ISO 13485:2016 Vs ISO 9001:2015

Ms. Khwunsuda Anuan

Client manager – Regulatory Services - APAC Assessment Delivery Operations

Oct 07, 2021

By Royal Charter

bsi.

Relationship between ISO13485 and ISO9001

Relationship with ISO 9001

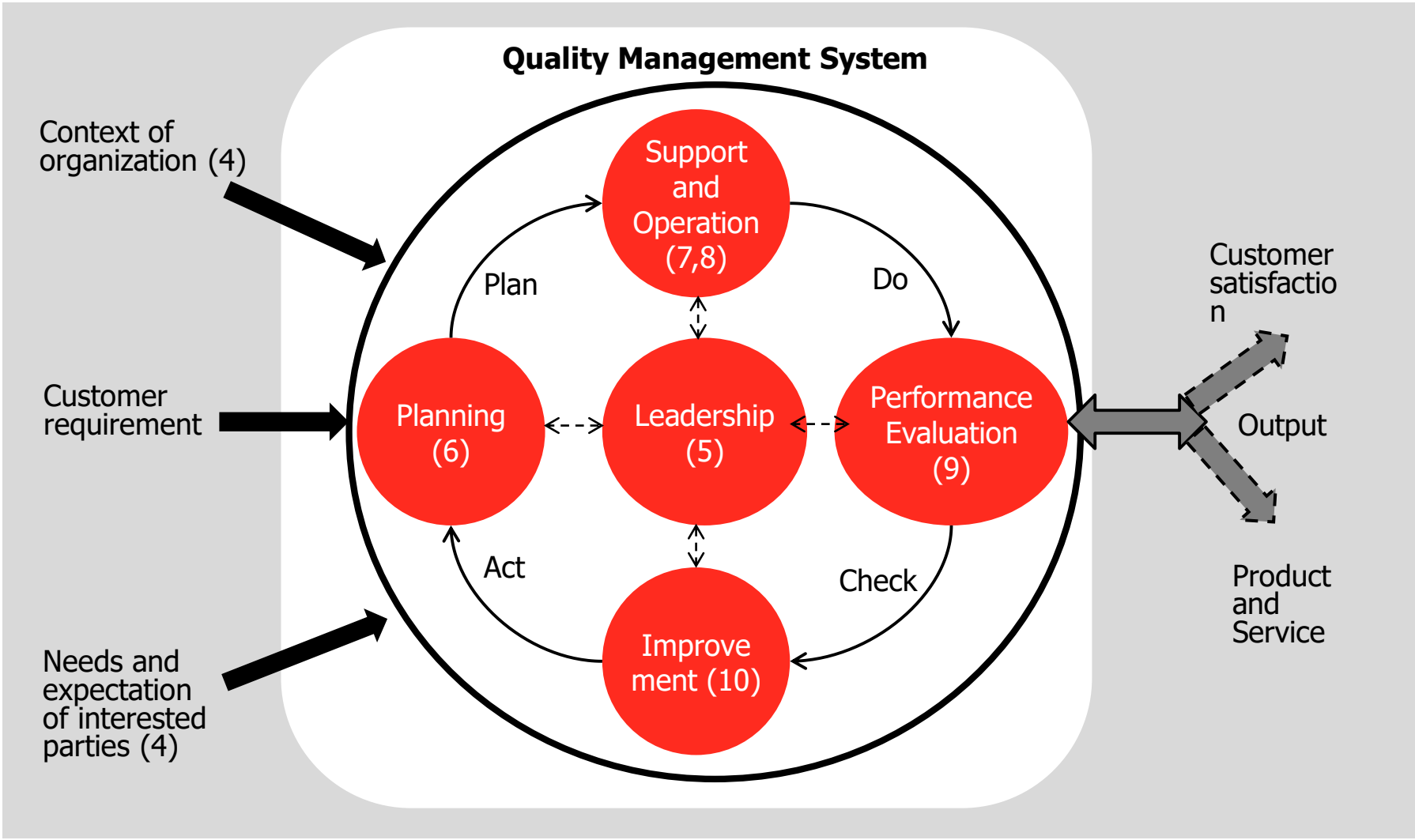
ISO 13485

Is for organizations structured in the same way as ISO 9001:2008

ISO 9001

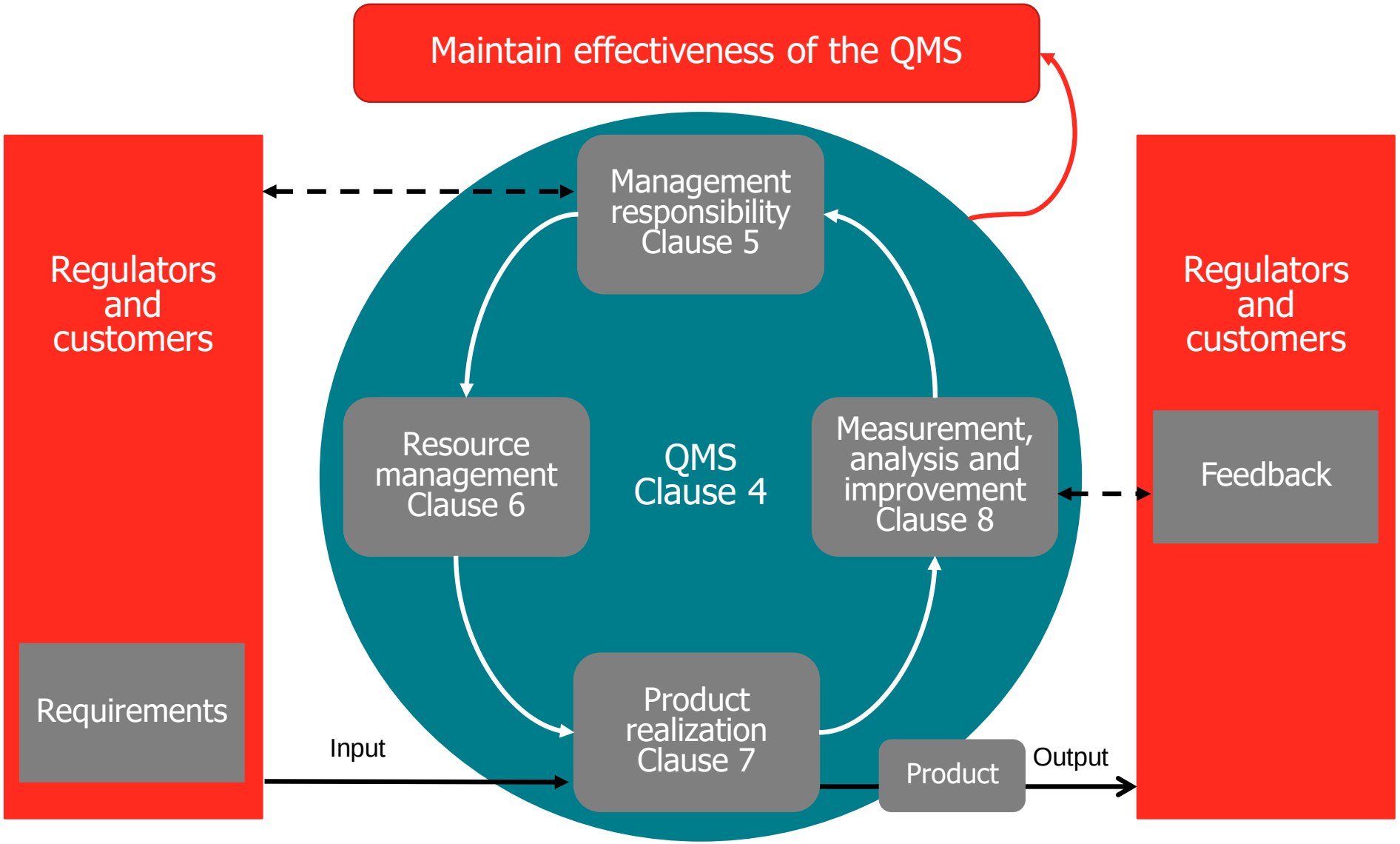
Is a quality management system appropriate for all types of organizations

