Key Activities for Certification of ISO 13485:2016

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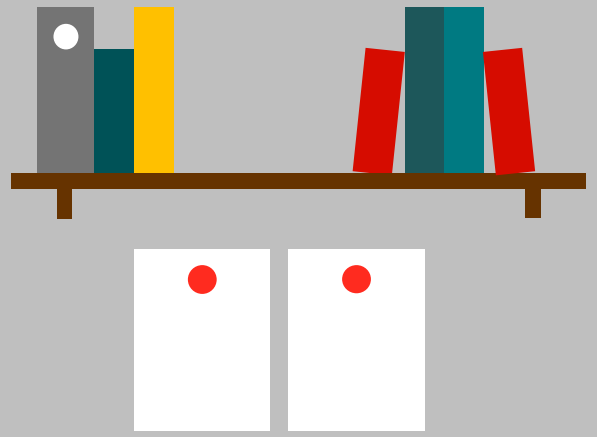
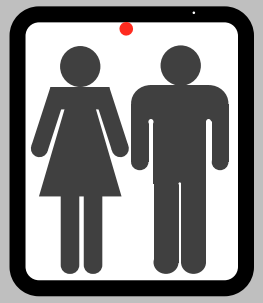
By Royal Charter

bsi.

Introductions

Welcome





Benefit

- Scope and the structure of ISO 13485:2016
- Concept of Requirements of ISO 13485:2016
- Identify the systems that are required to implement an ISO 13485:2016 quality management system (QMS) in order to gain/maintain certification to ISO 13485
- Develop your knowledge of how the requirements of ISO 13485:2016 are established and maintained in an organization

What is ISO 13485?

