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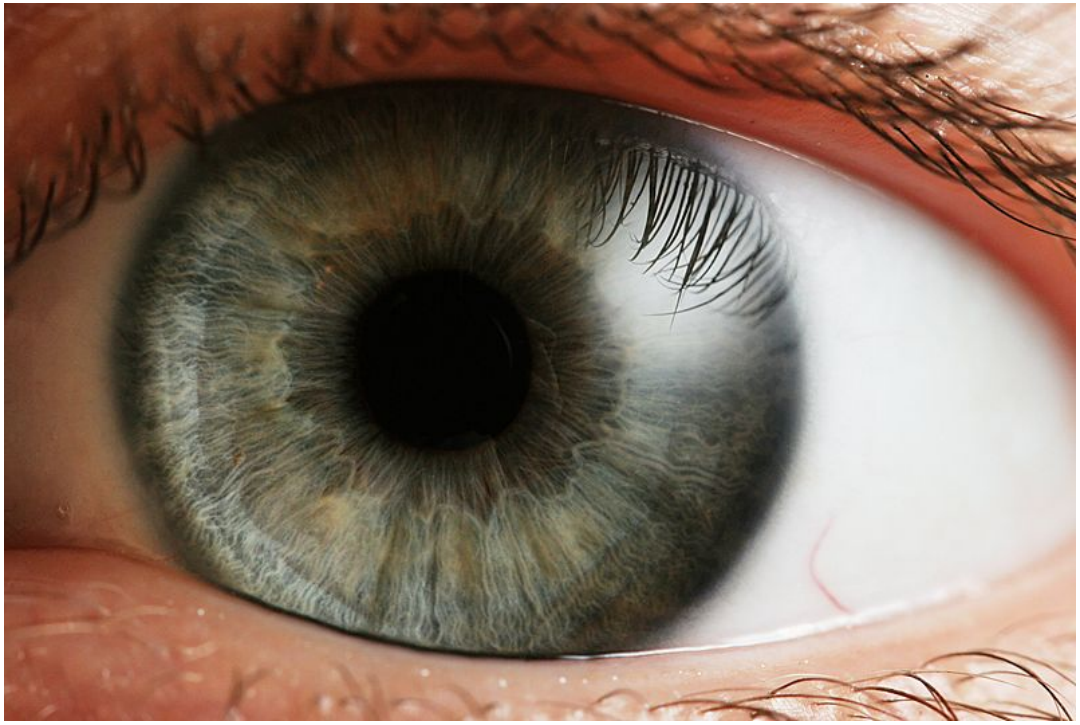
ISO 9001:2015



A look at the Revised Standard

Quotes

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"Quality management is a journey, not just a destination."

Emily Rhinehart

"If you can't explain it simply, you don't understand it well enough."

Albert Einstein

"It is not necessary to change. Survival is not mandatory."

W. Edwards Deming

"Quality is not an act. It is a habit."

Aristotle

"The definition of insanity is doing the same thing over and over again and expecting different outcomes."

Albert Einstein

Quotes

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"The idea of control and improvement are often confused with one another. That is because quality control and quality improvement are inseparable."

Ishihara

"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 means doing it right when no one is looking."

Henry Ford

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

Tom Peters

"Quality is not what happens when what you do matches your intentions. It is what happens when what you do matches your customers expectations."

Guaspan

Quotes

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"It takes less time to do the thing right, than it does to explain why you did it wrong."

Henry Wadswarth Longfellow

"Quality is Magical, but Quality doesn't Magically happen."

Chuck Mignosa

"When a process works its Magic. When a process fails its Tragic."

Chuck Mignosa

"The Race for Quality has no finish line, so it is more like a Death March."