Process Model: ISO 9001:2015



Copyright © 2020 BSI. All rights reserved

Process model: ISO 13485:2016



Copyright © 2020 BSI. All rights reserved

ISO 13485 and ISO 9001 in detail

Clause 1.1: Scope: General

ISO 13485 specifies requirements for:

Organizations who

design **develop** **produce**

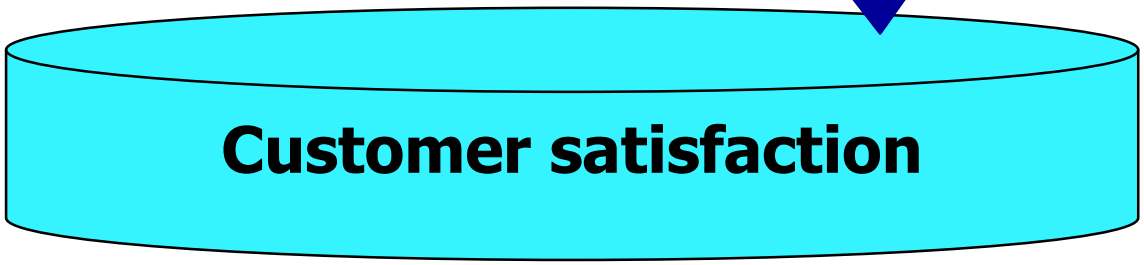
install or **service**

medical devices

Clause 1.1: Scope: General

ISO 9001 specifies requirements for all business to:

demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements



ISO 9001 versus ISO 13485: Summary

ISO 9001	ISO 13485
6 Documents	27 Documents
Aims for customer satisfaction through continual improvement	Customer satisfaction and continual improvement are not objectives
Covers all products uniformly	Different requirements for different types of products
Basis for voluntary certification	Basis for regulatory certification

ISO 13485
Clause 4 and 5
Vs ISO 9001

Copyright © 2020 BSI. All rights reserved

ISO 13485:2016: Clause 4

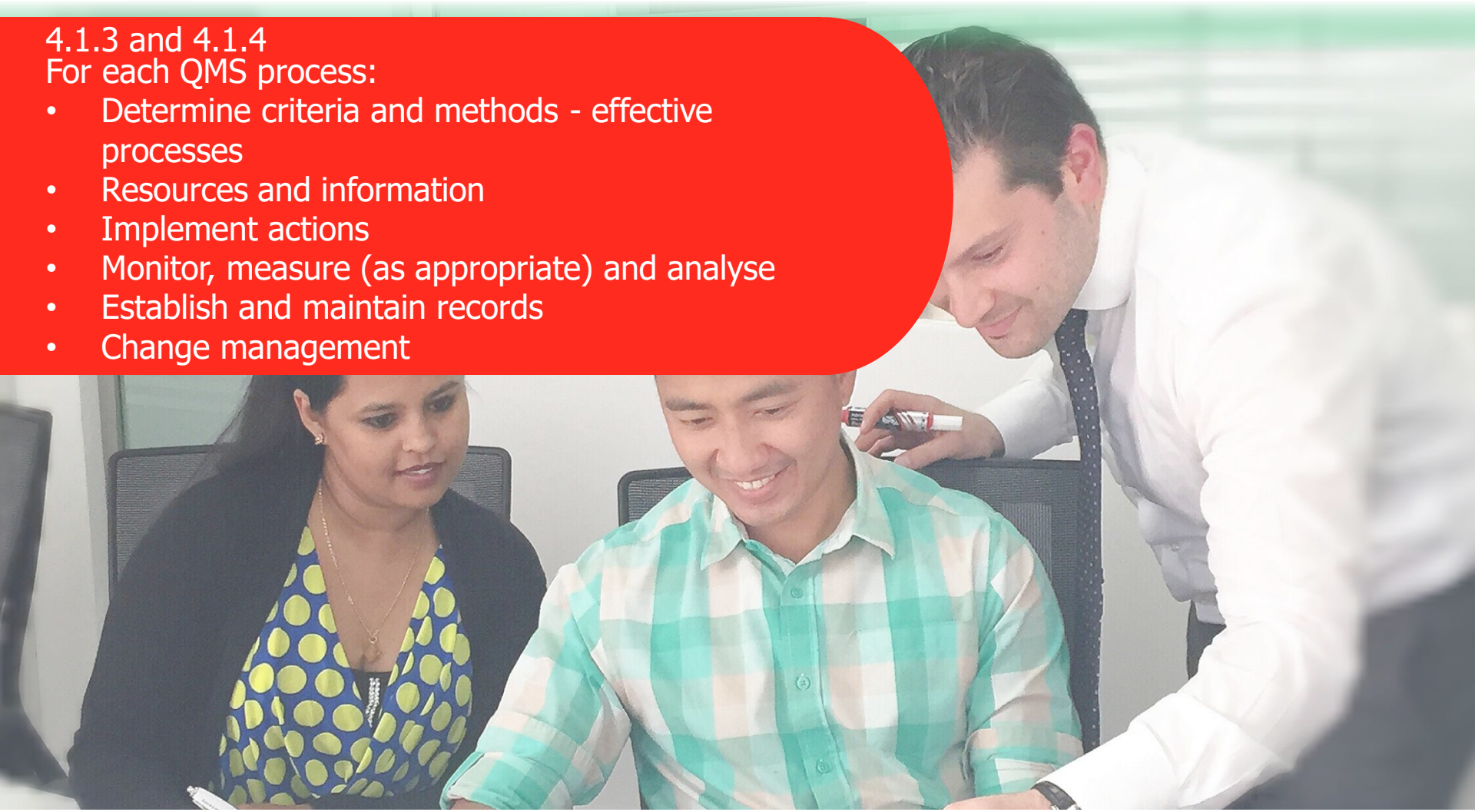
4.1.1 Quality management system:
- Document a QMS
- Maintain effectiveness
- Document the role(s) undertaken by the organization under the applicable regulatory requirements

