Quality Manual for Interoperability Testing

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Antilope Validation Partners

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Italy, Malta

Portugal, Spain

Romania, Bulgaria, Greece, Cyprus, Turkey

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

Quality Manual - documents

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)
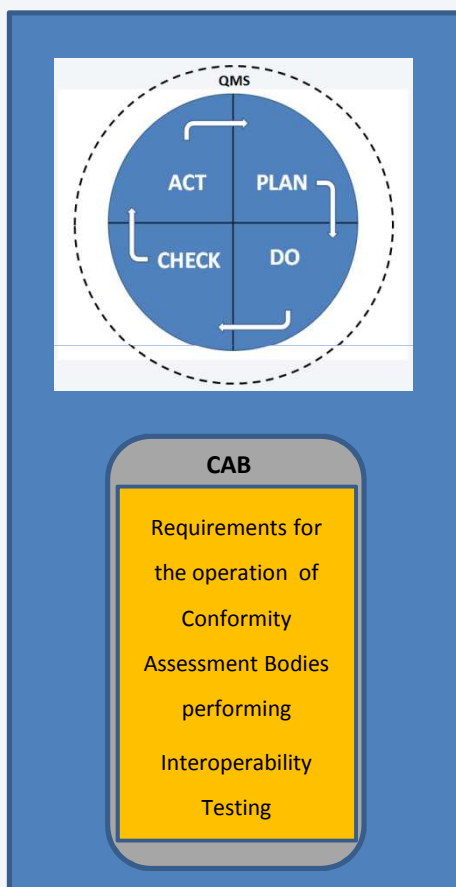D2.3b: Executive summary. Quality management System
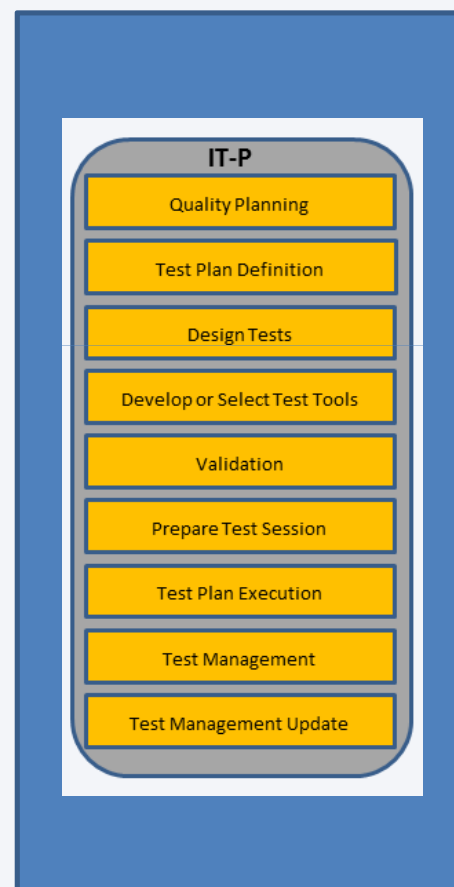D2.3c: Executive summary. Interoperability Testing Processes

Quality Manual for Interoperability Testing

Part I
D2.1 Quality Management System

QMS

ACT — PLAN
CHECK — DO

CAB

Requirements for the operation of Conformity Assessment Bodies performing Interoperability Testing

Part II
D2.2 Interoperability Testing Processes

IT-P

- Quality Planning
- Test Plan Definition
- Design Tests
- Develop or Select Test Tools
- Validation
- Prepare Test Session
- Test Plan Execution
- Test Management
- Test Management Update

Quality Manual for Interoperability Testing

A brief look into:

Part I: Quality Management System

"Requirements for entities
performing Interoperability Testing"

Quality Management System (one definition)

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.

