

# HITCH

## Establishing Quality Management for Interoperability Testing

Morten Bruun-Rasmussen  
mbr@mediq.dk

## 1- Interoperability (one definition)

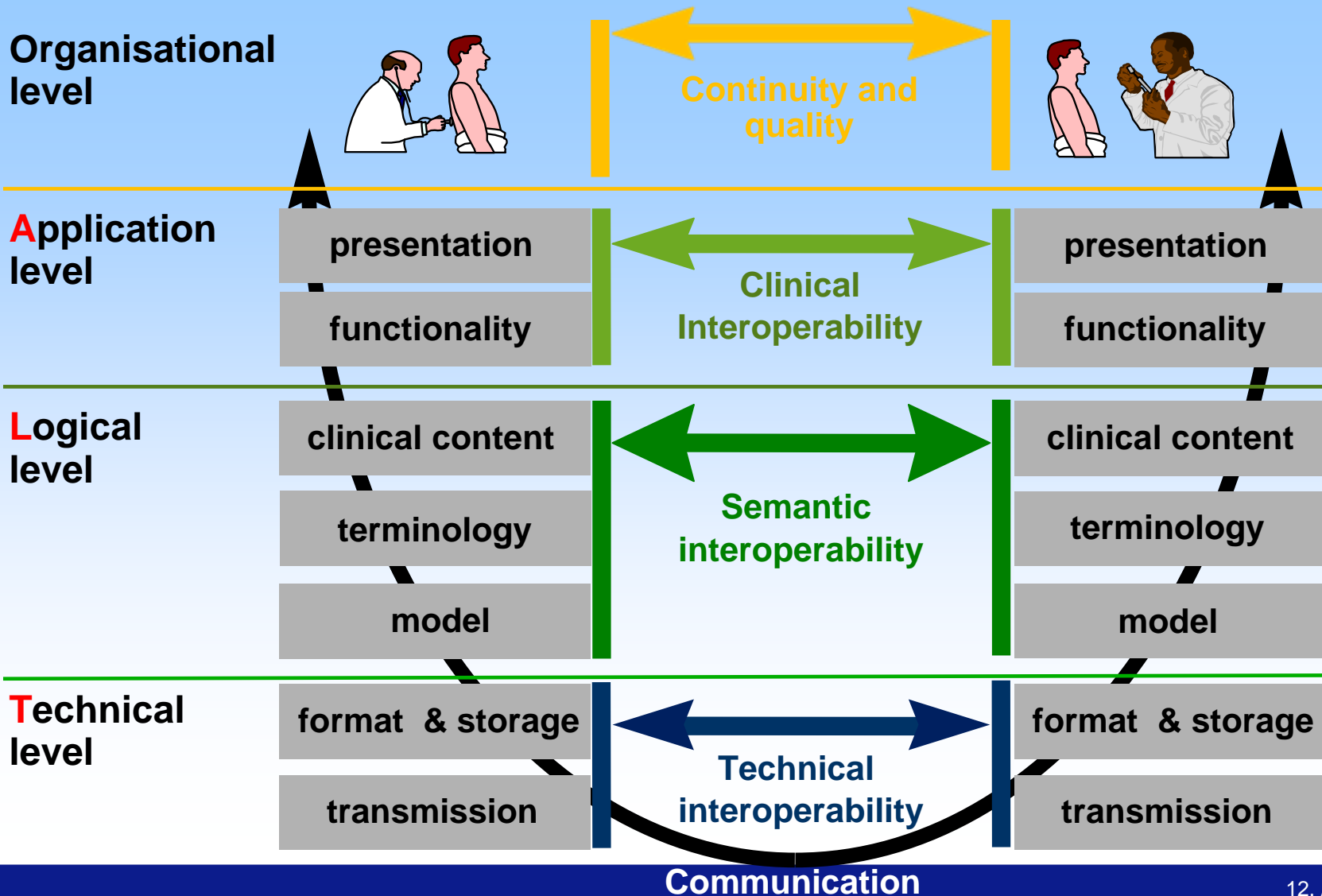
The ability of two or more  
systems or components  
  
