New Edition of ISO 9001:2015 – *Overview*

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Preview

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6. Actions to Address Risks and Opportunities (cl.6.1)

Do

Integrate and implement the actions to address risks and opportunities into QMS processes (4.4*; 6.1.2.b.1*)

1. Implementation of risk management framework (4.4.1**)
2. Implementation of risk management process (5**):
- Communication and consultation
- Determination of the situation (*context, risk criteria*)
- Risk assessment (identification — *risk list, risk source*; analysis — *consequences, likelihood, level of risk*; evaluation – *compare the level of risk and risk criteria*)
- Risk treatment (*Avoiding the risk by deciding not to start or continue with the activity that gives rise to the risk. Accepting or increasing the risk in order to pursue an opportunity. Removing the risk source. Changing the likelihood. Changing the consequences. Sharing the risk with another party or parties. Retaining the risk by informed decision*)
- Monitoring and review of risk management process

Plan

Plan actions to address risks and opportunities (6.1.2.a*)

Project of risk management framework (4.3**):
- Context of the organization (4.1**; 4.3.1**)
- Relations with Policy, Objectives
- Responsibility (risk owner, etc.)
- Resources (personnel, methods, procedures, control of information, training)
- Risk management plan
- Internal and external communications; reporting mechanism

Control

Evaluate the effectiveness of actions to address risks and opportunities (6.1.2.b.2*)

Monitoring and analysis of risk management framework (4.5**):
- Evaluation of the quality of risk management
- Analysis of risk management plan implementation
- Review of risk management framework and evaluation of its effectiveness

Act

- **Give assurance that the QMS can achieve its intended result(s) (6.1.1.a*)**
- **Enhance desirable effects (6.1.1.b*)**
- **Prevent, or reduce, undesired effects (6.1.1.c*)**
- **Achieve improvement (6.1.1.d*; 4.6**)**

* Clauses of ISO 9001:2015

** Clauses of ISO 3100:2009

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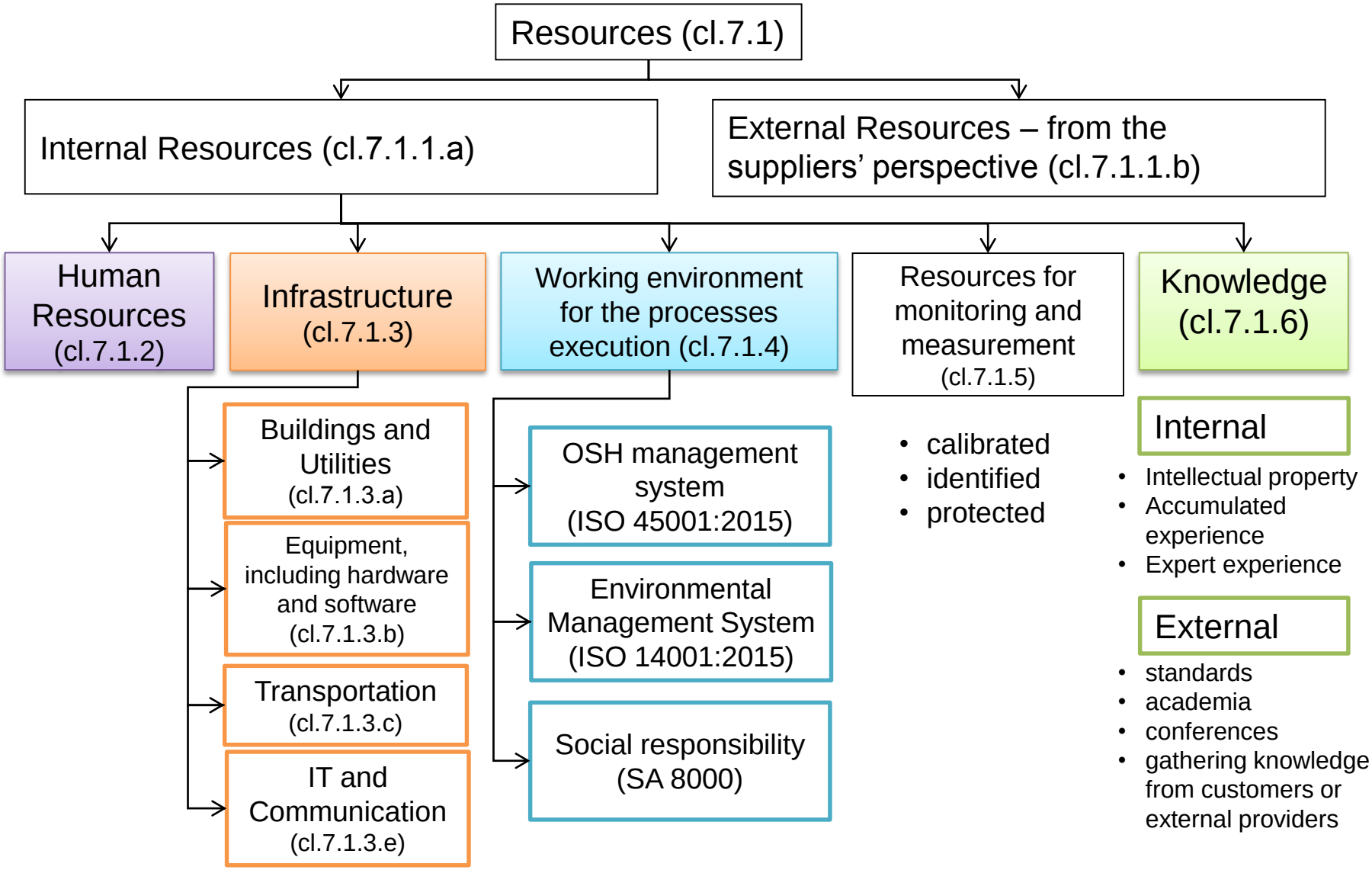
Resource Classification



