Awareness Training
ISO 9001:2015
QUALITY MANAGEMENT SYSTEM

About Qdot

www.qdot.ae

Qdot managed by a team of experienced professionals, is committed to promote quality & excellence culture in GCC (UAE, QATAR, KSA, Oman, Kuwait, Bahrain)by providing below mentioned services.

Management System Services

- ISO 9001, ISO 14001, ISO 45001, HACCP, ISO 22000, FSSC 22000, BRC GS, Halal, ISO 22716 (GMP),Organic Certification, ISO 27001, ISO 41001, ISO 37001, ISO 50001, ISO 55001, ISO 17020 & ISO 17025 etc

Training Services

- IRCA Approved Lead Auditor
- Awareness & Trainings on ISO Standards

Product Registration

- SABER, SQM, SFDA, CITC, IECEE, ECAS, EQM, RoSH, EESL, SLCP, G-Mark etc

Social Compliance

- SEDEX, SA 8000, amfori BSCI, ISO 26001, WRAP, GRLI, ESG, CTPAT etc

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UNDERSTANDING OF INTERNATIONAL PROSPECTIVE

KEY PLAYERS
(CONFORMITY ASSESSMENT BODIES)

- ILAC — INTERNATIONAL LABORATORY ACCREDITATION COOPERATION
- IAF — INTERNATIONAL ACCREDITATION FORUM
- EA — EUROPEAN COOPERATION FOR ACCREDITATION
- APLAC — ASIAN PACIFIC LABORATORY ACCREDITATION
- PAC — PACIFIC ASIA ACCREDITATION COOPERATION
- AB — ACCREDITATATION BODY (PNAC, UKAS, EIAC etc)
- CB — CERTIFICATION BODY (BVQI, SGS, INTERTEK, DNV)

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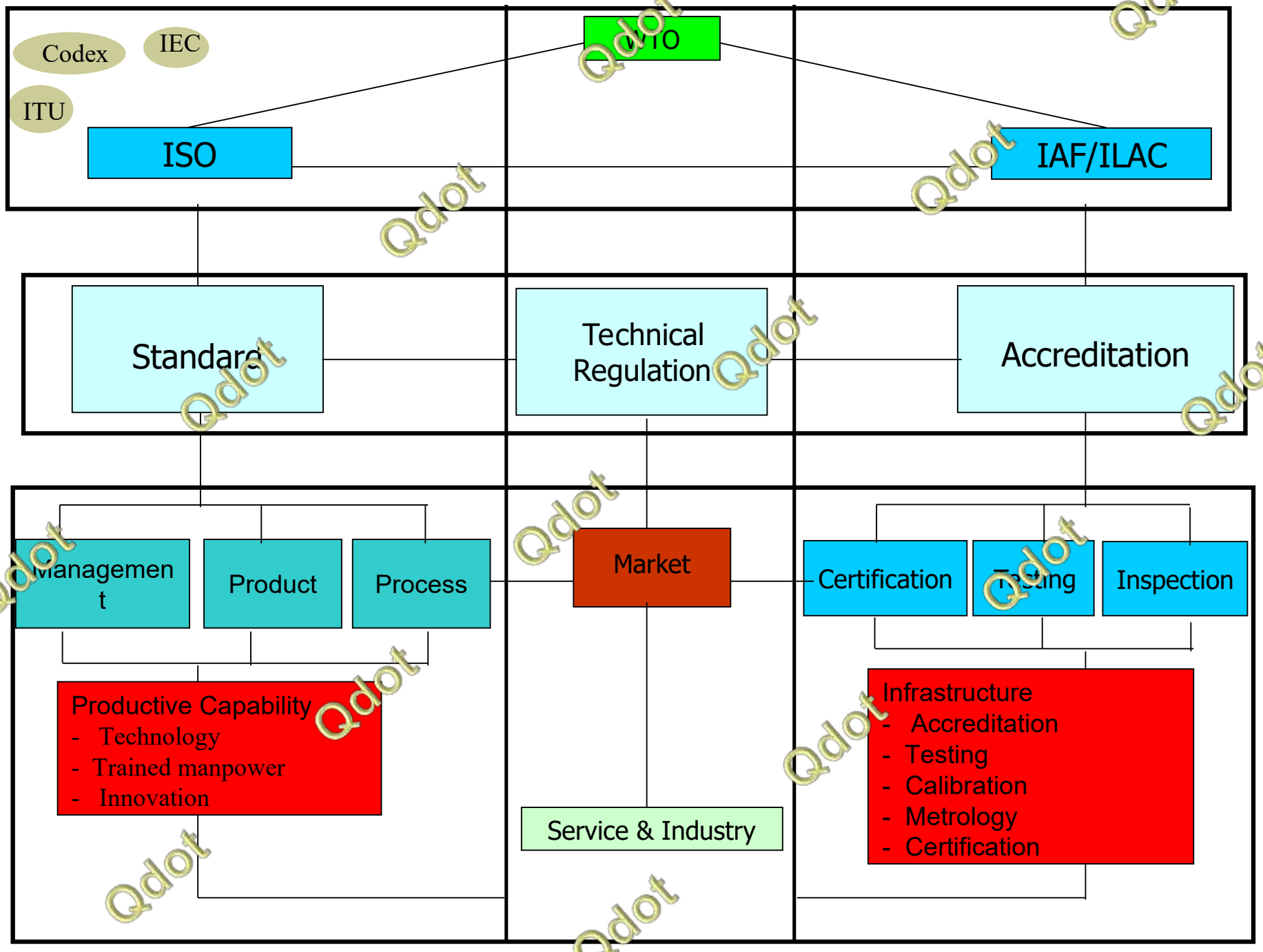
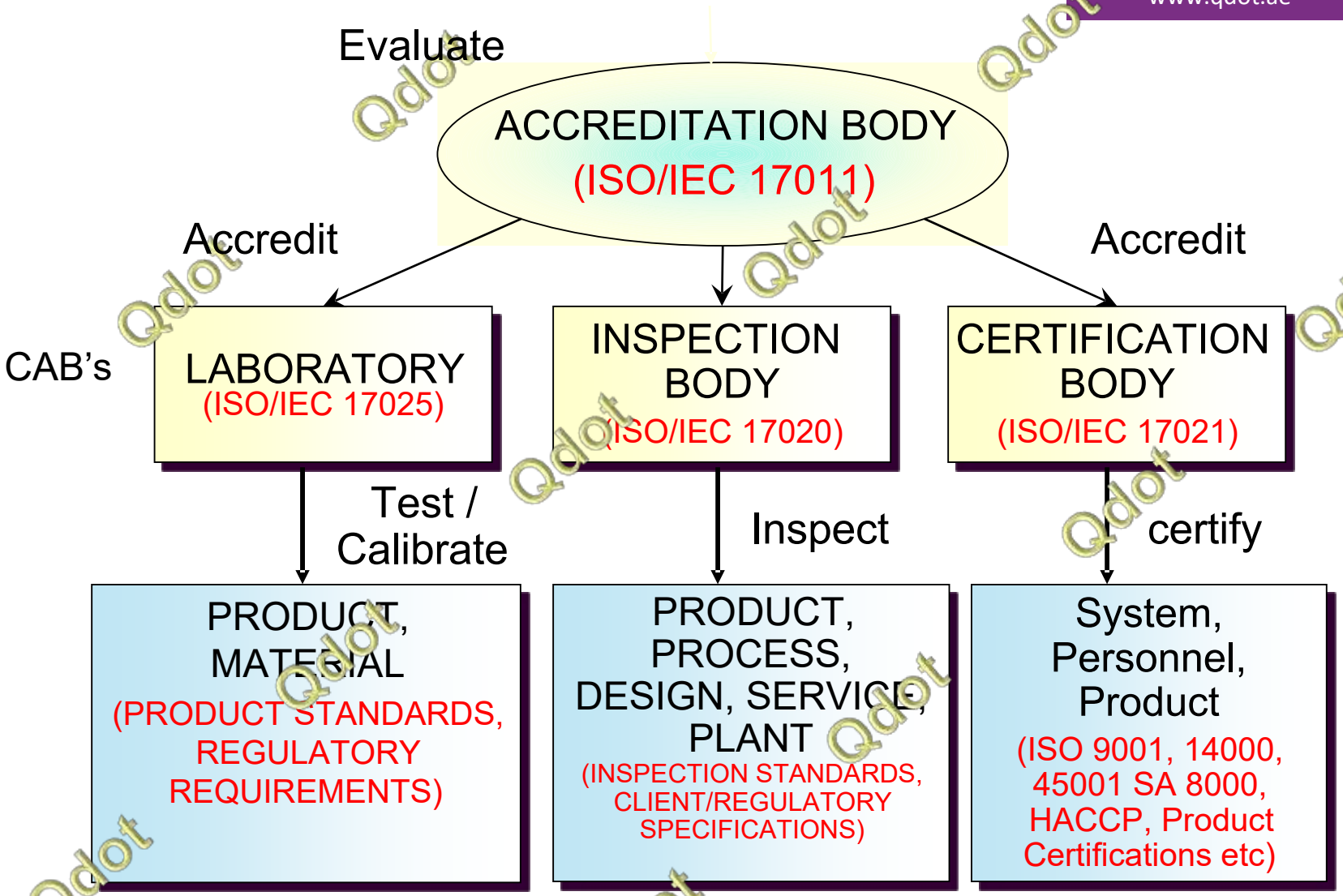

Codex
IEC
ITU
WTO
ISO
IAF/ILAC
Standard
Technical Regulation
Accreditation
Management
Product
Process
Market
Certification
Testing
Inspection
Productive Capability
- Technology
- Trained manpower
- Innovation
Service & Industry
Infrastructure
- Accreditation
- Testing
- Calibration
- Metrology
- Certification

ILAC, IAF, APLAC AND PAC



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What is ISO 9001?

ISO

The word "ISO" or International Organization for Standardization

9001

The series allocated for Quality System standards

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Standard Evolution

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Application of ISO 9001

- ISO 9001 is applicable to any type and any size of organization
  - It is not an industry specific or product specific standard
- ISO 9001 involves third party certification
  - an independent auditing agency audits the organization against the requirements of the standard and issues certificate on successful compliance
- ISO 9001 Certification is valid for three years
  - initial certification audit
  - yearly or half-yearly surveillance audits

Advantages of ISO-9001

Internal Benefits.

- Effective management
- Positive cultural change
- Yielding of quality consciousness
- Better documentation
- Systematic development
- Standardization & consistency
- Increase of efficiency & productivity
- Wastage control
- Institutionalized approach
- Cost effective production

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Advantages of ISO-9001

External Benefits

- Increase of organization image
- Customer satisfaction
- Increase of customer
- Increase of competitive power
- Better relation with supplier

What is Quality??

- Degree of Excellence
- Fitness for Purpose
- Meeting Requirements
- Meeting Customer/community Needs
- Delighting Customers
- Right First Time, All The Time

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What is Quality??

"Degree to which a set of inherent characteristics

fulfils requirements"

ISO 9001:2015

" The totality of features and characteristics of a product /

service that bear on it's ability to satisfy stated or implied

needs"

ASQC

Famous Quality Quotes

"Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives."

William A. Foster

"Quality is the result of a carefully constructed cultural environment"

Philip Crosby

Famous Quality Quotes

"Quality is everyone's responsibility."

W. Edwards Deming

"Quality is remembered long after the price is forgotten."

Gucci Family Slogan

"What I value in life is quality rather then quantity."