to exchange information  
  
and to use the information  
that has been exchanged

*Source: Institute of Electrical and Electronics Engineers.*

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

*New York, NY: 1990.*

## 2- Interoperability – ALT model

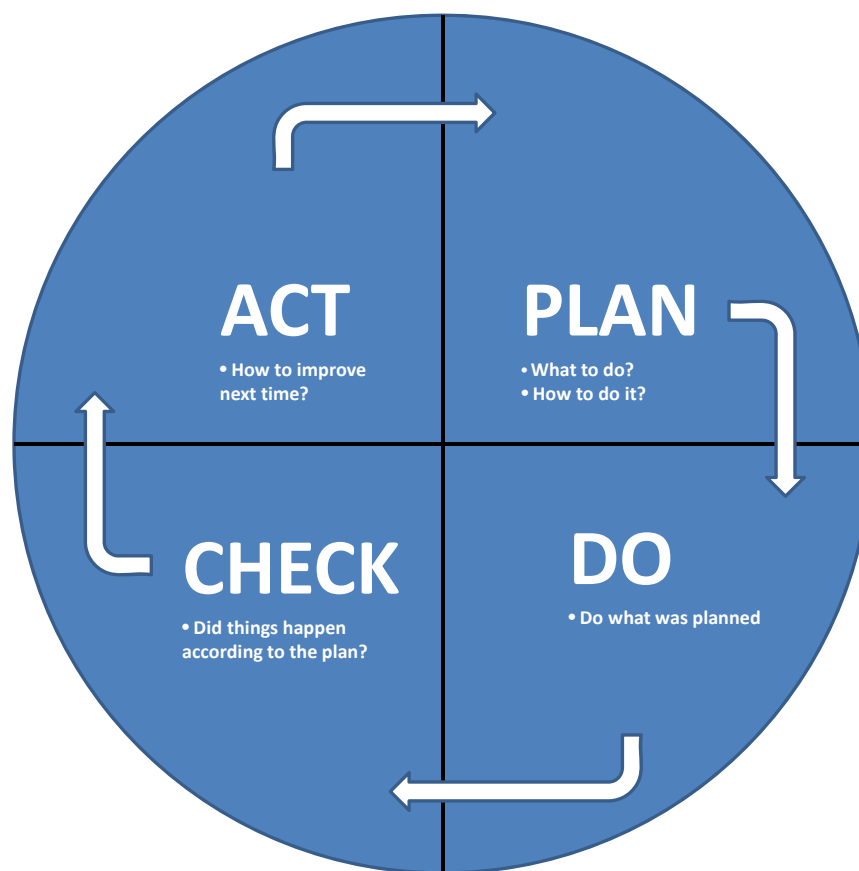


### 3- Quality Management System (one definition)

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*

