

Building Your Business Management System Using ISO 9001:2015

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Building Better Businesses...from the Inside Out



Introductions

- *Name*
- *Your affiliation*
- *Area of Expertise/Current Position/Department*
- *Expectations for today*

Objectives

- *Understand the function and benefits of a business management system*
- *Identify the major elements of a business management system*
- *Understand why an ISO 9001:2015 compliant system functions as a business management system*

Building Better Businesses...from the Inside Out



It's All About Your Business ...

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What is the function of business?

*To deliver value through
fulfilling the needs and
expectations of customers
and other stakeholders*

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How do you deliver value?

In other words,

what business are you in?

Think broadly -

- what is your purpose?
- what are your objectives?
- what do you do to meet those objectives?

How do you deliver value?

This is your business management system:

the interrelated elements of an organization to establish policies and objectives and the processes to achieve them

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Business Management System

Formal definition:

A **system** to manage **resources** and **processes** within a business

- to meet **customer needs** and expectations and
- to create a **sustainable organization**

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Business Management System

Benefits:

Customer – focused

- Increased satisfaction/loyalty
- Increased market share/
revenues

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Business Management System

Benefits:

- Leader driven
- Future oriented (address risks/opportunities)
- Aligned for the same purpose
- Shared objectives
- Better execution

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Business Management System

Benefits:

- Process Oriented
- Defined and systematic operations
- Repeatable approaches
- Consistent execution
- Reliable outcomes

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Business Management System

Benefits:

Sustainable

- Better use of resources
- Forward looking (opportunities)
- More efficient/effective

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Table Exercise

Thinking about your own organization,

- what business are you in?
- **what do you do to create value for your customers?**
- **what needs to be managed to create long term sustainability?**

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What impacts the ability of your organization to deliver value to your customers?

to meet its intended result of consistently supplying products and services that satisfy customer?

- organizational values and culture
- competition
- technology
- socio-economic conditions

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ISO9000:2015 calls this “context”.

4.1 Understanding the organization and its context

The organization shall determine **external and internal issues** that are relevant to its purpose and its strategic direction and that **affect its ability to achieve the intended result(s)** of its quality management system.

The organization shall monitor and review information about these external and internal issues.

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ISO 9000:2015 defines

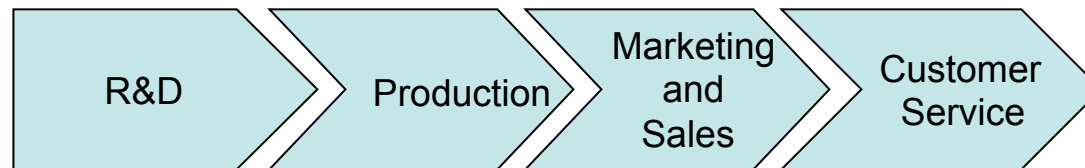
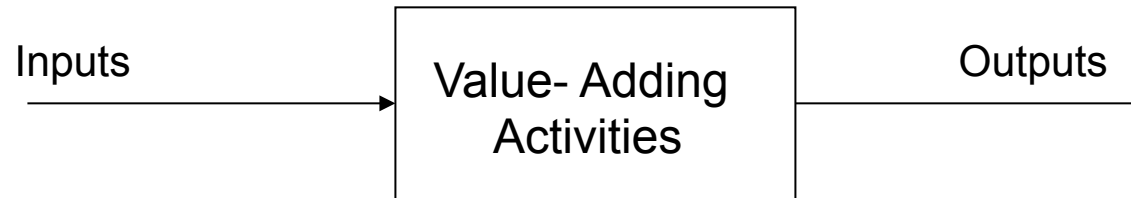
Quality

as **delivering value** by fulfilling the needs and expectations of your customers and other interested parties.