Quality Management System

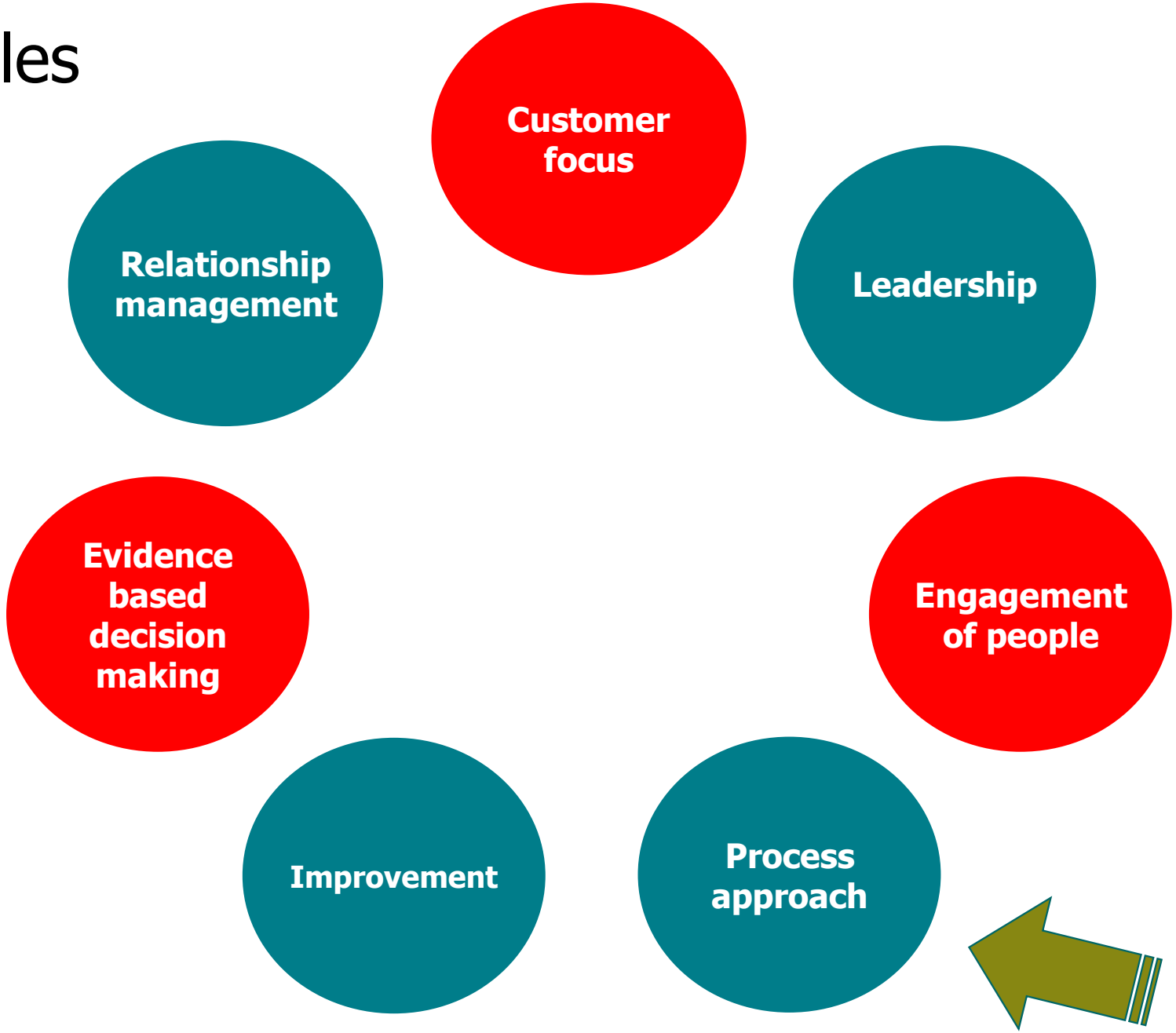
ISO 13485

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

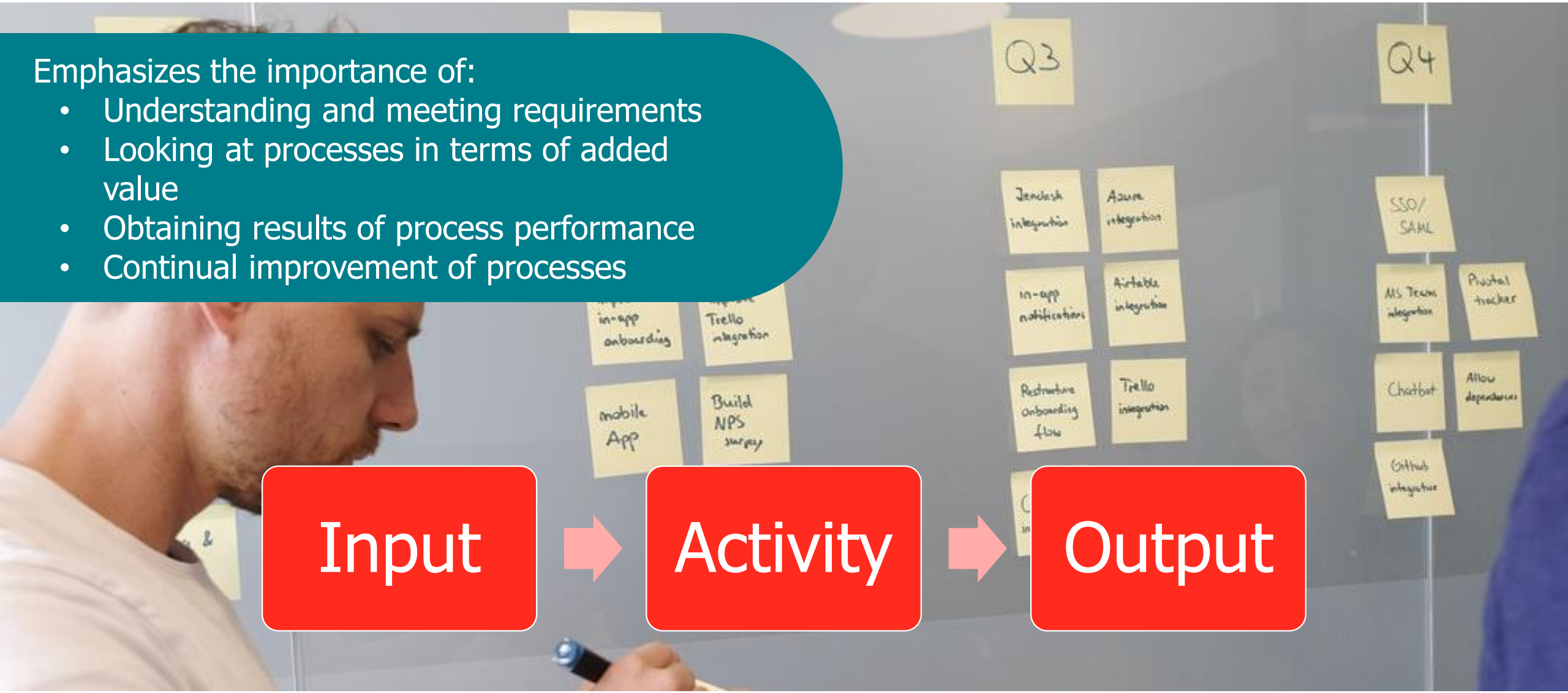
ISO 9001

Is a quality management system appropriate for all types of organizations

7 QM principles



Process approach

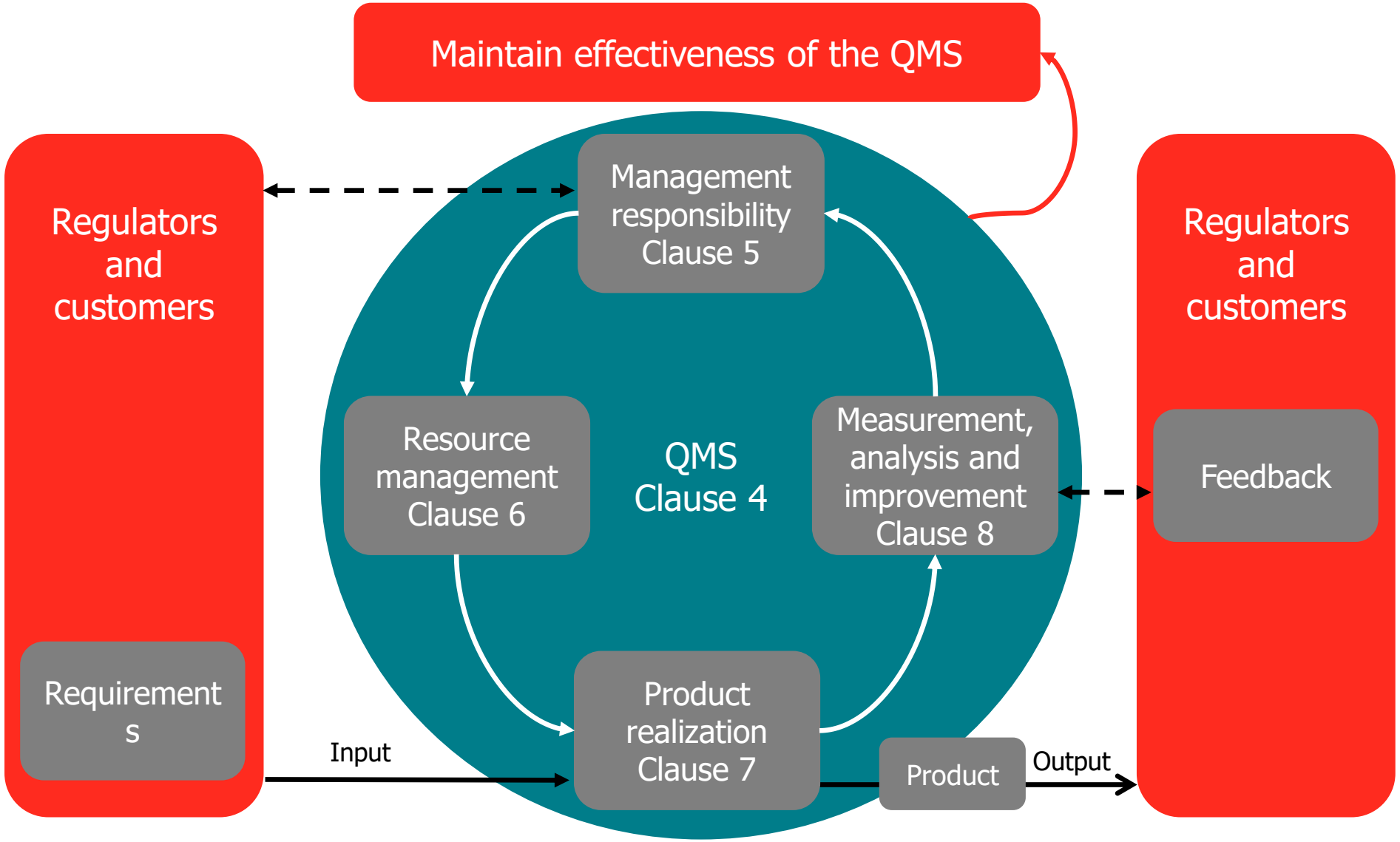


Emphasizes the importance of:

- Understanding and meeting requirements
- Looking at processes in terms of added value
- Obtaining results of process performance
- Continual improvement of processes

Input → Activity → Output

ISO 13485 Process model



Purpose, structure and requirements of ISO 13485

- 0. Introduction
- 1. Scope
- 2. Normative references
- 3. Terms and definitions
- 4. Quality management system