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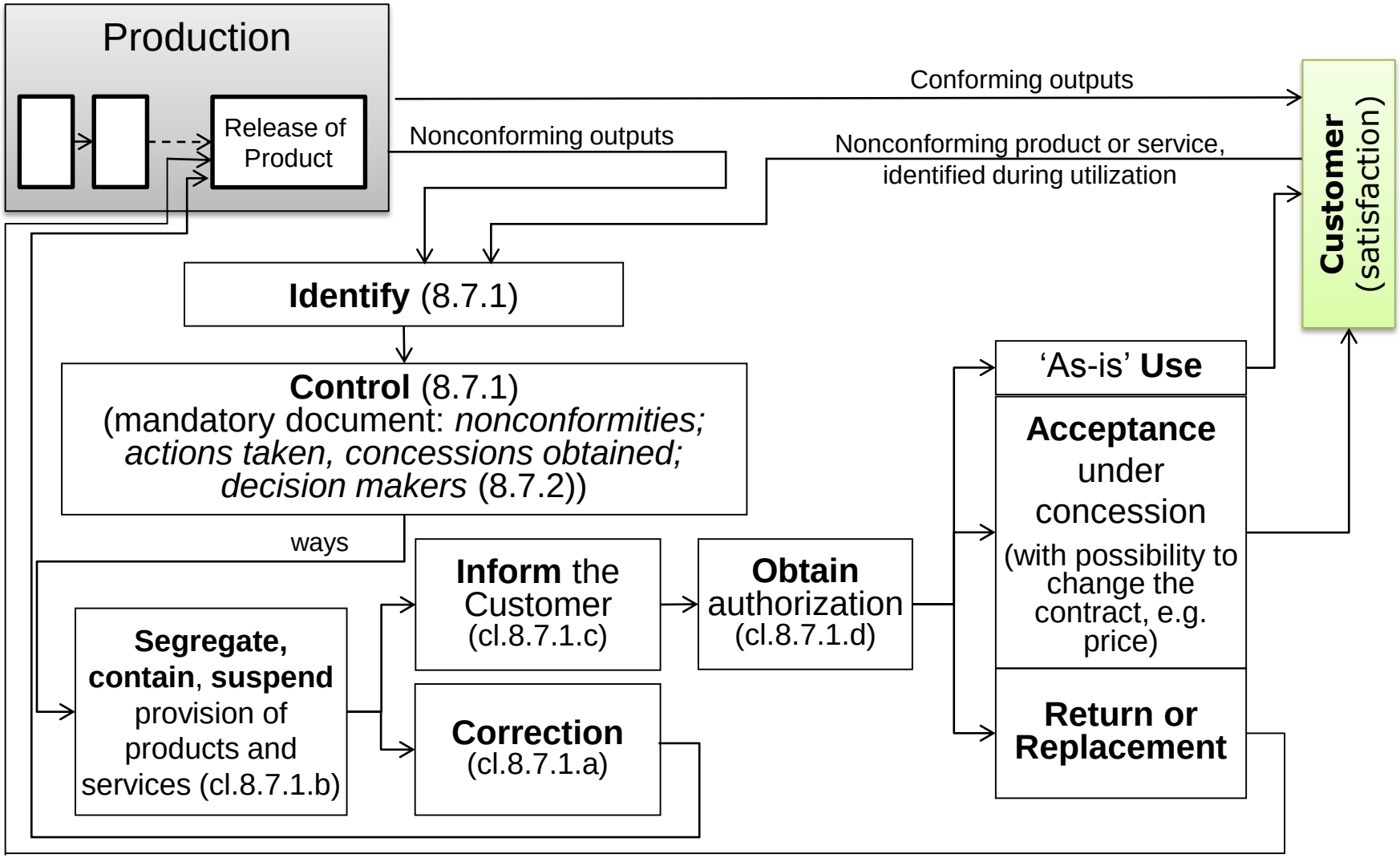
16. Control of nonconforming outputs (cl.8.7)



