



Advancing eHealth
Interoperability

Quality Manual for Interoperability Testing

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Presented by Jos Devlies, Eurorec



- Quality in manufacturing
 - A measure, stating that a product is free from defects and significant variations
- Quality in information technology product and services
 - Meeting the requirements of the customer
- Quality Assurance
 - Any systematic process for ensuring quality
- Quality and Quality Assurance for Interoperability Testing
 - An immature professional discipline



- Quality at data entry
 - Quality of the application
 - Quality of the user
- Quality in sharing data
 - Technical interoperability
 - Semantic interoperability
- Quality in using
 - Integrated on-site decision support
 - Research (trials, post marketing surveillance,..) & Management
- Quality needs to be
 - Assessed
 - Quality of assessment is essential



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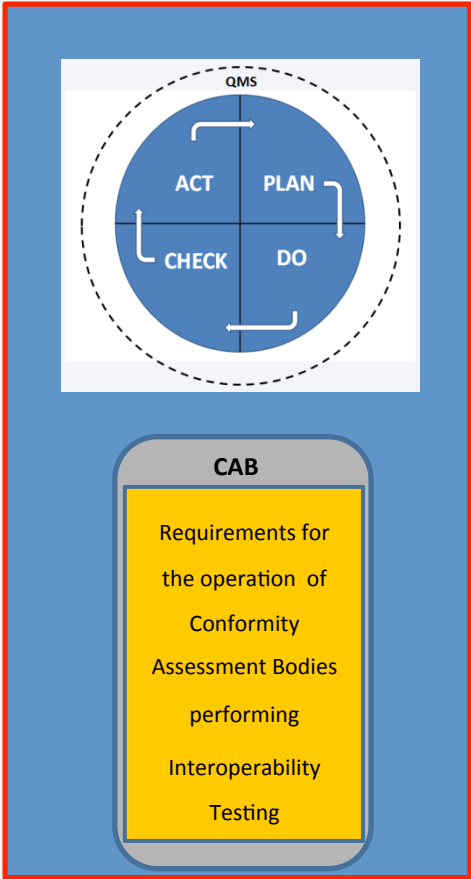
A brief look into:

Part I: Quality Management System

“Requirements for entities
performing Interoperability Testing”



Part I
D2.1 Quality Management System



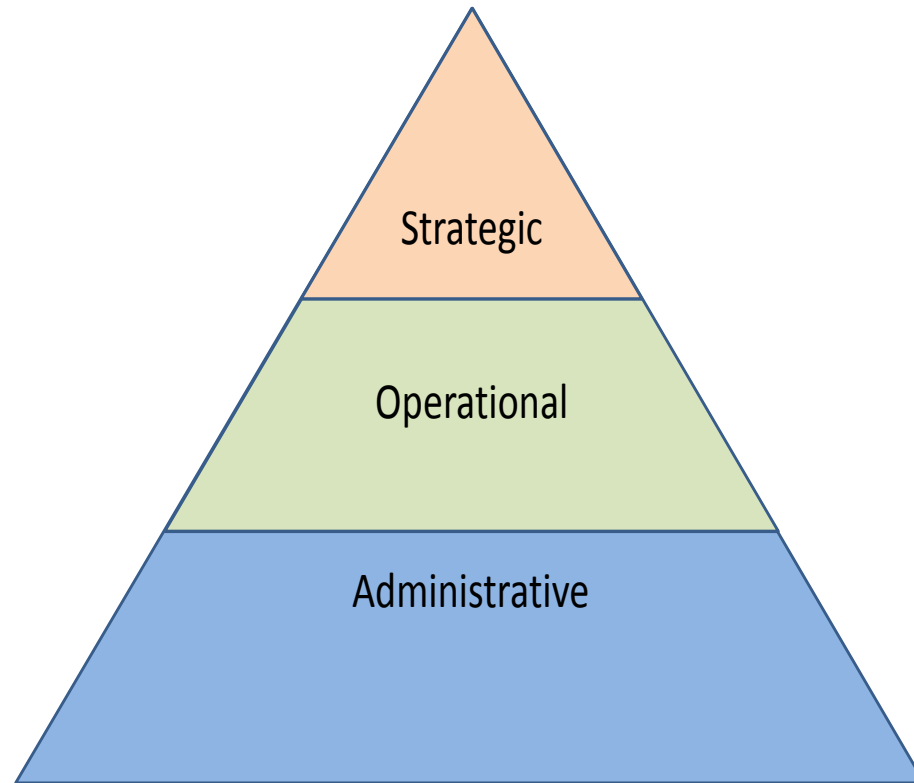
Part II
D2.2 Interoperability Testing Processes





