# Overview of

**Management Systems** 

(preview)

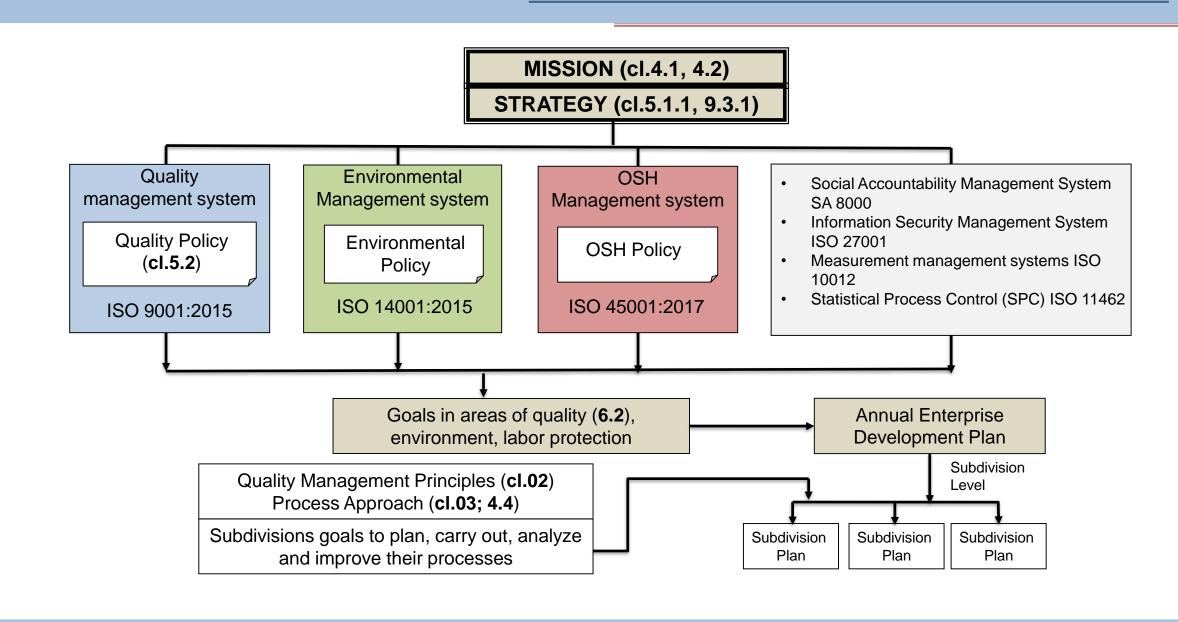


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- 1. General approaches for the standard management systems for the Organization
- 2. Leadership. Responsibility and authority
- 3. Actions to address risks and opportunities
- 4. Control of resources
- 5. Organizational knowledge
- 6. Competence
- 7. Awareness
- 8. Control of documented information

# 1.2. Deploying the organization's strategy and policy



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# 1.6. Context of the Organization

#### **Internal aspects**

- development strategy;
- management factors, including organizational structure;
- performance indicators;
- technical, technological and scientific level;
- production capabilities;
- resource factors, including infrastructure and production environment;
- state and prospects of development of the personnel;
- cultural and demographic factors;
- social factors



#### **External aspects**

- information from consumers and suppliers;
- competitive factors, including market share of the organization, market leaders tendencies, market stability;
- macroeconomic factors, such as economic situation, inflation forecast, credit availability;
- external scientific and technological factors;
- political factors, including political stability, public investment, international trade agreements;
- cultural and demographic factors.

#### **Context of the Organization Information gathering and analysis**

are carried out in the processes: 'Management review', 'Marketing', 'Control of Personnel', 'Design and development of products and services', 'Production and service provision', 'Control of documented Information'



#### Transfer of information about the context inside the organization

is carried out within the control of organizational knowledge and control of documented information framework.