- 5. Management responsibility
- 6. Resource management
- 7. Product realization
- 8. Measurement, analysis and improvement

- Annex A (informative) Comparison of content between ISO 13485:2003 and ISO 13485:2016

- Annex B (informative) Correspondence between ISO 13485:2016 and ISO 9001:2015

ISO 13485 QMS standard

The purpose of ISO 13485

Provide QMS requirements that are applicable to the medical device industry

Serve as the basis for:

- Regulatory compliance
- Contractual relationships
- Third party certification
- To facilitate 'global alignment'

ISO 13485:2016

Relationship with medical device legislation

Which organization can ask for certification of ISO 13485?

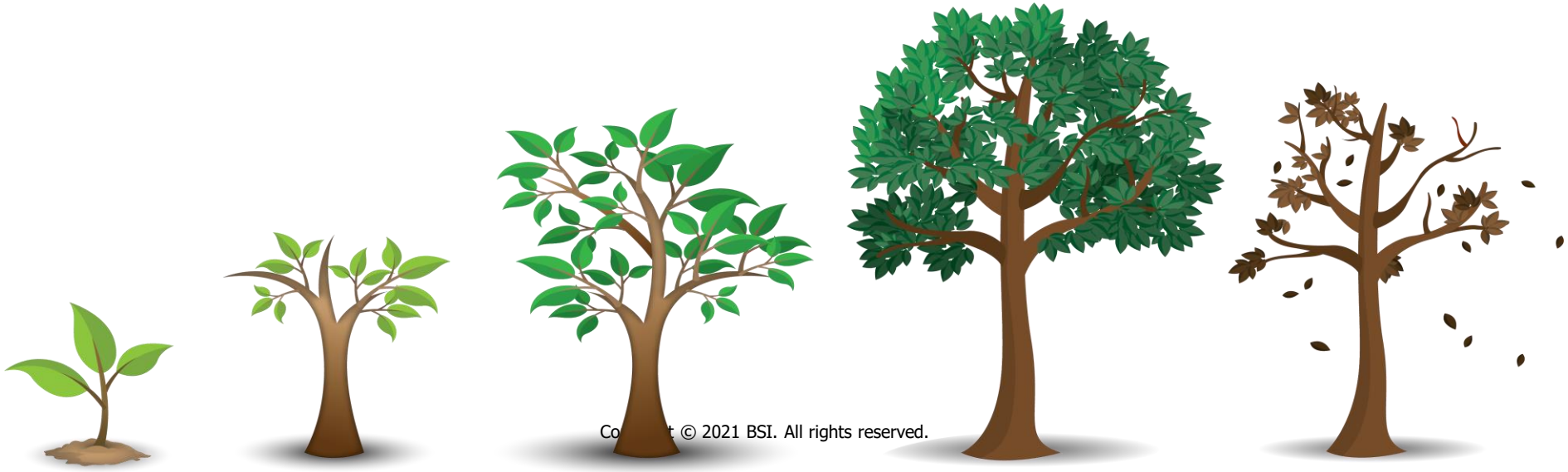
Who can ask for certification of ISO 13485?