Albert Einstein

Famous Quality Quotes

"Almost all quality improvement comes via simplification of design, manufacturing... layout, processes, and procedures."

Tom Peters

"Men are more important than tools. If you don't believe so, put a good tool into the hands of a poor workman."

John J. Bernet

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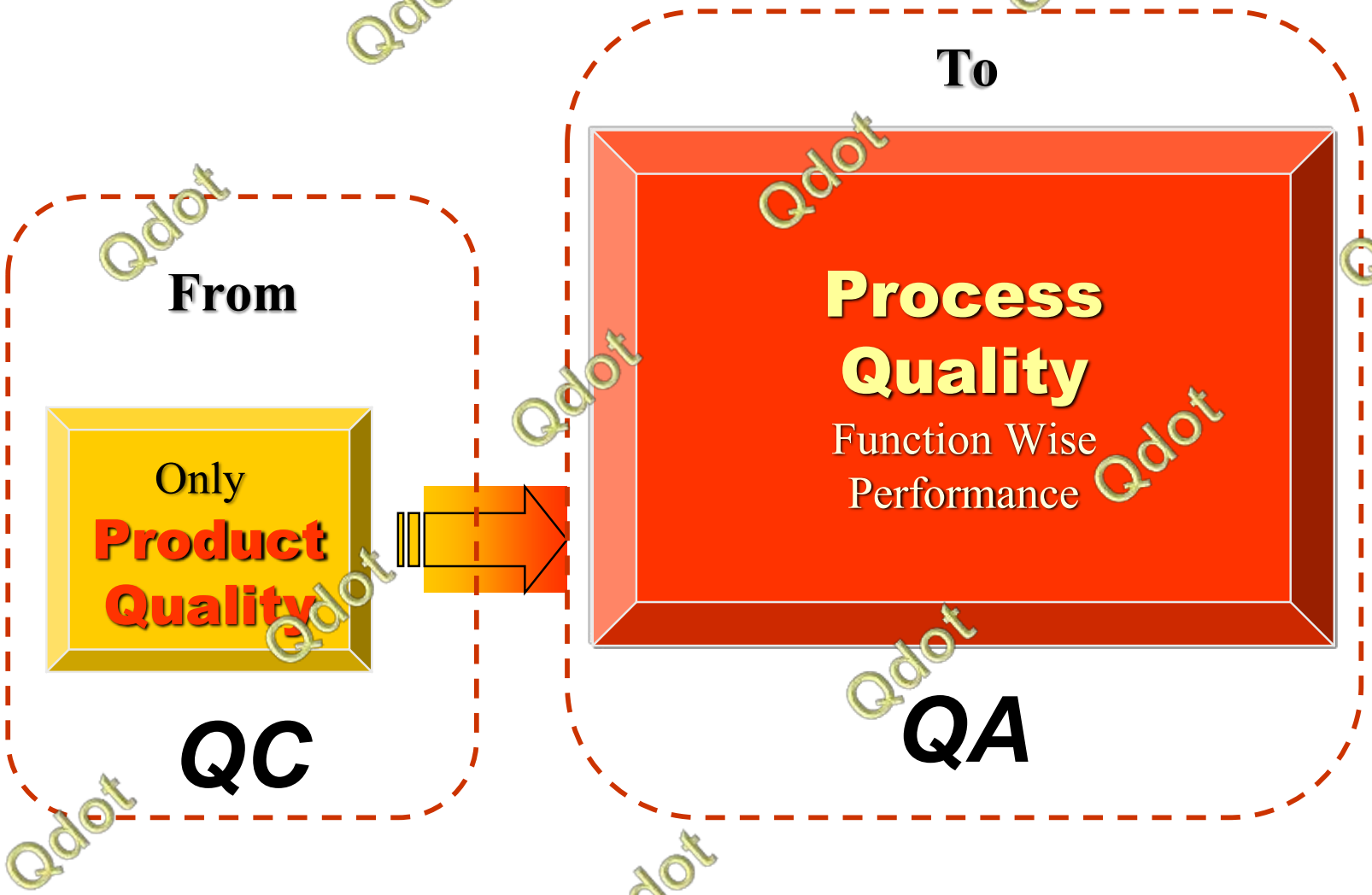
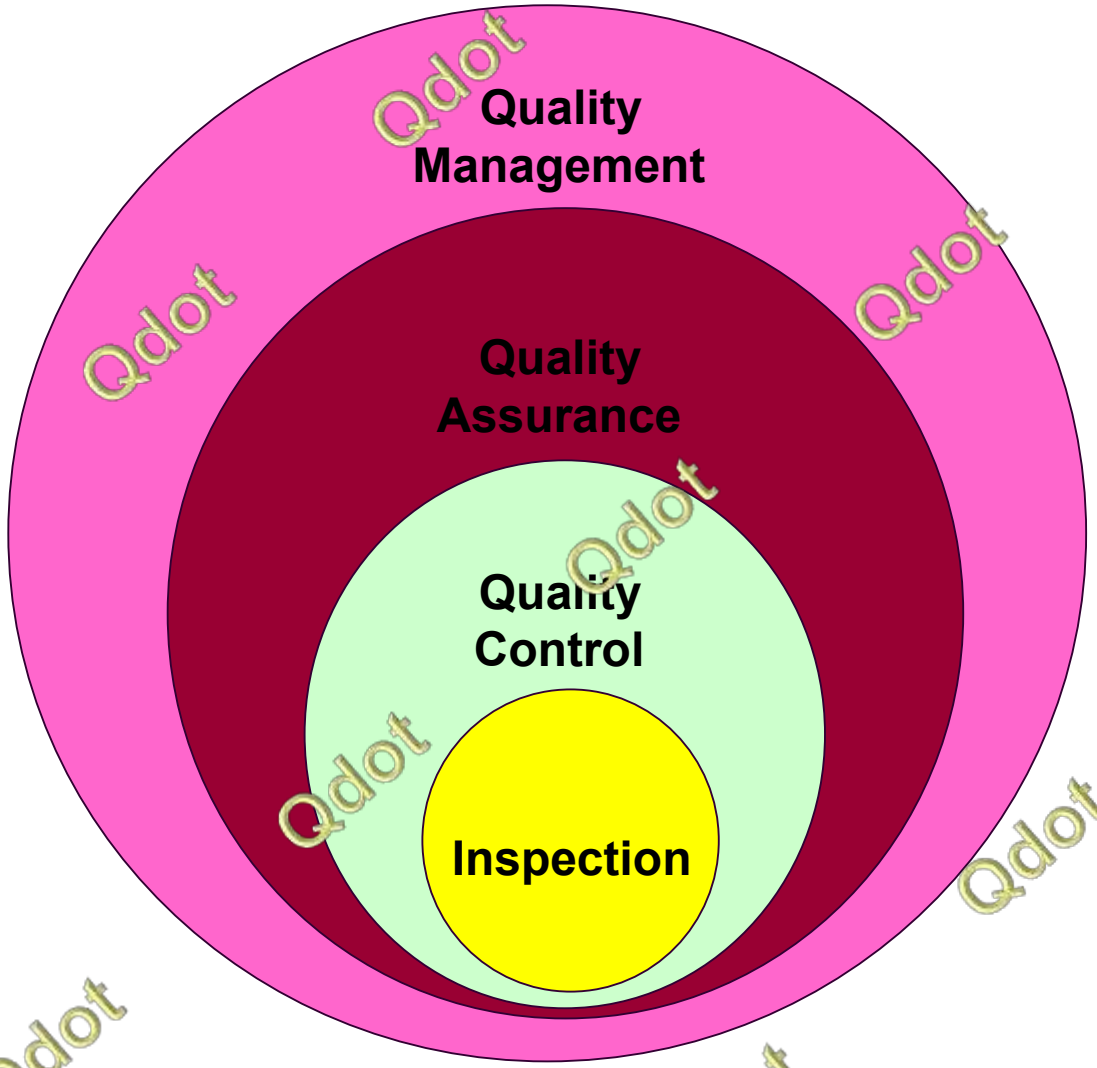
Changing Scope of Quality



Changing Scope of Quality



Quality Management

(Company wide Performance)

Quality Assurance

(Process Improvement)

Quality Control

(Prevention of defects)

Inspection

(Sorting good from bad products)

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Dimensions of Quality

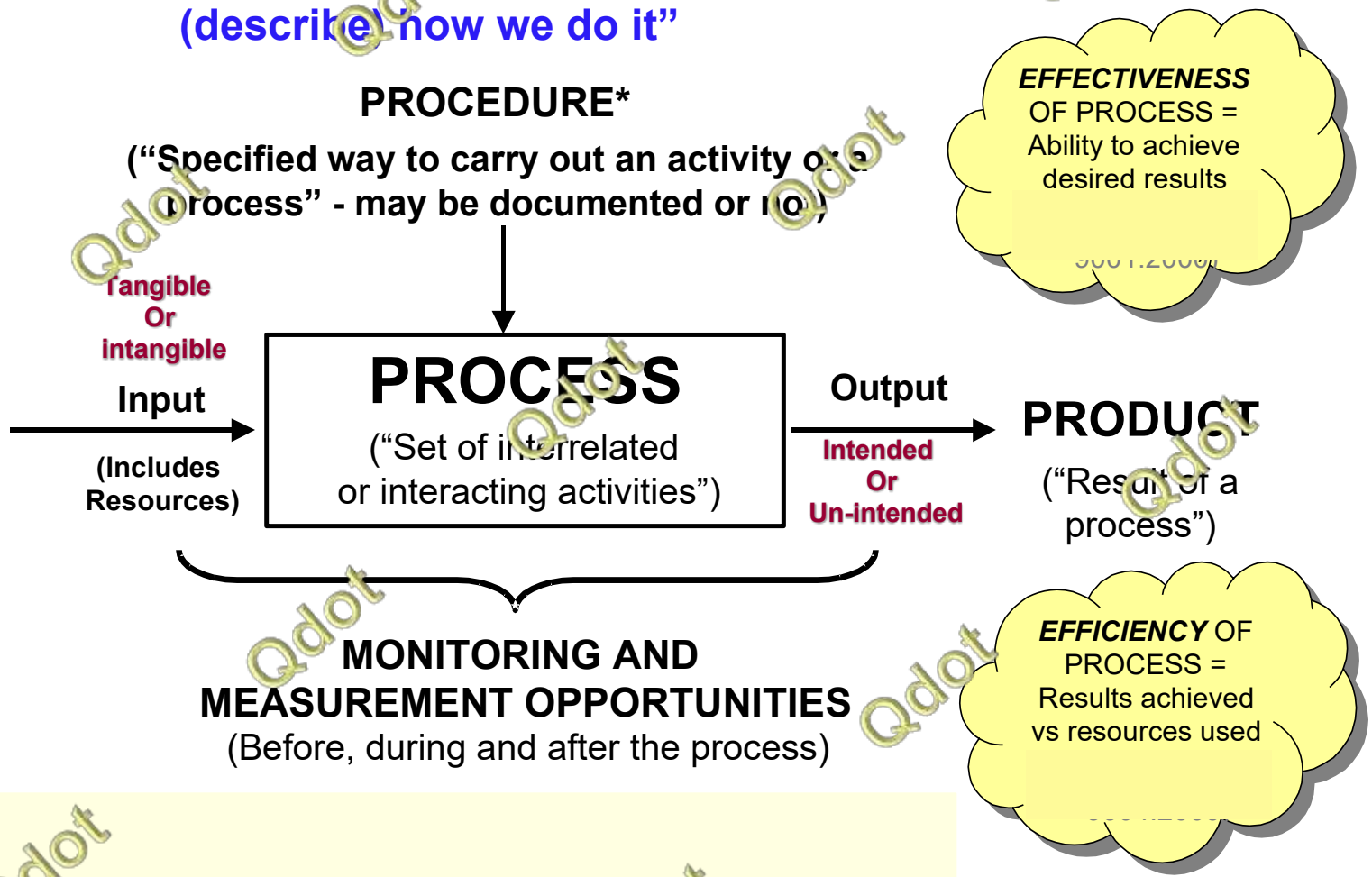
- Good looking
- Reliable
- Durable
- Easy to operate
- Made of best Materials
- Affordable
- Available
- Low Maintenance cost
- Size / Weight

