



Advancing eHealth
Interoperability

Quality Manual for Interoperability Testing

Morten Bruun-Rasmussen

mbr@mediq.dk



- 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 Manual for Interoperability Testing - PART I:

D2.1: Quality Management System for Interoperability Testing



Quality Manual for Interoperability Testing - PART II:

D2.2: Interoperability Testing Processes



D2.3a: Educational material (this presentation)

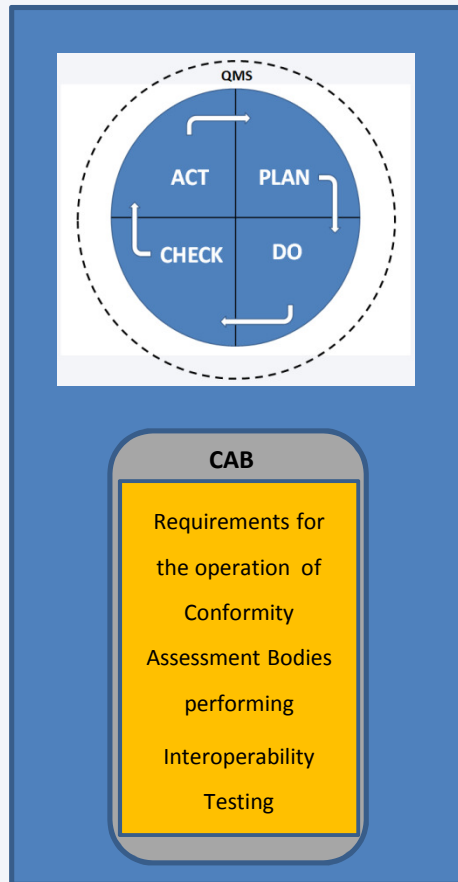
D2.3b: Executive summary. Quality management System

D2.3c: Executive summary. Interoperability Testing Processes



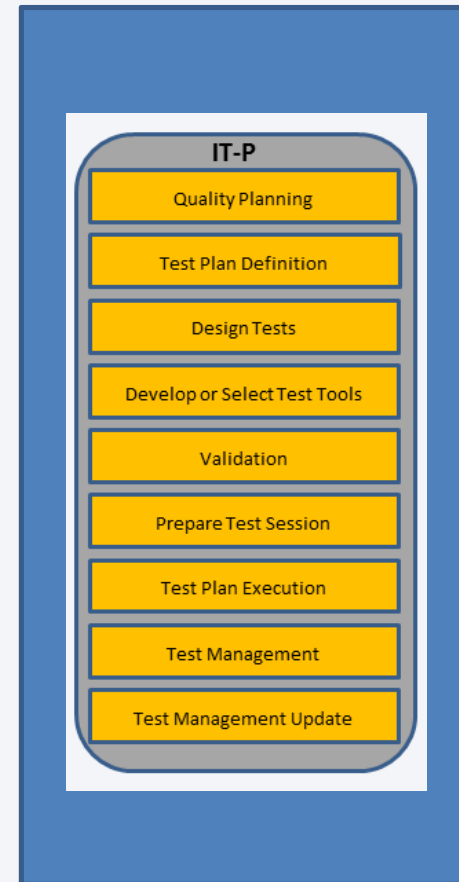
Part I

D2.1 Quality Management System



Part II

D2.2 Interoperability Testing Processes





Advancing eHealth
Interoperability

Quality Manual for Interoperability Testing

A brief look into:

Part I: Quality Management System

“Requirements for entities
performing Interoperability Testing”



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*



Advancing eHealth
Interoperability

Quality Manual for Interoperability Testing

A brief look into:

Part II: Interoperability Testing Processes



The ability of two or more
systems or components

to exchange information

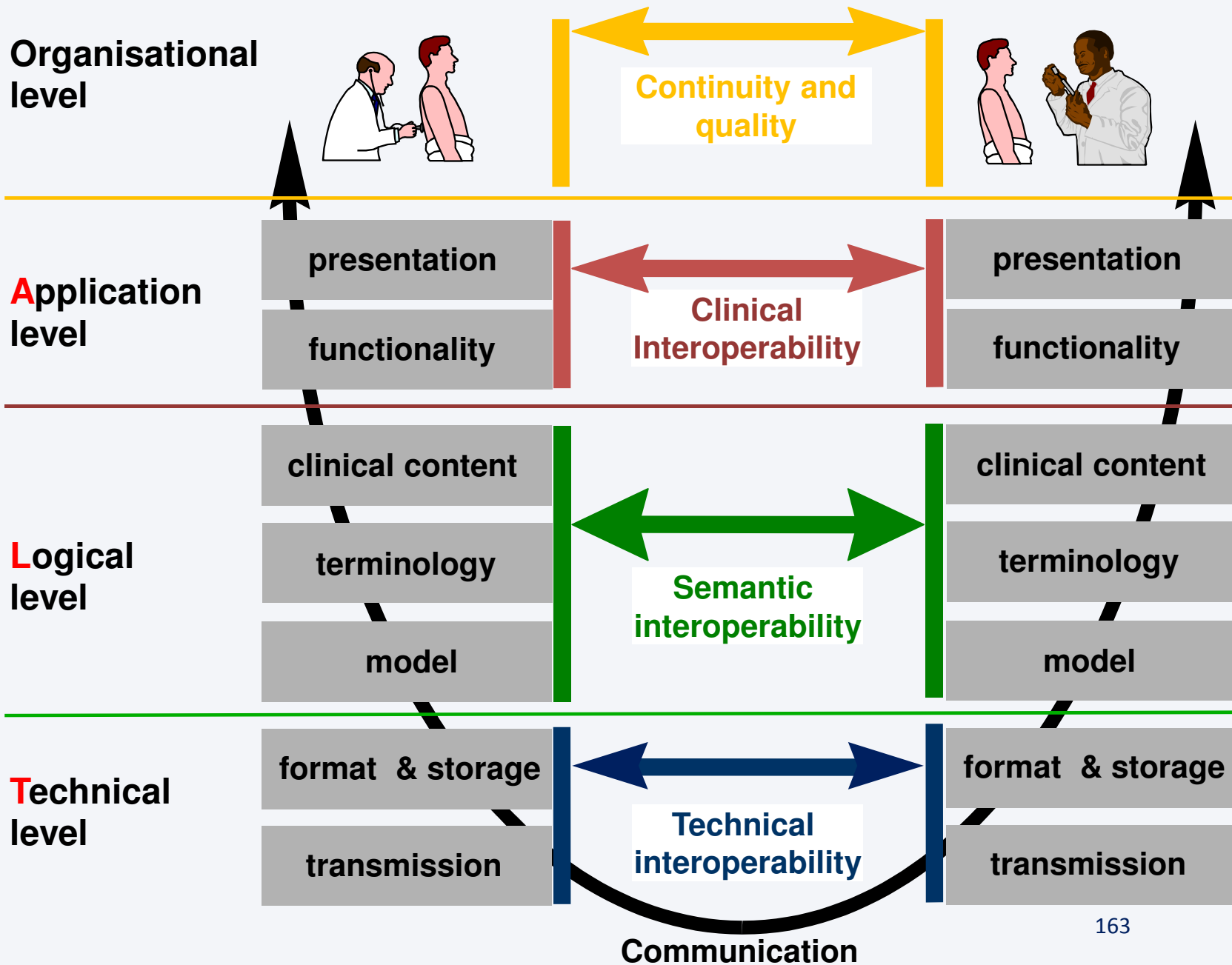
and to use the information
that has been exchanged

Source: Institute of Electrical and Electronics Engineers.

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

New York, NY: 1990.

Interoperability and the ALT-model



Interoperability Testing Processes Scope



- The Interoperability Testing Processes are generic and can be adjusted and customized by any Interoperability Testing entity
- The Interoperability Testing Processes is 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.

