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Books

Quality Management Systems (ISO 9001:2015)

Fahmi Abu Al-Rub

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PREFACE

The agro-food sector is of major importance in many economies worldwide. In many countries the food and drink industry is a leading industrial sector. Food is a serious component of everybody daily life activities and it is recognized the contribution of safe food to a healthy life. For this reason, food safety and the protection of end consumer health is of increasing concern not only for the consumers but also for governments, professional associations and all organizations involved in the food chain from the primary production to retailers and other food businesses that put food products at the disposal of the population. Food safety is used as a scientific discipline describing the handling, preparation, and storage of food in ways that prevent food-borne illness. This includes a number of routines that should be followed to avoid potential hazards. Food safety considerations include among others, the origins of food, the practices related with food labeling, food hygiene, food additives, control of hazards and good manufacturing practices. The prevention of the multiple type of hazards with very distinctive origins requires a comprehensive and integrated approach to food safety in order to address food safety risks in every day more complex and globalized food chains. All actors in a food chain have a responsibility to ensure the safety of food products at the stages of intervention, irrespective of the nature of the activities they carry out. This book is one of a collection that aims to facilitate to the users the understanding of relevant issues related with food safety.

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DEDICATION

To,

Our beloved teams at MonoJo Biotech and the Jordan University of Science and Technology (JUST) and everyone who contributed towards the success of this series of e-books.

This series of e-books has been prepared for the FOODQA Project which was co-funded by EU through Erasmus+.

The series of e-books has been composed with passion and is available for public access to provide a high quality reference on the best practices in food quality and safety that can be used by the food industry, relevant governmental bodies, students, professors, and academics.

Our heartfelt gratitude goes towards our Jordanian and European partners who dedicated their precious time and effort towards the success of this entire project.

We dedicate this work to our beloved country, Jordan, and its people and to our European partner countries.

- Prof. Fahmi Abu Al-Rub, Dr. Penelope Shihab, and Dr. Safwan Abu Al-Rub

Chapter 1

WHAT IS QUALITY ALL ABOUT

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Chapter Objectives

- To provide the basic understanding for Quality Management Systems
- To present the evolution of ISO 9001 over time
- To underline the significance of ISO 9001 for any company

Introduction

A quality management system (QMS) is a set of policies, processes and procedures required for planning and delivering (production/development/service) in the core business area of an organization of any kind and size.

The ISO standard 9001 is a set of requirements that define the implementation and maintenance of a quality management system for a company.

Above all, ISO 9001 is a management tool for improving customer satisfaction and for assisting organizations to be more efficient.

At the same time an important characteristic of the food industry is that, in order to cope with market needs as well as legal requirements, it has to satisfy both safety and quality criteria for it products. Food quality is one of the most complex concepts because it can be assessed only in relation to food safety. A food must meet legislative, technological, and hygiene requirements, as well as transport and handling requirements, and to satisfy its intended use. The food producers must select and implement an efficient quality management and within this system they must employ quality principles and tools.

The purpose of this e-book is to assist food producers, distributors, vendors and regulators, of different backgrounds and experiences, in finding information about quality management systems and how those QMS and in particular ISO 9001:2015, could improve the customer focus of the company and its overall performance.

The main purpose of this e-book is to increase the awareness level of both industry's top management and Academia for the Standard's significance as a Business tool, as well as to enhance their knowledge on ISO 9001:2015 and to present the Standard in its new and revised version of 2015.

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QUALITY MANAGEMENT STANDARD, ISO 9001:2015

Quality Management & The International Organization for Standardization (ISO)

Quality Management (**QM**) is the use of management techniques and tools to achieve consistent quality of products and services, i.e. to achieve maximum customer satisfaction at the lowest overall cost to the organization while continuing to improve the process. Specifically, for the food industry, that also involves the knowledge and application of techniques and programs for product safety. Quality management is, thus, the totality of functions involved in the determination and achievement of quality, including quality assurance and quality control.

Quality Assurance (QA) includes all activities designed to produce products and services of appropriate quality; i.e. all those planned or systematic actions necessary to provide adequate confidence that a product or service will satisfy given needs. QA focuses on the entire quality system including suppliers and ultimate consumers of the product or service.

Quality Control (QC) has a narrower focus than quality assurance. QC focuses on the process of producing the product or service with the intent of eliminating problems that might result in defects.

Often, however, "quality assurance" and "quality control" are used interchangeably, referring to the actions performed to ensure the quality of a product, service or process.

The International Organization for Standardization (ISO), is an independent, nongovernmental organization with a membership of 163 national standards bodies, that oversees the drafting of ISO 9001 and many other international standards. ISO, through its 163 member organizations, brings together experts "to share knowledge and develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges."

Since 1946, when delegates from 25 countries met at the Institute of Civil Engineers in London and decided to create a new international organization 'to facilitate the international coordination and unification of industrial standards'.

ISO has published 21,780 International Standards and related documents, covering almost all aspects of technology and every sector of manufacturing, including food safety. Practically, ISO International Standards impact everyone, everywhere.

ISO is derived from the Greek word isos, meaning equal. Whatever the country, whatever the language, we are always ISO.