## 4- Quality Management and the PDCA cycle

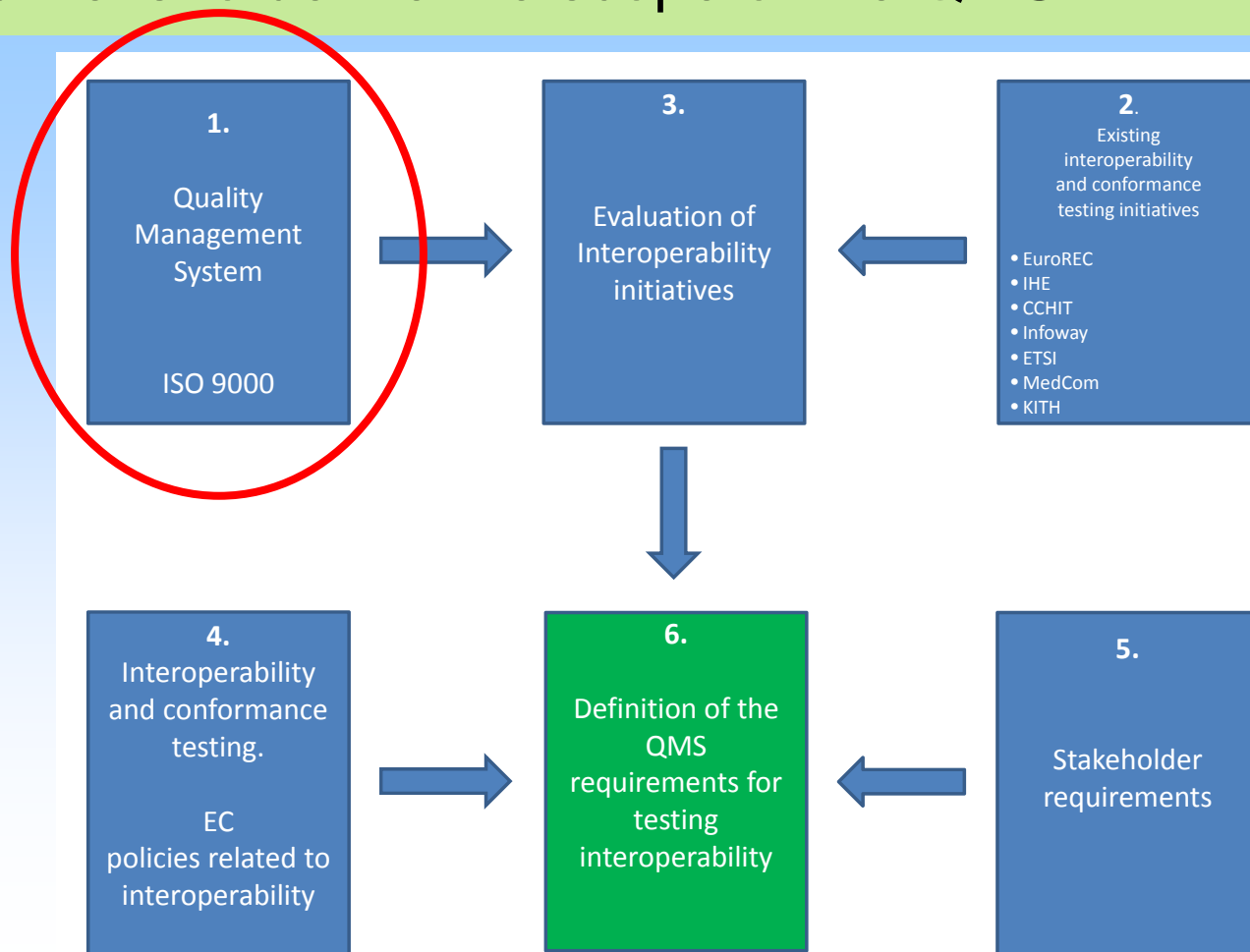


Source: *The Deming wheel (named after W. Edwards Deming).  
A model for continuous improvement.*

## 5- Profile QMS Requirements

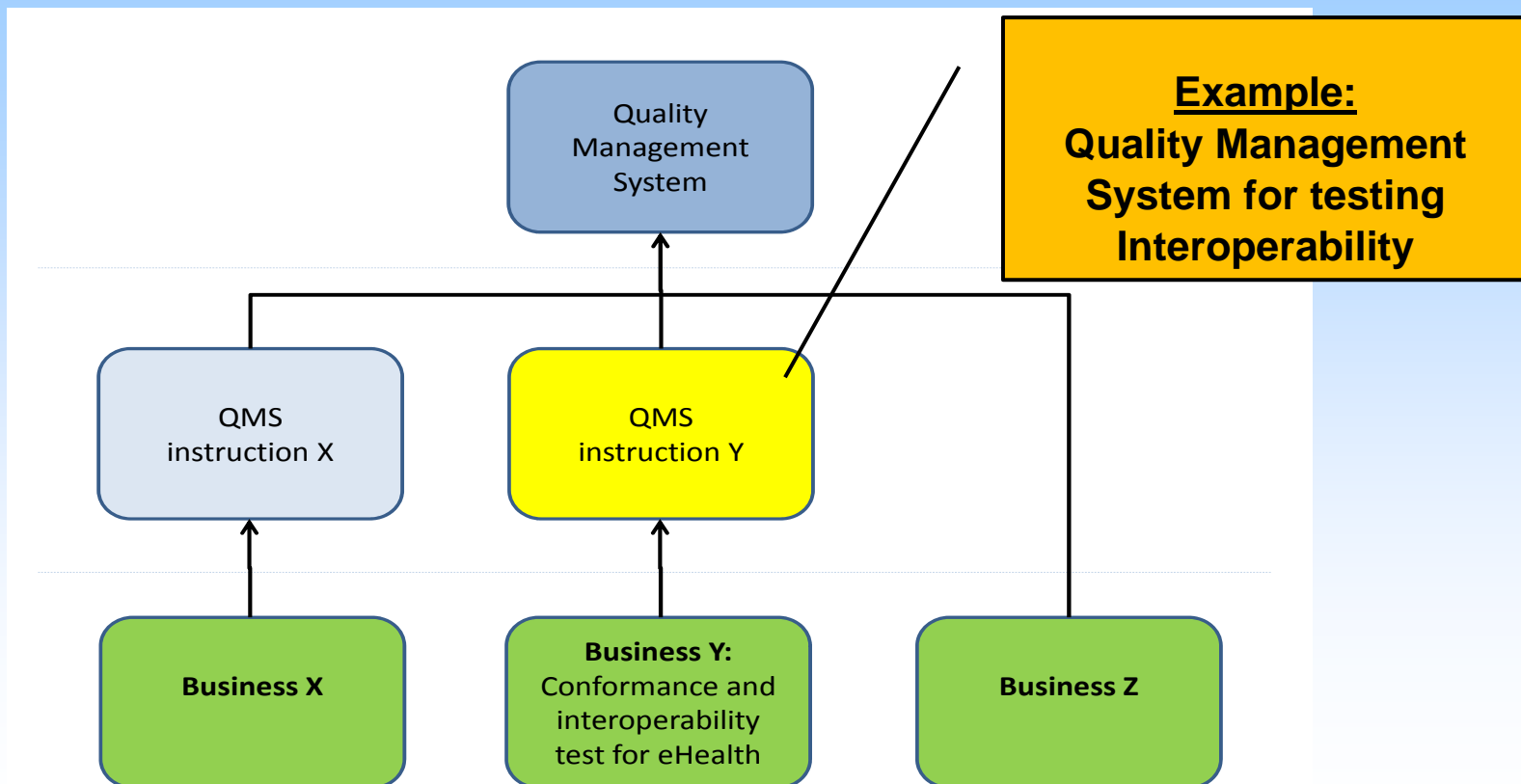
The objective is to define the scope of the QMS

