, at least partly, be considered as testing laboratory activity. This could even be further strengthened in the context of any future certification related testing.

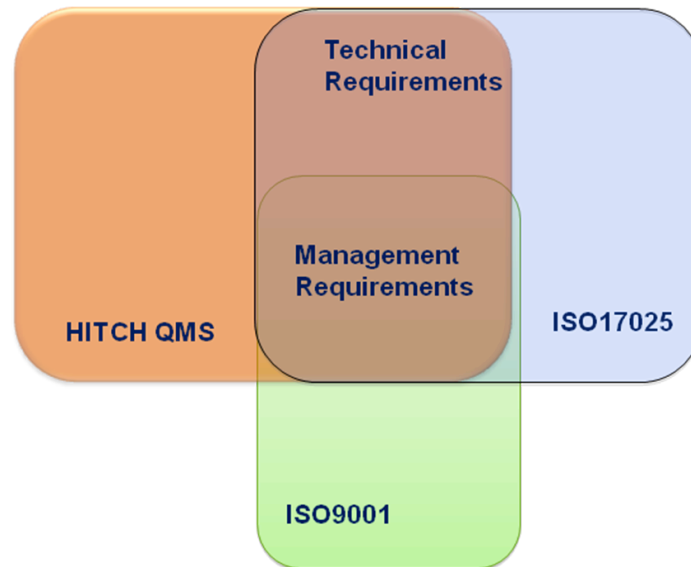
ISO 17025 classifies the requirements into management and technical requirements. Table 1 below lists the requirements in the two groups.

Management requirements	Technical requirements
4.1. Organization	5.1. General
4.2. Quality system	5.2. Personnel
4.3. Document control	5.3. Accommodation
4.4. Review of contract	5.4. Test methods and validation
4.5. Subcontracting	5.5. Equipment
4.6. Purchasing	5.6. Measurement traceability
4.7. Service to the client	5.7. Sampling
4.8. Complaints	5.8. Test items
4.9. Control of non-conforming work	5.9. Quality control
4.10. Improvement	5.10. Reports/calibration certificates
4.11. Corrective actions	
4.12. Preventive actions	
4.13. Control of quality records	
4.14. Internal audits	
4.15. Management review	

**Table 1: ISO 17025 requirements**

In contrast to ISO 17025 that is making a distinction between management and technical requirements, the current HITCH (IHE Connectathon) QMS, based on ISO 9001 standards, is focusing on the processes. These QMS processes are closer to the management requirements. The perception is therefore that current IHE QMS does not take into account the provisions of ISO 17025 with technical requirements.

Figure 1: Envisaged future relationship of HITCH/IHE QMS, ISO9001 and ISO 17025  
Figure 1 illustrates how HITCH envisages the evolution of the HITCH/IHE QMS in relations to the ISO 9001 and ISO 17025 standards.



**Figure 1: Envisaged future relationship of HITCH/IHE QMS, ISO9001 and ISO 17025**

The analysis leads to a conclusion that on the management/process side HITCH deliverables D1.2 [3] and D3.1 [6] are covering the requirements of both standards rather well. However, a more detailed check against provisions of ISO 17025 may reveal some aspects that perhaps have not been covered or not covered sufficiently well. Examples that could already be noticed are things like service to the clients, complaints, preventive and corrective actions. Other aspects may not be applicable in the context of an interoperability oriented QMS, such as perhaps subcontracting or purchasing. All this ISO 17025 related extension work should go hand in hand with further QMS improvements such as QMS documentation, process descriptions and measurable indicators that are part of the normal evolution of a QMS.

When analysing ISO 17025 technical requirements, the perception is that current HITCH QMS has not addressed some of the topics listed in ISO 17025, at least not from the same perspective as in that standard. Some aspects are currently covered in HITCH QMS, as for example personnel requirements are described in roles. However, ISO 17025 may be setting somewhat different requirements such as qualification of test laboratory staff and others. Other technical aspects such as test methods and validation are addressed quite in detail in the current HITCH QMS but ISO 17025 may highlight that more elaboration is needed.

## 2.3 Roadmap recommendations

This section summarises the feedback to deliverables of WP1. The topic listed here below need to be addressed in future and therefore need to be taken into the roadmap document.

- The development of the IHE Connectathon QMS is primed in HITCH and needs to evolve over coming years.
- The first element that needs to be strengthened is documentation of all processes.



- The next important element is to broaden the number of indicators that could be used for measuring the progresses.
- Processes dealing with education of monitors and participants need to be improved, leading to improved training material as well as means of getting the knowledge where it is needed.
- The requirements of ISO 17025 need to be analysed, likely leading to an update of the HITCH QMS
- Processes dealing with Connectathon organizational aspects need to be strengthened such that testing can proceed in an efficient way and that number of interruptions is minimized.