4.1.2
- Determine processes needed
- Apply processes
- Risk based approach
- Determine sequence and interaction of the processes

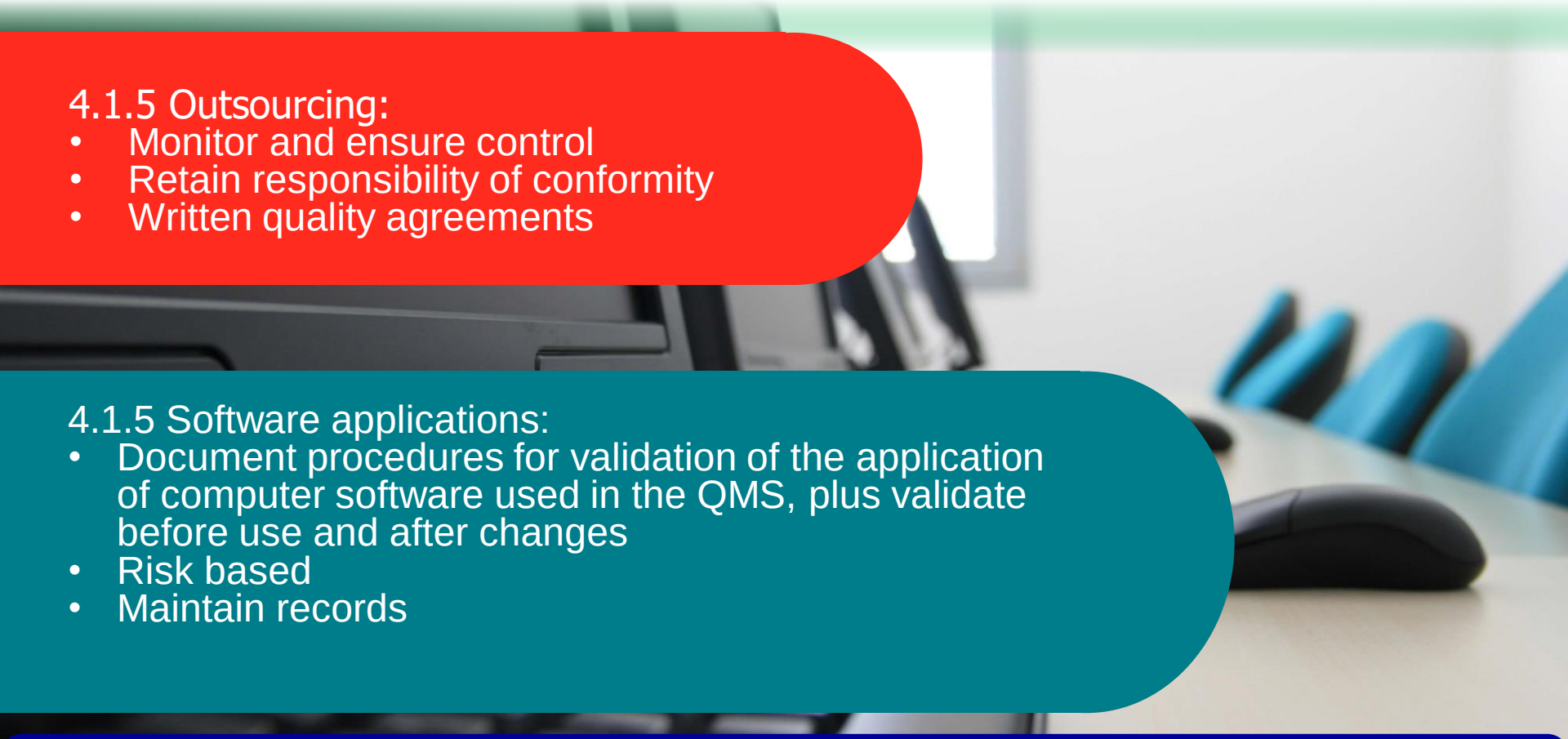
ISO 13485:2016: Clause 4

4.1.3 and 4.1.4
For each QMS process:

- Determine criteria and methods - effective processes
- Resources and information
- Implement actions
- Monitor, measure (as appropriate) and analyse
- Establish and maintain records
- Change management



ISO 13485:2016: Clause 4



4.1.5 Outsourcing:
- Monitor and ensure control
- Retain responsibility of conformity
- Written quality agreements

4.1.5 Software applications:
- Document procedures for validation of the application of computer software used in the QMS, plus validate before use and after changes
- Risk based
- Maintain records

Correspondence with ISO 9001 Clause 4.1, 4.,2, 4.4

bsi.

Clause 4.2: Documentation

4.2.1 General

4.2.2 Quality manual

4.2.3 Medical Device File

****4.2.4 Control of document**

****4.2.5 Control of record**

****Correspondence with ISO 9001 Clause 7.5**

Clause 5: Management responsibility

5.1 Management commitment	5.1
5.2 Customer focus	5.1.2
5.3 Quality policy	5.2
5.4 Planning	6
5.5 Responsibility, authority and communication	5.3
5.6 Management Review	9.3

Correspondence with ISO 9001

bsi.