According to iso.org, "ISO 9001 is a standard that sets out the requirements for a quality management system. It helps businesses and organizations to be more efficient and improve customer satisfaction."

This is a crucial element of current reality, as in recent decades mass production with a basically push strategy has changed to a more and more pull strategy with higher customer involvement and market orientation from industry's perspective and strategy. To satisfy the requirements of the triangle quality, cost and time the field of view of quality management has continuously been widened from considering "what" is done to "how" it is done.

Within a global economy with enormous and fierce competition, the survival and the development of a company depends on its ability to attract customers, to make them loyal and above all to, constantly, exceed their expectation and desires, in order to retain them.

Therefore, in order to cope with those tasks, the top management of any company must assure a high "degree to

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which a set of inherent characteristics fulfils requirements" (ISO 9000, 2005), in terms of maintaining a standard quality of products and services.

As Govind Ramu, chair of the ISO 9001:2015 U.S., quotes "ISO 9001:2015 is not a giant, scary monster. It's a commonsense approach to running any organization. When process owners complain about additional work that ISO 9001 creates, I always ask them, 'Tell me one thing in ISO 9001 you wouldn't do in a business.' With or without ISO 9001, the requirements outlined in the standard are fundamental to any business."

HISTORY OF QUALITY MANAGEMENT STANDARD ISO 9001

Historic Review of the ISO 9000 Standards

The ISO 9000 family of quality management systems standards is designed to help organizations ensure that they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to a product or program. ISO 9000 deals with the fundamentals of quality management systems, including the seven quality management principles upon which the family of standards is based.

The ISO 9000 family includes standards such as:

- The ISO 9001:2015-that covers the requirements of a QMS.
- The ISO 9000:2015-that includes the basic concepts and language.
- The ISO 9004:2009-that focuses on improving the efficiency and effectiveness of a QMS.
- The ISO 19011:2011-that includes guidelines for the conduction of internal and external audits of QMSs.

ISO 9001 deals with the requirements that organizations wishing to meet the standard, must fulfill.

ISO 9000 was first published back in 1987. It was based on the British Standard, BS 5750 series of standards from BSI that were proposed to ISO in 1979.

Actually it was back in 1959, when the US Department of Defense (1959) issued a specification for quality – Quality Program Requirements (MIL-Q-9858) (US Department of Defense, 1959), and later in 1973, the UK Defence Standards DEF STAN 05-21/1 – "Quality Control System Requirements for Industry" (Ministry of Defence, 1973) was published and based on earlier North Atlantic Treaty Organization (NATO) quality standards issued at the end of the 1960s.

Practically, all these standards changed the emphasis from post-production quality inspection and control to ensuring that quality was built into the manufacturing processes from the beginning, thus introducing the concept of quality assurance.

Year	Conformance standard	Title
1979	BS 5750: 1979	Quality systems: Part 1. Specification for design, manufacture and installation
1987	BS 5750: 1987; ISO 9001: 1987; EN 29000; ANSI/ ASQC Q91	ISO title: Quality systems – Model for quality assurance in design/development, production, installation and servicing

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1994	ISO 9001: 1994: ANSI/ASQC Q9001-1994	Quality systems – Model for quality assurance in design, development, production, installation and servicing
2000	ISO 9001: 2000	Quality management systems Requirements
2008	ISO 9001: 2008	Quality management systems – Requirements
2015	ISO 9001: 2015	Quality management systems – Requirements

Table 1: Development of quality management standards.

Source: "Developing a knowledge management policy for ISO 9001: 2015", John P. Wilson, Larry Campbell, JOURNAL OF KNOWLEDGE MANAGEMENT, VOL. 20 NO. 4 2016, PAGE 831

Recent Years

The 2000 version of the standard (ISO 9001:2000) sought to make a radical change in thinking. It placed the concept of process management at the heart of the standard, making it clear that the essential goals of the standard – which had always been about 'a documented system' not a 'system of documents' – were reinforced. The goal was always to have management system effectiveness via process performance measures. This third edition makes this more visible and so reduced the emphasis on having documented procedures if clear evidence could be presented to show that the process was working well. Expectations of continual process improvement and tracking customer satisfaction were also made explicit in this revision. A new set of eight core quality management principles, designed to act as a common foundation for all standards relating to quality management, were also introduced namely:

- Improved consistency with traceability
- Enhanced customer focus
- Focused leadership
- The involvement of people
- A system approach to management
- Continual improvement
- A factual approach to decision making
- Mutually beneficial supplier relationships

The fourth edition of the standard (ISO 9001:2008) arrived on November 14th 2008. This revision contains minor amendments only. The aim of this revision is to clarify existing requirements and to improve consistency of approach with other management standards, like ISO 14001:2015.

During September 2015, a revised version – ISO 9001:2015 – was launched to bring the standard up to date, reflecting latest quality management good practice. Whilst some requirements have been tightened, the standard is now far less prescriptive and has even greater integration with other ISO management standard thanks to a common high-level structure.

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The following Infographic (www.advisera.com/9001academy), indicates the changes in the revised Standard.

