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*Quality
Management
System*

**Standard
Management
Systems**

2018

Introduction

What this book is about?

- ✓ unified approach to building standard management systems, including:
 - ISO 9001:2015 Quality Management Systems. Requirements.
 - ISO 14001:2015 Environmental Management Systems. Requirements with guidance for use.
 - ISO 45001:2018 Occupational health and safety management systems - Requirements with guidance for use.
- ✓ main principles of management and their implementation in the organization's management system.
- ✓ understanding and implementation of all ISO 9001:2015 requirements.

Special attention is paid to the new requirements of the latest versions of management system standards:

- *Understanding the organization and its context;*
- *Understanding the needs and expectations of interested parties;*
- *Actions to address risks and opportunities;*
- *Organizational knowledge;*
- *Control of externally provided processes, products and services.*

The processes of the quality management system are defined and described based on the real-life enterprise QMS implementation.

How is this book different from all other similar books?

The book is aimed at providing readers with **knowledge** and **understanding** of the requirements of the ISO 9001:2015 standard and the **ability** to **independently develop** the organization's quality management systems.

Practical focus is the main feature of the book. When writing the textbook, we have incorporated over 20 years of authors' experience in developing, implementing and bringing to certification of ISO 9001, ISO 14001, ISO 45001 standard management systems.

Particular attention is paid to the **process approach implementation**, including the definition of QMS processes, development of process **models** and process **criteria**.

The book contains a lot of **illustrations**, tables, and diagrams that **facilitates** the comprehension.

Terms and Abbreviations

The following abbreviations are used in the book:

CL	Clause of the Standard
ME	Measuring equipment
MSP	Management system procedure
QMS	Quality management system
QMF	Quality system form
Sec.	Section of this book

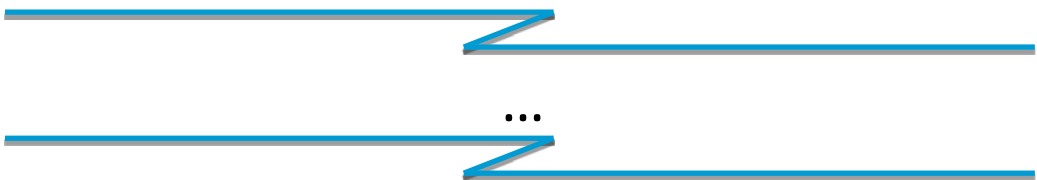
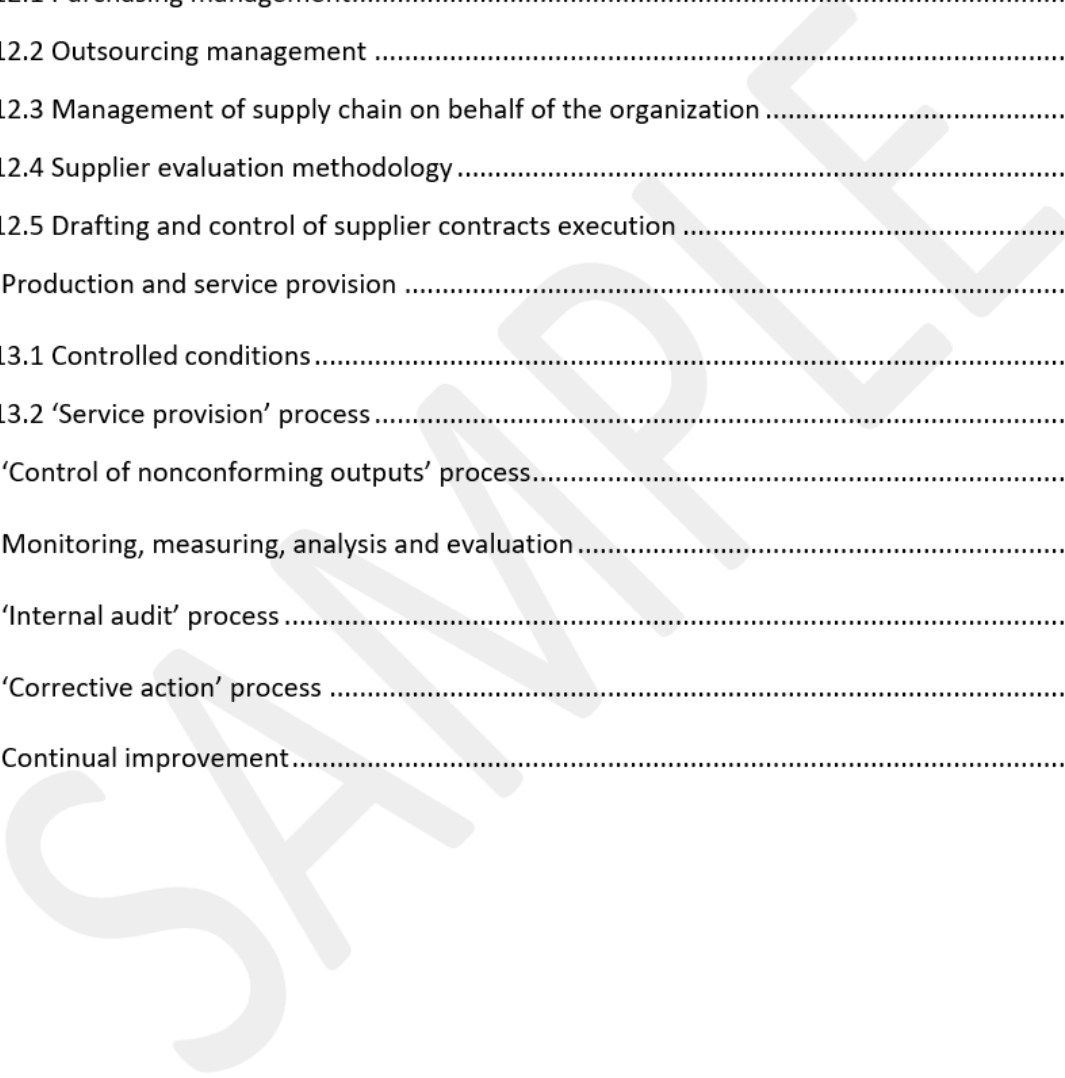
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1 General approaches for the standard management systems of the organization