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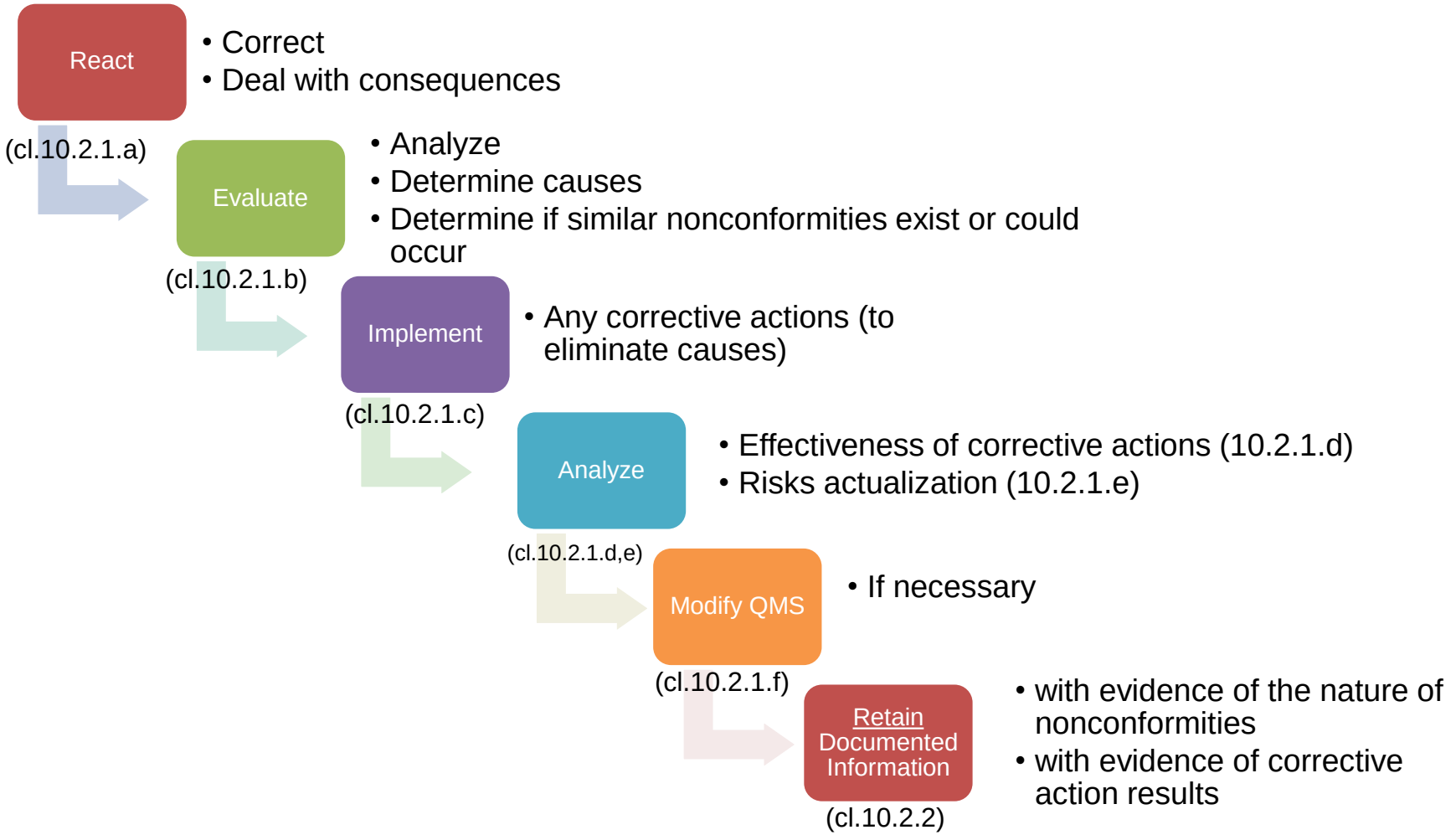
Actions to address nonconformity



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