Figure 1: Infographic indicating the History in quality management standard. www.advisera.com

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Chapter 2

THE SEVEN (7) QUALITY MANAGEMENT PRINCIPLES

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Chapter Objectives

- To indicate the correlation between the 7 quality management principles and the ISO 9001 Standard
- To present one by one the 7 quality management principles
- To describe the rationale of those principles and the benefits derived by them
- To present some typical actions undertaken when applying a principle
- To identify the basic steps towards the adaption of each principle

Introduction

According to the ISO, ISO 9000, ISO ¬9001 and related ISO quality management standards are based on seven Quality Management Principles (QMPs). The achievement of those QMPs, is essential for the efficient and successful management of any organization worldwide.

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The revised version of ISO 9001:2015 Standard, is based on the following Seven principles of Quality management:

- QMP 1 – Customer focus.
- QMP 2 – Leadership.
- QMP 3 – Engagement of people.
- QMP 4 – Process approach.
- QMP 5 – Improvement.
- QMP 6 – Evidence-based decision making.
- QMP 7– Relationship management.

Figure 2– Seven principles of Quality management

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CUSTOMER FOCUS

Introduction

"The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations". (ISO 9000: 2015)

According to the American Management Association (AMA), as the knowledge economy evolves into an "experience economy," successful firms will be those that can deliver better customer experiences by using empathy skills to build new brands or develop new consumer experiences.

Rationale

"Sustained success is achieved when an organization attracts and retains the confidence of customers and other interested parties on whom it depends. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to sustained success of an organization". (ISO 9000: 2015).

Explanation

Customer focus is the ability of an organization to efficiently and effectively concentrate on the work that enhances the experiences of customers with products and services. Through their customer-focus efforts, companies can drive up the value that's received by customers. This often means gaining a good understanding of the various customer segments, producing quality at acceptable costs, and delivering on all commitments.

The fact that customer focus has become a hugely important business issue became crystal clear when the Human Resource Institute (2004) conducted its most recent Major Issues Impacting People Management survey. It found that European respondents ranked "Focus on the Customer" first out of 120 issues and North American respondents ranked it fourth. Since then, various other surveys on issues such as leadership and innovation have supported the preeminent importance of customer focus in businesses today.

Sources

1 **Organizational Sources**: Data, facts and figures gathered from the organization, especially from the "front – line" employees, or from on-line assessments and questionnaires by the end-users

2 **Experiential Sources**: The professional experience and judgment of executives and employees

3 **Stakeholder Sources:** The values, concerns and organizational decisions of people who are involved in the organization

4 **Scientific evidence**: Findings from published scientific research regarding customer focus concept

Typical Actions

Some of the possible actions that an organization can take to increase Customer Focus could include:

1. To identify and recognize the direct and indirect customer of the organization who receive value from the organization.
2. To understand customers' current and future needs and expectations

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3. The organization must link its objectives to customer needs and expectations
4. It must communicate customer needs and expectations throughout the organization
5. It must plan, design, develop, produce, deliver and support products and services to meet customer needs and expectations
6. It must measure and monitor customer satisfaction and take appropriate actions;
7. It must determine and take action on relevant interested parties' needs and appropriate expectations that can affect customer satisfaction
8. It must actively *manage relationships with customers to achieve sustained success.*

Proposed steps

1. **Defining Objectives and Information Needs**: What are the aims? What do we need to know based on the aims? Can we clearly articulate our information needs? Who needs to know what, when and why?
2. **Collecting Data**: Do we have or can we collect meaningful and relevant data to meet our information needs? What are the types of data we need, quantitative or /and qualitative?
3. **Analyzing Data:** How can we turn the data into relevant insights? How can we put the data into context and extract information? What are the most appropriate tools to analyze the data?
4. **Presenting Information:** How can we best present and communicate the insights and information to inform decision makers?
5. **Making Customer Focused Decisions:** How do we ensure that the available data is used to make the best decisions? How do we create a knowledgeable to action culture? How do we avoid the knowing-doing gap?

Key benefits

(As per ISO 9000:2015)

- There is an increase in customer value
- There is an increase in customer satisfaction
- There is an improvement in customer loyalty
- It enhances in repeat business
- It enhances in reputation of the organization
- There is an expansion of customer base
- There is increase in revenue and market share.

LEADERSHIP

Introduction

"Leaders at all levels establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization objectives."

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Rationale

Creation of unity of purpose and direction and engagement of people enable an organization to align its strategies, policies, processes and resources to achieve its objectives.

Explanation

Leadership is a process by which leaders help themselves and others to do the right things within a given framework. They set a clear strategy, they build an inspiring vision, and create something new. Leadership is about mapping out where you need to go to "win" as a team or an organization.

Sources

Experiential Sources: The professional experience and judgment of executives and top management

Stakeholder Sources: The values, concerns and organizational decisions of people who are involved in the organization

Scientific evidence: Findings from published scientific research regarding leadership concept

Academic Background: Relevant studies, vocational training, seminars and life - long learning, professional development.