Work  
methodology



## 6- Quality Management System Instruction

A QMS instruction in an organisation is a specialisation for a specific area or business domain



## 8- ISO 9000 principles

There are eight quality management principles defined in ISO 9000:2005

1. **Customer focus**
2. **Leadership**
3. **Involvement of people**
4. **Process approach**
5. **System approach to management**
6. **Continual improvement**
7. **Factual approach to decision making**
8. **Mutually beneficial relationship**



## 8- Eight principles for interoperability testing QMS

### Example. Principle 1, Customer focus

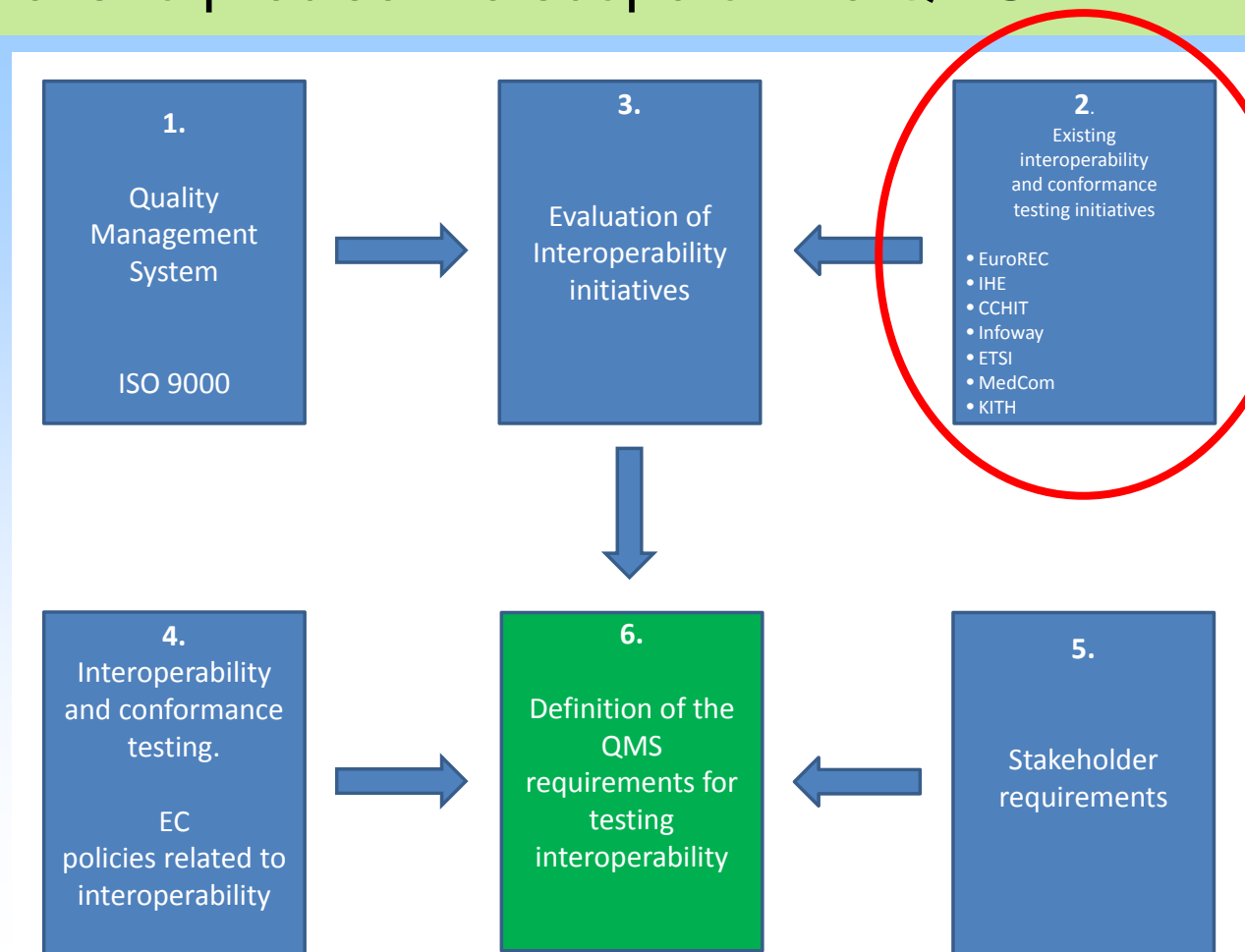
The customer in the context of interoperability QMS is vendors and developers of eHealth applications.