ISO 13485
Clause 6
Vs ISO 9001

Copyright © 2020 BSI. All rights reserved

ISO 13485: Clauses 6.1 and 6.2

6.1: Provision of resources; determine and provide resources for quality management system

6.2: Human resources:

- Ensure personnel are competent on the basis of appropriate education, training, skills and experience
- Evaluate effectiveness of training (methodology proportionate to risk)
- Maintain records

Correspondence with ISO 9001 clause 7.1-7.4

ISO 13485: Clause 6.3 Infrastructure

- Prevent product mix up
- Ensure orderly handling
- Maintenance of equipment applies to production, control of work environment, monitor and measurement
- Document intervals

Correspondence with ISO 9001 clause 7.1.3

ISO 13485: Clause 6.4 Work environment and contamination control

6.4.1 Work environment
- Document requirements
- Competence for temporary work
- Reference to cleanroom standards

6.4.2 Contamination control
- Document requirements
- Sterile medical devices

Correspondence with ISO 9001 Clause 7.1.4

ISO 13485
Clause 7
Vs ISO 9001

Copyright © 2020 BSI. All rights reserved

ISO 13485 Clause 7 Vs ISO 9001 Clause 8

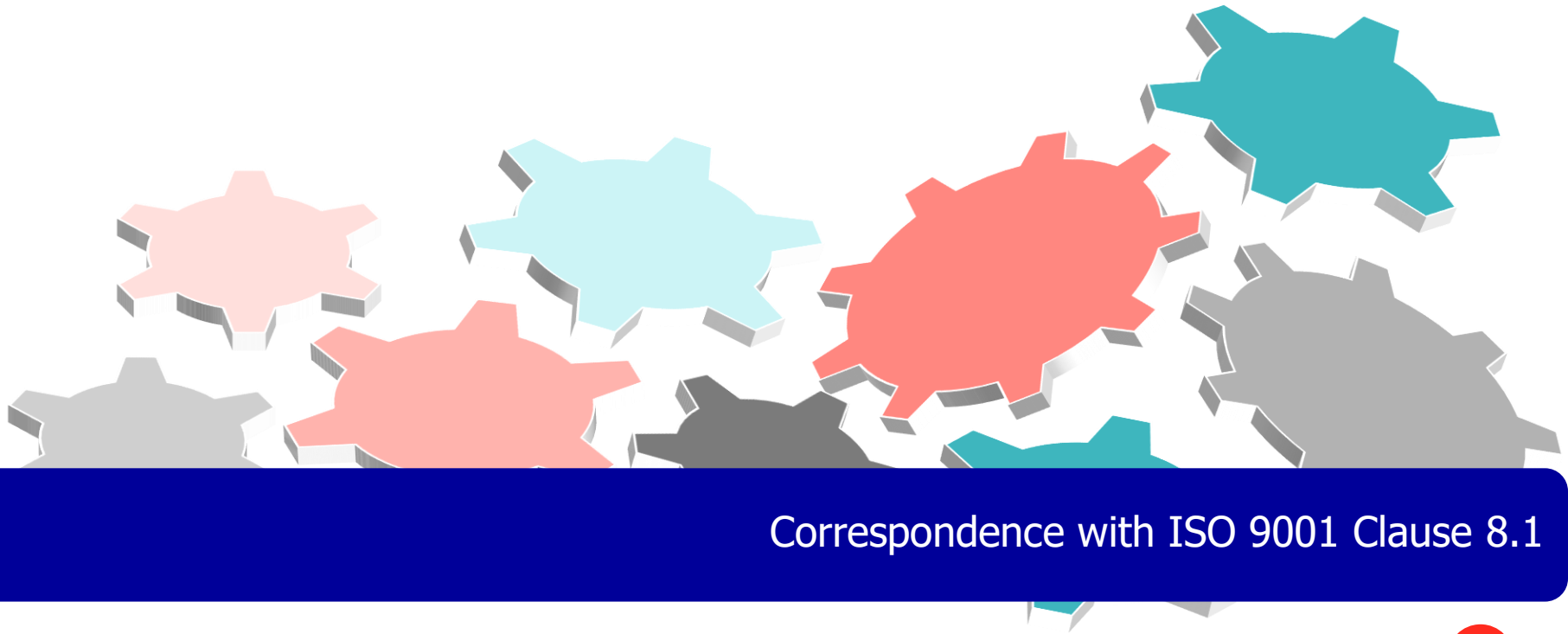
7.1 Planning product realization	8.1
7.2 Customer related processes	8.2
7.3 Design and development	8.3
7.4 Purchasing	8.4
7.5 Production and service provision	8.5
7.6 Control of measuring and monitoring equipmen	7.1.5

Correspondence with ISO 9001

bsi.

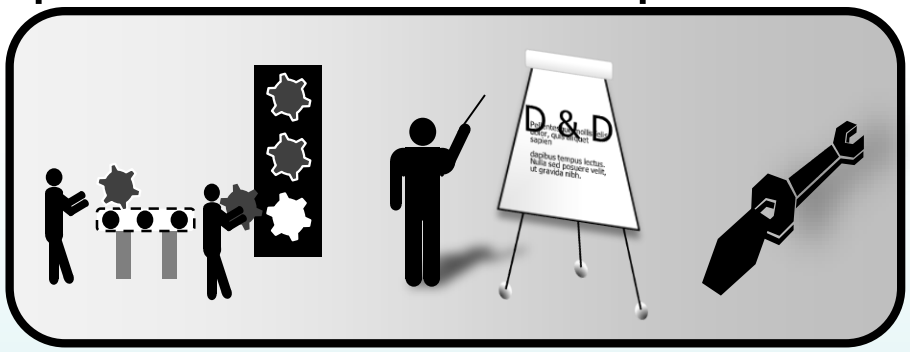
ISO 13485:
Clause 7.1 Planning of product realization

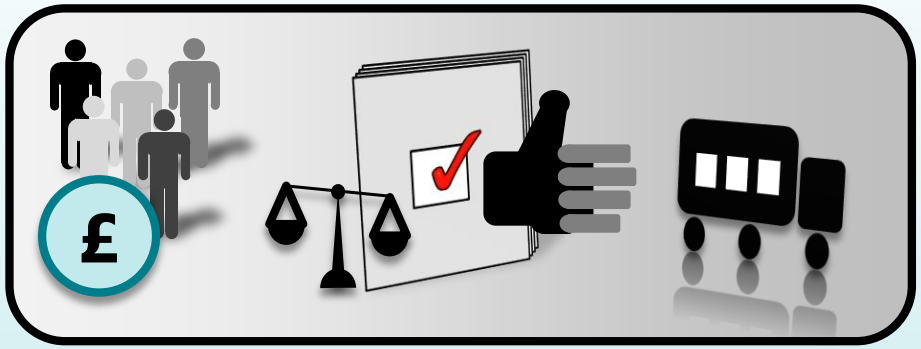
- Plan processes
- Risk management throughout product realization
- ISO 14971
- Document process and keep records



Correspondence with ISO 9001 Clause 8.1

ISO 13485:
Clause 7.2.1 Determination of requirements related to product





- Items not specified by the customer but needed for intended use
- Consider user training

- Customer requirements (orders) including delivery and post-delivery activities
- Regulatory requirements

Correspondence with ISO 9001 Clause 8.2.2

ISO 13485:
Clause 7.2.2 Review of requirements related to the product

Contract review; this is to be done prior to commitment to supply the product

Correspondence with ISO 9001 Clause 8.2.3 and 8.2.4

bsi.