Organization involved in one or more stages of the life-cycle of a medical device:

- design and development
- production
- storage and distribution
- installation
- servicing
- final decommissioning and disposal of medical devices.

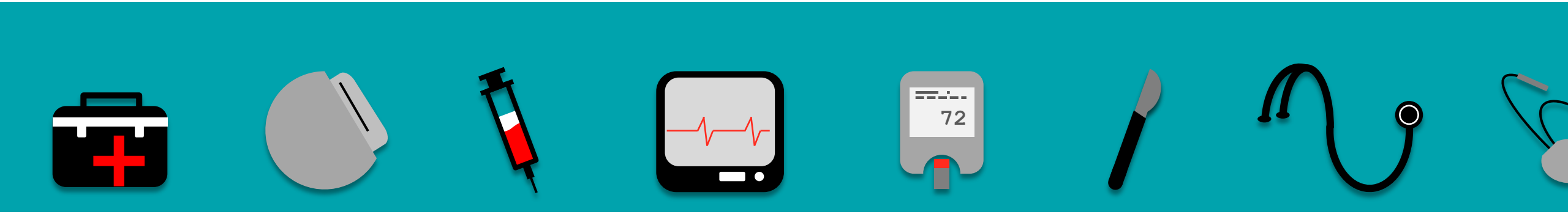
The requirements in this International Standard can also be used by organization related to medical device:

- suppliers
- external parties providing product and service i.e.:
- raw materials, components, subassemblies, medical devices, sterilization services, calibration services, distribution services, maintenance services



What is Medical Device?

'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the **specific medical purpose.**



What is Medical Device?

Purpose:

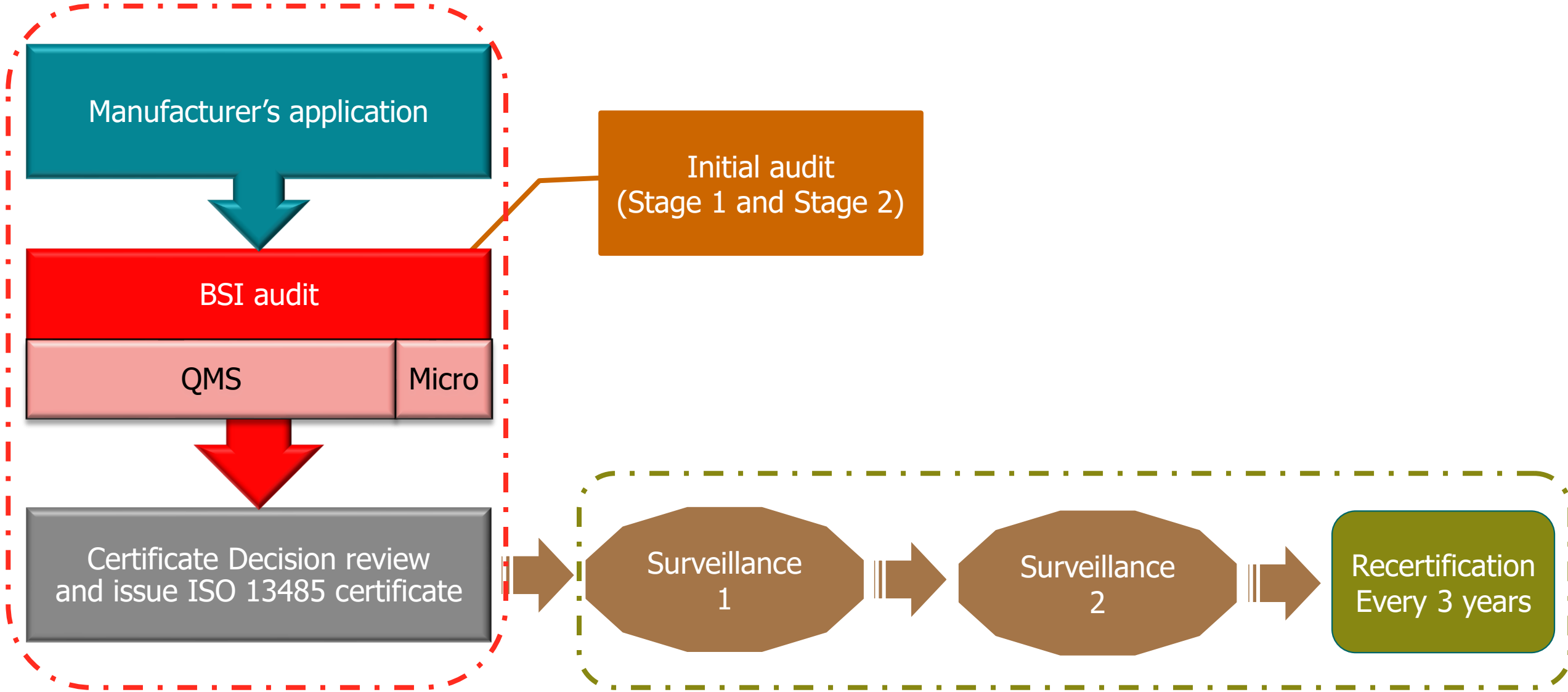
- diagnosis, prevention, monitoring, treatment of alleviation of disease and compensation for an injury
- investigation, replacement, modification, or support of the anatomy or of a physiological process
- supporting or sustaining life
- control of conception
- disinfection of medical devices;
- providing information by means of in vitro examination of specimens derived from the human body;