ISO 9000	Leaders establish unity of purpose and direction of the organisation. They should create and maintain the internal environment in which people can become fully involved in achieving the organisation's objectives.
Interoperability (procedures and policies)	Leaders should define clear objectives for conformance and interoperability testing. Leaders should create and maintain an environment for conformance and interoperability testing, including involving people in order to achieve the organisation's objectives and goals.
Example	<ul style="list-style-type: none"> <li>a. Describing needs for all stakeholders (internal, vendors, hospitals, GP's, government, telecom)</li> <li>b. Clear objective/vision</li> <li>c. Creating/defining shared values</li> <li>d. Providing training...</li> <li>e. Inspiring, encouraging ...</li> </ul>

## 9- Profile QMS Requirements

The objective is to precise the scope of the QMS

Methodology  
for  
the work



## 10- Existing interoperability initiatives - description

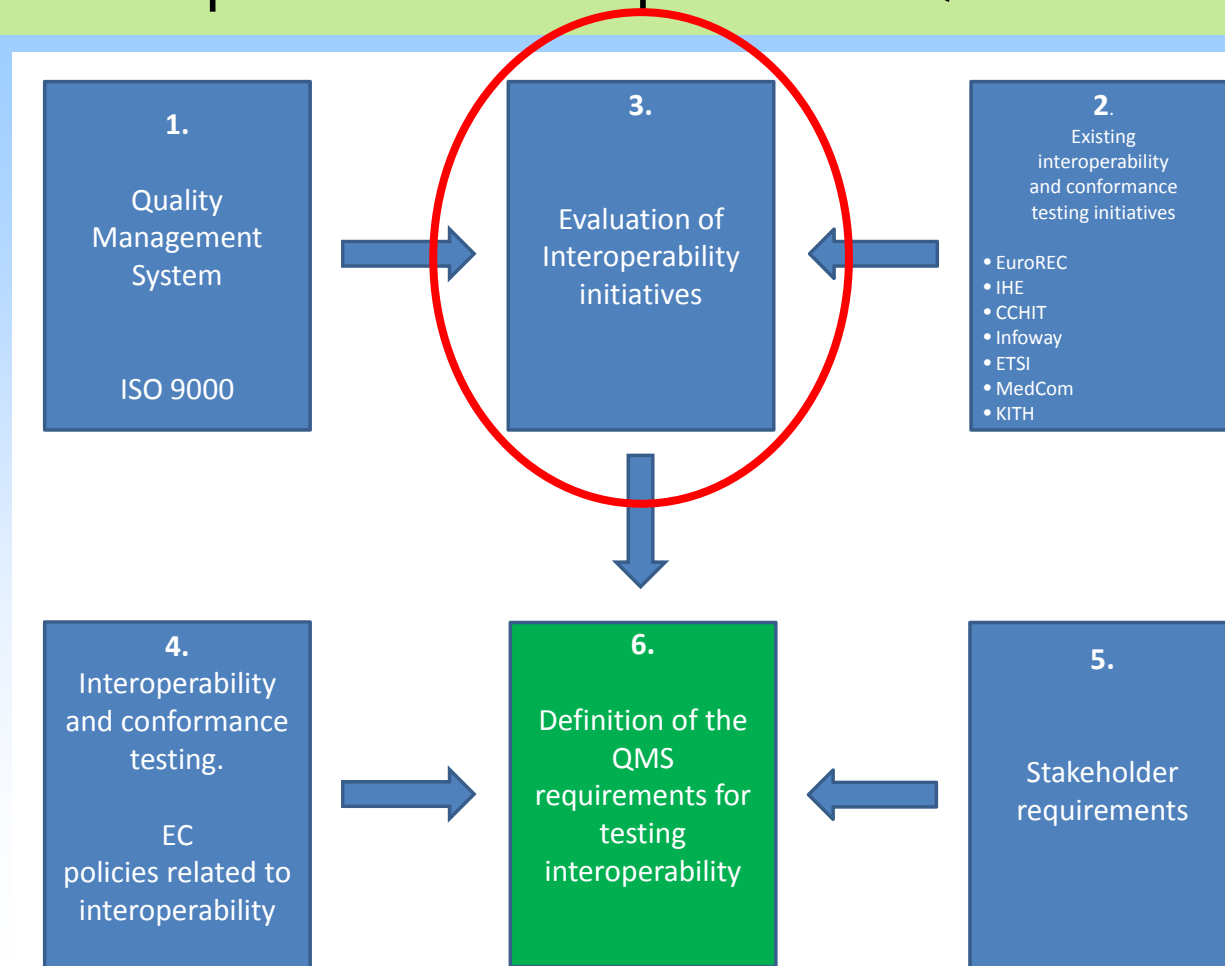
1. **EuroRec**
2. **IHE**
3. **CCHIT (USA)**
4. **Infoway (CAN)**
5. **Continua**
6. **OpenECG**
7. **ETSI**
8. **MedCom**
9. **KITH**