1.1 International management system standards

The following are the main International management system standards:

- [ISO 9001:2015 Quality Management Systems. Requirements.](#)
- [ISO 14001:2015 Environmental Management Systems. Requirements with guidance for use.](#)
- [ISO 45001:2018 Occupational health and safety management systems — Requirements with guidance for use.](#)
- [ISO 2600:2010 Guidance on social responsibility. SA 8000:2014 Social Accountability.](#)

They define the general requirements of any organization's management system, regardless of industry affiliation.

The latest editions of international management systems standards are designed in such a way that they all have a common basis (general requirements) and each standard has its distinctive requirements (Figure 1.1-01).

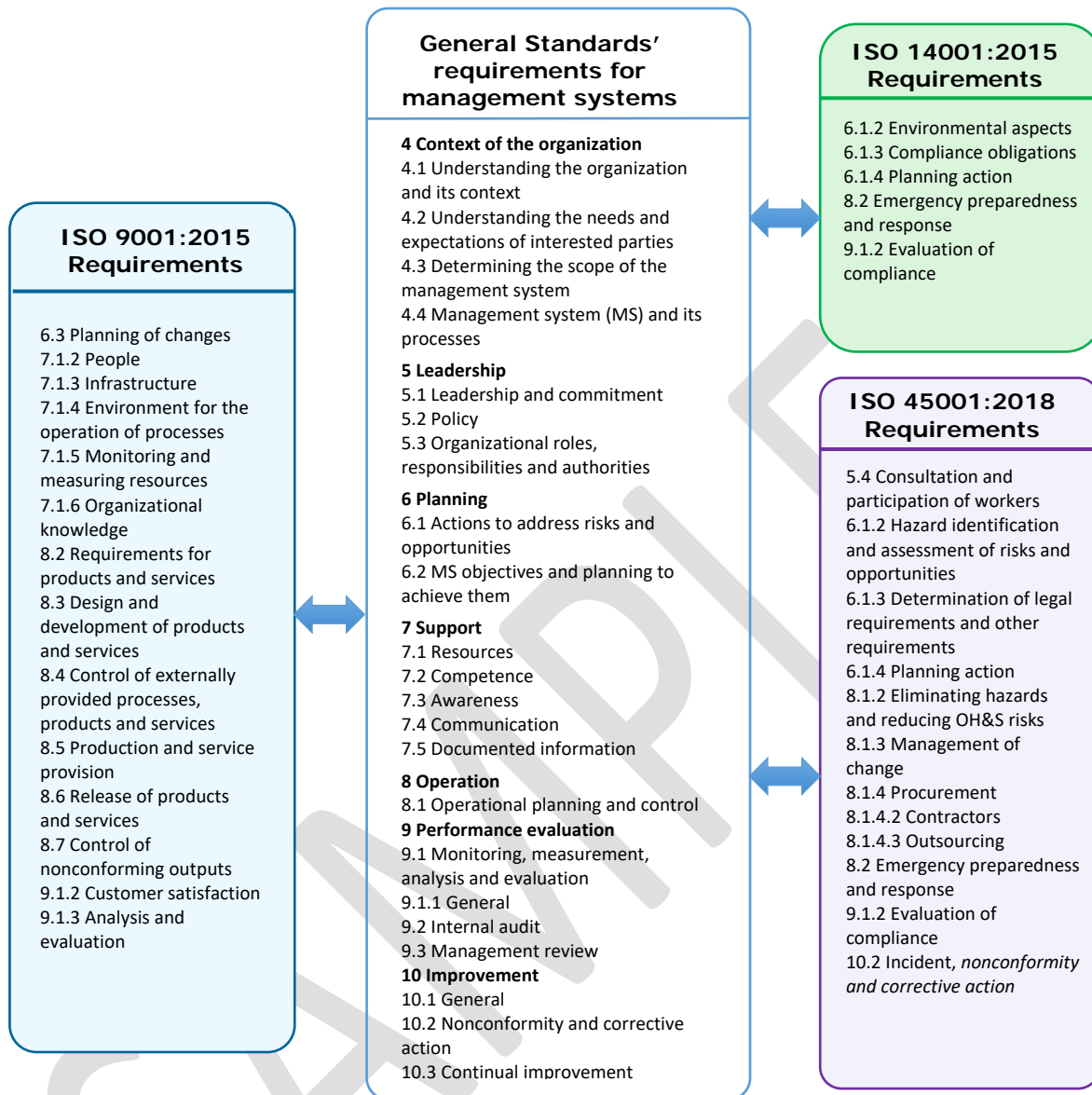


Figure 1.1-01 ISO 9001:2015, ISO 14001:2015 and ISO 45001:2018 Requirements Comparison

We will look at the main provisions laid down in all standard systems, which are the basis for the organization's sustained success.

1.2 Deploying the organization's strategy and policy

To achieve the sustained success of an organization, it's management system must ensure that the strategy and policy of the organization are fully deployed (Figure 1.2-01).

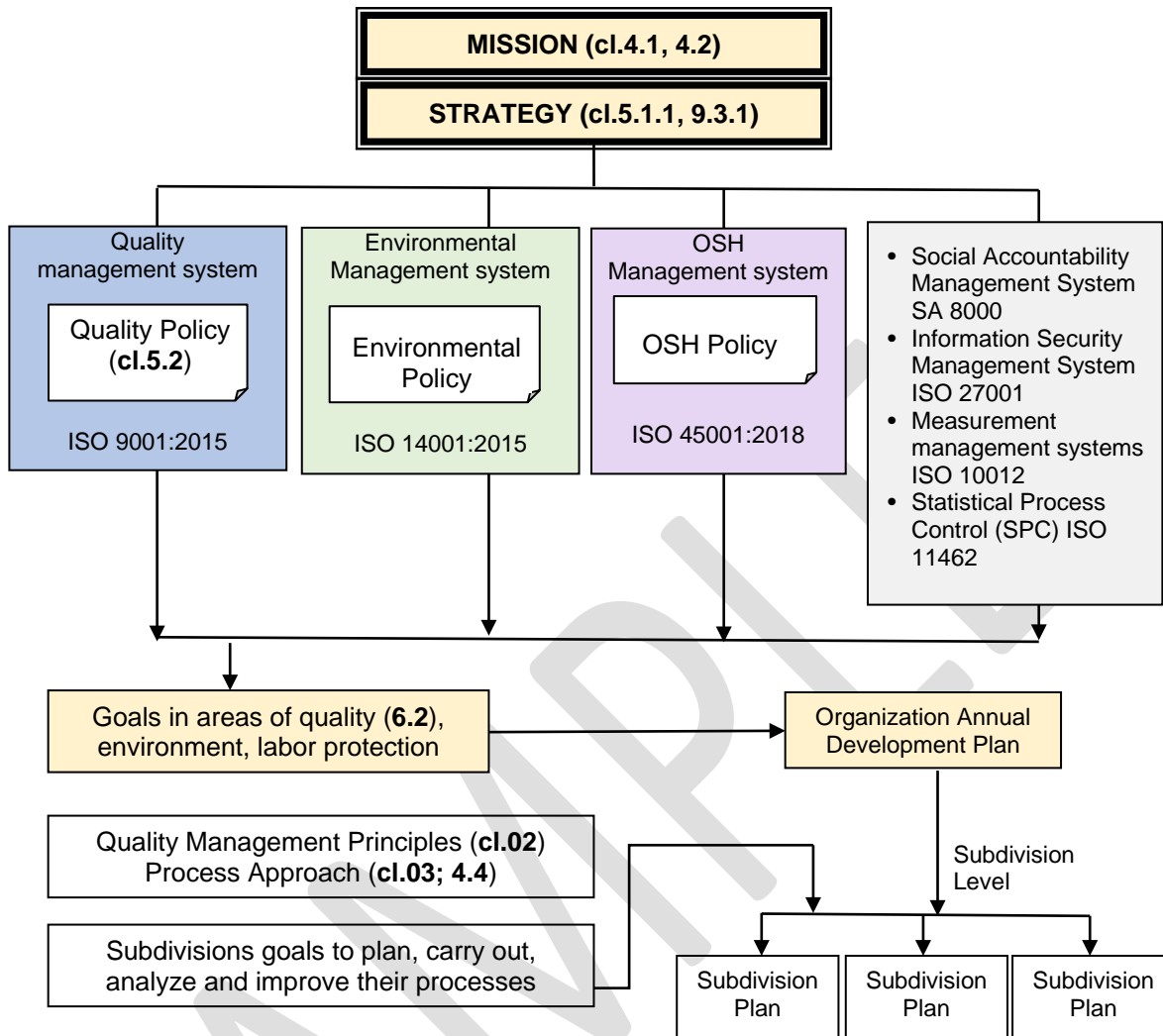


Figure 1.2-01. Deploying the organization's strategy and policy scheme.