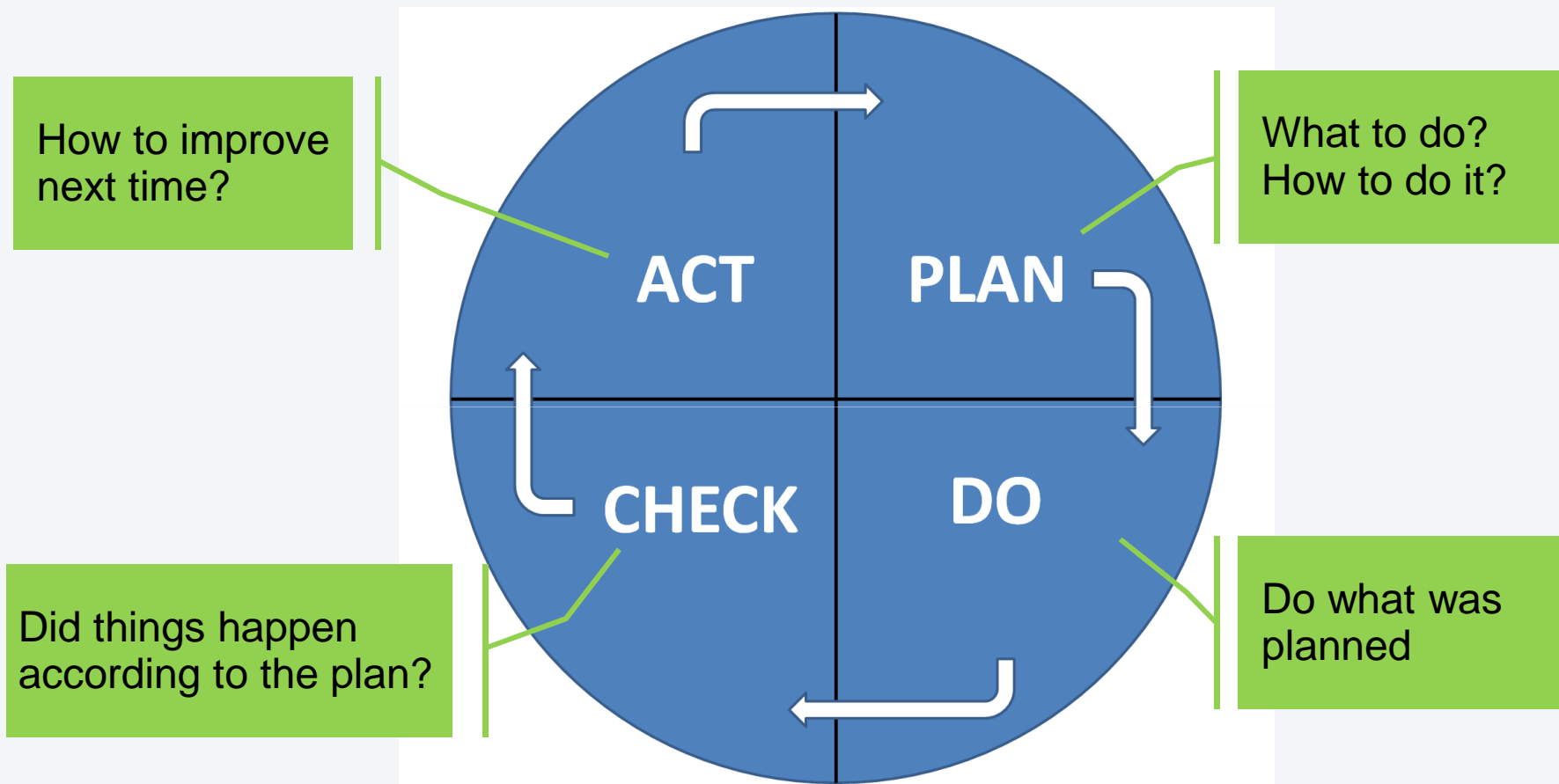*Source:* *ISO 9000: Quality Management Systems*

Quality Management levels

Policy statements including clear objectives derives from the policy

Description of processes – how to policy statements are implemented

Supporting documents to be used to implement the policies

ACT

PLAN

CHECK

DO

How to improve next time?

What to do? How to do it?

Did things happen according to the plan?

Do what was planned

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

Requirements for:
Personnel and test methods

- 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.

Quality Manual for Interoperability Testing

A brief look into:

Part II: Interoperability Testing Processes

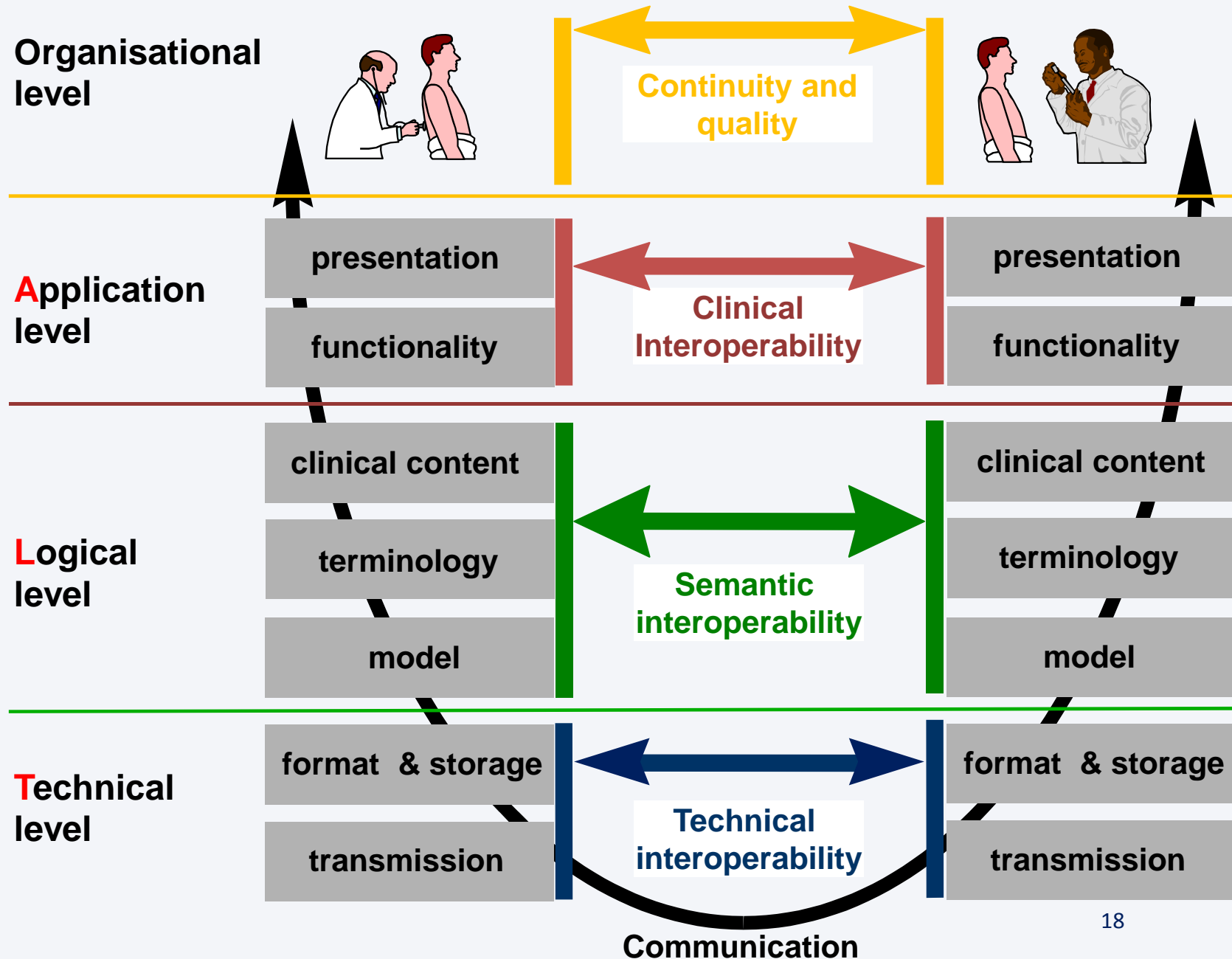# Interoperability (one definition)

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

Organisational level

Continuity and quality

Application level

presentation

functionality

Clinical Interoperability

presentation

functionality

Logical level

clinical content

terminology

model

Semantic interoperability

clinical content

terminology

model

Technical level

format & storage

transmission

Technical interoperability

format & storage

transmission

Communication

18

- 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.

IT-P: Actors and roles

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
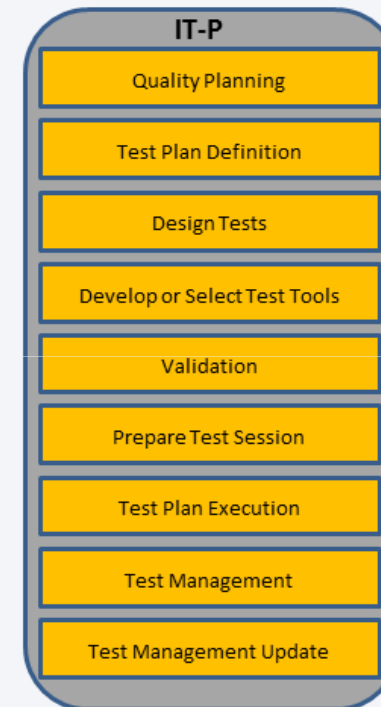
- Why?

- 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.

- 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.

Work to be done

- 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.

- 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.

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

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/