Typical Actions

Some of the possible actions that an organization can take to enhance Leadership could include:

Identify and Engage all Relevant Stakeholders by Considering:

1. Listing all stake holders who impact the value stream carefully.
2. Ensure to include all the stake holders cutting across functions in end-to-end process management.
3. Buy-in all stake holder constituents impacted by the process change
4. Facilitating communication between the departments and functions
5. Facilitating value stream transformation
6. Installing the service level agreements to track and monitor the performance of the constituents

Build Quality Culture by:

1. Defining the vision and strategies for achieving it
2. Communicating the vision and demonstrate personal commitment
3. Creating & maintaining an awareness of quality
4. Providing evidence of management leadership on quality.
5. Providing opportunities for self-development and empowerment.
6. Providing opportunities for participation in management process.
7. Instituting recognition & rewards mechanism

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Proposed Steps

1. **Defining Objectives**: What are the aims? What do we need to know based on the aims?
2. **Collecting Data**: Do we have or can we collect meaningful and relevant data to meet our aims? What are the types of data we need, quantitative or /and qualitative?
3. **Analyzing Data:** How can we turn the data into relevant insights? How can we put the data into context and extract information? What are the most appropriate tools to analyze the data?
4. **Presenting Information:** How can we best present and communicate the insights and information to inform decision makers?
5. **Making Leadership Decisions:** How do we ensure that the available data is used to make the best decisions? How do we create a knowledgeable to action culture? How do we avoid the knowing-doing gap?

Key Benefits

- Increased effectiveness and efficiency in meeting the organization's quality objectives
- Better coordination of the organization's processes
- Improved communication between levels and functions of the organization
- Development and improvement of the capability of the organization and its people to deliver desired results.

ENGAGEMENT OF PEOPLE

Introduction

The term engagement originally referred to "how fully people are psychologically present during particular moments of role performance." Kahn defined engagement as: "the harnessing of organization members' selves to their work roles in engagement, people employ and express themselves physically, cognitively, emotionally during role performance".

"Engagement of people" is one of the stated quality management principles mentioned in the ISO 9001:2015 standard, while Section 7 of the standard deals with "Resources" and the role of people and the environment that those people create as a result. What the standard doesn't specify is what means the ISO 9001:2015 practitioner should use to engage the employees, and therefore encourage a level of buy-in that ensures that the project itself and resulting QMS performance can flourish.

So, what can we do to give us this foundation that will ensure our employees have the enthusiasm and "know-how" to facilitate a smooth 9001 implementation and continued performance?

It is essential for the organization that all people are competent, empowered and engaged in delivering value. Competent, empowered and engaged people throughout the organization enhance its capability to create value.

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

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Rationale

To manage an organization effectively and efficiently, it is important to involve all people at all levels and to respect them as individuals. Recognition, empowerment and enhancement of skills and knowledge facilitate the engagement of people in achieving the objectives of the organization.

Explanation

This is the third of the Seven principles of Quality management and the term "Involvement of People" has been change to "Engagement of People". The Eight principle definition stated "People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit." The Seven principle definition states "It is essential for the organization that all people are competent, empowered and engaged in delivering value.

Competent, empowered and engaged people throughout the organization enhance its capability to create value." Engaging people means employees are committed to their organisation's goals and values, motivated to contribute to organisational success, and are able at the same time to enhance their own sense of well-being.

An engaged employee experiences a blend of job satisfaction, organizational commitment, job involvement and feelings of empowerment. When we talk of engagement of people it means that all the employees are competent, empowered and they are delivering value. An engaged employee will have a better perception of job importance. An engaged employee will have better clarity of job expectation. There will be more improvement opportunities. There will be regular feedback and dialog with supervisors. The Quality of working relationships of an engaged employee with peers, superiors, and subordinates is much improved. There is effective employee communication.

Sources

Organizational Sources: Data, facts and figures gathered from the organization, especially from the "front – line" employees, or from on-line assessments and questionnaires by the end-users.

Experiential Sources: The professional experience and judgment of executives and employees.

Stakeholder Sources: The values, concerns and organizational decisions of people who are involved in the organization.

Typical Actions

Engagement of people. Creating value for your customers will be easier if you have competent, empowered and engaged people at all levels of your business or organization.

- Communicate with people to promote understanding of the importance of their individual contribution.
- Promote collaboration throughout the organization.
- Facilitate open discussion and sharing of knowledge and experience.
- Empower people to determine constraints to performance and to take initiatives without fear.
- Recognize and acknowledge people's contribution, learning and improvement.
- Enable self-evaluation of performance against personal objectives.
- Conduct surveys to assess people's satisfaction, communicate the results, and take appropriate actions.

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Proposed Steps

- Ensure that people's abilities are used and valued
- Make people accountable
- Enable participation in continual improvement
- Evaluate individual performance
- Enable learning and knowledge sharing
- Enable open discussion of problems, constraints

Key Benefits

- Improved understanding of the organization's quality objectives by people in the organization and increased motivation to achieve them
- Enhanced involvement of people in improvement activities
- Enhanced personal development, initiatives and creativity
- Enhanced people satisfaction
- Enhanced trust and collaboration throughout the organization
- Increased attention to shared values and culture throughout the organization

PROCESS APROACH

Introduction

While the process approach is by no means a new requirement, anecdotal evidence suggests that it is poorly understood.