Mission is the main common goal of the organization, the meaning of its existence. In accordance with good practice, the mission includes concise wording of:

- Purpose (or orientation of the activity) of the organization;
- Market orientation;
- Main competitive advantage;
- List of interested parties.

The organization's strategy is a long-term plan of actions that determines the priorities of strategic tasks, resources and the sequence of steps to achieve a mission.

Based on the adopted strategy, a set of standards is selected, the requirements of which the organization's management system must meet, and a policy is worded.

In accordance with good practice, the policy has the structure shown in figure 1.2-02 and includes:

- Wording of obligations to implement the management principles, in relation to the characteristics of the organization, including continuous improvement;
- Commitments on risk management as part of decision making;
- Obligations to develop an information security system;
- A list of selected management systems standards, including ISO 9001:2015 and an obligation to implement their requirements.

Section I (title)	<p>Quality Policy</p> <p>_____</p> <p>(Organization title)</p>
Section II (mission statement)	<p>Quality Policy of '[Organization Title]' is aimed at the implementation of the mission – [mission statement including external aspects]</p>
Section III	<p>Statement of the commitments to implement the principles of quality management in relation to the characteristics of the organization, including:</p> <ul style="list-style-type: none"> - Risk based thinking; - Continual improvement + - The obligation to implement the requirements of international standard ISO 9001:2015
Section IV 1 st Manager signature	<p>[1st Manager Position] _____ (1st Manager Name)</p>

Figure 1.2-02 Quality policy structure

The Policy has to be documented, understandable and accessible to interested parties, including personnel.

Based on the Strategy and Policy, Objectives are adopted at various levels of the organization. The Objectives should:

- be documented and be measurable;
- relate to ensuring the conformity of products and services and increasing customer satisfaction;
- be monitored;
- be brought to the attention of the staff;
- be updated when necessary.

1.3 Planning to achieve quality objectives in the organization

In accordance with good practice, documenting objectives and planning their achievement is done through the implementation of the organization's Annual development program (Figure 1.3-01).

Organization's Annual Development Program

#	Content of activities	Subdivision	Cost If applicable	Responsible	Deadline	Reporting
1	2	3	4	5	6	7
1.	(Quality objectives wording)					
1.1 1.2 ...	(Actions to achieve the goals)					

Figure 1.3-01. Organization's Annual Development Program Form

The Program includes:

- necessary actions;
- allocation of resources required to deploy the necessary activities;
- distribution of responsibility and authority to achieve each goal;
- a time frame for each goal;
- how the results will be evaluated.

Quality objectives at the subdivision (or process) level includes two components:

1. Subdivision objectives, resulting from the organization's Annual development program;
2. Objectives aimed at developing and improving activities, based on the resources of the subdivision (or process).

Thus, as a result of the organization's policy deployment, each employee will work towards the interested parties' satisfaction.

1.4 Management principles in International standards

Seven common principles that form the basis of the standard management system are:



Customer focus
Leadership
Engagement of people
Process approach
Improvement
Evidence-based decision making
Relationship management

1. Customer focus – making customer satisfaction the highest priority of the organization's activities.

The system level is implemented as follows.

The immediate tasks of senior leadership of the organization are:

- ensuring the definition and implementation of customer requirements,
- addressing risks and opportunities associated with customer satisfaction,
- increasing customer satisfaction

There are three types of activities in the management system that are relevant to customers:

- 'Marketing',
- 'Contract analysis',
- 'Customer communication', including post-delivery activity.

The importance of monitoring and analyzes of customer satisfaction information is highlighted by allocation of these requirements into a separate clause of a standard in the general requirements for the management system performance evaluation.

2. Leadership – is the environment in the organization created by senior management, which provides support for quality management by all members of the organization to achieve the declared objectives. It is implemented via acceptance by senior management of the following obligations:

- Strategic planning, including the development of strategic activities, policies and objectives of the organization, based on external and internal context, and the integration of standards requirements into business processes;
- Ongoing management review, including provision of resources, performance analysis and promotion of improvements in the management system;
- Demonstrating commitment to the process approach, risk-oriented thinking, effective management and compliance with standards, personnel involvement
- Responsibility for the management system effectiveness.

Application of Leadership principle ensures:

- taking into account the needs of all interested parties;
- formation of a clear vision of the organization's future;
- establishing bold objectives and objectives;
- creation and maintenance of common values, impartiality and the definition of ethical behavior at all levels of the organization;
- creating an atmosphere of trust and work without fear;
- providing the organization's personnel with the required resources, training and freedom of action within the framework of responsibility;
- inspiration, encouragement and recognition of employees' contributions.