Interoperability Testing Processes

Nine interconnected steps



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 complexity**
- **Fit of testing, managerial and monitoring skills.**
- **Rigorous standardisation and conformance.**



- It will describe the test strategy and its implementation.
- Activities are 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**
- improve eHealth deployment**
- adoption of International eHealth standards**



Advancing eHealth
Interoperability

Thank you

More information on the Quality Manual

Part I: D2.1 Quality Management System for Interoperability Testing

Part II: D2.2 Interoperability Testing Processes

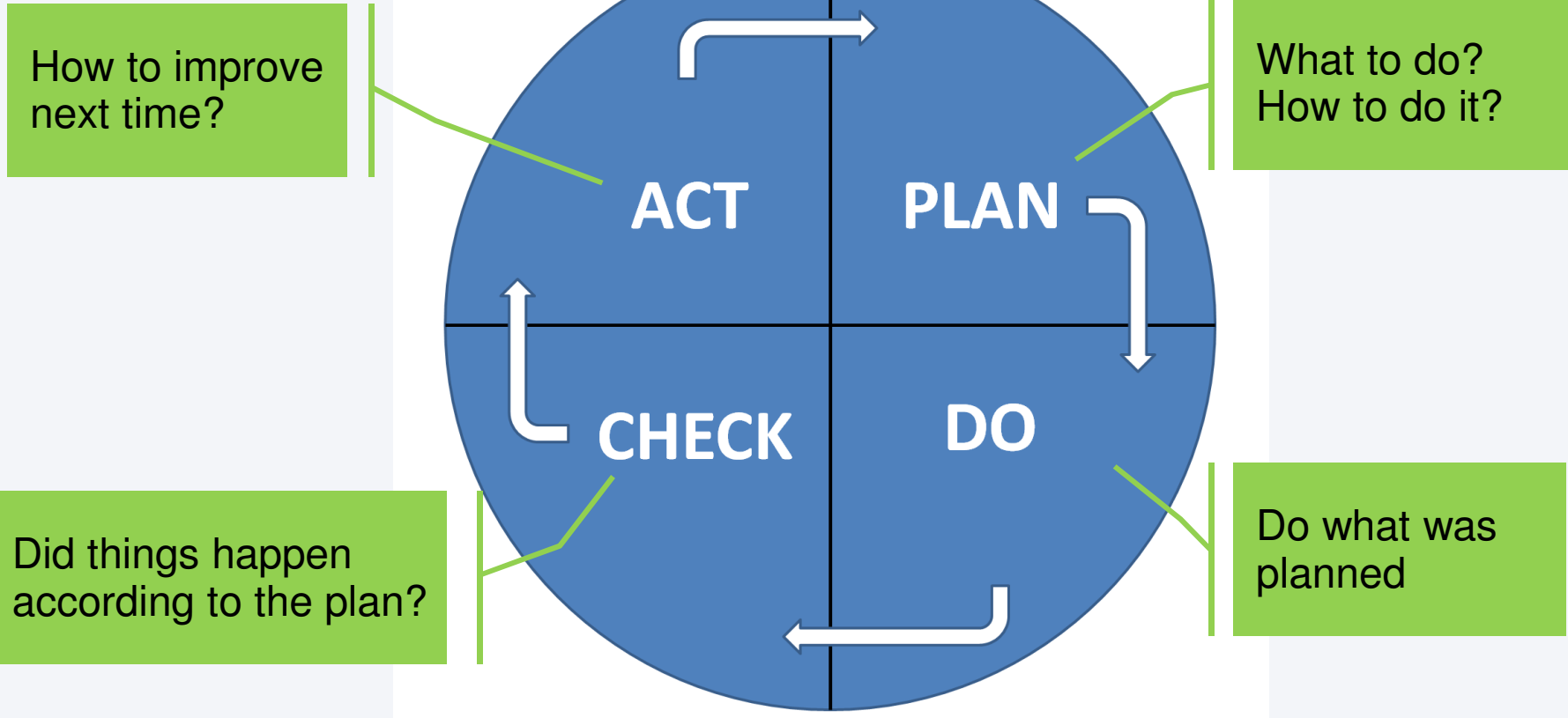
Is available on the Antilope website <http://www.antilope-project.eu/>



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



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
- 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.