#### Use of information about the context

is carried out in the QMS processes when planning and making managerial decisions

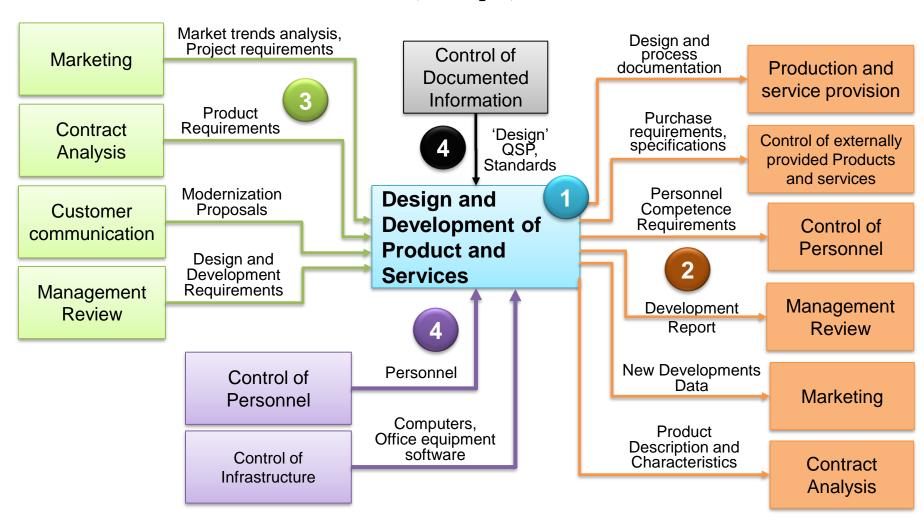
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# 1.10 Process approach implementation stages

# 'Product Design and Development' Process Model according to BS 6143-1992 (Example)



## 3. Actions to address risks and opportunities

## **Planning**

# Planning of actions to address risks and opportunities Risk management framework draft

- Understanding of context of the Organization
- Connection to Policy
- Communication
- · Responsibility and Authority
- Resources

### Verification

# Evaluation of the effectiveness of actions to address risks and opportunities Monitoring and analysis of risk management framework

- analysis of actions to address risks and opportunities in the organization implementation effectiveness;
- analysis of changes as a result of risk management in QMS processes;
- analysis of communication methods effectiveness;
- analysis of adequacy and effectiveness of resources use, including personnel, budge, methodologies, procedures, training programs, and knowledge.

## Implementation

# Integration and implementation of actions to address risks and opportunities into the QMS processes

- 1. Implementation of risk management framework
- Propagating among the personnel of the information about the importance of actions to address risks and opportunities for decision making on all levels of the organization;
- Inclusion of 'Actions to address risks and opportunities of the Process' section in all documented procedures (QSP) that regulate QMS processes operation;
- Inclusion in job description.
- Regular risk management training on all levels of the organization.
- 2. Risk management in QMS process:
- · Communication and consultation
- Definition of situation (context, risk criteria)
- Risk assessment (<u>identification</u>: risk list, risk source; <u>analysis</u>: consequences, likelihood, risk level; <u>evaluation</u>: comparison of risk level and risk criteria)
- Risk treatment (avoiding risk via making a decision not to start (or stop) the activity that could cause risk occurrence. Acceptance or increase of risk to use the opportunity. Risk source elimination. Change of likelihood or consequences. Distribution of risk with another party or parties. Risk retention based on the decision)
- Monitoring and analysis of risk management in QMS process

## **Action**

#### **Achieving improvement**

- 1. Program QMS improvements, including:
- Enhance desirable effects in the QMS;
- Prevent, or reduce, undesired effects in OMS;
- Breakthrough projects;
- Activities aimed at increase of efficiency of actions to address risks and opportunities and providing resources including budget;
- Conclusions that QMS can achieve intended result(s).
- 2. Ongoing QMS improvements.
- 3. Ongoing improvements of the QMS process.

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# Questions? Please email to training@c-bg.com

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