- ❑ Background
- ❑ Organisation
- ❑ Interoperability initiative
- ❑ Dissemination level

## 11- Profile QMS Requirements

The objective is to precise the scope of the QMS

Methodology  
for  
the work



## 12- Existing interoperability initiatives - evaluation

The aim of the evaluation is to identify “gaps” in the existing interoperability QMS procedures

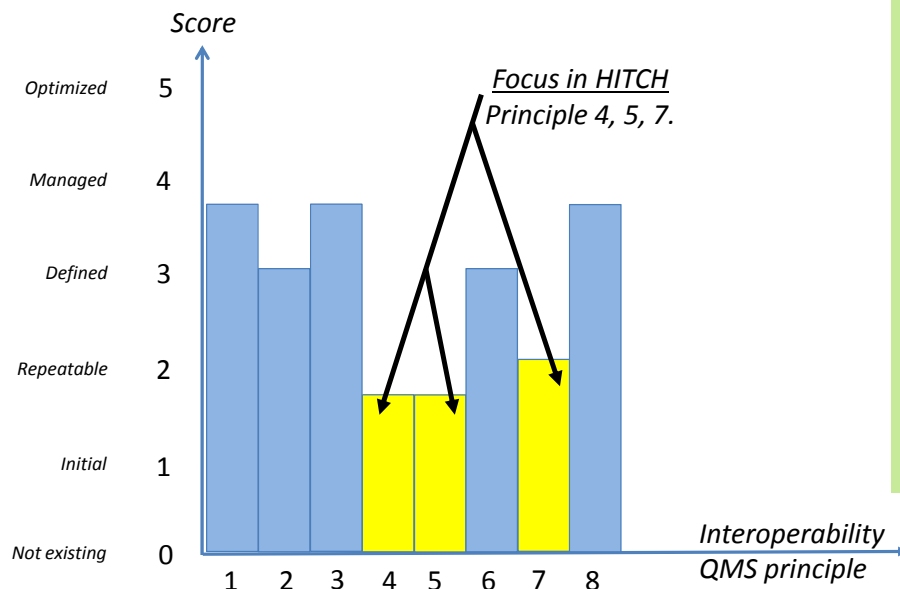
The scale has been inspired by COBIT

Score	Name	Comments
0	Not existing	There are no identifiable activities.
1	Initial	Some activities appear. Implementation and methods are variable depending on competences and experience of personnel.
2	Repeatable	Still lack of documentation, but there are similarities between activities
3	Defined	Procedures are created but not followed in many cases.
4	Managed	Procedures are followed. There are auditable controls.
5	Optimized	Procedures and workflows are backed by IT systems.

COBIT: Control Objectives for Information and related Technology. A set of best practices (framework) for information Technology Management.