The process approach was first introduced in ISO 9001:2000. And while the concept of a process-based quality management has not changed, the requirements in the latest version of the standard, ISO 9001:2015, have become more specific and less ambiguous.

So, what actually is a process approach? And why is it important? And, most importantly, how can you get your employees to apply it?

Rationale

A process is a set of interrelated activities that transform activity inputs into outputs.

Quality management systems consist of interrelated processes. Understanding how those results are produced by any of these systems enables an organization to optimize the specific system and its actual performance.

Explanation

'Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system' - Introduction of ISO 9001:2015.

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Chart 3: Pdca Cycle.

The process approach is a management strategy which incorporates the plan-do-check-act cycle and risk-based thinking. It means that processes are managed and controlled. It also means that we not only understand what the core processes are, but we also consider how they fit together.

The requirement for a process-based quality management system is nothing new. The requirement to "establish, implement, maintain and continually improve" is familiar from both ISO 9001:2000 and ISO 9001:2008. The key changes are:

- For organizations already adopting ISO 9001:2008, a key factor in transitioning to ISO 9001:2015 is the extent to which the process approach has been adopted.
- Clause 4.4 of ISO 9001:2015 sets out specific requirements for the adoption of a process approach e.g. organisations must monitor, measure and use related performance indicators to determine effective operation and controls.
- Top management must promote, engage and support employees to follow a process approach.

Why a process approach is so important

Organizations are typically structured into departments which are managed by a department head. The head is responsible for what comes out of the department.

Most departmental heads never interact with the external customer, only internal ones. As such, they are divorced from how the customer really feels.

If key performance indicators are set by departments this compounds the problems. Heads try to maximize the performance of their departments to the possible detriment of other departments further down the line.

The process approach introduces horizontal management, controlling processes which flow across departmental boundaries.

An appointed employee is accountable from start to finish. They follow the whole picture from process initiation to process completion. They understand what the stakeholders involved in the process want and have delegated authority to act, so as to achieve this. An employee's first loyalty is to their assigned projects, products or services - rather than their own departments.

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Using a process approach in a quality management system facilitates:

- Understanding and consistency in meeting requirements.
- Viewing processes in terms of value-add.
- Achieving effective process performance.
- Improving process performance based on analysis and evaluation of the data and information.

Sources

Organizational Sources: Data, facts and figures gathered from the organization

Experiential Sources: The professional experience and judgment of executives and employees, previous processes involved

Stakeholder Sources: The values, concerns and organizational decisions of people who are involved in the organization

Typical Actions

ISO 9001:2015 employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. This means the organization needs to:

1. Determine required process inputs and expected outputs,
2. Assign responsibilities and authorities for processes,
3. Identify risks and opportunities for processes, and plan to address them in an optimum way.

Proposed Steps

Define the processes of the quality management system

ISO 9001 does not provide you with a list of core quality management system processes that an organization needs to include. The organization must determine these for themselves. Some processes' examples:

- Internal training, leadership and performance evaluation.
- Manufacturing, design, distribution, development, service, delivery and assembly management.
- Revenue assurance / business process outsourcing.
- New customer management.
- Equipment management.
- Supplier approval and re-evaluation.
- Risk identification and management.
- Contract change or revenue assurance management.
- Complaint handling.
- Information management.
- Audit and inspections.
- Other QHSE requirements.

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A good question would be:

- How are we constantly providing products and services which meet customer and applicable statutory and regulatory requirements?
- How are we enhancing customer satisfaction?

These are the processes which need to be controlled. The organization must then map out the inter-relationships between its core processes.

Assign responsibilities and authorities for processes

The organization then needs to work out who is responsible for what process. Rather than focusing on functions, should focus on the process across the department. Particular attention to the interdependencies and the interactions is needed. Other significanr actions could be to:

- Involve employees in building the process-based quality management system.
- Train individuals so they understand their roles and accountabilities in respect of the core processes to ensure they see their processes end-to-end.
- Restructure the audit programme around processes not functions.
- Train auditors to follow processes across departments, paying particular attention to interdependencies and interactions.
- Provide documented information to support the operation of processes and ensure you have confidence that the processes are being carried out as planned.
- Give procedures and work instructions another name.

Identify risks and opportunities, and plan to address them

Risk-based thinking is an extension of preventive action. It requires organizations to determine risks and opportunities to processes, products and services, as well as the quality management system. And the organization must also take proportionate steps to address these actions. **This means monitoring and measuring the performance of processes**. **For more information about risk-based thinking, please see this article.**

A process-based quality management system requires careful planning, structure and continuous optimization. Key to this is ensuring your stakeholders are engaged. Employees must always be looking for opportunities to meet customer requirements and enhance customer satisfaction.

Key Benefits

- Enhanced ability to focus effort on key processes and opportunities for improvement.
- Consistent and predictable outcomes through a system of aligned processes.
- Optimized performance through effective process management, efficient use of resources, and reduced cross-functional barriers.
- Enabling the organization to provide confidence to interested parties as to its consistency, effectiveness and efficiency.