3. Engagement of people – is a provision of physical, emotional and intellectual state that motivates employees to do their job in the best possible way. The engagement of people determines the management system effectiveness. The task is to make the requirements of the standards a part of the ideology of each employee's activity. This is achieved via:

- Training;
- Distribution of responsibility and authority;
- Personnel motivation.

Application of Engagement of people principle ensures that employees:

- understand the importance of their contribution and role in the organization;

- identify the factors interfering with their activities;
- accept the responsibility for solving problems;
- evaluate their activities in comparison with personal objectives and objectives;
- actively seek improvement of their competence, knowledge and experience;
- freely transfer their knowledge and experience;
- openly discuss problems and controversial issues.

4. Process approach - is a seeing organization's activities as a set of interrelated and interacting processes. These processes are the object of management.

Application of Process approach principle ensures:

- systematic definition of the actions required to obtain the desired result;
- establishing a clear responsibility for the core activities management;
- analysis and measurement of core activities capabilities;
- definition of main activities interaction within the organizational subdivisions and between them;
- focus on factors such as resources, methods and materials that contribute to improvement of core activities of the organization;
- assessing risks, consequences and impacts of activity on customers, suppliers and other interested parties.

5. Improvement of products, processes, and management system – is the adaptation to the ever-changing requirements of all interested parties. Improvement is a prerequisite for business existence. Business is dynamic. If there is no movement forward, the rollback begins.

System improvement of processes is carried out by performing the following for each process:

- Process criteria activities along the chain: monitoring > measurement > analysis of trends > elimination of causes of negative effects and development of causes of positive effects;
- Addressing risks and opportunities.

Management system improvement is carried out via:

- Breakthrough projects;
- Small steps improvements.

Application of Improvement principle ensures:

- Coordinated approach to improve operations deployment across the organization;

- Employees training in the ways and methods of improvement;
- Turning the improvement of products, processes and management system into the task of every employee of the organization;
- Developing objectives for guiding and monitoring of improvements;
- Recognition and confirmation of improvements.

6. Evidence-based decision making - based on established facts to reduce the risks of economic and other losses. This is ensured by:

- availability of each management system process criteria;
- application of methodology for determining process criteria based on quality management methodologies, including statistical methods;
- reliability of evidence through the use of appropriate resources for monitoring and measurement.

Evidence-based decision making is implemented:

- when analyzing and evaluating the conformity of products and services, the degree of customer satisfaction, the effectiveness of the management system, the effectiveness of planning, the indicators of external suppliers;
- when conducting internal audits;
- in management review.

Application of Evidence-based decision-making principle ensures:

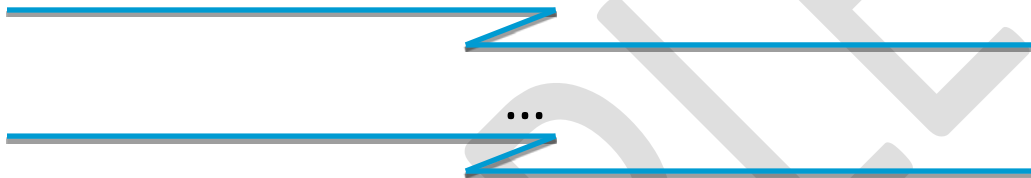
- Confidence in data and information reliability and accuracy;
- Availability of data for those who need it;
- Data and information analysis using reliable methodologies;
- Making decisions and taking actions based on actual analysis, balanced with experience and intuition.

7. Relationship management – is the control of the organization's interaction with all interested parties at all levels. Interested parties are individuals and legal entities that create added value for the organization or are somehow interested in the activities of the organization or are under its influence.

This provides the establishment of interested parties relevant to the management system and ensures balance of interests between each stakeholder and the interests of the organization.

Application of Relationship management principle ensures:

- establishing relationships with external providers and other interested parties based on the balance of short-term achievements of long-term plans;
- combining knowledge, experience and resources with partners;
- identification and selection of major external providers;
- transparent and open exchange of information, including plans for the future;
- collaboration in development and improvement activities;
- inspiration, encouragement and recognition by interested parties of improvements and achievements of the organization.



1.10 Process approach implementation stages

Standard management systems have a single process approach implementation program which is carried out in 10 stages.

Stage 1 – Define (name) QMS processes.

According to the established international practice, the following 18 basic processes of the organization management system were defined:

Clause 5 ‘Leadership’ – one process:

- Management review.

Clause 6 ‘Planning’ – one process:

- Actions to address risks and opportunities.

Clause 7 ‘Support’ – six processes:

- Control of personnel.
- Control of infrastructure.
- Control of monitoring and measuring resources.
- Control of organizational knowledge.
- Internal communication.
- Control of documented information.

Clause 8 ‘Operation’ – eight processes:

- Marketing
- Contract analysis
- Customer communication
- Design and development of products and services
- Control of externally provided processes, products, and services
- Control of nonconforming process outputs, products, and services
- Production and service provision
- Postdelivery activity

Clause 9 'Performance evaluation' – one process:

- Internal audit

Clause 10 'Improvement' – one process:

- Corrective action.