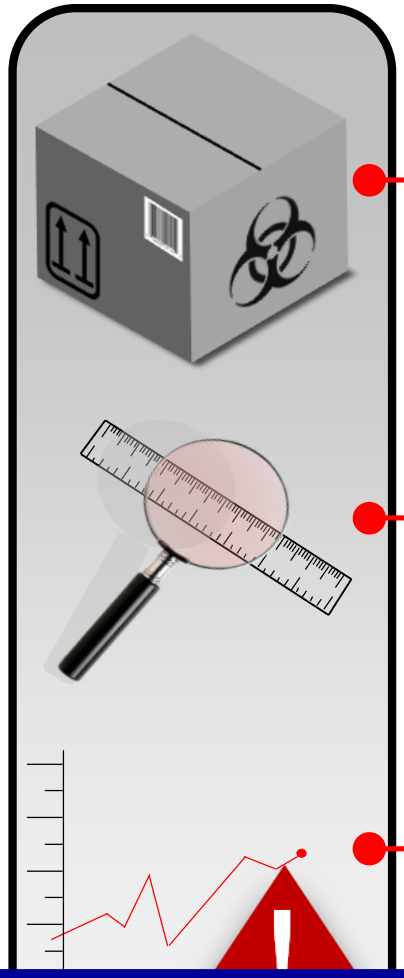
ISO 13485:
Clause 7.2.3 Communication

Plan and document arrangements for communicating with customers

Correspondence with ISO 9001 Clause 8.2.1

ISO 13485 Clause 7.3 Vs ISO 9001 Clause 8.4 Design and development

ISO 13485 Clause 7.4 Vs ISO 9001 Clause 8.4



7.4.1 Purchasing process
Criteria for evaluation and selection of suppliers; Performance and risk; Plan monitoring and re-evaluation process; Additional record requirements

8.4.1
8.4.2

7.4.2 Purchasing information
Purchasing specifications; Written agreements with suppliers; Notification of changes

8.4.3

7.4.3 Verification of purchased product
Verification based on risk/supplier evaluation; Change control

8.4.1
8.4.2
8.6

Correspondence with ISO 9001

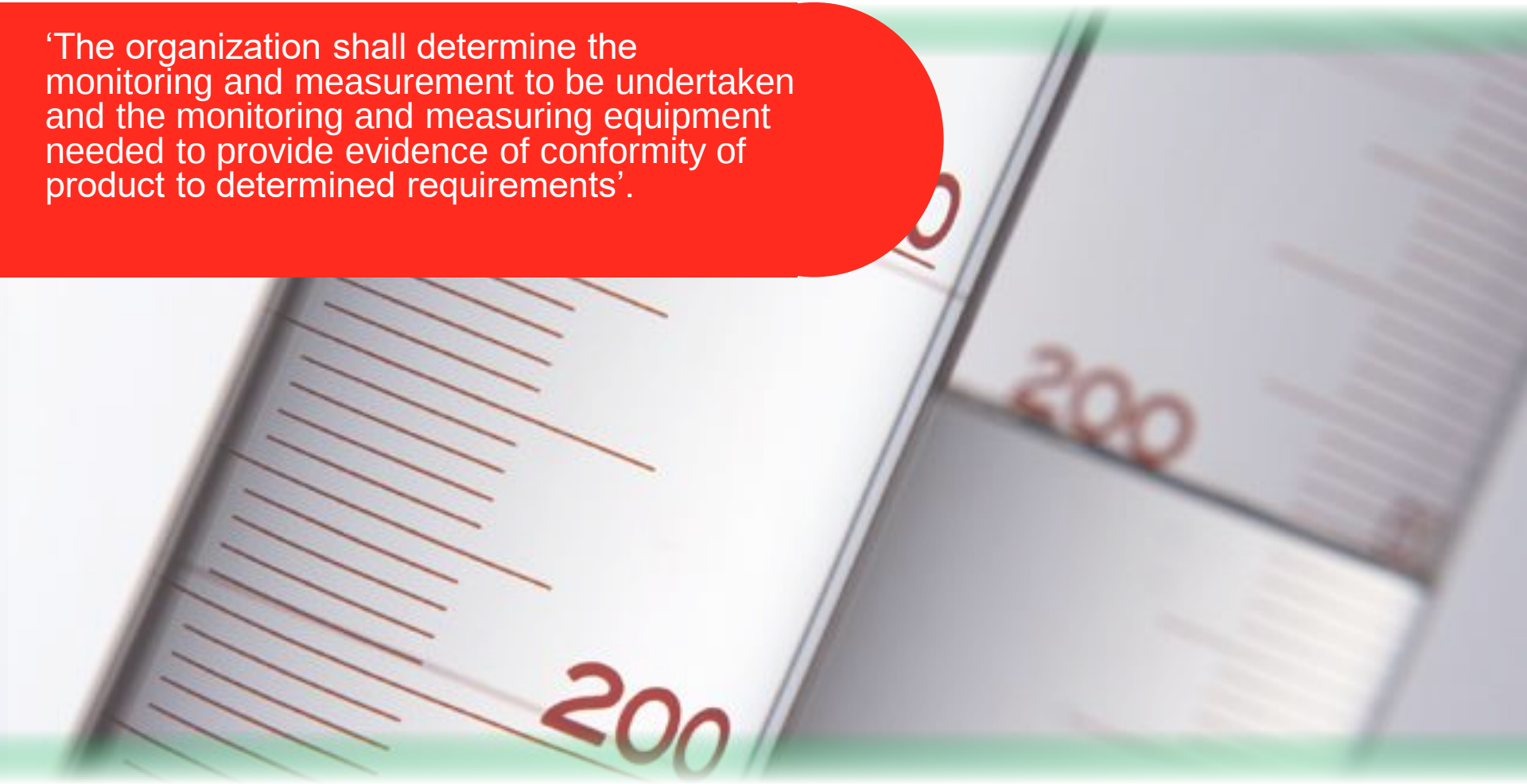
ISO 13485 Clause 7.5 Vs ISO 9001 Clause 8.5