Factors Affecting Quality

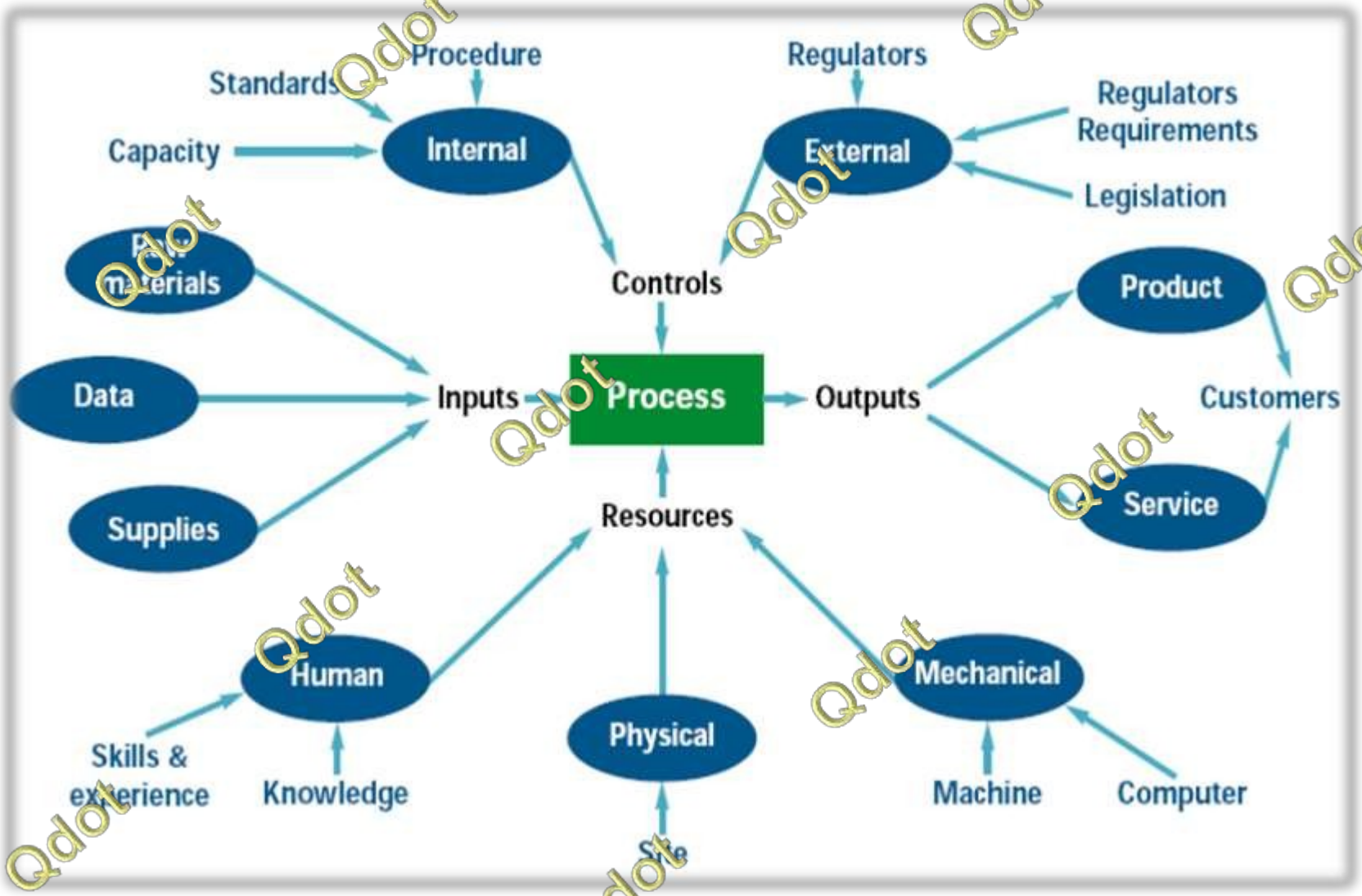
- Human Resource
- Financial Resources
- Work Environment
- Technical Resources.
- Management System
- Communication System
- Motivation
- Organizational Quality
- Individual Quality

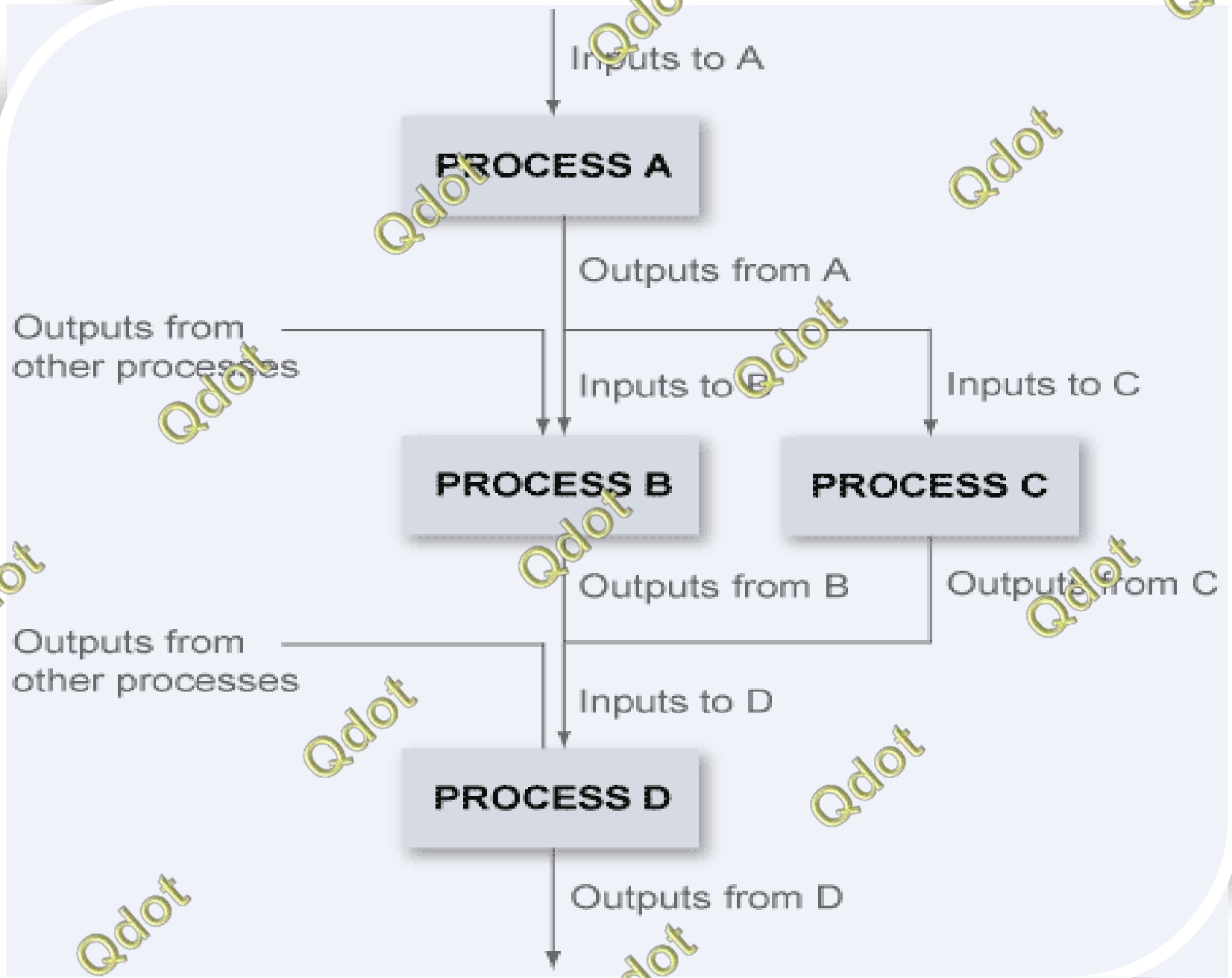
"Process & its Relationships"

"Processes describe what we do and procedures (describe) how we do it"



What is a Process?




Inputs to A
PROCESS A
Outputs from A
Outputs from other processes
Inputs to B
Inputs to C
PROCESS B
PROCESS C
Outputs from B
Outputs from C
Outputs from other processes
Inputs to D
PROCESS D
Outputs from D

Process Mapping

- Total and transparent view of the process.
- Clear and logical way of thinking about our process.
- A way of communicating our process to others.
- Highlights potential ‘fail’ and ‘delay’ points.
- Highlights precisely how stakeholders are operationally involved.
- Identifies how we can strategically seek feedback for process improvement purposes.

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Flowcharting

- A graphical approach to map a process.
- Identifies distinct elements in the process.
- Classifies these elements into processes, decisions, delays, data etc...
- Orders the elements sequentially.

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Flowcharting Symbols

- Each element is represented by a symbol.
- There are different standards for flowchart symbols. Main one is ISO 5807:1985.
- There are many, many different symbols (and many different types of flowcharts).
- The core symbols tend to be constant.
- But there are really no strict rules.
- Symbols can be tailored for your own use.