Unknown

Goal of this Session

- Discuss the major changes to the Standard
- No discussion of TC 176 or subcommittees
- Knowledge of ISO 9001:2008 is assumed
- Many unchanged clauses are not addressed

- Commentary: hopefully kept to a minimum

Competency Domains

1. Fundamental principles of quality management.
2. Understand how can high-level structure apply to your QMS
3. Understand, interpret and plan the ISO 9001 changes.
4. Plan the QMS transition based on ISO 9001
5. Understand the differences between ISO 9001:2008 and ISO 9001:2015
6. Continual improvement of a QMS based on ISO 9001:2015

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New Clause Layout

ISO 9001:2008	ISO 9001:2015
4 Quality Management System	**4** Context of the Organization
5 Management Responsibility	**5** Leadership **6** Planning
6 Resource Management	**7** Support
7 Product Realization	**8** Operation **9** Performance Evaluation
8 Measurement, Analysis, Improvement	**10** Improvement

Correlation of ISO 9001:2008 and 2015

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ISO 9001:2008	ISO 9001:2015
4 Quality management system	4 Quality management system
4.1 General requirements	4.4 Quality management system and its Processes
4.2 Documentation requirements	7.5 Documented information
4.2.1 General	7.5.1 General
4.2.2 Quality manual	4.3 Determining the scope of the quality management system 7.5.1 General 4.4 Quality management system and its processes
4.2.3 Control of documents	7.5.2 Creating and updating 7.5.3 Control of documented information
4.2.4	7.5.2 Creating and updating 7.5.3 Control of documented information

Correlation of ISO 9001:2008 and 2015

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ISO 9001:2008	ISO 9001:2015
5 Management responsibility	5 Leadership
5.1 Management commitment	5.1 Leadership and commitment 5.1.1 Leadership and commitment for the quality management system
5.2 Customer focus	5.1.2 Customer focus
5.3 Quality policy	5.2 Quality policy
5.4 Planning	6 Planning for the quality management system
5.4.1 Quality objectives	6.2 Quality objectives and planning to achieve them
5.4.2 Quality management system planning	6 planning for the quality management system 6.1 Actions to address risks and opportunities 6.3 Planning of changes

Correlation of ISO 9001:2008 and 2015

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ISO 9001:2008	ISO 9001:2015
5.5 Responsibility, authority and communication	5 Leadership
5.5.1 Responsibility and authority	5.3 Organizational roles, responsibilities and authorities
5.5.2 Management representative	**Title Removed** 5.3 Organizational roles, responsibilities and authorities
5.5.3 Internal communication	7.4 Communication
5.6 Management review 5.6.1 General 5.6.2 Review input	9.3 Management review

Correlation of ISO 9001:2008 and 2015

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ISO 9001:2008	ISO 9001:2015
6 Resource management	7.1 Resources
6.1 Provision of resources	7.1.1 General 7.1.2 People
6.2 Human resources	**Title Removed** 7.2 Competence
6.2.1 General	7.2 Competence
6.2.2 Competence, training and awareness	7.2 Competence 7.3 Awareness
6.3 Infrastructure	7.1.3 Infrastructure
6.4 Work environment	7.1.4 Environment for the operation of processes

Correlation of ISO 9001:2008 and 2015

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ISO 9001:2008	ISO 9001:2015
7 Product realization	8 Operation
7.1 Planning of product realization	8.1 Operational planning and control
7.2 customer-related processes	8.2 Determination of requirements for products and services
7.2.1 Determination of requirements related to the product	8.2.2 Determination of requirements related to products and services
7.2.2 Review of requirements related to the product	8.2.3 Review of requirements related to the products and services
7.2.3 Customer communication	8.2.1 Customer communication
7.3 Design and development	8.5 Design and development of products and services
7.3.1 Design and development planning	8.3 Design and development of products and services 8.3.1 General 8.3.2 Design and development planning

Correlation of ISO 9001:2008 and 2015

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ISO 9001:2008	ISO 9001:2015
7.3 .2Design and development inputs	8.3.3 Design and development inputs
7.3.3 Design and development outputs	8.3.5 Design and development outputs
7.3.4 Design and development review 7.3.5 Design and development verification 7.3.6 Design and development validation	8.3.4 Design and development controls
7.3.7 Control of design and development changes	8.3.6 Design and development changes
7.4 Purchasing	8.4 Control of externally provided products and services
7.4.1 Purchasing process	8.4.1 General 8.4.2 Type and extent of control of external provisions
7.4.2 Purchasing information	8.4.3 Information for external providers