## 3 FEEDBACK TO WP2

### 3.1 Feedback on test management tools

Evolution of testing in the 2011 Connectathon in Pisa demonstrated once again very vividly the importance of test management tools. They are essential for achieving high level of testing activity coordination, resulting in the overall high throughput of the testing event.

For the last few years, IHE Connectathon is using Gazelle as the test management tool. It is very positive that Gazelle has reached such a level of maturity that future events can profit from that. The feedback from the IHE Connectathon final report [10] highlights the above claim in the best way. Almost all participants expressed their satisfaction with the registration of devices and profiles, the tasks fully handled by Gazelle.

While Gazelle is already in good shape, further development of the Gazelle tool is still essential. In that development, the following items are identified as most pressing:

- Extending the functionality of the tool
- Improving the performance
- Improving the robustness
- Ergonomic (user interface) improvements
- Multilingual support is incomplete and needs to be extended
- Extending the integration of Gazelle with other dedicated test tools

One aspect of Gazelle evolution deserves a particular attention. It has been noticed that test results, especially in presence of problems revealed by a test, need to be examined with respect to test requirements. This examination needs to clarify the reasons for failing the test and the kind of corrections that would resolve the problem. To achieve that, the development of new Gazelle functionality needs to be linked with development of test specification methodology.

### 3.2 Feedback on other test tools

Testing tools are essential for many aspects of a smooth testing process. Among other positive effects, the use of tools increases productivity in test execution, reliability in results obtained, traceability of test evolution and repeatability of tests.

Testing tools are increasingly used to improve the interoperability of eHealth systems. For the future, the set of tools as well as their functionality need to be extended. Most important extensions are listed below:

- The coverage in terms of number of test cases per profile and number of profiles that have appropriate test tools need to be increased. The most important examples are as identified in deliverable D2.2 [5] in tables 1 and 2 for a number of interoperability functionalities. These include: Terminology services, eHealth devices workflow, eInclusion record and devices workflow, EHR exchanges, Healthcare Provider Directory (HPD), IHE-XUA++ (Cross Enterprise User Assertion), Document Digital Signature (DSG), as specified in ETSI TS 101 903: XML Advanced Electronic Signatures XadES, DICOM network services from various IHE profiles, especially in IHE's Radiology, Cardiology, Eye Care, Radiation Oncology, Mammography, other structured documents.
- The level of test automation needs to be increased wherever feasible.
- Specific tools for testing various profiles need to be integrated with Gazelle such that configuration is imported from Gazelle, tests are automatically started and results are uploaded into Gazelle with minimal human intervention.
- Complex tests spanning across more than one profile need to be automated.
- Ergonomic aspects of tool usage need to be improved.
- Feedback reporting and tracking for problems within the tools detected during testing need to be improved. This is a tooling issue but could also be considered a Quality Management issue.
- Usage of dedicated testing techniques and languages need to be further examined. This examination should include for example web services and the testing language TTCN-3 (Deliverable D2.2 Appendix 7.2), but other techniques could also be considered.

### 3.3 Feedback on test specification methodology

The methodology of test specification development is inherently linked with the test tools and therefore has a significant impact on interoperability.

Test tools implement test cases that are derived from profile documentation given in IHE technical frameworks. Currently this is the responsibility of the Technical Project Manager. At this point, tests are developed and included using Gazelle. An improved test development methodology could define what kind of test specification documents are to be used, which methodology should be used for deriving test cases and how the test specification could be approved by relevant groups. Among other things, methodology based on ISO 9646 as described in Deliverable D2.2 could be further investigated.

### 3.4 Roadmap recommendations

This section will summarise the feedback to deliverables of WP2.

WP2 deliverable D2.1 [4] provided a good basis for understanding and evaluating the test tools that are used in testing the interoperability of eHealth systems. Deliverable D2.2 [5] identified the gaps and concluded that many areas are not sufficiently covered with appropriate test tools

The major testing tool topics to be addressed in the future and to be taken into the roadmap document are:

- Further development of new features of the Gazelle test management tool (as elaborated in chapter 3.1 of this document)
- Development of specific test tools identified as missing at this point in time
- Further significant improvements in the level of automation, integration and ergonomics of test tools

The above tool development needs to be supported by methodology of deriving the tests from the profiles as well as improvements in integration of specific test tools into the Gazelle test management tool.

## 4 CONCLUSIONS

This document provided the feedback on the current status of QMS introduction and status of test tools, both considered as important for improving the interoperability of eHealth systems. This feedback is a snapshot of this particular point in time where early impact of HITCH results can be noticed but where more time and more work is required in the direction that HITCH has set. The kind of analysis performed in this deliverable should become one of the regular annual QMS activities where status of achievements is assessed and further work is planned.