Stage 2 - Define process inputs and outputs

Stage 3 - Determine the sequence and interaction of these processes

According to the recommendations of ISO/TC 176/SC 2/N 544R process model is used to visualize internal, external flows and processes interactions. According to British standard BS 6143-1992 building of process model is done in 4 Steps:

1. Name the **Main Process**
2. Define **Outputs** (arrows) and **Consumer Processes** (rectangles with names)
3. Define **Inputs** (arrows) **Supplier Processes** (rectangles with names)
4. Determine **Control Actions** (arrows on top of the **Main Process** with references to standard documentation, based on which the process is performed) and **Resources** (arrows below the **Main Process** – with specification of the required resources)

An example of a process model is shown in figure 1.10-01.

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

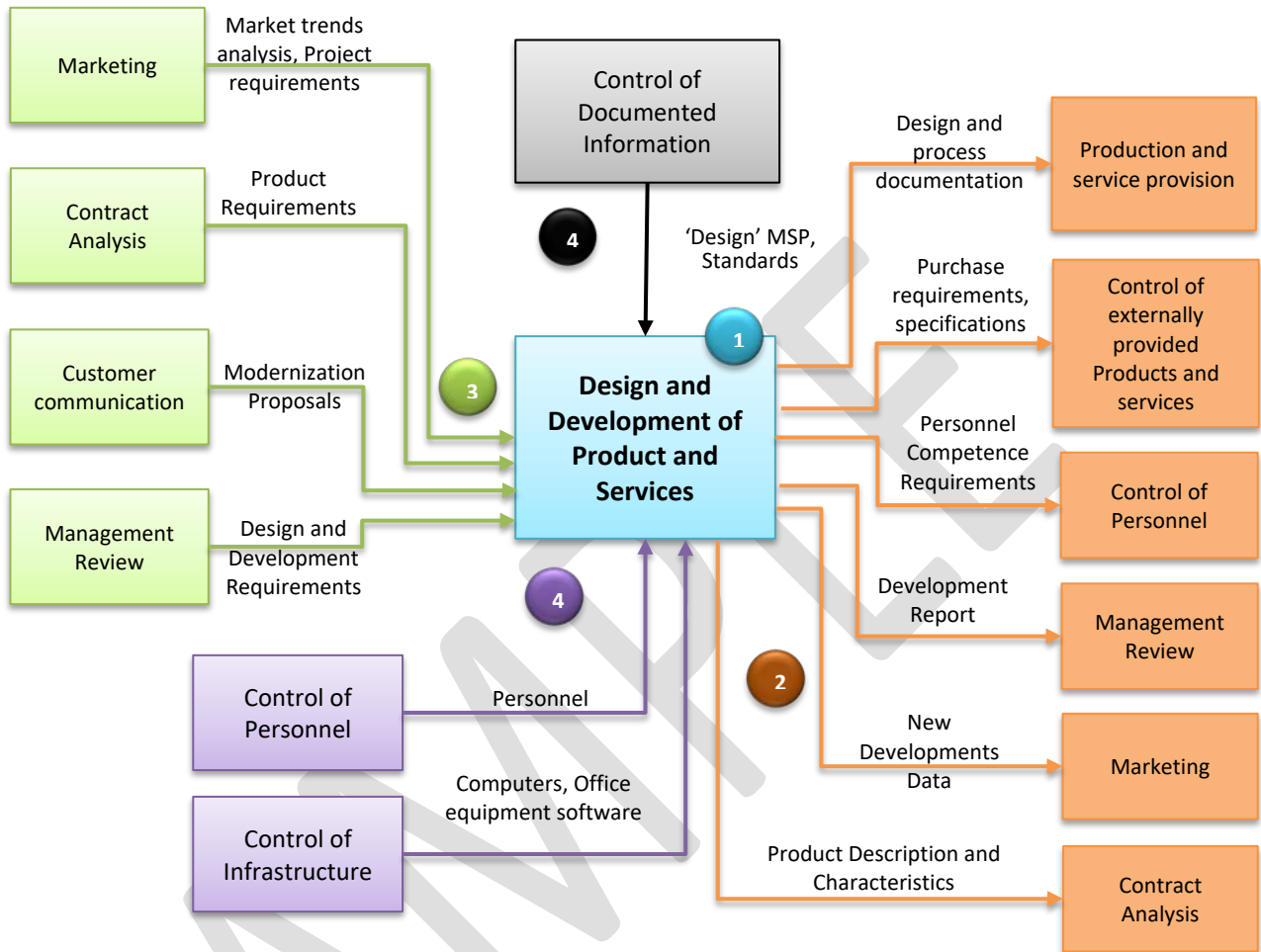


Figure 1.10-01. Process model example

Step 1 – the process is called ‘Design and development of products and services’.