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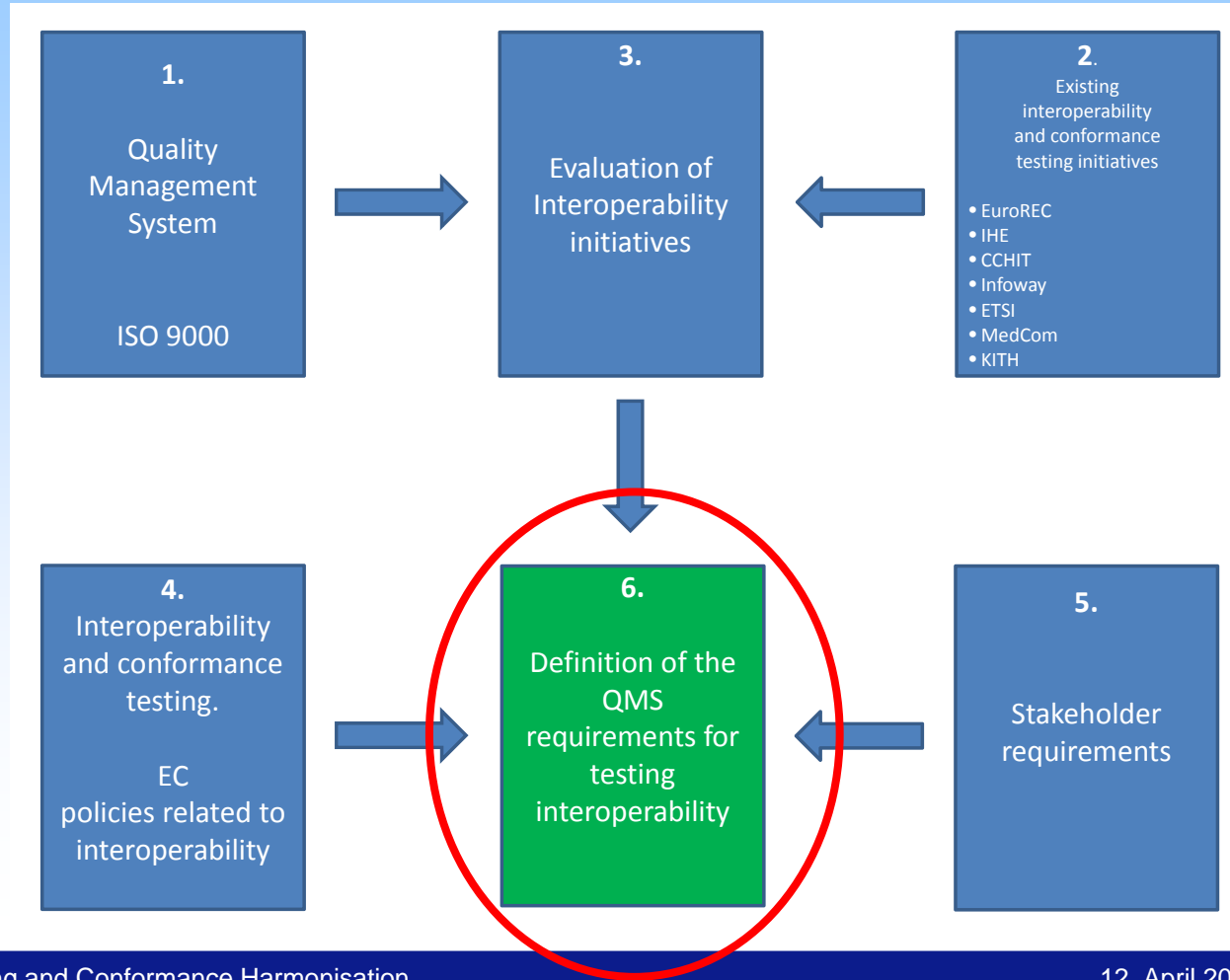


- P1: Customer focus
- P2: Leadership
- P3: Involvement of people
- P4: Process approach**
- P5: System approach to management**
- P6: Continual improvement
- P7: Factual approach to decision making**
- P8: Mutually beneficial relationship

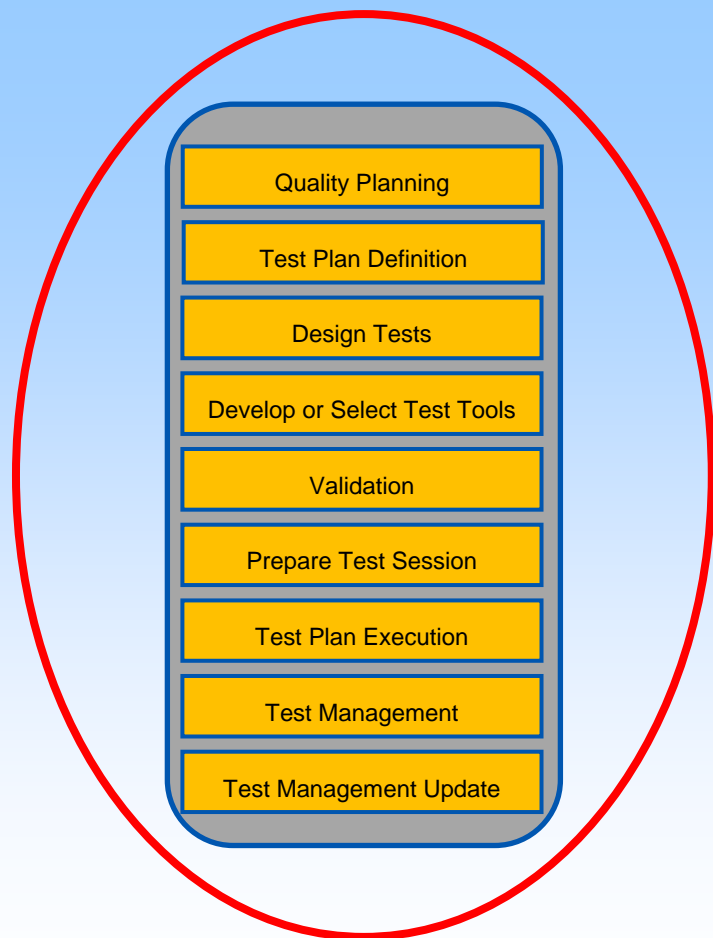
# 14- Profile QMS Requirements

The objective is to precise the scope of the QMS

Methodology  
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## 15- Interoperability Testing Processes (IT-P)