Common Flowcharting Symbols

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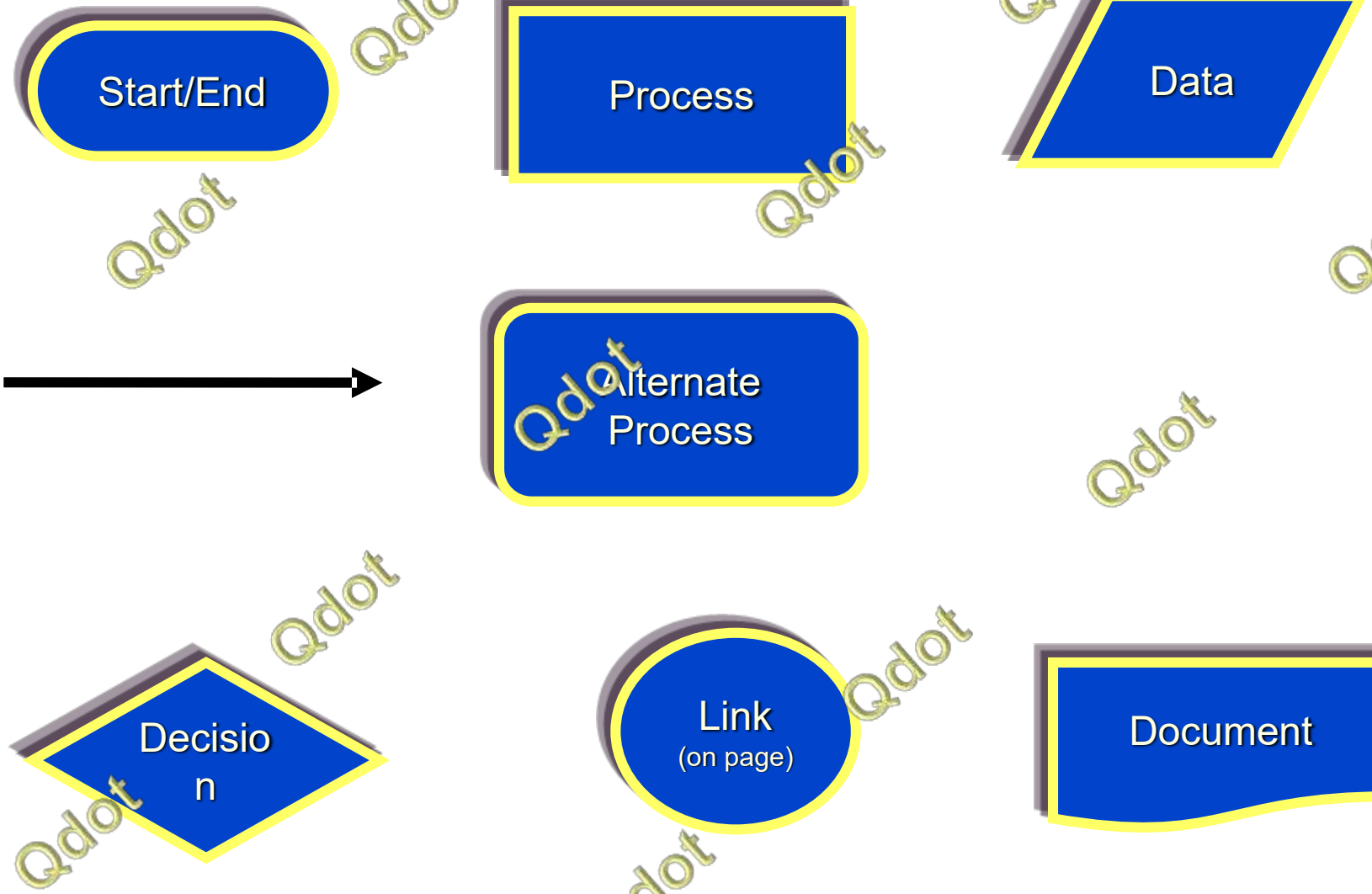

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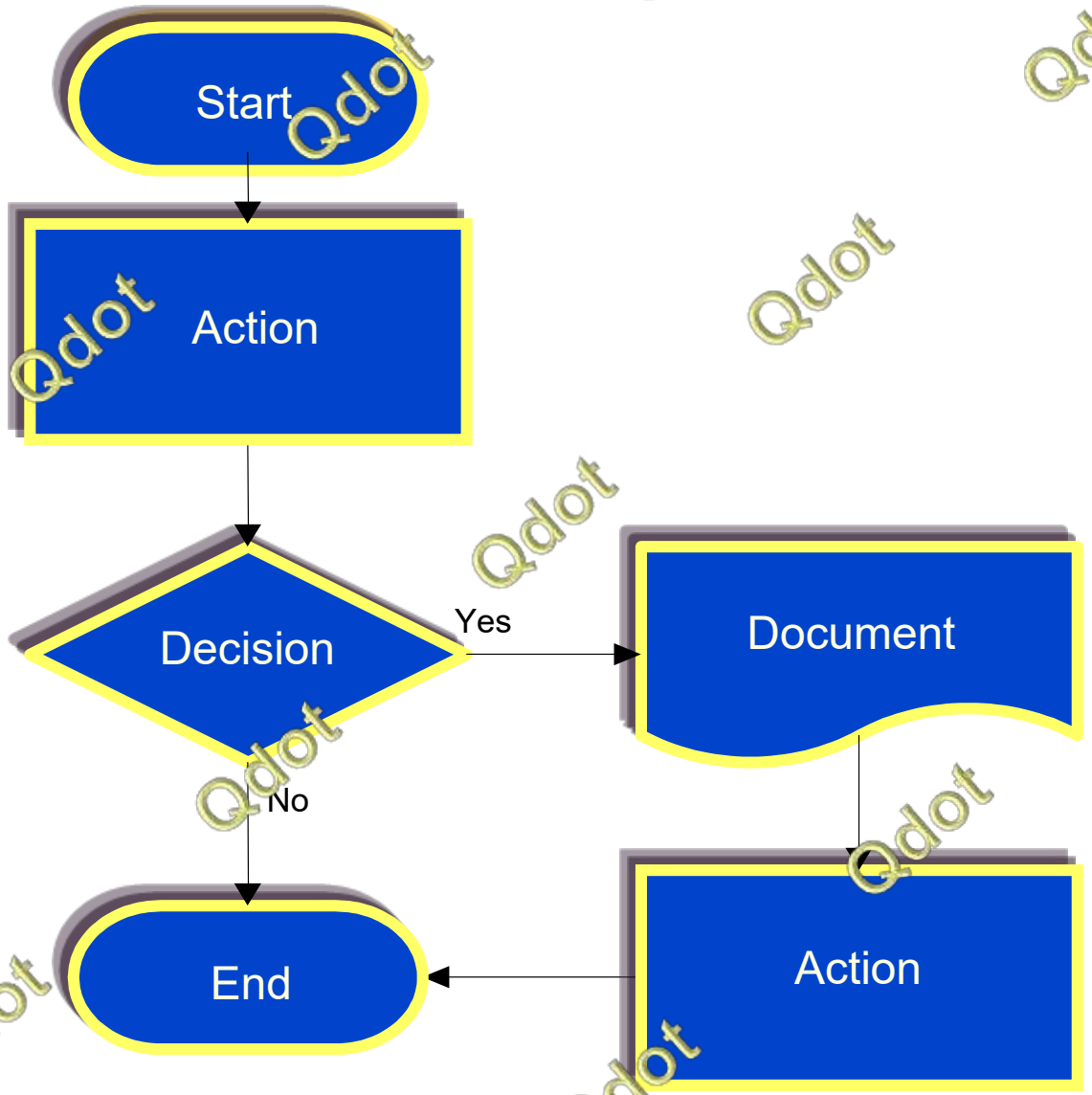
Basic Flowchart Example



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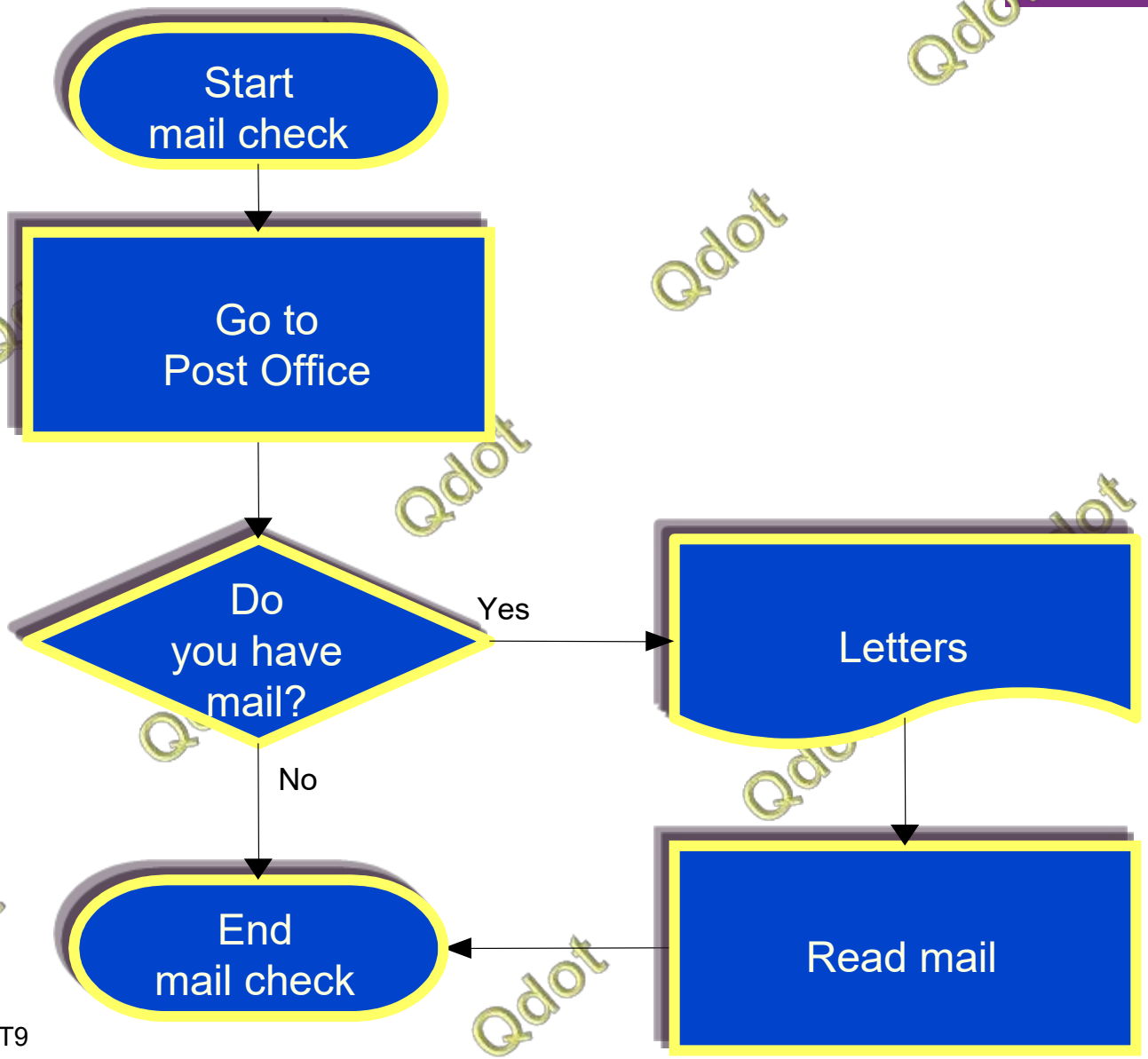
Basic Flowchart Example