ISO 13485 Clause 7.5 Vs ISO 9001 Clause 8.5

Requirements – ISO 13485:2016	Requirements – ISO 9001:2015
7.5 Production and service provision	8.5 Production and service provision
7.5.1 Control of production and service provision	8.5.1 Control of production and service provision
7.5.2 Cleanliness of product.	No equivalent clause
7.5.3 Installation activities	No equivalent clause
7.5.4 Servicing activities	No equivalent clause
7.5.5 Particular requirements for sterile medical devices.	No equivalent clause
7.5.6 Validation of processes for production and service provision	8.5.1 Control of production and service provision
7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems.	No equivalent clause
7.5.8 Identification	8.5.2 Identification and traceability
7.5.9 Traceability.	8.5.2 Identification and traceability
7.5.10 Customer property.	8.5.3 Property belonging to customers or **external providers**
7.5.11 Preservation of product.	8.5.4 Preservation

ISO 13485 Clause 7.6 Vs ISO 9001 Clause 7.1.5

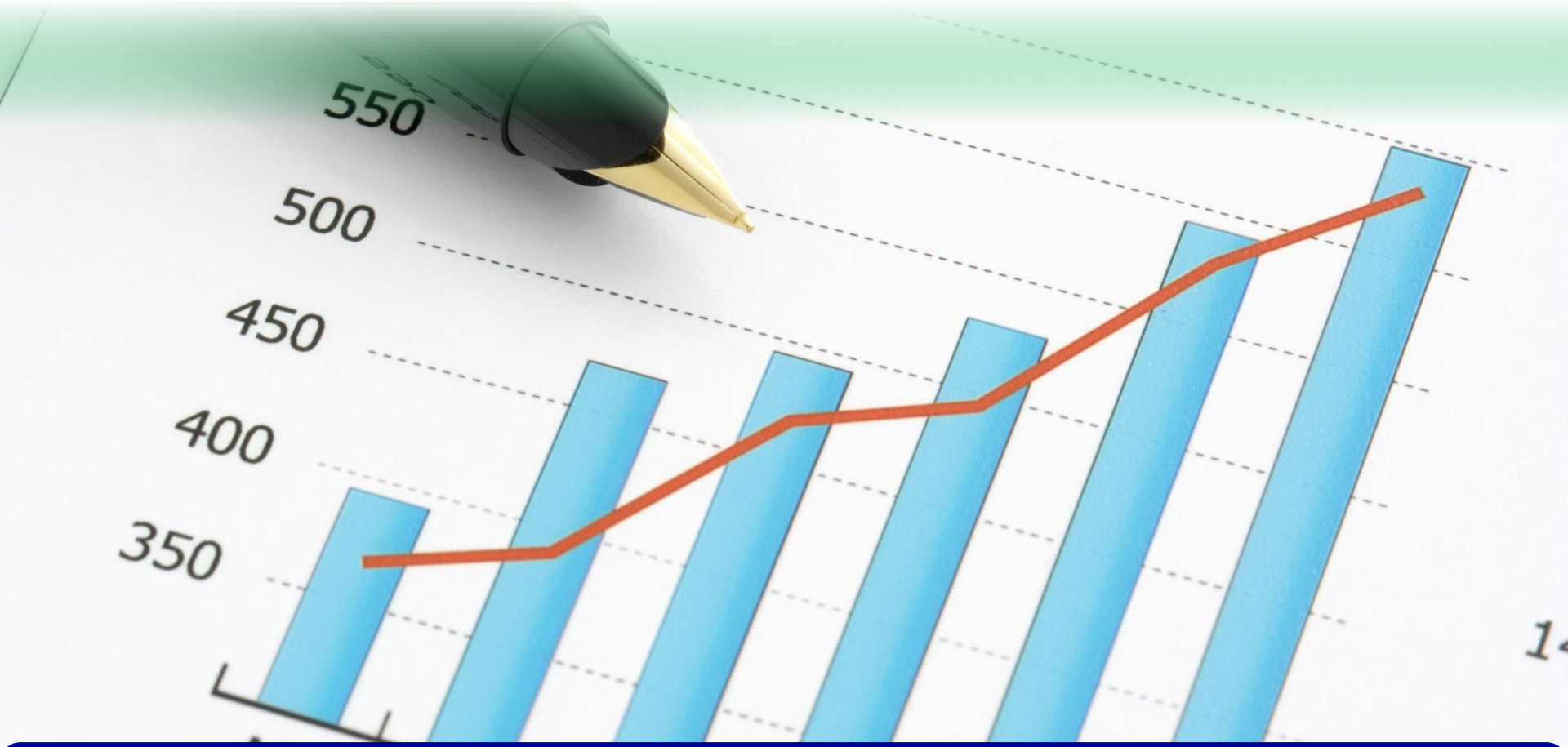
‘The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements’.