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IMPROVEMENT

Introduction

"Successful organizations have an ongoing focus on improvement". *(ISO Org.)*

Organizational Improvement is a dynamic and continuous process, that involves everyone within the organization from top management, to managers, and employees.

Rationale

"Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities". (ISO Org.)

Organizational improvement is a prerequisite for any company or organization in order to operate as effectively as possible.

Explanation

Improvement is the fifth of the Seven principles of Quality management and can be mapped to the sixth of the Eight Quality principle which is **"Continual Improvement"**. The term **"Continual Improvement"** has been change to **"Improvement"**. The fifth principle of the Eight Quality principle **"System approach to management"** no longer exist in the Seven principles of quality management. The Eight principle definition stated "Continual improvement of the organization's overall performance should be a permanent objective of the organization." The Seven principle definition states "Successful organizations have an ongoing focus on improvement." Improvement is the improvement in organizational efficiency and effectiveness in total.

According to Kenneth A. Potocki and Richard C. Brocato, five guiding principles are being used to make outstanding improvements in organizational performance: measurements/benchmarking, leadership, employee involvement, process improvement, and customer focus.

The organization should employ a consistent organization-wide approach to improvement of the organizations' methods, tools and metrics for improvement. The organization should provide people with the appropriate training in the methods and tools for improvement on an on-going basis. The organization should, also, make improvement of products, processes, and services.

The organization should establish the goals to guide and lead.

Sources

Organizational sources: Technical Reports, Data, facts measurements and figures gathered from the organization.

Scientific sources: Findings from published scientific research regarding organizational improvement and performance.

Experiential sources: The professional experience and judgment of top management, managers and employees.

Stakeholder sources: The values, concerns and feedback of people who interact with the organization.

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Typical Actions

1. Determine, measure and monitor key indicators to demonstrate the organization's performance.
2. Make all data needed available to the relevant people.
3. Build organizational commitment to quality by engaging everyone in the Organization
4. Build organizational culture and mentality for quality by coping with mistakes rather as opportunities for knowledge and improvement
5. Set measurable processes and use feedback to improve those processes
6. Ensure people are competent via continuous training to contribute to organizational improvement
7. Improve coordination and collaboration between all departments and functions within the organization

Proposed Steps

Some of the possible steps that an organization can take includes (As per ISO 9000:2015):

- Establishment of improvement objectives at all levels of the organization.
- Education and training of people at all levels on how to apply basic tools and methodologies to achieve improvement objectives.
- Ensuring that people are competent to successfully promote and complete improvement projects.
- Development and deployment of processes that are able to implement improvement projects throughout the organization.

Key Benefits

(As per ISO 9000:2015)

- There is improved process performance, organizational capability and customer satisfaction.
- There is enhanced focus on root cause investigation and determination, followed by prevention and corrective actions.
- There is enhanced ability to anticipate and react to internal and external risks and opportunities.
- There is enhanced consideration of both incremental and breakthrough improvement.
- There is improved use of learning for improvement. There is enhanced drive for innovation.
- It can track, review and audit the planning, implementation, completion and results of improvement projects.
- It can integrate improvement consideration into development of new or modified products and services and processes.
- It can recognize and acknowledge improvement.

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EVIDENCE – BASED DECISION MAKING

Introduction

Evidence based decision making, is the sixth of the seven of quality management principles, which is the ISO 9001 is based on. Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

Rationale

"Decision making can be a complex process, and it always involves some uncertainty. It often involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand cause-and-effect relationships and potential unintended consequences. Facts, evidence and data analysis lead to greater objectivity and confidence in decision making." (ISO 9000: 2015)

Explanation

The organization should base their decisions on process performance data generated by the management system, includes audit data, customer complaints and nonconformity data as inputs to decision making. Effective decisions are based on the analysis of data and information. It means that managers make a decision on basis of various measurements, balanced with the experience and intuition within the management system.

Evidence includes any data or information that might be used to determine the truth of an assertion, and it could be a quantitative or qualitative data.

Building evidence requires the careful collection of the right data. And yet our understanding of the word "data" is confused. People often wrongly believe that the word "data" has a narrow numeric definition. This is incorrect. Data comes in many forms – sounds, text, graphics, and pictures are as much data as are numbers. Consequently, it is important to become familiar with the available data collection methodologies. On the other hand the quality of data should be assessed for their reliability and validity to become useful.

The organizations need to build appropriate IT infrastructure to collect, analyze, present the data and consequently make the rightest decision. This includes (a) databases, data warehouses, data marts, etc. to store the data; (b) networks and connections to share the information and to make is accessible; and (c) the software to analyze and share the data. Also, the organizations need to ensure the competency of the persons that collect and analyze the data, this is because the employees of an organization who need to take insights from the analysis and turn them into actionable knowledge. Accordingly, the organizations should accessible data to the relevant competent persons.

Sources

Scientific evidence: Findings from published scientific research.

Organizational evidence: Data, facts and figures gathered from the organization.

Experiential evidence: The professional experience and judgment of practitioners.

Stakeholder evidence: The values and concerns of people who may be affected by the decision.