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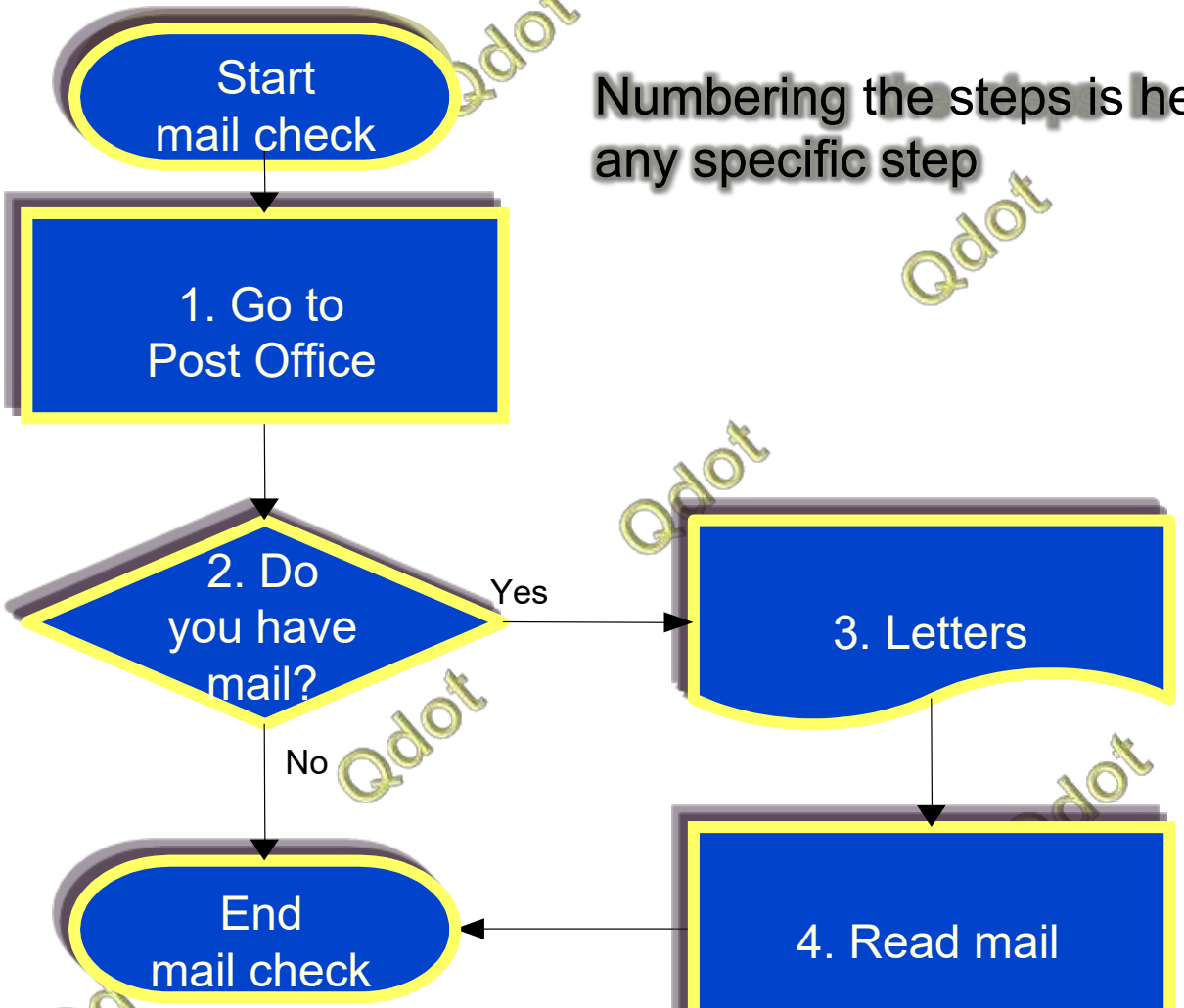
Basic Flowchart Example



Numbering the steps is helpful to elaborate any specific step

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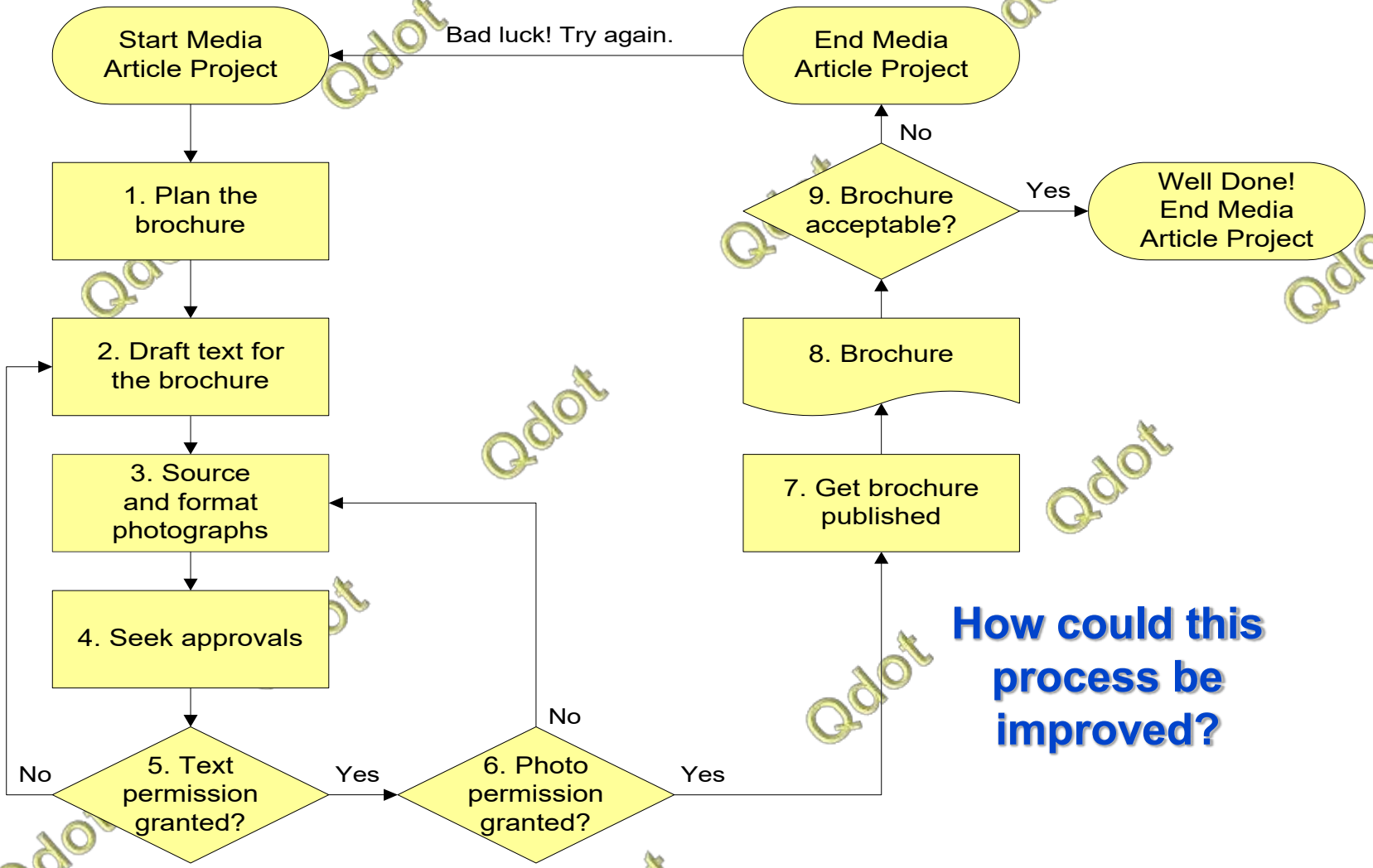
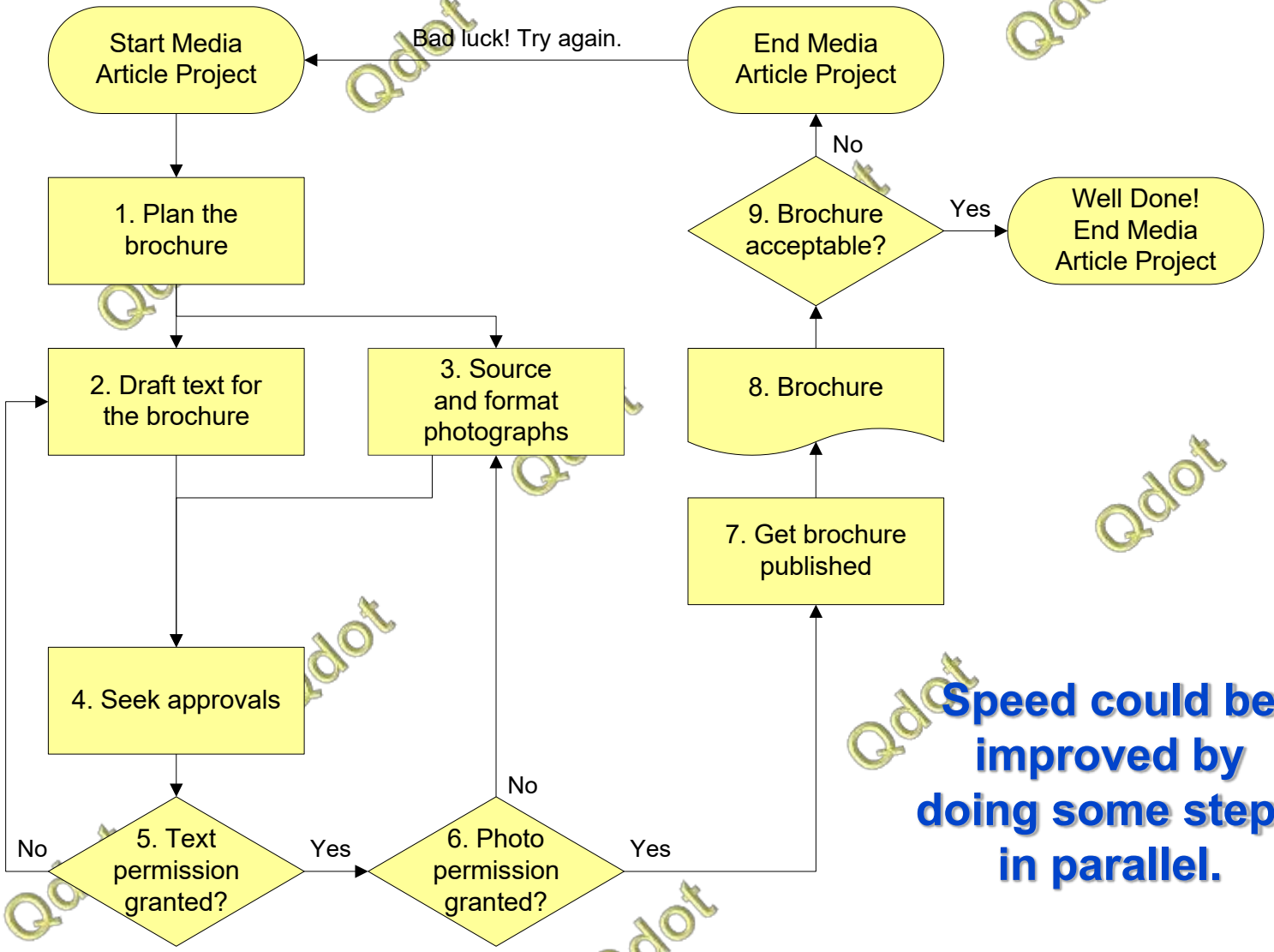
Improving Processes via Flowcharts