Correlation of ISO 9001:2008 and 2015

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ISO 9001:2008	ISO 9001:2015
7.4.3 Verification of purchased products	8.6 Release of products and services
7.5 Production and services provision	8.5 Production and services provision
7.5.1 Control of productions and services provision	8.5.1 Control of production and services provision 8.5.5 Post-delivery activities
7.5.2 Validation of processes for production and services provision	8.5.1 Control of production and services provision
7.5.3 Identification and traceability	8.5.2 Identification and traceability
7.5.4 Customer property	8.5.3 Property belonging to customers or external providers
7.5.5 Preservation of Product	8.5.4 Preservation
7.6 Control of monitoring and measuring equipment	7.1.5 Monitoring and measuring resources

Correlation of ISO 9001:2008 and 2015

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ISO 9001:2008	ISO 9001:2015
8.0 Measurement, analysis and improvement	9.1 Monitoring, measurement, analysis and evaluation
8.1 General	9.1.1 General
8.2 Monitoring and measurement	9.1 Monitoring, measurement, analysis and evaluation
8.2.1 Customer satisfaction	9.1.2 Customer satisfaction
8.2.2 Internal audit	9.2 Internal audit
8.2.3 Monitoring and measurement of processes	9.1.1 General
8.2.4 Monitoring and measurement of product	8.6 Release of products and services

Correlation of ISO 9001:2008 and 2015

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ISO 9001:2008	ISO 9001:2015
8.3 Control of nonconforming product	8.7 control of nonconforming process outputs, products and services
8.4 Analysis of data	9.1.3 Analysis and evaluation
8.5 Improvement	10 Improvement
8.5.1 Continual improvement	10.1 General 10.3 Continual improvement
8.5.2 Corrective action	10.2 Nonconformity and corrective action
8.5.3 Preventive action	**Clause Removed**
	6.1 Actions to address risks and opportunities (see 6.1.1, 6.1.2)

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Change 8 Quality Principles to 7

Current 8 QMPs	Proposed 7 QMPs
1. Customer focus	1. Customer focus
2. Leadership	2. Leadership
3. Involvement of people	3. Engagement and competence of people
4. Process approach	4. Process approach
5. System approach to management	5. Improvement
6. Continual improvement	6. Informed decision making
7. Factual approach to decision making	7. Relationship management
8. Mutually beneficial supplier relationships	

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0.3 Significant Changes

1. Redrafting to make the Standard more generic and more easily applicable by service industries
   - Replace Product with Goods and Services
   - Clauses revised to reduce the prescriptive nature of some requirements which were originally derived from practices in the hardware sector. (eg. 7.3 and 7.6)

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0.3 Significant Changes Cont.

2.Context of the Organization

3. Process Approach

4. Risk and Preventive Action

- Risk Analysis concepts are introduced
- Preventive Action is no longer a clause (8.5.3)
- Preventive Action concepts are deployed throughout the Standard (eg. New clauses 4.1 and 6.1)
- **No requirement for formal risk management**

Some Areas & Types of Risk

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AREAS

- Personnel risks
- Product risks
- Process risks
- Supply chain risks
- Regulatory risks
- Reputation risk
- Financial risks

Two types of Risk

Qualitative

And

Quantitative

Many analysis methods are available

Risks can be internally or externally generated

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0.3 Significant Changes Cont.

5.Documented Information

- Terms Document and Record have been replaced throughout by **"Documented Information"**

6. Control of External Provision of Goods and Services
7. Exclusions eliminated – **Now Applicability**
8. Supplier eliminated – **External Provider**

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3 Terms and Definitions

(These may be included in ISO 9001 or in ISO 9000)

1. Organization
2. Interested Party
3. Requirement
4. Management System
5. Top Management
6. Effectiveness
7. Policy
8. Objective
9. Risk
10. Competence
11. Documented Information
12. Process
13. Performance
14. Outsource
15. Monitoring
16. Measurement
17. Audit
18. Conformity
19. Nonconformity
20. Correction
21. Corrective Action
22. Continual Improvement
23. External Provider
24. Applicability