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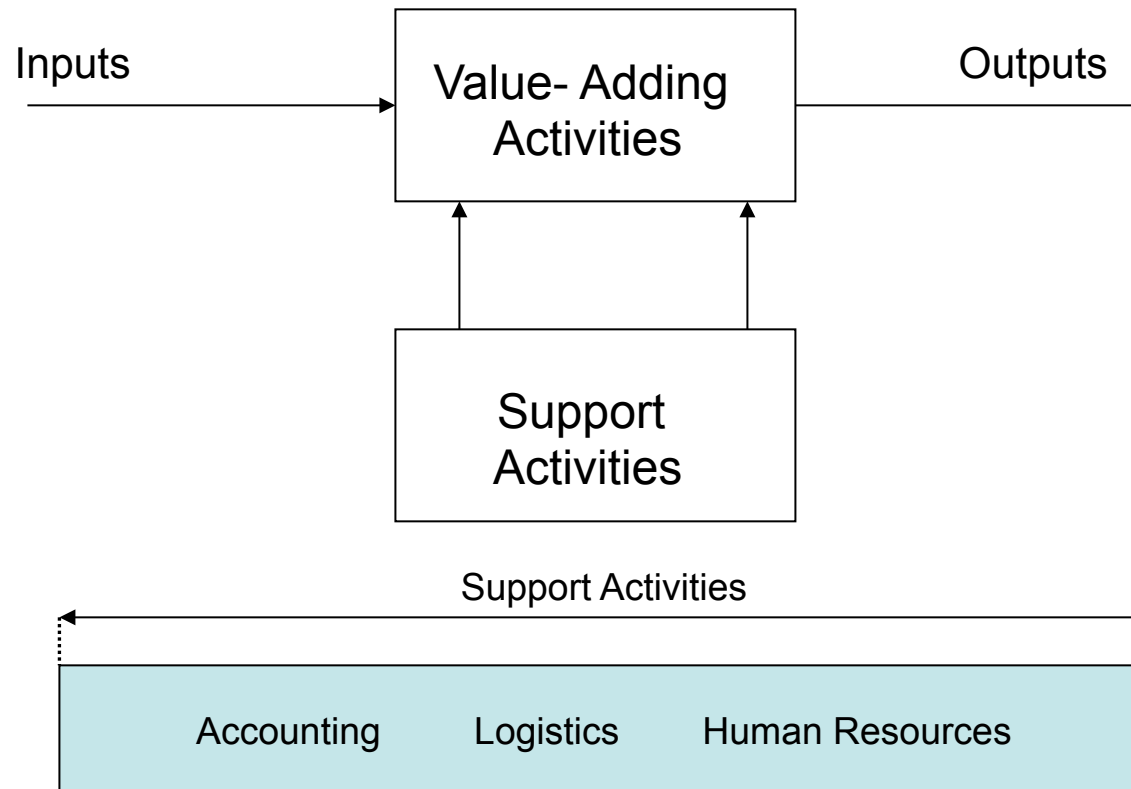


Business Management System



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Business Management System



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Table Exercise

Thinking about your own organization,

- what is your value chain?
- what processes are involved?
- how are these processes connected?

Business Management System

4.4 Quality management system and its processes:

The organization shall establish, implement, maintain and continually improve a quality management system, including **the processes needed and their interactions...**

The organization shall **determine the processes** needed for the quality management system and their application....

Business Management System

4.4 Quality management system and its processes:

The organization shall

- determine the inputs required and the outputs expected from these processes
- **determine the sequence and interaction** of these processes .

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Business Management System

4.4 Quality management system and its processes:

The organization shall

- determine and apply the **criteria and methods** (including monitoring, measurements and related performance indicators) needed to **ensure the effective operation and control** of these processes
- determine the resources needed for these processes and ensure their availability;

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4.4 Quality management system and its processes:

The organization shall

- assign responsibilities and authorities for these processes;
- **address the risks and opportunities** as determined in accordance with the requirements...;

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Business Management System

4.4 Quality management system and its processes:

The organization shall

- **evaluate these processes and implement any changes** needed to ensure that these processes **achieve their intended results**; assign the responsibilities and authorities for these processes .
- improve the processes and the quality management system.