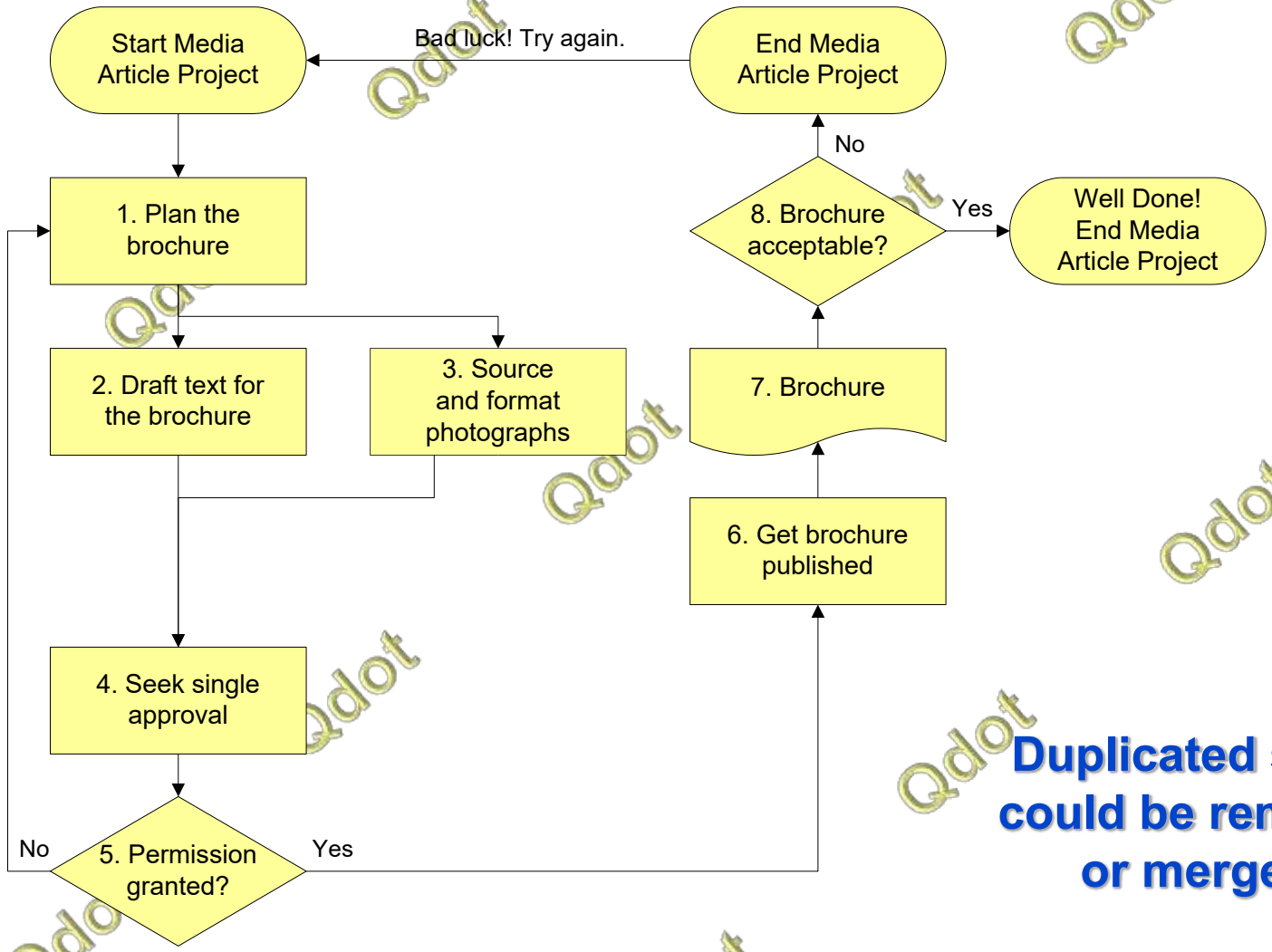
How could this process be improved?

Improving Processes via Flowcharts



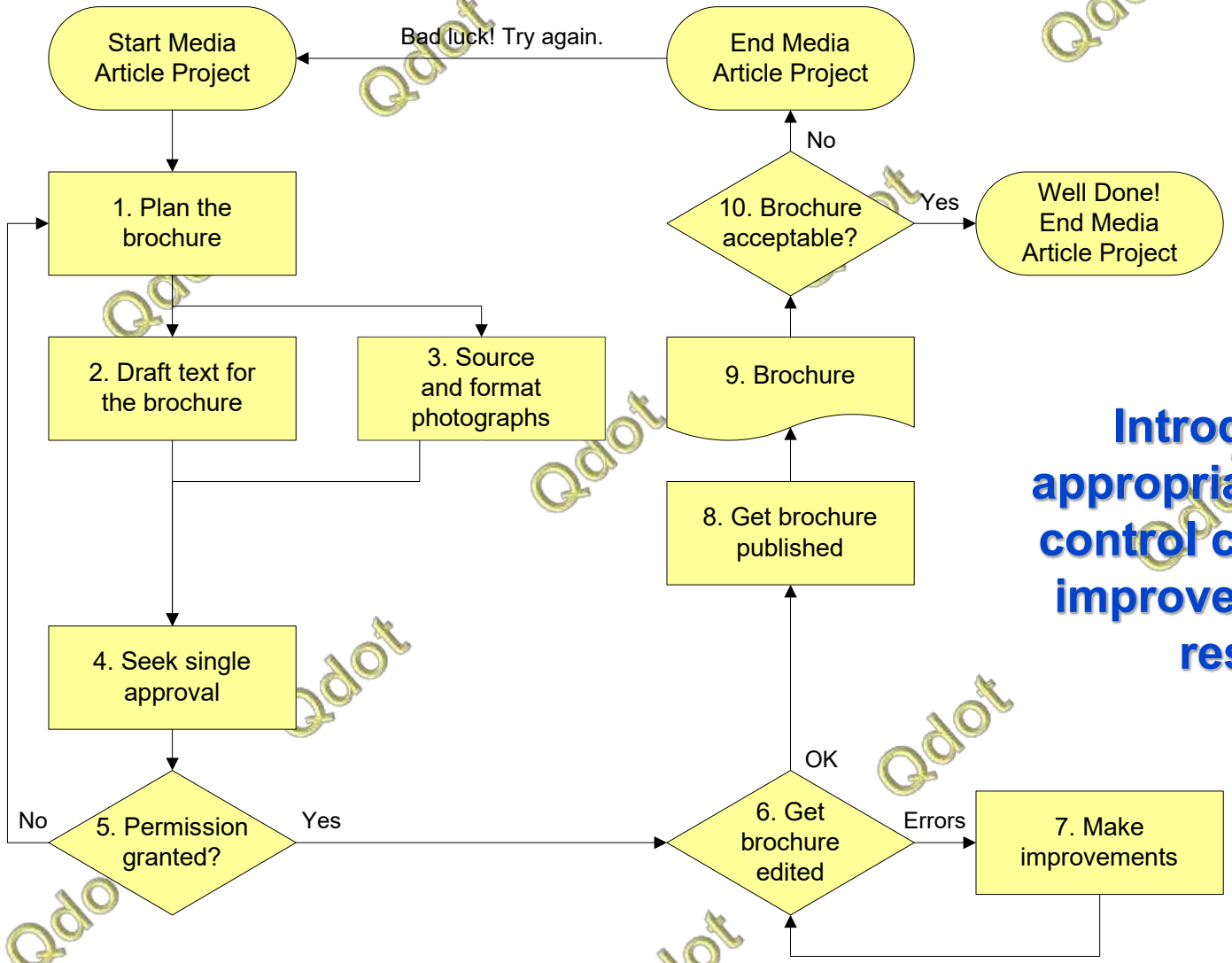
Speed could be improved by doing some steps in parallel.

Improving Processes via Flowcharts



Duplicated steps could be removed or merged.

Improving Processes via Flowcharts



Introducing appropriate quality control could help improve the final result

“The Questioning Technique”

Analyze the entire process, then ask the following questions about each task or step:

WHAT: Why is it done at all? / Why is it necessary? / Why not eliminate it?

WHERE: Why is it done there? / Why not change the Place? / Why not change the sequence? / Why not combine?

WHEN: Why is it done now? / Was it the suitable time? / Why not change it?

WHY: Why is it done? What is the Purpose behind? Why done like this?

WHO: Why does the person do it? / Why not change the person? / Why not change the sequence? / Why not combine?

HOW: Why is it done this way? / Why not do it in a different way? / Why not improve it? / Why not make it easier?

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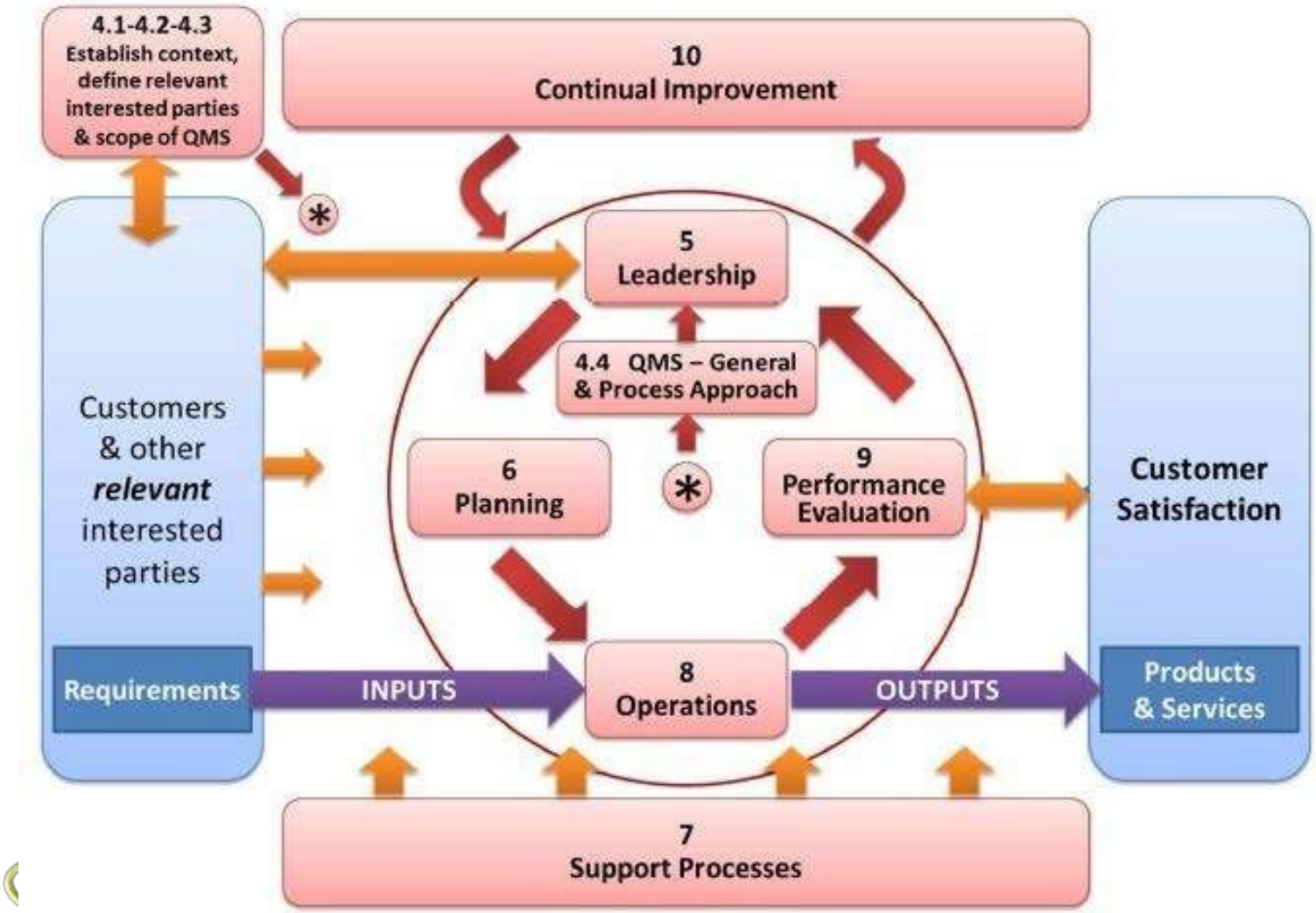
Process based QMS