4.1 Understanding the Organization and its Context

- Determine internal and external issues that are relevant to its purpose and strategic direction
- Update such determinations when needed.
- Consider issues arising from
  - Changes, trends that can have an impact on objectives
  - Relationships with & perceptions/vales of interested parties
  - Governance issues, strategic priorities, internal policies
  - Resource availability, priorities, technological change

[Consider an Organizational Profile]

Company Structure

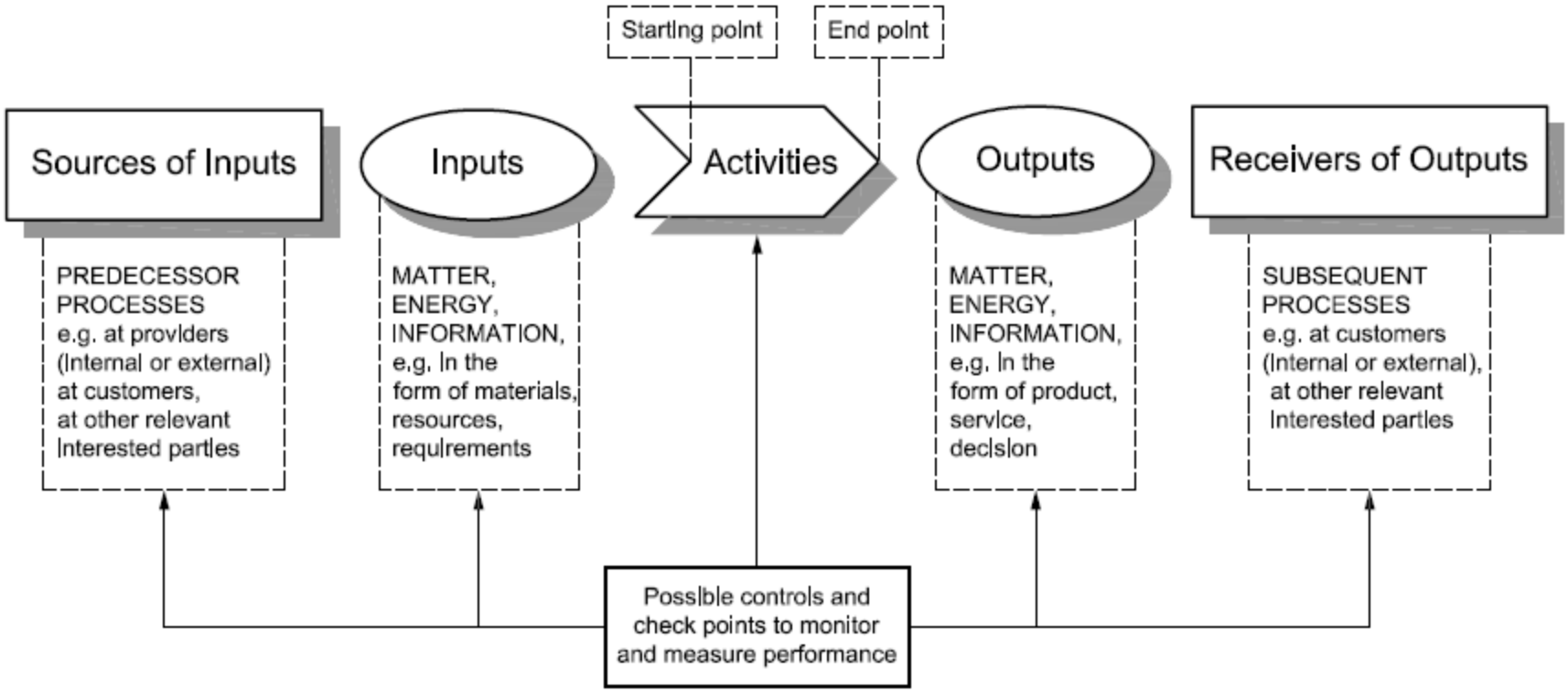
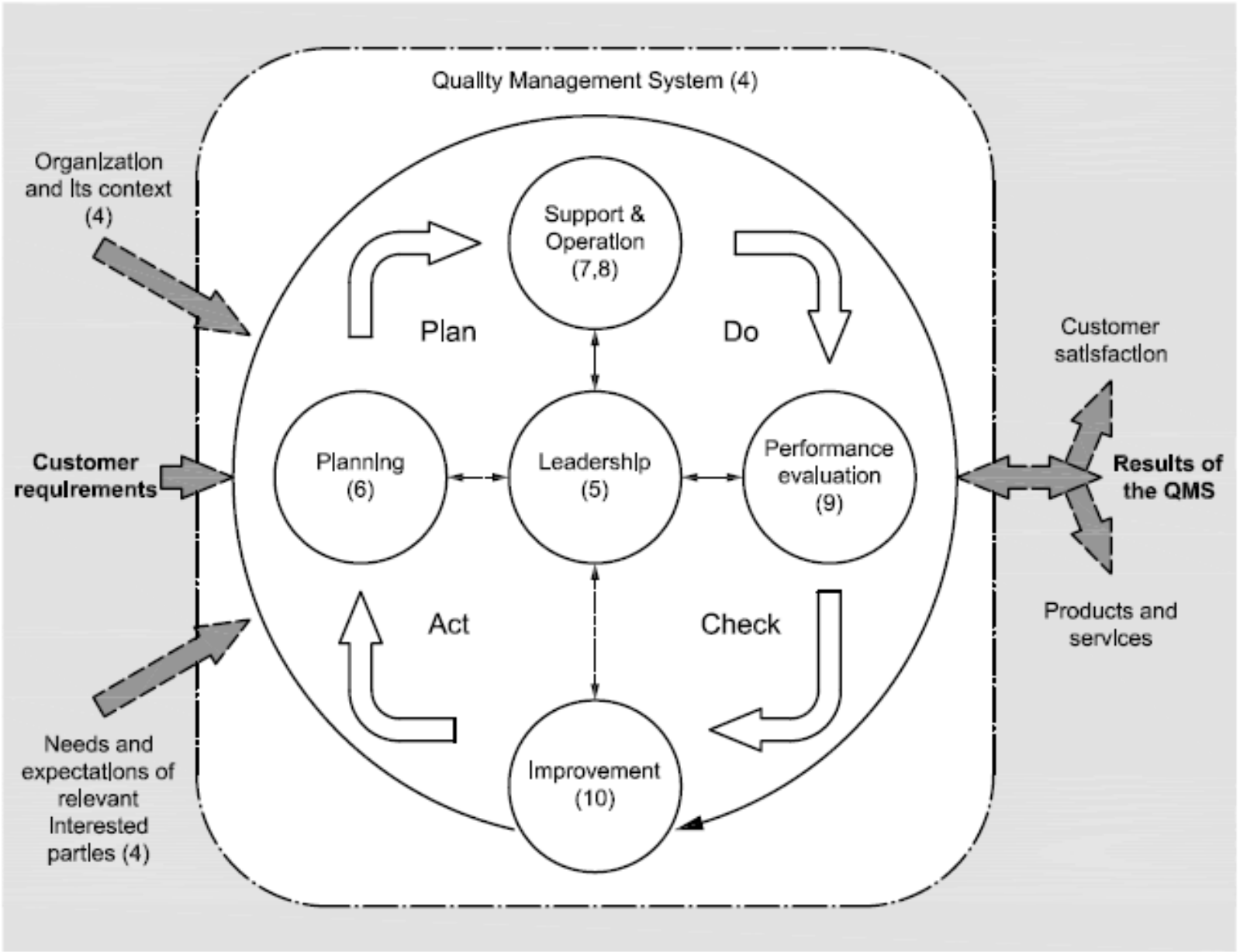