Device shall not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body

Definition as incorporated into national or regional law

Certification Step

Certification process and maintaining of certificate



Key Step of Implementation Quality Management System (QMS)

Clause 4 and 5. Scope of Quality Management System

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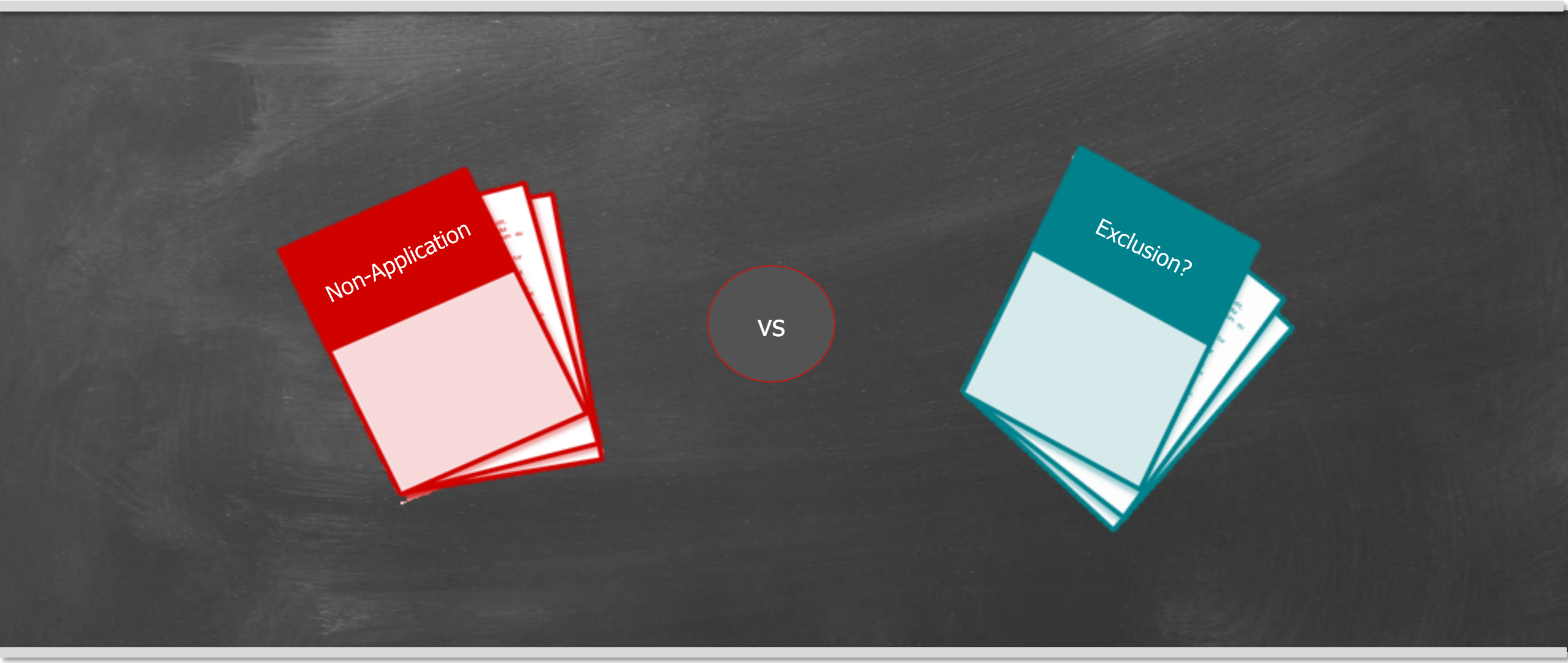
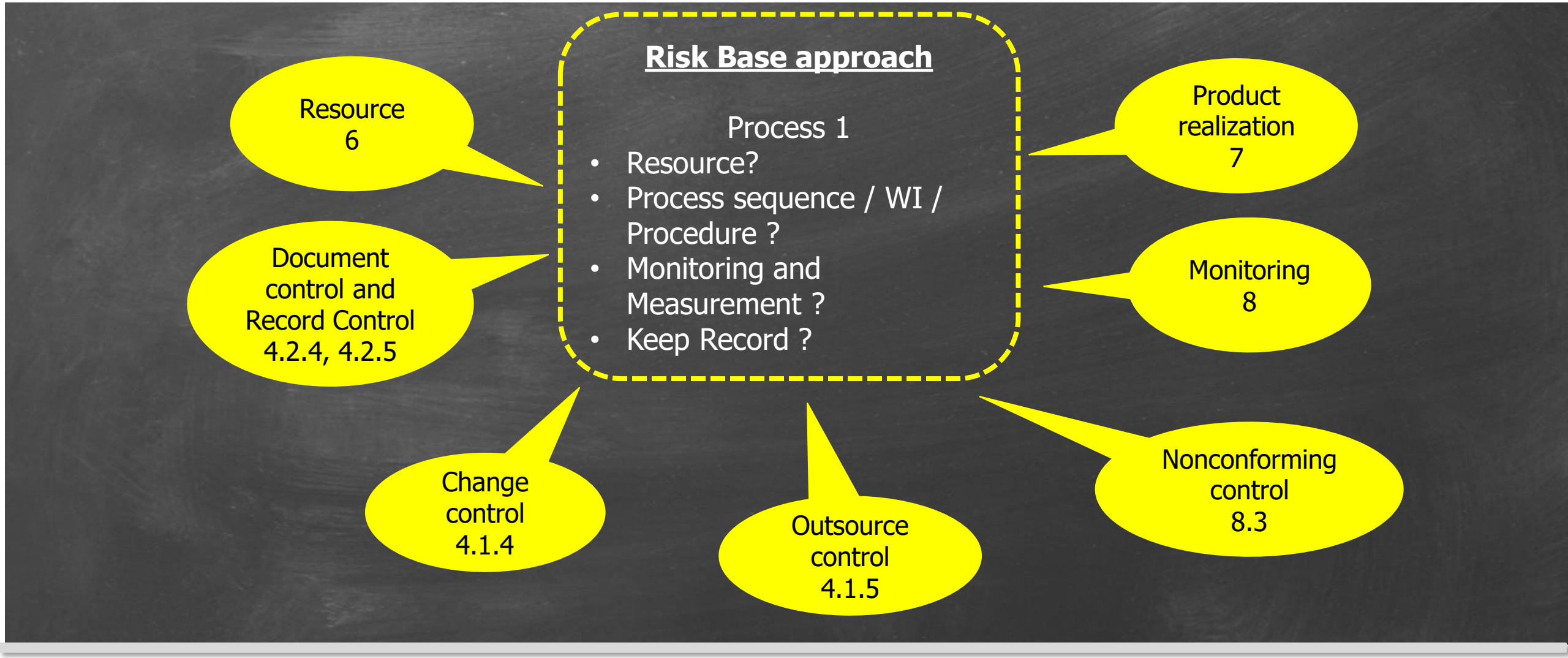
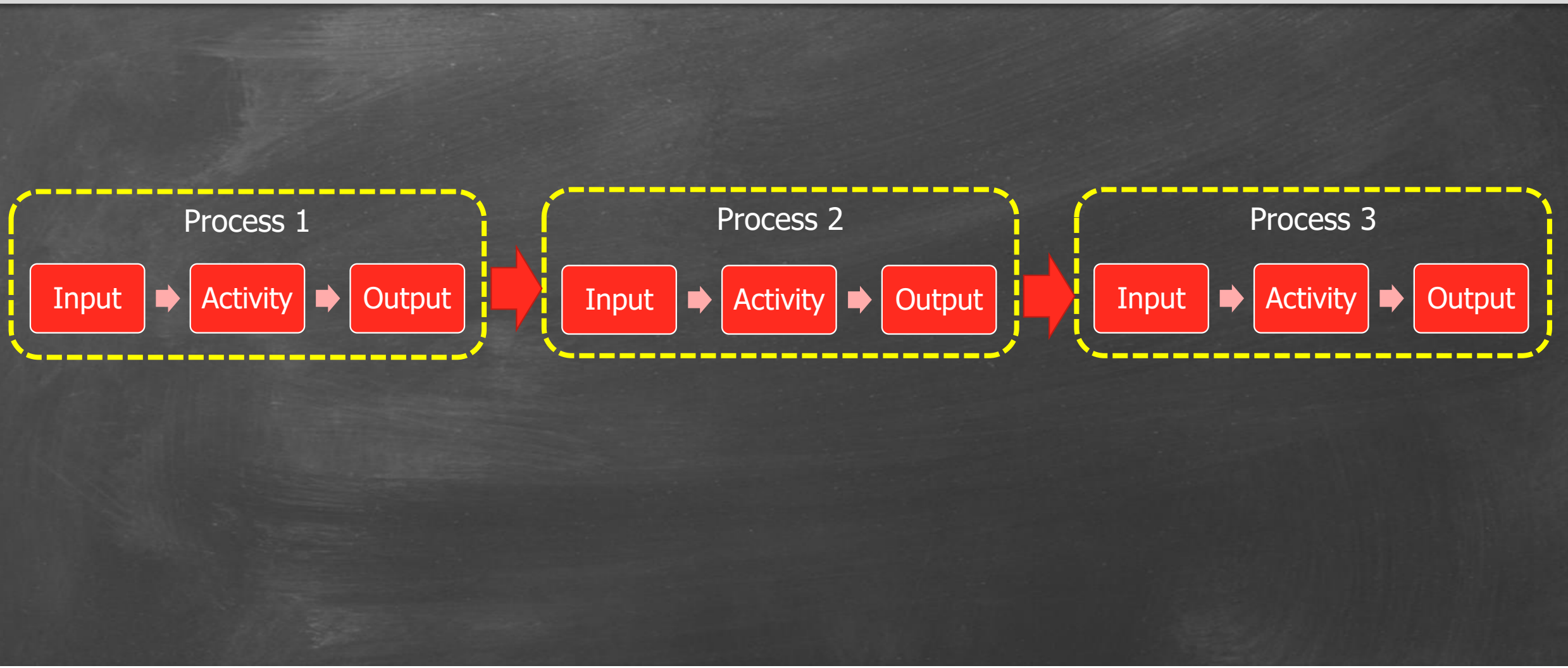