ISO 9001:2015 Requirements

High Level Structure - HLS

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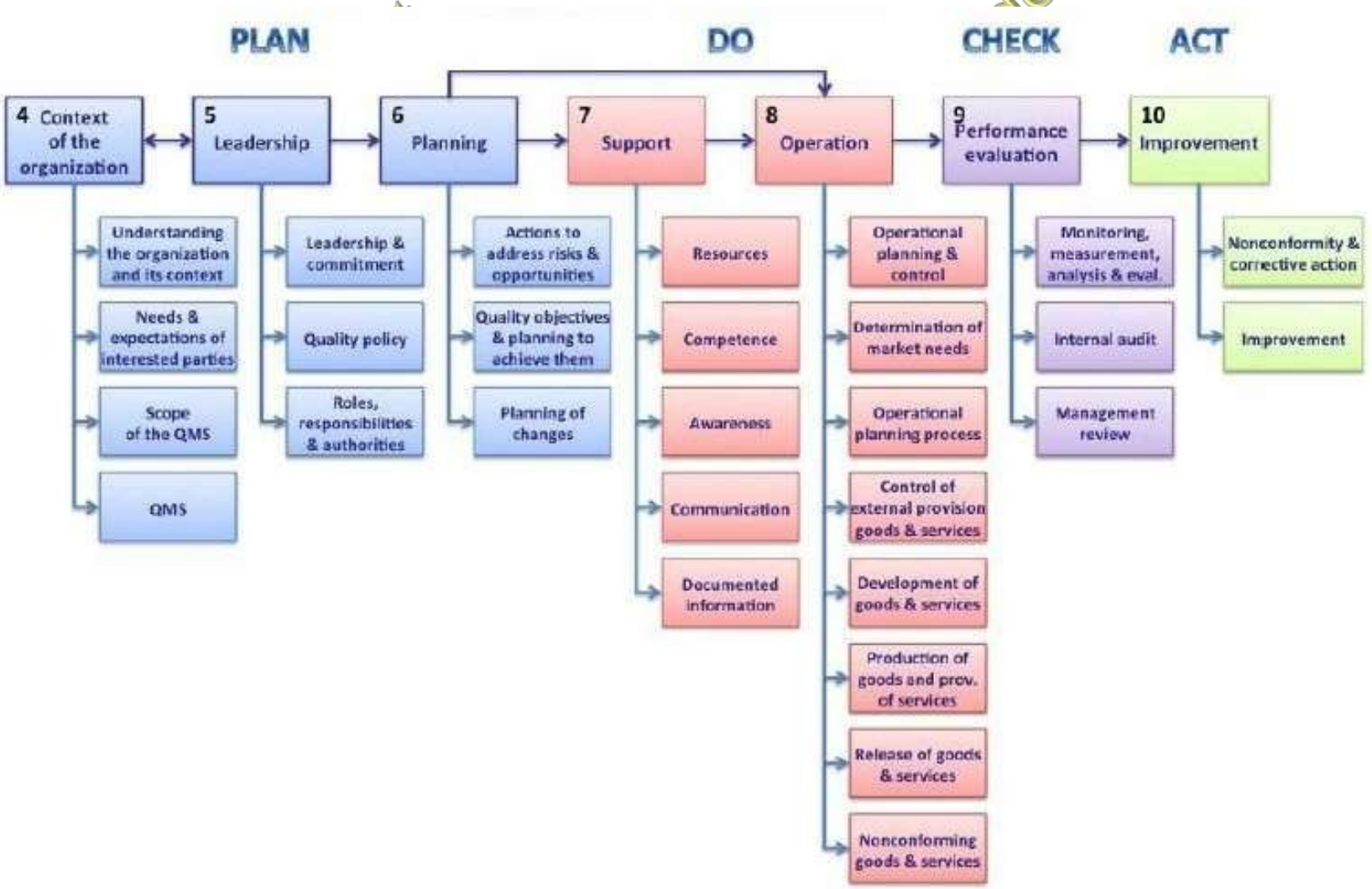
PDCA in ISO 9001:2015



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 QMS.

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

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

INTERNAL ISSUES OF CONCERN

Example

Type	Issue	Bias
Technological	Organization currently has adequate technological resources to consistently produce its products	Positive
Employee base	Availability of skilled workforce in the area remains high	Positive
Employee base	Employee turnover is low	Positive
Supply Chain	Quality issues pertaining to raw materials or critical services may not be addressed properly when using sole source or limited-source suppliers	Negative

EXTERNAL ISSUES OF CONCERN

Example

Type	Issue	Bias
Competition	Organization does not have significant competition in this market at this time.	Positive
Society & Culture	Organization's Products or Services not present any particularly controversies that would result in negative reactions from society or the public.	Neutral
Labor		
Statutory/Regulatory		
Economic		

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

"the interested parties & Their Requirements"

The organization shall monitor and review information about these interested parties and their relevant requirements.

INTERESTED PARTIES

Example

Interested Party	Internal or External	Reason for Interest
Customers	External	Direct recipient of organization's Products or Services
Employees	Internal	Responsible for realization organization's Products or Services
End users	External	organization's products may be resold by direct customers or other end users, who are directly impacted by the quality of Products or Services
Suppliers (vendors)	External	Provide supporting services or raw materials
Regulators	External	Dictate controlling regulations that impact on the management system and organization's Products or Services
Public	External	While a low risk, failure of organization's Products or Services could impact on public safety.
Certification Bodies	External	Assess conformity of organization to ISO 9001:2015 and so must be kept notified of changes to the QMS.
Competitors	External	Provide challenges to organization's ability to provide Products or Services to customers.

ORGANIZATIONAL RISKS

Example

Risk	Likelihood	Severity	Mitigation
Business interruption due to natural disaster	Low	High	Develop Business Continuity Plan
Business interruption due to labor dispute	Low	Low	Comply with UAE labor law
Critical equipment failure	Medium	High	Develop Backup plan
Product recall	Medium	High	Focus of strong QA & QA, and verification & validation of product before delivery to customer
Loss of critical supplier(s)	Medium	High	Develop dual sourcing
Loss of critical personnel	High	Medium	Focus required on succession development on each critical position

4.3 Determining the scope of the quality management system

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization shall consider:

a) the external and internal issues

b) the requirements of relevant interested parties

c) the products and services of the organization.

- Scope shall be documented
- State the types of products and services covered
- Provide justification for any exclusion

4.4 Quality management system and its processes

The organization shall determine the processes needed for the quality management system and their application throughout the organization,

and shall;

a) determine the **inputs required** and the **outputs expected** from these processes

b) determine **the sequence and interaction** of these processes;

c) determine and apply the **criteria** and methods

d) determine the **resources** needed for these processes and ensure their availability;

e) assign the **responsibilities** and **authorities** for these processes;

f) address the **risks** and **opportunities**

g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;

h) improve the processes and the quality management system.

5 Leadership

New description of responsibilities

5.1 Leadership and commitment

5.1.1 Leadership and commitment with respect to the QMS

- More proactive role of management
- Integration of QMS requirements into **business processes**

5.1.2 Customer focus

- Identify and address risks that can affect conformity of products and services and customer satisfaction

TOP MANAGEMENT COMMITMENT

Top management shall demonstrate leadership and commitment by:

a) taking ***accountability*** for the effectiveness of the QMS;

b) ensuring that the ***quality policy*** and ***quality objectives*** are established

c) ensuring the ***integration*** of the ***QMS requirements*** into the **business processes**;

d) promoting the use of the ***process approach*** and ***risk-based thinking***;

e) ensuring that the ***resources availability***

f) communicating the ***importance of effective QMS***;

g) ensuring that the QMS achieves its ***intended results***;

h) engaging, directing and supporting ***persons to contribute*** to the effectiveness of the QMS;

i) promoting ***improvement***;

j) supporting other relevant ***management roles***

CUSTOMER FOCUS

Top management shall demonstrate leadership and commitment by ensuring:

a) customer and applicable ***statutory and regulatory requirements*** are determined, understood and consistently met;;

b) the ***risks and opportunities*** that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c) the focus on enhancing ***customer satisfaction*** is maintained.

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QUALITY POLICY

5.2.1 Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:

a) is appropriate to the purpose and context of the organization and supports its strategic direction;

b) provides a framework for setting quality objectives;

c) includes a commitment to satisfy applicable requirements;

d) includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the quality policy

The quality policy shall:

a) be available and be maintained as documented information;

b) be communicated, understood and applied within the organization;

c) be available to relevant interested parties, as appropriate.

ORGANIZATIONAL ROLES, RESPONSIBILITIES AND AUTHORITIES

Top management shall ensure that the responsibilities and authorities for relevant roles are *assigned*, *communicated* and *understood* within the organization.

Top management shall assign the responsibility and authority for:

a) ensuring that the *QMS conforms to the requirements* of Standard;

b) ensuring that the *processes are delivering* their intended outputs;

c) reporting on the *performance of the QMS* and on *opportunities for improvement*

d) ensuring the promotion of *customer focus* throughout the organization;

e) ensuring that the *integrity of the QMS is maintained* when changes to the QMS are planned and implemented.

6 Planning for the QMS

6.1 Actions to address risks and opportunities

Planning to consider:

- **issues** referred to in clause 4.1
- **requirements** in clause 4.2
- actions to address **risks** and **opportunities**

Could include avoidance, mitigation, elimination or acceptance

6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

When planning for the QMS , the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s);

b) enhance desirable effects;

c) prevent, or reduce, undesired effects;

d) achieve improvement.

The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement the actions into its QMS processes ;

2) evaluate the effectiveness of these actions.

NOTE 1

Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2

Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

6.2 Quality objectives and planning to achieve them

The organization shall establish quality objectives at relevant functions, levels and processes needed for the QMS.

The quality objectives shall:

a) be consistent with the quality policy;

b) be measurable;

c) take into account applicable requirements;

d) be relevant to conformity of products and services and to enhancement of customer satisfaction;

e) be monitored;

f) be communicated;

g) be updated as appropriate.

The organization shall maintain documented information on the quality objectives.

6.2 Quality objectives and planning to achieve them

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

a) what will be done;

b) what resources will be required;

c) who will be responsible;

d) when it will be completed;

e) how the results will be evaluated.

6.3 Planning of changes

The organization shall consider:

a) the purpose of the changes and their potential consequences;

b) the integrity of the QMS;

c) the availability of resources;

d) the allocation or reallocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

7.1.2 People

NEW

7.1.3 Infrastructure

7.1.4 Environment for the operation of processes

7.1.5 Monitoring and measuring resources

NEW

7.1.6 Organizational knowledge

NEW

- Necessary for the operation of the QMS and its **processes**
- Knowledge shall be **maintained** and **made available** as necessary

7.1 Resources

People

Infrastructure

Environment for the operation of processes

Monitoring and measuring resources

ORGANIZATIONAL KNOWLEDGE

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by

experience. It is information that is used and shared to achieve the organization's objectives.

NOTE 2 Organizational knowledge can be based on:

a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from

failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);

b) external sources (e.g. standards; academia; conferences; gathering knowledge f rom customers o r

external providers).

7.2 Competence

The organization shall:

a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of QMS;

b) ensure that these persons are competent on the basis of appropriate education, training, or experience;

c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

d) retain appropriate documented information as evidence of competence.

NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

7.3 Awareness

The organization shall ensure that persons doing work under the organization's control are aware of:

a) the quality policy;

b) relevant quality objectives;

c) their contribution to the effectiveness of the QMS, including the benefits of improved performance;

d) the implications of not conforming with the QMS requirements.

7.4 Communication

The organization shall determine the internal and external communications relevant to the QMS, including:

a) on what it will communicate;

b) when to communicate;

c) with whom to communicate;

d) how to communicate;

e) who communicates.

7.5 Documented information

The organization's quality management system shall include:

a) documented information required by this International Standard;

b) documented information determined by the organization as being necessary for the effectiveness of QMS

NOTE

The extent of documented information for a quality management system can differ from one organization to another due to:

— the size of organization and its type of activities, processes, products and services;

— the complexity of processes and their interactions;

— the competence of persons.