Figure 1 — Schematic representation of the elements of a single process

SIPOC – Supplier – Inputs – Processes – Outputs - Customer

Plan – Do – Check - Act



Note: Numbers In brackets refer to the clauses In thls Internatlonal Standard.

Company

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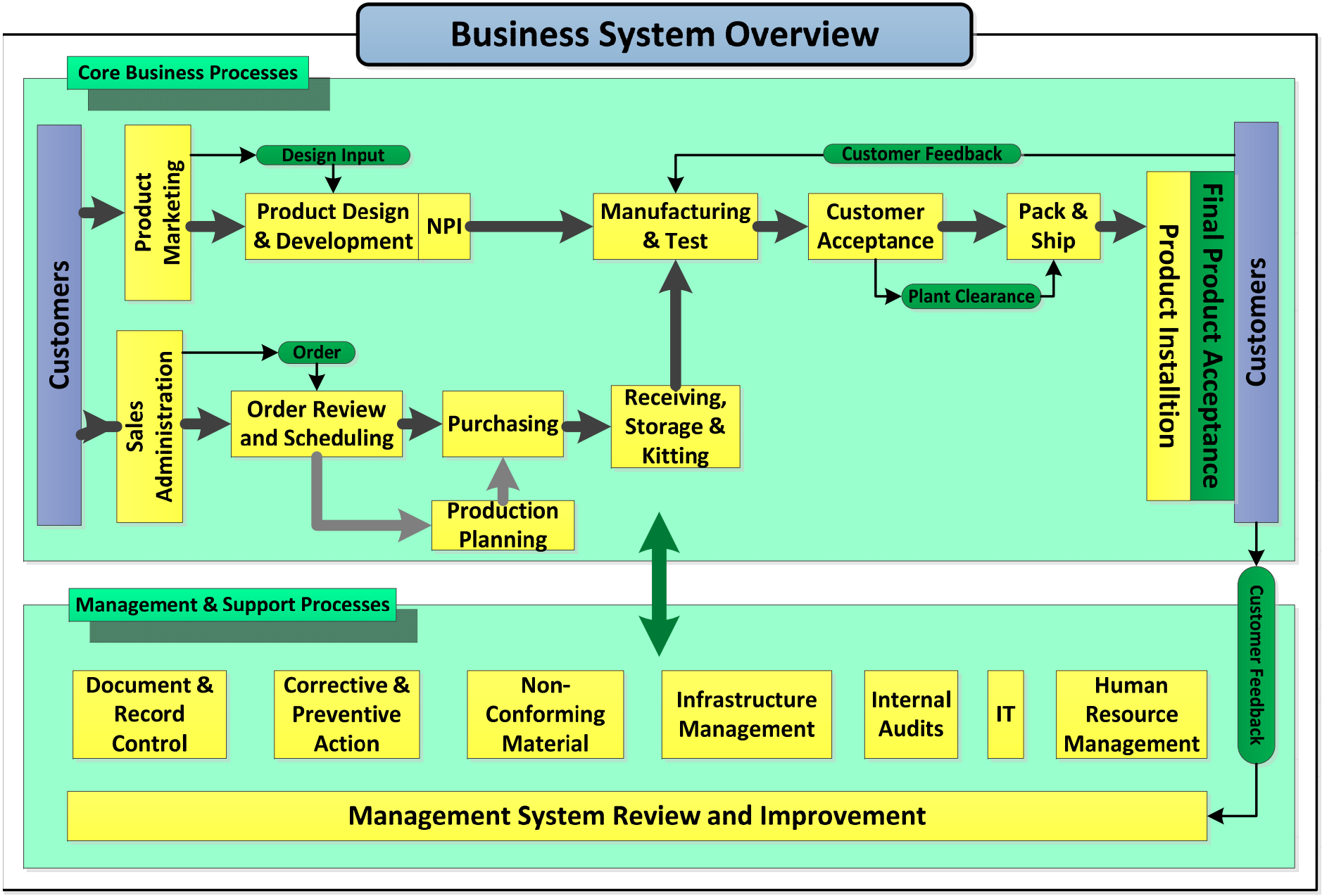

4.2 Understanding the Needs and Expectations of Interested Parties

- Determine the interested parties that are relevant to the QMS and the requirements of those parties
- Update such determinations when needed.
- Consider the following relevant interested parties:
  - Direct Customers
  - End Users
  - Suppliers, distributors retailers or others involved in the supply chain
  - Regulators and others

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4.4.2 Process Approach

The organization shall apply a process approach

a) Determine the processes…

b) Determine the inputs & outputs from each process

c) Determine their sequence and interaction

d) Determine the risks to conformity and customer satisfaction if unintended outputs are delivered or process interaction is ineffective

e) Determine criteria, methods, measurements and related performance indicators needed to ensure that both the operation and control of these processes are effective

4.4.2 Process Approach (cont.)

f) Determine the resources and ensure availability

g) Assign responsibilities and authorities

h) Implement actions required to achieve results

i) Monitor, analyze……these processes ensuring they continue to deliver the intended outputs

j) Ensure improvement of these processes.