Business Management System

5.1 Leadership and commitment

Top management shall

- ensure that the quality policy and quality objectives are established for the quality management system and **are compatible with the context and strategic direction** of the organization;
- ensure the **integration of the quality management system requirements into the organization's business processes;**

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Business Management System

5.1 Leadership and commitment

Top management shall

- ensure that the **resources needed** for the quality management system **are available**;
- ensure that the quality management system **achieves its intended results**;
- engage, direct and support persons to contribute to the effectiveness of the quality management system;
- promote improvement

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5.1. Customer focus

Top management shall ... ensure that

- customer and applicable statutory and regulatory **requirements are determined, understood and consistently met;**
- **risks and opportunities** that can affect conformity of products and services and the ability to enhance customer satisfaction **are determined and addressed;**
- **focus on enhancing customer satisfaction is maintained.**

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Business Management System

6.1 Actions to address risks and opportunities

...the organization shall consider the issues...and requirements.. and determine risks and opportunities that need to be addressed to

- give assurance that the quality management system can **achieve its intended results(s)**;
- **enhance desired effects**;
- prevent, or reduce, undesired effects;
- achieve improvement.

Business Management System

6.1 Actions to address risks and opportunities

The organization shall **plan**:

- actions to address these risks and opportunities.
- how to
 - **integrate and implement the actions into it quality management system**
 - **Evaluate the effectiveness of these actions**

Actions taken... shall be proportionate to the potential impact on the conformity of products and services.

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Business Management System

6.2 Quality objectives and planning to achieve them

When planning **how to achieve its quality objectives**, the organization shall determine:

- what will be done;
- what resources will be required;
- who will be responsible
- when it will be completed
- how results will be evaluated.

Business Management System

A system to **manage resources** and **processes** within a business

- to meet customer needs and expectations and
- to create a sustainable organization

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Table Exercise

Thinking about your own organization,

- what resources need to be managed?
- how are your processes managed (controlled)?

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7.1 Resources

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

People

Infrastructure

Environment

Knowledge

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8.1 Operational planning and control

The organization **shall plan, implement and control the processes** needed to meet the requirements for the provision of products and services, and to implement the actions determined by...

- **determining requirements** for products/services
- **establishing criteria** for the processes and acceptance of products/service
- **determining resources** needed to achieve conformity to product/service
- **implementing control** of processes...

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8.5 Control of production and service provision

The organization shall implement production and service provision under **controlled conditions**:

- the availability of documented information that **defines the characteristics** of the products to be produced, the **services to be provided**, or the **activities to be performed** and the **results to be achieved**;...
- the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control ...have been met;

Business Management System

A system to manage resources and processes within a business

- to **meet customer needs and expectations** and
- to **create a sustainable organization**

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9.1.2 Customer satisfaction

The organization shall monitor customers' perceptions of the **degree to which their needs and expectations have been fulfilled.**

The organization shall determine the methods for obtaining, monitoring and reviewing this information

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9.1.3 Analysis and evaluation

The organization shall analyze and evaluate ... data...arising from monitoring and measurement,..."

- conformity of products and services
- customer satisfaction
- **performance and effectiveness of the quality management system**
- **if planning has been implemented effectively**
- effectiveness of actions taken to address risks and opportunities
- the need for improvements...

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9.3 Management Review

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, **effectiveness and alignment with the strategic direction of the organization.**

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10 Improvement

The organization shall determine and select opportunities for improvement and implement any necessary actions to **meet customer requirements** and **enhance customer satisfaction**

Business Management System

ISO 9001:2015 helps you to establish maintain and improve your

system to **manage resources and processes** within a business

- to **meet customer needs and expectations** and
- to **create a sustainable organization**

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Business Management System

Benefits:

- Customer – focused
- Leader driven
- Process Oriented
- Sustainable

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Objectives

- *Understand the function and benefits of a business management system*
- *Identify major elements of a business management system*
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“The function of business is to attract and maintain customers.”

– Peter Drucker

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Questions?



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