A Quality Management System is a set of interrelated or interacting elements that organisations use to direct and control how quality policies are implemented and quality objectives are achieved.

Source: *ISO 9000: Quality Management Systems*



Policy statements including clear objectives derives from the policy

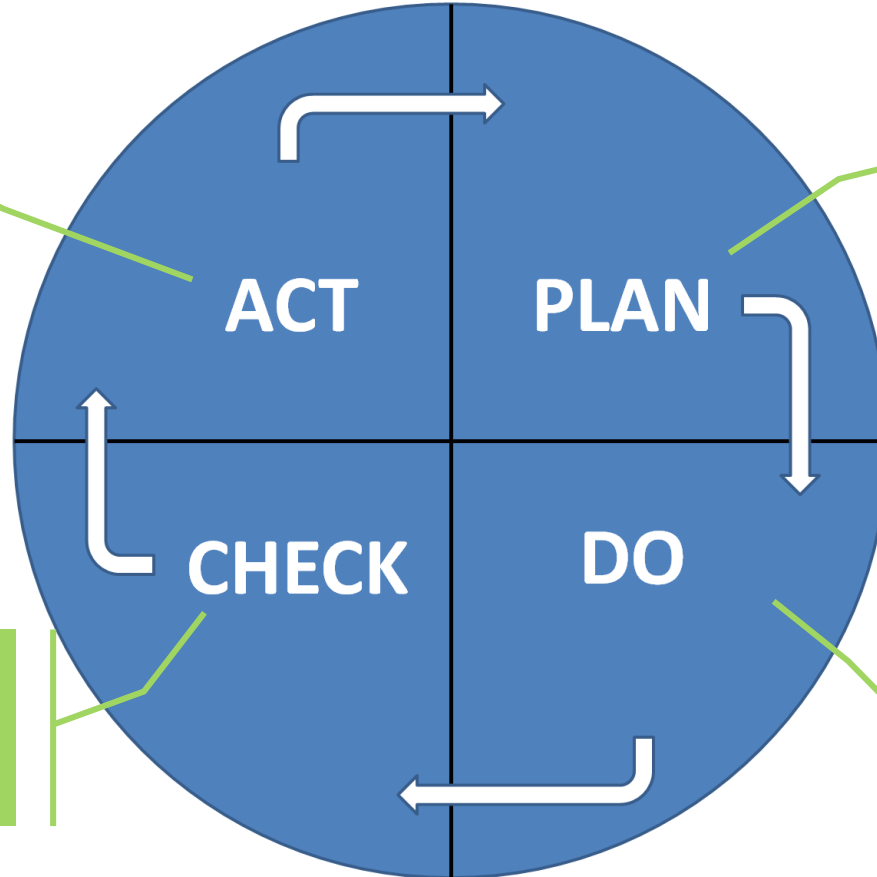
Description of processes – how are the policy statements implemented

Supporting documents to be used to implement the policies



How to improve next time?

What to do?
How to do it?



Do what was planned

Did things happen according to the plan?