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Typical Actions

1. Determine, measure and monitor key indicators to demonstrate the organization's performance.
2. Make all data needed available to the relevant people.
3. Ensure that data and information are sufficiently accurate, reliable and secure. Analyze and evaluate data and information using suitable methods.
4. Ensure people are competent to analyze and evaluate data as needed.
5. Make decisions and take actions based on evidence, balanced with experience and intuition.

Proposed Steps

Defining Objectives and Information Needs: What are the aims? What do we need to know based on the aims? Can we clearly articulate our information needs? Who needs to know what, when and why?

Collecting Data: Do we have or can we collect meaningful and relevant data to meet our information needs? What are the types of data we need, quantitative or /and qualitative?

Analyzing Data: How can we turn the data into relevant insights? How can we put the data into context and extract information? What is the most appropriate tools to analyze the data?

Presenting Information: How can we best present and communicate the insights and information to inform decision makers?

Making Evidence-Based Decisions: How do we ensure that the available evidence is used to make the best decisions? How do we create a knowledgeable to action culture? How do we avoid the knowing-doing gap?

Key Benefits

1. Improved decision-making processes
2. Improved assessment of process performance and ability to achieve objectives
3. Improved operational effectiveness and efficiency
4. Increased ability to review, challenge and change opinions and decisions
5. Increased ability to demonstrate the effectiveness of past decision

RELATIONSHIP MANAGEMENT

Introduction

"Effective relationships allow business partners to leverage each other's resources and learn from each other". (Chadee et al., 2016; Kale et al., 2000; Mathews, 2006).

Today's businesses and organizations do not work isolated. Identifying the important relationships you have with interested parties such as the customers and suppliers as well as any other stakeholder – and setting out a plan to interact effectively with them – will lead to sustainable development and ultimate success.

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Rationale

"Interested parties influence the performance of an organization.

Sustained success is more likely to be achieved when the organization manages relationships with all of its interested parties to optimize their impact on its performance. Relationship management with its supplier and partner networks is of particular importance". (ISO Org. 2015)

Explanation

Relationship management aims to create a partnership between the organization and its audience rather than consider the relationship merely transactional. Consumers who experience that a business not only responds to their needs, but continuously tries to exceed their expectations are more likely to continue using the products and services of that particular company. Furthermore, pursuing and maintaining a standard level of communication with customers and users allows the business to identify potential sources of costly problems before they actually occur.

Relationship management involves any process or strategy used to build support or loyalty towards the business or its particular products and services. Generally, relationship management is performed at the customer level and at the business level to achieve different goals.

Business relationship management consists of knowledge, skills, and behaviors (or competencies) that foster a productive relationship between a service organization (internal department or an external provider) and their business partners.

Sources

Organizational evidence: Technical Reports, Data, facts measurements and figures gathered from the organization and the feedback gained by customers and collaborators.

Scientific evidence: Findings from published scientific research regarding organizational improvement and performance.

Experiential evidence: The professional experience and judgment of top management, managers and employees

Stakeholder evidence: The values, concerns and feedback of people who interact with the organization

Typical Actions

Determine relevant interested parties (such as suppliers, partners, customers, investors, employees, and society as a whole) and their relationship with the organization.

- Determine and prioritize interested party relationships that need to be managed.
- Establish relationships that balance short-term gains with long-term considerations.
- Pool and share information, expertise and resources with relevant interested parties.
- Measure performance and provide performance feedback to interested parties, as appropriate, to enhance improvement initiatives.
- Establish collaborative development and improvement activities with suppliers, partners and other interested parties.

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- Encourage and recognize improvements and achievements by suppliers and partners.

Proposed Steps

1. **Defining Objectives and Information Needs**: What are the aims? What do we need to know based on the aims? Can we clearly articulate our information needs? Who needs to know what, when and why?
2. **Collecting Data**: Do we have or can we collect meaningful and relevant data to meet our information needs? What are the types of data we need, quantitative or /and qualitative?
3. **Analyzing Data:** How can we turn the data into relevant insights? How can we put the data into context and extract information? What is the most appropriate tools to analyze the data?
4. **Presenting Information:** How can we best present and communicate the insights and information to inform decision makers?
5. **Making Relationships Management Decisions:** How do we ensure that we maintain effective relationships? How do we create a knowledgeable to action culture? How do we avoid the knowing-doing gap?

Key Benefits

- Enhanced performance of the organization and its interested parties through responding to the opportunities and constraints related to each interested party.
- Common understanding of goals and values among interested parties.
- Increased capability to create value for interested parties by sharing resources and competence and managing quality-related risks.
- A well-managed supply chain that provides a stable flow of goods and services.

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Chapter 3

HOW A COMPANY CAN GET STARTED & CERTIFIED WITH THE STANDARD

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Chapter Objectives

To present in a simple way the steps that a company has to apply, in order to study, understand, implement and finally be certified to the ISO 9001:2015 Standard.

HOW I CAN GET STARTED

ISO 9001:2015 is the new business improvement tool that helps drive continual improvement and deliver results in your organization. It helps any kind of business to stand out, gain a competitive edge, and grow.