5.1 Leadership and Commitment

a.) Ensure policies and G&O are compatible with the strategic direction of the organization.

c.) Ensuring the integration of QMS requirements into the organization's business processes.

d.) Promoting awareness of the Process Approach

h.) Engaging, directing, supporting persons to contribute to the effectiveness of the QMS

i.) Promoting improvement and innovation

j.) Supporting other managers to demonstrate leadership in their areas of responsibility.

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5.1 Leadership and Commitment cont.

Top Management shall demonstrate leadership and commitment with respect to customer focus by ensuring that

b.) the risks which can affect conformity of goods and services and customer satisfaction are identified and addressed **[FMEA]**

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5.3 Organizational Roles, Responsibilities and Authorities

Top Management shall be accountable for the effectiveness of the quality management system and shall assign the responsibility and authority for…

Note that a defined "Management Representative" has been removed. (although the tasks remain)

6.1 Address Risks and Opportunities

Determine Risks and opportunities that need to be addressed to: **[SWOT]**

a.) Assure the QMS can achieve its intended outcomes

b.) …achieve conformity & customer satisfaction

c.) Prevent or reduce undesired effects

The organization shall plan actions to address these R&O and integrate actions into the QMS and evaluating the effective of actions **[FMEA]**

6.2 Quality Objectives and Planning

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

a.) What will be done
b.) What resources are required
c.) Who will be responsible
d.) When it will be completed
e.) How results will be evaluated

[SMART goals]

7.1.4 Monitoring, Measuring Devices

In its attempt to make "calibration" requirements less manufacturing-centric, many of the requirements of ISO 9001:2008 have been removed.

Auditors will have to have a higher level of understanding of calibration and metrology rather than relying on the Standard's requirements

Customer surveys etc. can now be considered as a monitoring device

7.1.5 Knowledge

Competency Requirements remain, but Knowledge is new.

Determine the knowledge necessary for the operation of the QMS and its processes.

7.3 Awareness

Persons doing work under the organization's control shall be aware of

a.) The Quality Policy

b.) Relevant quality objectives

c.) Their contribution to the effectiveness of the QMS, including the benefits of improved quality performance

d.) The implications of not conforming with QMS requirements

7.5.2 Creating & Updating (documentation)

The organization shall ensure:

a.) Identification and description (eg. Title, date, author, or reference number)

b.) Format (language, software version, graphics) and media (paper, electronic)

c.) Review and approval for suitability and adequacy

Permissions and version control are addressed to also cover electronic documents

8.3 Operational Planning Process

Implement a process to determine the following:

b.) Actions to identify and address the risks related to achieving conformity of goods and services to requirements. **[FMEA]**

Note: This can be referred to as a quality plan

8.4 Control of External Provision of Goods and Services

No longer "Purchasing" and language extends to the realm of outsourcing and partnerships, managed services etc.

Exercise appropriate controls based on risks

The Organization shall monitor their performance and keep documented information

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8.5 Development of Goods and Services

8.5.1 Development Processes

Consistent with the Process Approach and taking into account risks, opportunities **[DFMEA, DVP&R]**

8.5.2 Development Controls

8.5.3 Development Transfer (to production etc.)

Verification and Validation and Design Review requirements are de-emphasized (perhaps as service design is considered)

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8.6 Production of Goods, Provision of Services

8.6.1 Control of production of goods and provision of services

i.) prevention of nonconformity due to human error, such as unintentional mistakes and intentional rule violations ***[Poke Yoke]***

8.6.2 Identification and Traceability

8.6.3 Property belonging to customers or external providers

8.6.4 Preservation of Goods and Services

8.6.5 Post Delivery Activities

8.6.6 Control of Changes

9 Performance Evaluation

9.1.1 Evaluate the performance of processes (4.4)

Evaluate the performance and effectiveness of the Quality Management System ***[KPIs]***

9.1.2 As appropriate, shall obtain data relating to customer feedback and customer views and perceptions of the organization, its processes and its goods and services.