Clause 4 and 5. Scope of Quality Management System

Clause 4 and 5: Scope of Quality Management System



Clause 4 and 5: Scope of Quality Management System



Clauses 6: Resource

Clause 7

7.1 Planning product realization

7.2 Customer related processes

7.3 Design and development

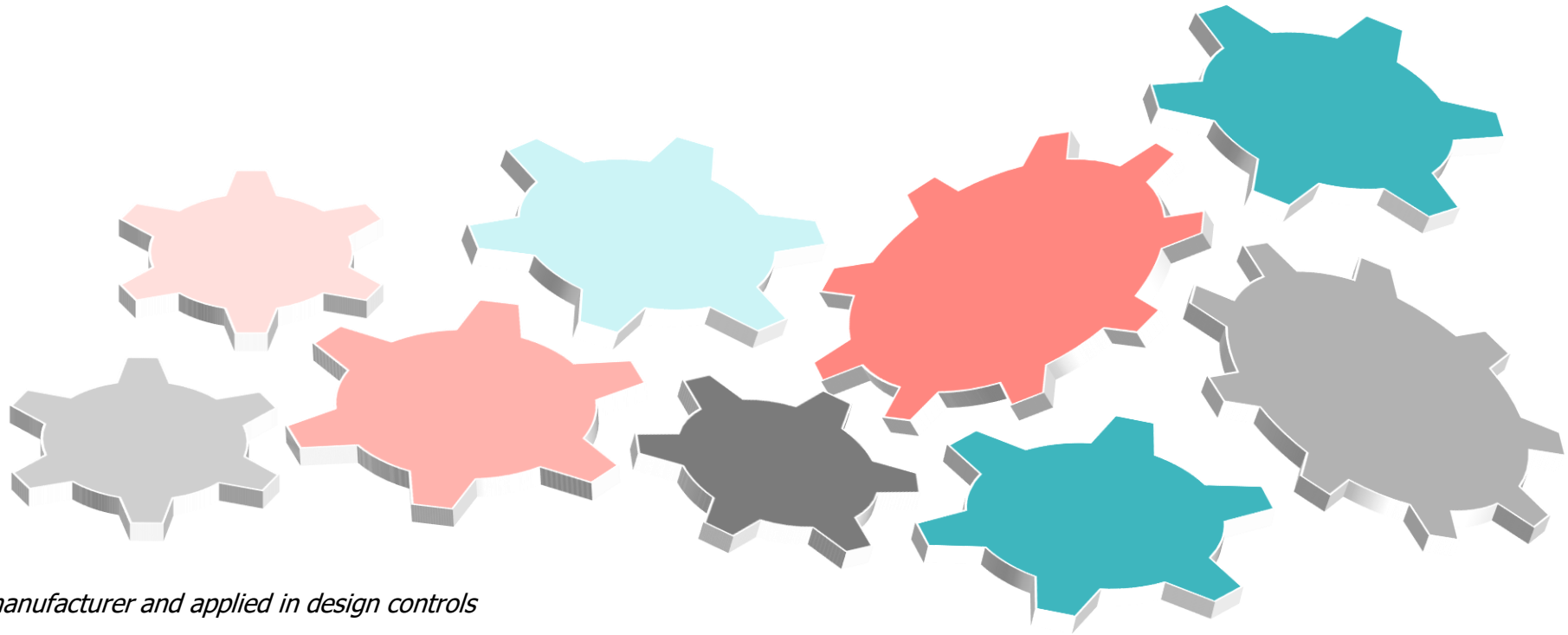
7.4 Purchasing

7.5 Production and service provision

7.6 Control of measuring and monitoring equipment

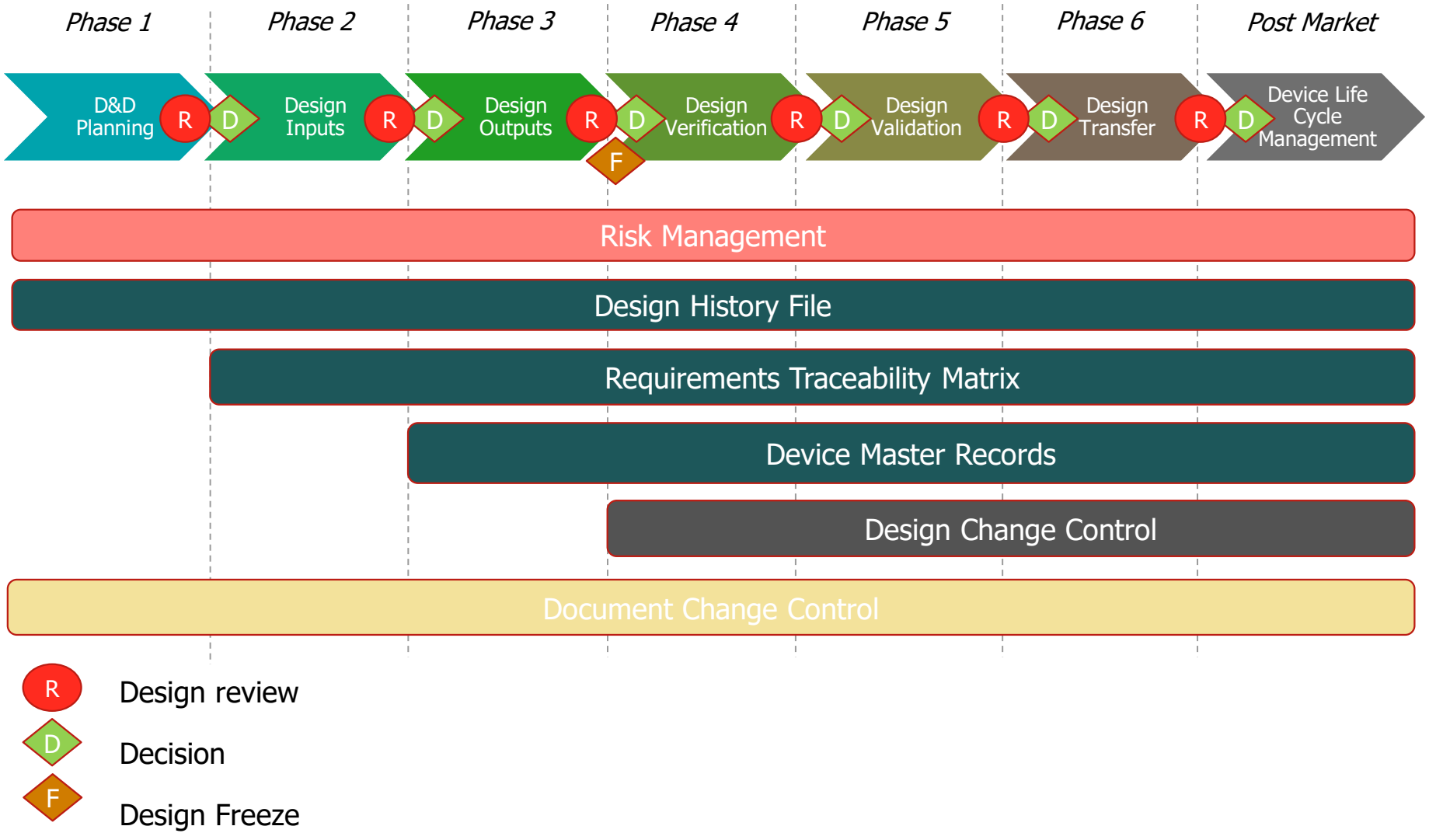
Clause 7.1 - Planning of product realization

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



**Applicable only if legal manufacturer and applied in design controls*

Clause 7.3 -Design and development



Clause 7.5 – Production and service provision