ISO 13485
Clause 8
Vs ISO 9001

Copyright © 2020 BSI. All rights reserved

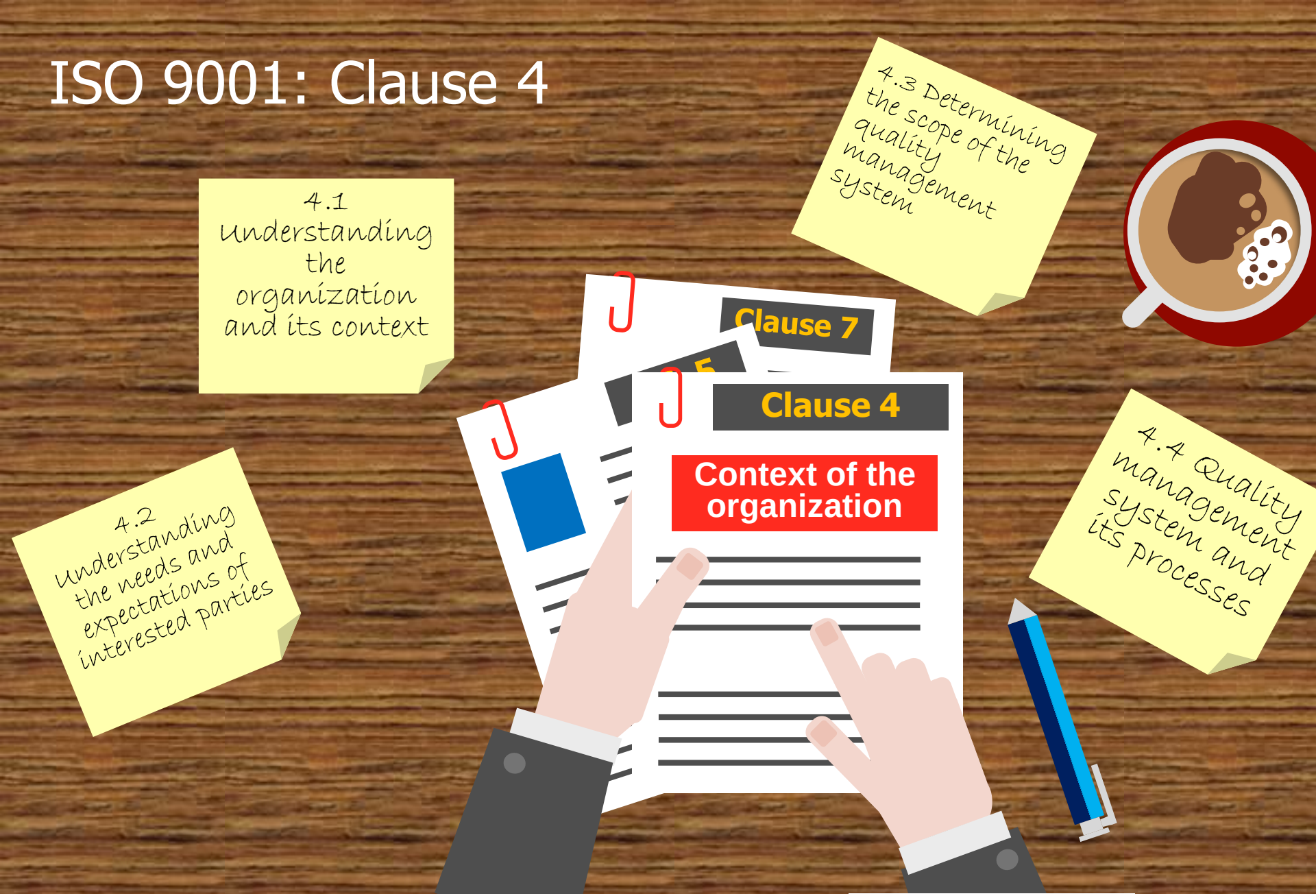
ISO 13485
Clause 8: Monitoring and measurement



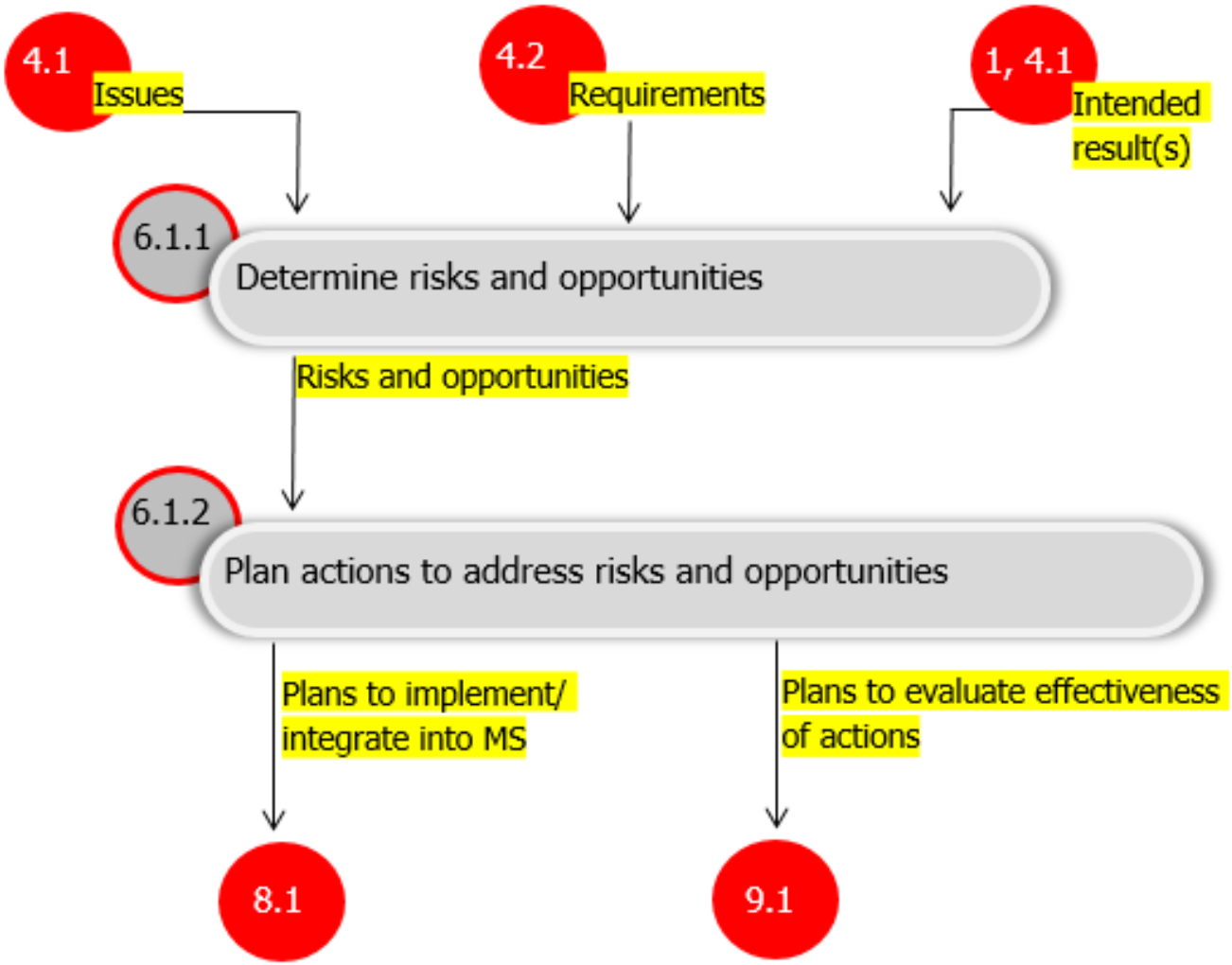
Correspondence with ISO 9001 Clause 9 and 10.