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9.2 Internal Audit

"status and importance of processes" is replaced with consideration of quality objectives, the importance of the processes concerned, the related risks

d.) Ensure that the results of the audit are reported to relevant management for evaluation

e.) Take appropriate action without undue delay

"Corrections and corrective actions….to eliminate detected nonconformities and their causes" is removed. There is no reference to nonconformances

9.3 Management Review

M.R. shall be planned and carried out taking into account the changing business environment and in alignment with the strategic direction of organization.

Information on the performance of the QMS including trends and indicators for:

1.) Nonconformities and Corrective Actions
2.) Monitoring and measurement results ***[KPIs]***
3.) Audit results
4.) Customer feedback
5.) Supplier and external provider issues
6.) Process Performance, product conformity ***[KPIs]***

9.3 Management Review - Inputs

a) **Status of action from previous MR**
b) **Changes** in external & internal issues that are **relevant to the QMS**
c) Information on the performance and effectiveness of the QMS
    1) **Customer** satisfaction & **feedback** from relevant interested parties
    2) 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) Performance of external providers
d) Adequacy of resources
e) Effectiveness of actions taken to address risks and opportunities (see 6.1)
f) **Opportunities for improvement**

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9.3 Management Review - Outputs

ISO 9001:2008	ISO 9001:2015
Improvement of the effectiveness of the QMS and its processes.	Opportunities for improvement
Improvement of product related to customer requirements	Any need for changes to the QMS
Resource needs	Resource needs

10.1 Nonconformity and Corrective Action

When a nonconformity occurs

a.) React to it, and as applicable
- take action to control and correct it,
- deal with the consequences

[containment actions]

b.) Evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere ….

…. Determine if similar nonconformities exist or could potentially occur. ***[system-wide C.A.]***

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10.2 Improvement

The organization shall improve the QMS, processes and goods and services…. through

a.) results of the analysis of data
b.) changes in the context of the organization
c.) changes in identified risk (6.1)
d.) new opportunities

The organization shall evaluate, prioritize and determine the improvement to be implemented

Note that this is not Continuous Improvement

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Annex A – Quality Management Principles

- Customer Focus
- Leadership
- Engagement of People
- Process Approach
- Improvement
- Evidence-based Decision Making
- Relationship Management

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Conclusions and Commentary

- ISO 9001:2015 is a total rewrite
- New concepts
  - Risk assessment throughout
  - Process Approach is Mandatory
  - More performance measurement – KPI
  - Strategic Planning
- Goods & Services – less manufacturing language
- More on outsourcing and partnerships
- Include the QMS principles in ISO 9001

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Conclusions and Commentary cont.

- Documents & Records - documented information
- Leadership replaces Management Responsibility
- Goods & Services – less manufacturing language
- More on outsourcing and partnerships
- Include the QMS principles in ISO 9001

Conclusions and Commentary cont.

- Risk Assessment is very good
- Strategic Planning - Integration with the business
- Keep the definitions in ISO 9001
- Continuous Improvement is replaced
- No more PDCA or structure
- A Risk: More service-friendly leads to a loss of specificity around manufacturing

Conclusions and Commentary cont.

- Need to understand more quality tools
  - FMEA (Failure Modes Effects Analysis)
  - SWOT (Strengths, Weaknesses, Opportunities, Threats)
  - KPI's (Key Performance Indicator)
  - Hoshin Planning

    A method devised to capture and cement strategic goals as well as flashes of insight about the future and develop the means to bring these into reality.
  - Poke Yoke (Error Proofing)
  - Customer Surveys
  - "Risk is the Compass" (or similar) internal audit
- What will be the impact on auditors?

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Questions

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Devos Associates Inc. (Advisors to Industry)
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And So It Begins

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