Source: *The Deming wheel (named after W. Edwards Deming).
A model for continuous improvement.*



- Organisation
- Management system
- Document control
 - General procedures
 - Approval and issue
 - Changes
- Review of requests, tenders and contracts
- Complaints



- Control of nonconforming testing work
- Improvement of the processes
- Corrective action
 - Cause analysis
 - Selection and implementation of corrective actions
 - Monitoring of corrective actions
- Preventive action
- Control of records
 - Technical records
- Internal audits
- Management reviews



- Personnel
 - ensure the competence of all who perform test, evaluate results, and sign test reports
 - formulate the goals with respect to the education, training and skills of the Interoperability Test entity
 - use personnel who are employed by, or under contract to, the Interoperability Test entity
 - maintain job descriptions for managerial, technical and key support personnel involved in tests
- Test methods
 - Use methods and procedures as described in the Quality Manual Part II. D2.2 Interoperability Testing Processes.



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A brief look into:

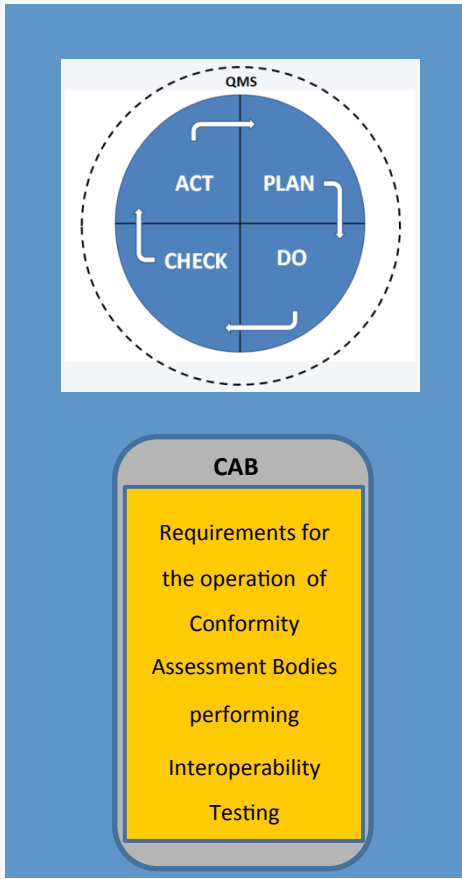
Part II: Interoperability Testing Processes

“Quality Requirements for the Interoperability
Testing Processes”



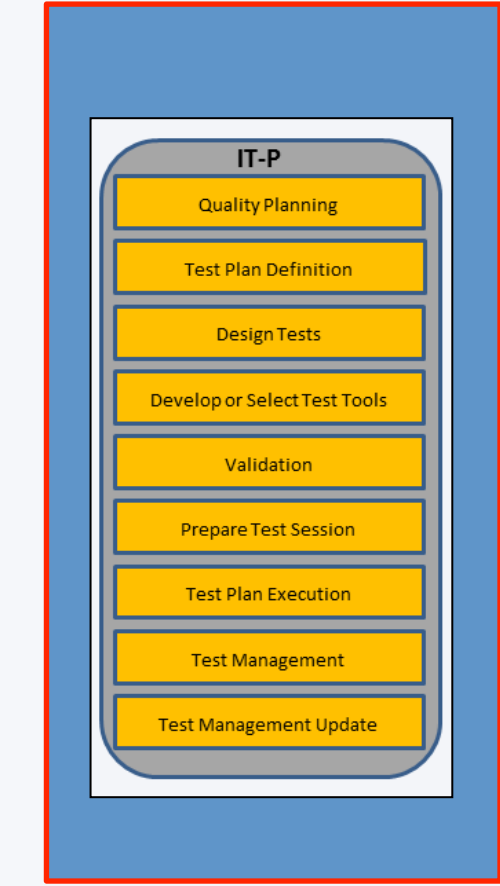
Part I

D2.1 Quality Management System



Part II

D2.2 Interoperability Testing Processes





The ability of two or more
systems or components

to exchange information

and to use the information
that has been exchanged

Source: Institute of Electrical and Electronics Engineers.

IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries.

New York, NY: 1990.



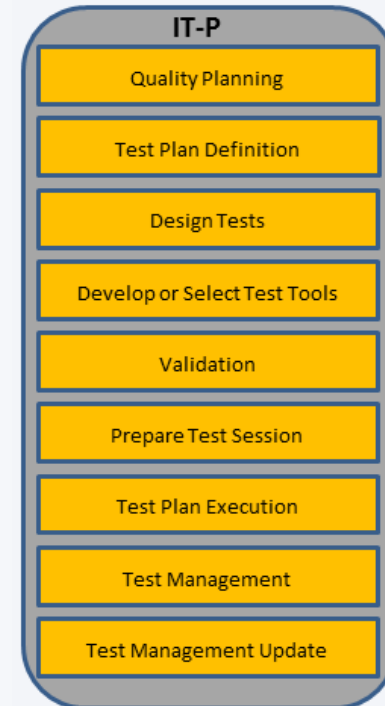
- The Interoperability Testing Processes are generic and can be adjusted and customized by any Interoperability Testing entity
- The Interoperability Testing Processes are a set of interconnected “guidelines” that describes how to run a test session from start to end.
- Each process has defined input and output and can be maintained and improved in isolation and by different people with the required experience and skills.



Term	Definition
Top Level Management	The top level management coordinates the different activities. It gets reports from QA Manager, Test Manager and Auditors
QA Committee	A committee has the role to ensure the quality of the testing process, discusses the needs and decides on what needs to be done in terms of quality.
QA Manager	Manages the QA process. Gets input from the QA Committee and reports to Top Level Management.
Test Manager(TM)	Manages the testing. Organises the testing activities, reports to the Top Level Management. Follows the rules from the QA Committee to ensure the overall quality of the process
Testing team	Performs the tests and is under the supervision of the Test Manager.
System Under Test (SUT) Operators	SUT Operators execute their SUTs test steps required by the test
Auditors	Auditors verify that the QMS process is correctly used. The auditors report to the Top Level Management.



1. Quality Planning
2. Test Plan Definition
3. Design Tests
4. Develop or Select Test Tools
5. Validation
6. Prepare Test Session
7. Test Plan Execution
8. Test Management
9. Test Management Update





- Why?
- Objective
- Work to be done
- Risk planning
- Roles and responsibilities

- Checklist: How to adjust and localise the process description



- Interoperability Testing is a complex activity and can be clearly identified as a project on its own, with several tasks.
- It is important to identify and allocate the right persons with testing skills as well as managers organising and monitoring the testing processes.
- A good planning will help the individual testers to be sure that conformance and interoperability requirements are sufficient tested, independent of what person who performed the test.

Example: Test Plan Definition Objective



- The test plan definition will describe the test strategy and its implementation.
- All activities are carefully defined and planned in order to test profile specification in a given context.



- Definition of the scope and objective
- Specification of the test design
- Development or the selection of the test tools
- Preparation of the test session:
- Execution of the test session
- Reporting of test results.

Example: Process Test Plan

Definition

Risk planning



- The equilibrium between resources, schedule and the test design needs to be established.
- A bad risk assessment and a weakness on the requirements specifications are also possible causes of failure.
- If customers notice a weakness in the quality of products, they will no longer have confidence in the testing process of a particular project.
- If the feedback to the organisation that has made the specification (eq. a profile for patient identification) is not well documented, the testing process has no sense or will be the bad quality.

Example: Test Plan Definition Roles and responsibilities



- The test plan definition is under the responsibility of the Test Manager who organises the complete testing process.



A Quality Management System will ensure continuous improvement of Interoperability



Quality Management of Interoperability Testing will improve eHealth deployment



A Quality Management System for interoperability testing will facilitate the adoption of International eHealth standards