Additional Course for ISO 9001

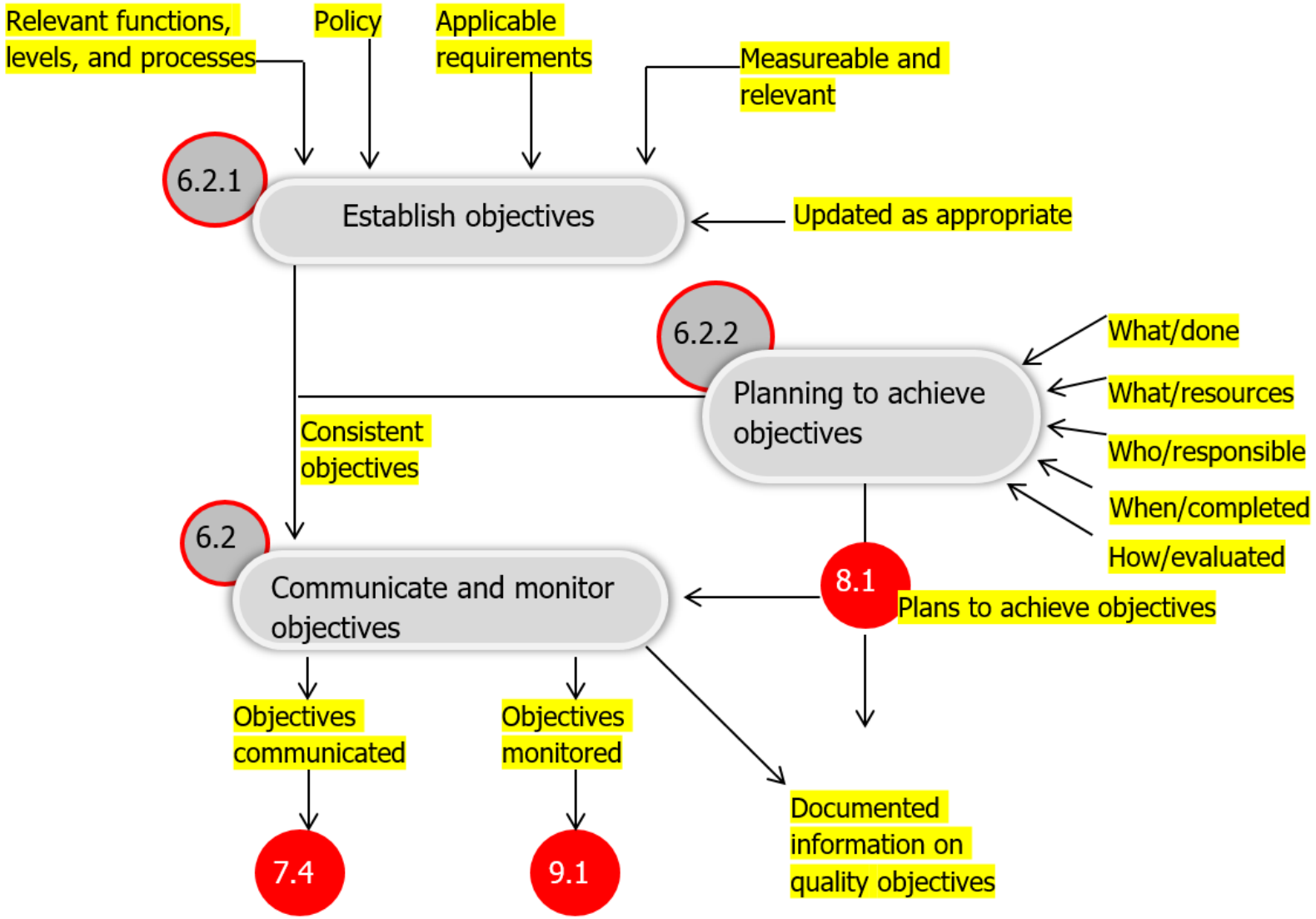
ISO 9001: Clause 4



ISO 9001: Clause 6 Planning

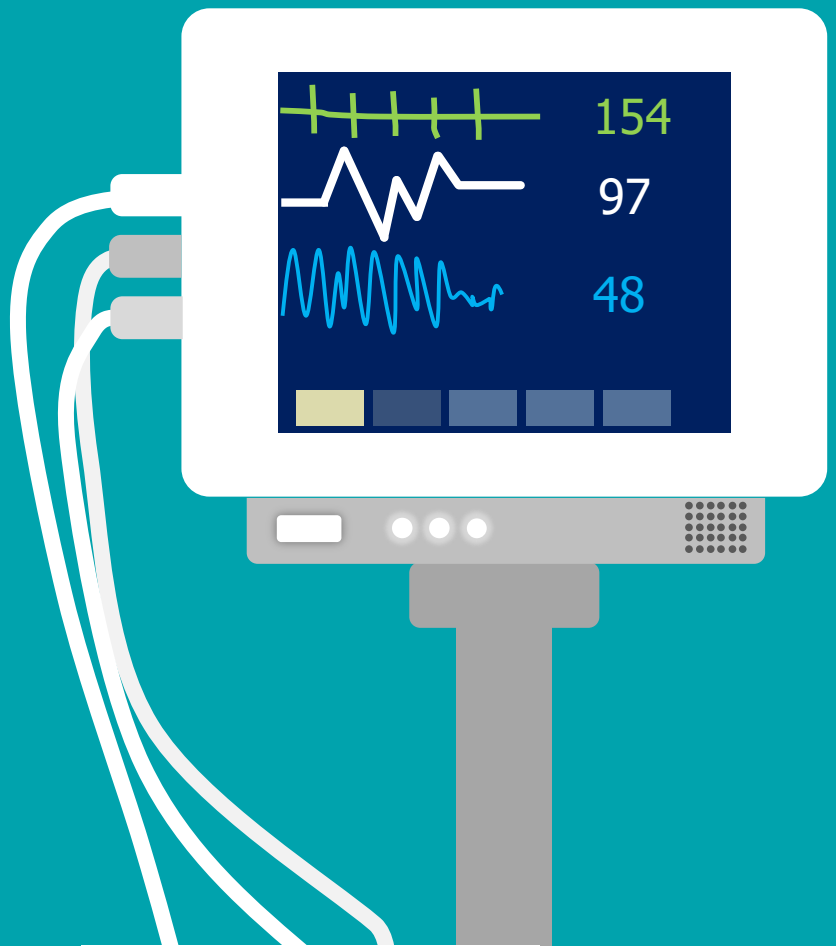


ISO 9001: Clause 6 Planning



ISO 9001: Clause 8.5.5

Property belonging to customers or external providers



Reflective quiz

And finally……

Thank you for participating.

...making excellence a habit.™