Step 2 – Process outputs:

- Design and process documentation – to ‘Production and Service provision’ process;
- Purchase requirements, specifications – to ‘Control of externally provided Products and services’ process;
- Personnel Competence Requirements – to ‘Control of Personnel’ process;
- Development report – to ‘Management review’ process;
- New developments data – to ‘Marketing’ process;
- Product description and characteristics- to ‘Contract analysis’ process.

Step 3 – Process inputs:

- Design and Development Requirements – from ‘Management review’ process;
- Market trends analysis, Project requirements – from ‘Marketing’ process;
- Product Requirements – from ‘Contract analysis’ process
- Product modernization proposals – from ‘Customer communication’ process.

Step 4

- Process is managed according to the ‘Design and development’ MSP and standards from the ‘Control of documented information’ process;
- Process resources are: personnel – from ‘Control of personnel’ process and computers, office equipment, software from ‘Control of infrastructure’ process.

Interrelated process models are the business model of the organization (Figure 1.10-02). In the below example, the outputs and inputs are simplified.

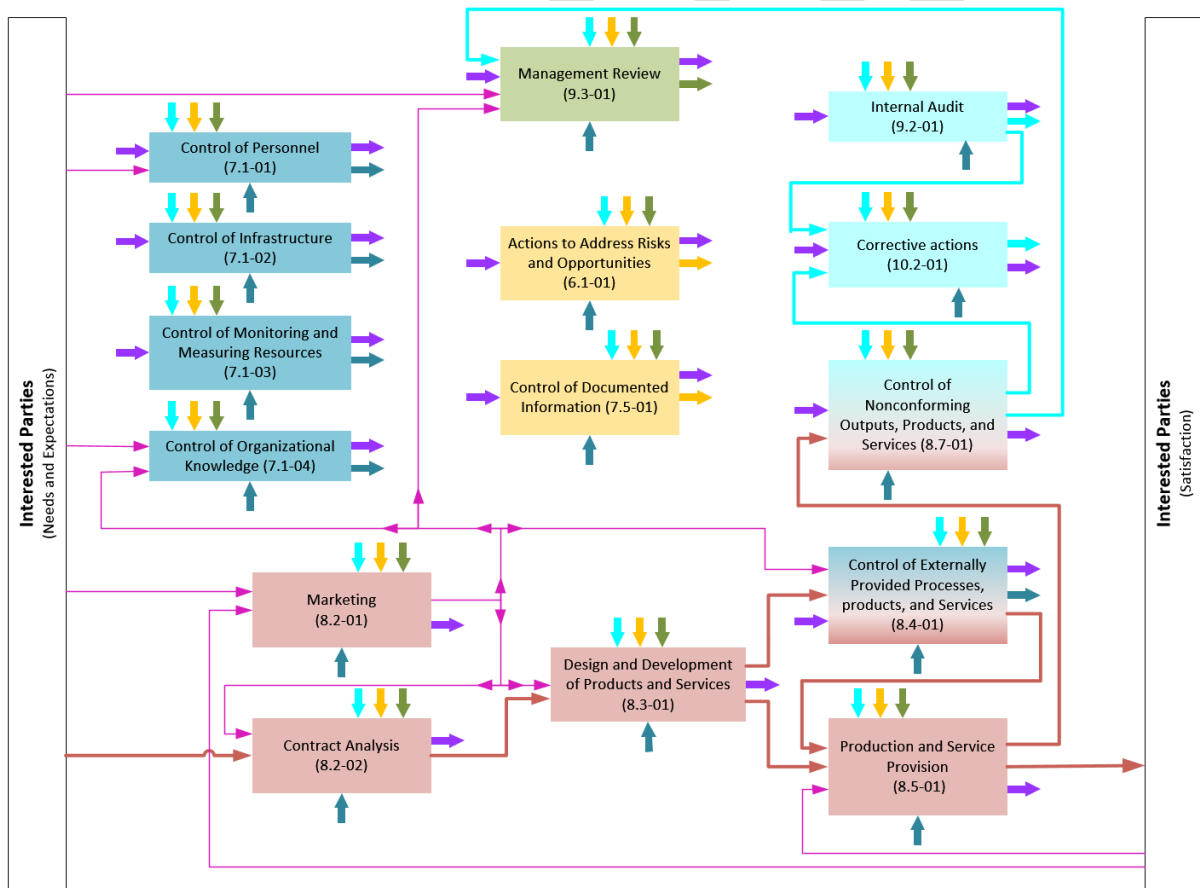


Figure 1.10-02. Business model of the organization (example)

Stage 4 of Process approach implementation is to define process criteria and the methods of its measurement.

According to ISO/TC 176/SC 2/N 544R recommendations, the following are the basic two criteria:

- Effectiveness – ability to achieve planned results;
- Efficiency – ratio of results achieved to the resourced used.

Effectiveness	Efficiency
Ability to achieve planned results	The balance between the restuls achieved and the resources used
$E = I_a / I_p$	$P = I_a / I_r$
I_a – indicator of achieved result	I_r – Indicator of resources used
I_p – indicator of planned result	

Stage 5 - Define resources for process execution.

Stage 6 - Distribute responsibility and authority for the processes.