Clause 7.5.1 Control of production and service provision

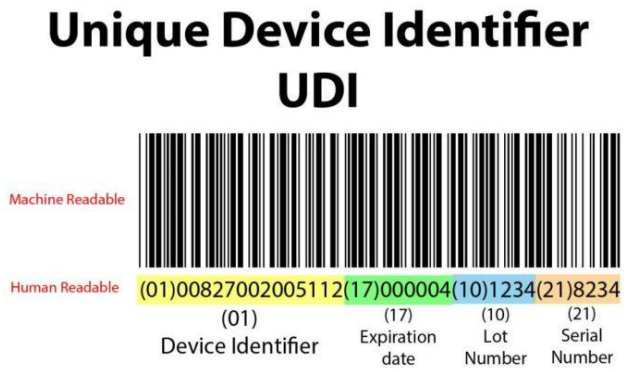
Clause 7.5.2 Cleanliness of product

Clause 7.5.3 Installation activities

Clause 7.5.4 Servicing activities

Clause 7.5 – Production and service provision

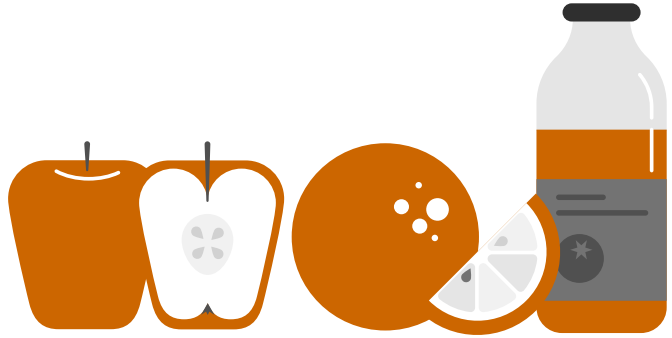
Clause 7.5.8 Identification



Clause 7.5.9 Traceability

Clause 7.5 – Production and service provision

Clause 7.5.10 Customer Property



Clause 7.5.11 Preservation of Product

Clause 8: Measurement, Analysis and Improvement

Plan and implement measurement, monitoring, analysis and improvement:

- Ensure conformity of product
- Ensure conformity of QMS
- Maintain effective QMS
- Statistical techniques

Q & A

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