7.5.2 Creating and updating

When creating and updating documented information, the organization shall ensure appropriate:

a) identification and description (e.g. a title, date, author, or reference number)

b) format (e.g. language, software version, graphics)

c) media (e.g. paper, electronic);

d) review and approval for suitability and adequacy.

7.5.3 Control of documented information

Documented information required shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

For the control of documented information, the organization shall address the following activities, as applicable:

a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;

c) control of changes (e.g. version control);

d) retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of QMS shall be identified as appropriate, and be controlled.

Documented information retained as evidence of conformity shall be protected from unintended alterations.

8 Operation

8.1 Operational planning and control

8.2 Determination of requirements for products and services

8.3 Design and development of products and services

8.4 Control of externally provided products and services

8.5 Production and service provision

8.6 Release of goods and services

8.7 Control of nonconforming process outputs, products and services

Process and risk-based approach

8.1 Operational planning and control

The organization shall plan, implement and control the processes needed to meet the requirements, by:

a) determining the requirements for the products and services;

b) establishing criteria for:

   1. the processes;
   2. the acceptance of products and services;

c) determining the resources needed to achieve conformity to the product and service requirements;

d) implementing control of the processes in accordance with the criteria;

e) determining, maintaining and retaining documented information to the extent necessary:

   1. to have confidence that the processes have been carried out as planned;
   2. to demonstrate the conformity of products and services to their requirements.

The organization shall ensure that outsourced processes are controlled

8.2 Requirements for products and services

Customer communication

a) *providing information* relating to products and services;

b) *handling enquiries*, contracts or orders, including changes;

c) obtaining *customer feedback* relating to products and services, including customer complaints;

d) handling or controlling *customer property*;

e) establishing specific requirements for *contingency actions*, when relevant.

Determining the requirements for products and services

a) the requirements for the products and services are defined, including:

   1. any applicable *statutory and regulatory requirements*;
   2. those *considered necessary* by the organization;

b) the organization *can meet the claims* for the products and services it offers.

8.2.3 Review of the requirements for products and services

The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers.

The organization shall conduct a review before committing to supply products and services to a customer, to include:

a) requirements *specified by the customer*, including the requirements for delivery and post delivery activities;

b) requirements *not stated by the customer*, but necessary for the specified or intended use, when known;

c) requirements *specified by the organization*;

d) *statutory and regulatory* requirements applicable to the products and services;

e) *contract or order requirements* differing from those previously expressed.

The organization shall ensure that contract or order requirements differing from those previously defined are *resolved*.

The customer's requirements shall be *confirmed* by the organization *before acceptance*, when the customer does not provide a documented statement of their requirements.

8.2.3 Review of the requirements for products and services

The organization shall retain documented information, as applicable:

a) on the results of the review;

b) on any new requirements for the products and services.

Changes to requirements for products and services

When the requirements for products and services are changed

The organization shall ensure that;

a) relevant documented information is amended, and

b) that relevant persons are made aware of the changed requirements,

8.3 Design and development of products and services

The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services

8.3.2 Design and development planning

In determining the stages and controls for design and development, the organization shall consider:

a) the nature, duration and complexity

b) the required process stages,

c) the required verification and validation activities;

d) the responsibilities and authorities involved;

e) the internal and external resource

f) the need to control interfaces between persons involved

g) the need for involvement of customers and users

h) the requirements for subsequent provision of products and services;

i) the level of control expected for the design and development process by customers and other relevant interested parties;

j) the documented information needed

8.3.3 Design and development inputs

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

a) functional and performance requirements;

b) *information derived* from previous similar design and development activities;

c) *statutory and regulatory* requirements;

d) *standards or codes of practice* that the organization has committed to implement;

e) *potential consequences of failure* due to the nature of the products and services.

Inputs shall be adequate for design and development purposes, complete and unambiguous.

Conflicting design and development inputs shall be resolved.

The organization shall retain documented information on design and development inputs.

8.3.4 Design and development controls

The organization shall apply controls to the design and development process to ensure that:

a) the *results to be achieved are defined*;

b) *reviews are conducted* to evaluate the ability of the results of design and development to meet requirements;

c) *verification activities are conducted* to ensure that the design and development outputs meet the input requirements;

d) *validation activities are conducted* to ensure that the resulting products and services meet the requirements for the specified application or intended use;

e) any *necessary actions are taken* on problems determined during the reviews, or verification and validation activities;

f) *documented information* of these activities is retained.

8.3.5 Design and development outputs

The organization shall ensure that design and development outputs:

a) *meet the input* requirements;

b) are *adequate* for the subsequent processes for the provision of products and services;

c) *include or reference monitoring and measuring requirements*, as appropriate, and acceptance criteria;

d) *specify the characteristics* of the products and services that are essential for their intended purpose and their safe and proper provision.

The organization shall retain documented information on design and development outputs.

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8.3.6 Design and development changes

The organization shall *identify, review and control changes* made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is *no adverse impact* on conformity to requirements.

The organization shall retain documented information on:

a) design and development changes;

b) the results of reviews;

c) the authorization of the changes;

d) the actions taken to prevent adverse impacts.

8.4 Control of externally provided processes, products and services

The organization shall ensure that externally provided processes, products and services conform to requirements.

The organization shall determine the *controls* to be applied to externally provided processes, products and services when:

a) products and services from external providers are *intended for incorporation* into the organization's *own products and services*;

b) products and services are provided *directly to the customer(s)* by external providers on behalf of the organization;

c) *a process, or part of a process*, is provided by an external provider as a result of a decision by the organization.

The organization shall determine and apply *criteria for the evaluation*, *selection*, *monitoring of performance*, and *re-evaluation of external providers*, based on their ability to provide processes or products and services in accordance with requirements. The organization shall *retain documented information* of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and extent of control

The organization shall:

a) ensure that externally provided processes remain *within the control* of its QMS;

b) define both the controls that it intends to apply to an *external provider* and those it intends to apply to the *resulting output*;

c) take into consideration:

   1) the *potential impact* of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;

   2) the effectiveness of the *controls applied by the external provider*;

d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 Information for external providers

The organization shall ensure the *adequacy* of requirements *prior to their communication* to the external provider.

The organization shall communicate to external providers its requirements for:

a) the processes, products and services to be provided

b) the approval of:

   1) products and services;

   2) methods, processes and equipment;

   3) the release of products and services;

c) *competence*, including any required qualification of persons;

d) the external providers' *interactions with the organization;*

e) control and monitoring of the external providers' performance to be applied by the organization;

f) *verification or validation activities* that the organization, or its customer, intends to perform at the external providers' premises.

8.5.1 Control of production and service provision

Controlled conditions shall include, as applicable:

a) the availability of documented information that defines:

   a) 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

   b) 2) the results to be achieved;

b) the availability and use of suitable monitoring and measuring resources;

c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

d) the use of suitable infrastructure and environment for the operation of processes;

e) the appointment of competent persons, including any required qualification;

f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) the implementation of actions to prevent human error;

h) the implementation of release, delivery and post-delivery activities

8.5.2 Identification and traceability

8.5.3 Property belonging to customers or external providers

8.5.4 Preservation

8.5.5 Post-delivery activities

8.5.6 Control of changes

8.6 Release of products and services

The release of products and services to the customer shall not proceed until the *planned arrangements* have been *satisfactorily completed*, unless otherwise approved by a relevant authority and, as applicable, by the customer.

The organization shall retain documented information on the release of products and services.

The documented information shall include:

a) evidence of conformity with the acceptance criteria;

b) traceability to the person(s) authorizing the release.

8.7 Control of nonconforming outputs

The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their *unintended use or delivery*.

The organization shall take *appropriate action* after identification of non conformity. This shall also apply to *detection after delivery of products, during or after the provision* of services.

The organization shall deal with nonconforming outputs in one or more of the following ways:

a) correction;

b) segregation, containment, return or suspension of provision of products and services;

c) informing the customer;

d) obtaining authorization for acceptance under concession.

Conformity to the requirements shall be *verified when corrected*.

The organization shall retain documented information that describes the nonconformity, describes the actions taken, any concessions obtained and identifies the authority deciding the action in respect of the nonconformity.

ISO 9001:2015 High-Level Structure

NEW CLAUSE

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

- Determine **what** to monitor and measure
- Determine **methods** for monitoring, measurement, analysis and evaluation
- Evaluate the **quality performance** and effectiveness of the QMS

9.1.2 Customer satisfaction

- Obtain information on customer **views and opinions** of the organization and its products and services.

NEW

9.1.3 Analysis and evaluation

- Uses of results of analysis and evaluation are listed in detail.
- It includes input to management reviews.

NEW

9.1 Monitoring, measurement, analysis and evaluation

The organization shall determine:

a) what needs to be monitored and measured;

b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;

c) when the monitoring and measuring shall be performed;

d) when the results from monitoring and measurement shall be analyzed and evaluated.

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.

NOTE

Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

9.1.3 Analysis and evaluation

The results of analysis shall be used to evaluate:

a) *conformity* of products and services;

b) the degree of customer satisfaction;

c) the performance and effectiveness of the QMS

d) if planning has been implemented effectively;

e) the effectiveness of actions taken to address risks and opportunities;

f) the performance of external providers;

g) the need for improvements to the QMS.

9.2 Internal audit

The organization shall conduct internal audits at planned intervals

The organization shall:

a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

b) define the audit criteria and scope for each audit;

c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

d) ensure that the results of the audits are reported to relevant management;

e) take appropriate correction and corrective actions without undue delay

f) retain documented information as evidence

9.3 Management review

"Top management shall review the organization's QMS, at planned intervals, to ensure;

a) its continuing suitability,

b) adequacy,

c) effectiveness and

d) alignment with the strategic direction of the organization"

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9.3.2 Management review inputs

a) the status of actions from *previous management reviews*;

b) changes in *external and internal issues* that are relevant to the quality management system;

c) information on the performance and effectiveness of QMS, including trends in:

   1) *customer satisfaction* and *feedback from relevant interested parties*;
   2) the extent to which *quality objectives* have been met;
   3) process performance and conformity of products and services;
   4) nonconformities and corrective actions;
   5) monitoring and measurement results;
   6) audit results;
   7) the performance of *external providers*;

d) the adequacy of resources;

e) the effectiveness of actions taken to address *risks and opportunities*

f) opportunities for *improvement.*

9.3.3 Management review outputs

The outputs of the management review shall include decisions and actions related to:

a) opportunities for improvement;

b) any need for changes to the quality management system;

c) resource needs.

The organization shall retain *documented information* as evidence of the results of management reviews.

10 IMPROVEMENT

10.1 General

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

These shall include:

a) improving products and services to meet requirements as well as to address future needs and expectations;

b) correcting, preventing or reducing undesired effects;

c) improving the performance and effectiveness of QMS

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.2 Nonconformity and corrective action

When a nonconformity occurs, including any arising from complaints, the organization shall:

a) react to the nonconformity and, as applicable:
   1) take action to control and correct it;
   2) deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
   1) reviewing and analyzing the nonconformity;
   2) determining the causes of the nonconformity;
   3) determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the quality management system, if necessary.

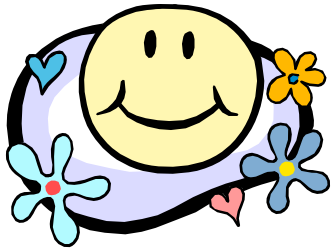
Corrective actions shall be appropriate to the effects of the nonconformities encountered

The organization shall retain *documented information* as evidence

10.3 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the QMS.

The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.



Thank You!!

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