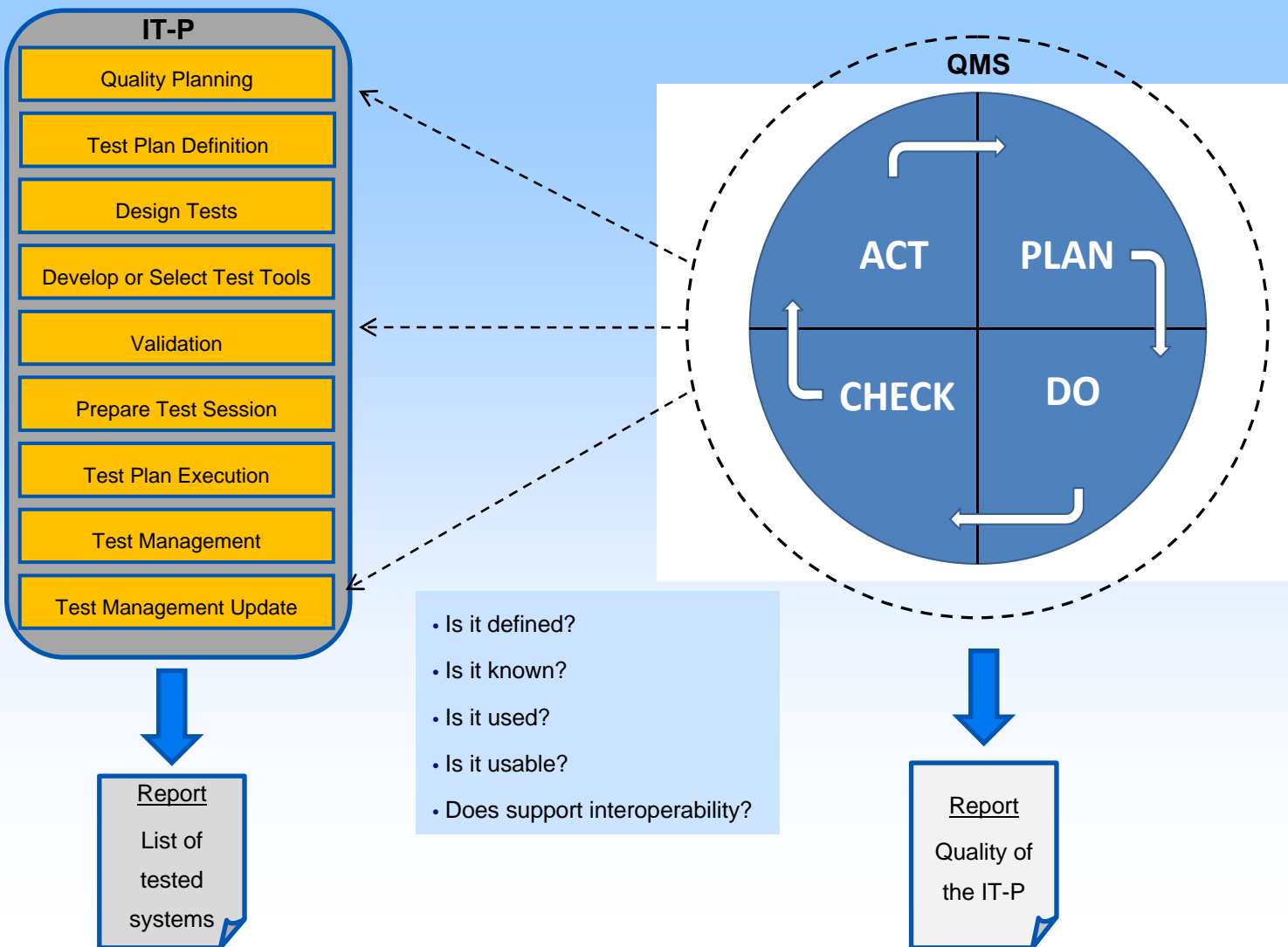
A comprehensive guideline for  
Interoperability Testing  
of eHealth systems

Based on pan-European  
best practice

IHE will use it for  
Connecathon



# 16- Quality Manual



## 17- Lessons learned: The journey to improved interoperability

Quality Management is a non-existing professional discipline for Interoperability Testing of eHealth Systems

Not easy: Requires change in culture, multidisciplinary cooperation, common understanding for the needs and a professional approach to both Interoperability Testing and Quality Management

**\* HITCH have started the journey \***

A comprehensive guideline to Interoperability Testing Processes  
An adequate Quality Management System

## 18- Thank you for your attention

« in God we trust, for the rest we test »

*A. Petrenko*