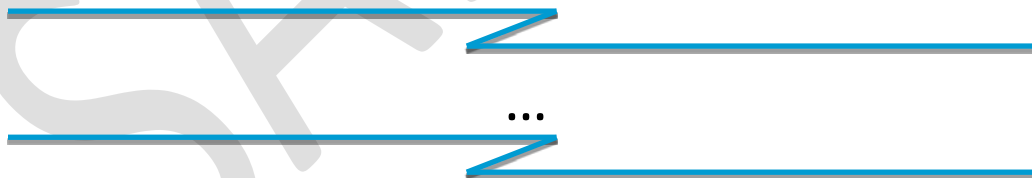
Stage 7 - Identify risks and opportunities.

Stage 8 - Conduct monitoring and measuring of process criteria.

Stage 9 - Improve the process.

Stage 10 - Maintain documented information.

Further we will review the implementation of those stages.



4.3 'Control of monitoring and measuring resources' process

The 'Control of Monitoring and Measuring Resources' process includes definition of the requirements, ensuring availability and maintenance of the three components of monitoring and measuring resources:

- measuring equipment (ME);
- monitoring and measuring methodologies;

- personnel conducting monitoring and measuring.

The diagram of 'Control of Monitoring and Measuring Resources' process is shown in figure 4.3-01.

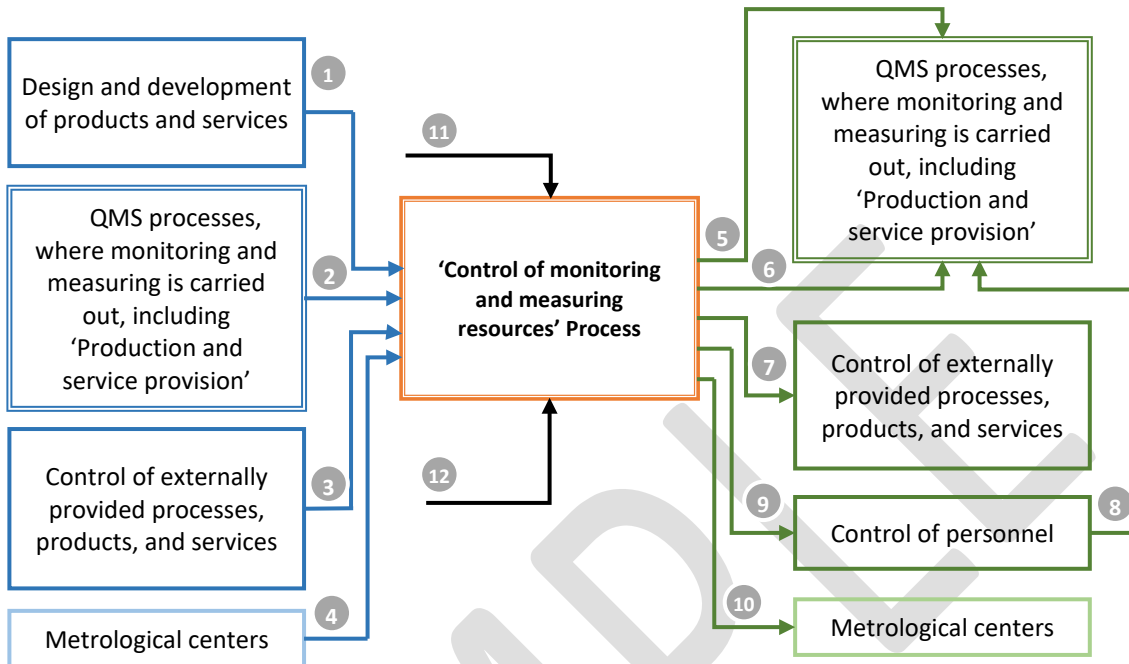


Figure 4.3-01 'Control of Monitoring and Measuring Resources' Process Model

'Control of Monitoring and Measuring Resources' Process Model Flows

- ① Monitoring and measuring data
- ② Requests for new ME.
- ③ ME to be verification
- ④ Purchased ME
- ⑤ Verified ME
- ⑥ ME verification and calibration schedule
- ⑦ Verified ME
- ⑧ ME purchase requests
- ⑨ Trained personnel, who conduct monitoring and measuring
- ⑩ Approved requests for personnel training

- 10 ME to be verification
- 11 [MSP 7.1-01 Control of personnel](#)
[MSP 7.1-03 Control of monitoring and measuring resources](#)
[MSP 7.5-01 Control of documented information](#)
[MSP 8.4-01 Control of external processes, products, and services](#)
[MM 6.1-01-01 Actions to address risks and opportunities in QMS processes](#)
- 12 'Control of monitoring and measuring resources' Process budget

'Control of Monitoring and Measuring Resources' process includes 4 sub processes:

- Creating data for monitoring and measuring;
- Control of Measuring Equipment;
- Control of monitoring and measuring methodologies;
- Training of personnel who conducts monitoring and measuring.

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