It is more than a quality management system, it's a complete operational tool designed to improve performance. It uses a process approach to ensure customer satisfaction and places quality right at the heart of your organization, complementing business strategy and helping enhance performance over time. This has been designed with the needs of modern businesses in mind. It provides a framework which helps you to focus on ensuring you anticipate your business environment and customer needs. It's flexible and agile so you can make it work for your business. That's how ISO 9001 really adds value.

ISO 9001 was revised in 2015 to bring it up to date with the needs of modern businesses and to add even more value. It's based on the high-level structure which is a common framework for all new management system standards. This helps keep consistency, align different management system standards, offer matching sub-clauses against the top-level structure and apply common language across all standards. It makes it easier for organizations to incorporate their quality management system, into core business processes, make efficiencies, and get more involvement from senior management.

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Plan-Do-Check-Act (PDCA) is the operating principle of ISO 9001. It's applied to all processes and the QMS as a whole. The following diagram shows how Clauses 4 to 10 of ISO 9001 can be grouped in relation to PDCA.

Figure 4: Pdca Cycle In Correlation To ISO 9001 Clauses

* Clause 4 Context of the organization, Clause 5 Leadership, Clause 6 Operation, Clause 7 Support

STEPS TO BE UNDERTAKEN

There are many ways an organization can implement a quality management system.

In-depth advice is available from a number of different resources, including the publication ISO 9001 for small businesses – What to do, but here are a few tips to get you started.

Step 1 – Define the objectives of the organization. Why does the organization want to implement the standard?

Step 2 – Make sure senior management is on board. It is crucial that everyone – from the top down – is supportive of the initiative and its objectives. If you are struggling with this, several accurate publications could help.

Step 3 – Identify your organization's key processes for meeting your objectives as well as your customers' needs. Within each of these processes, make sure you understand your customers' requirements and can guarantee that these are met – each and every time. This will form the basis of your quality management system.

Step 4 – Buy the Standard and appoint a Quality Manager that will study the Standard and will act as an internal Ambassador in order to generate commitment and determination for adopting and implementing the QMS. Also, appoint the Quality team.

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STEPS TOWARD CERTIFICATION

There is no obligation to be certified to ISO 9001, so a good first step is evaluating whether certification makes sense for the specific organization. As mentioned earlier certification usually reassures customers that products and services are in line with their expectations. In some cases it is a prerequisite to work with certain clients especially from specific countries.

However, especially for companies within the food industry, QMS could play an essential role in an exchange because food safety and quality attributes may not be directly observable by the consumer. Therefore a certified QMS, provides a level of safety to the consumer and a sense of quality assurance.

Main considerations:

- Current level of conformance with ISO 9001 requirements
- Amount of resources that the company will dedicate to this project for development and implementation
- Amount of support that will be required from a consultant and the associated costs
- Costs for ISO 9001 registration, surveillance and recertification audits

In case that an Organization decides to get certified, the first step is to find a certification body as ISO does not perform certification. In doing so, they should:

- Build up a team and train the employees for the overall scope as well as the implementation processes.
- Identify and evaluate as many certification bodies as possible
- Check if the certification body uses the relevant casco standard. Casco (ISO's committee on conformity assessment) has produced a number of standards related to the certification process. ISO/IEC TS 17021-3:2013 sets out the requirements for bodies providing audit and certification to QMS's
- Check that the certification body is accredited. Accreditation is not compulsory. While non-accreditation does not necessarily mean an organization is not reputable, being accredited does provide independent confirmation of its competence.

WHAT IS ACCREDITATION?

Accreditation is the process in which certification of competency, authority, or credibility is displayed.

Organizations that issue credentials or certify third parties against official standards must be themselves formally accredited by accreditation bodies usually known as "accredited certification bodies". The accreditation process ensures that their certification practices are acceptable, thus they are competent to test and certify third parties, behave ethically and employ suitable quality assurance.

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Chapter 4

HOW THE STANDARD IS STRUCTURED

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Chapter Objectives

To present in a simple way the steps that a company has to apply, in order to study, understand, implement and finally be certified to the ISO 9001:2015 Standard.

WHAT IS ISO 9001:2015

ISO 9001 is the global standard certification that enhances the consistency and quality of deliverables by organizations spread across industries. It is one of the most sought after standards worldwide. However, an enterprise has to demonstrate high-level of commitment and consistency to achieve it in the first attempt.

Since its inception in 1987 when the first draft was published by the International Organization for Standardization (ISO), several revisions have been made so far to make it relevant and contemporary. The latest revision is published in September 2015. ISO is an international organization based in Geneva Switzerland with more than 160 member countries.

WHAT IS NEEDED FOR ISO 9001:2015 CERTIFICATION

ISO 9001:2015 applies to a great variety of industries irrespective of geographic area, size, and type of business.

According to ISO Organization reports, more than a million industries have been accredited worldwide. The

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certification improves organization processes and procedures and improves efficiency drastically.

ISO is a continuous improvement process. ISO certification can be done by an organization on a standalone basis, but it is better if a competent consultant either legal entity or experienced professional is hired. They can offer consultancy, guidance and training to make the certification a smooth and manageable procedure.

HOW THE STANDARD IS STRUCTURED

- ISO 9001:2015 certification introduces a few changes and revisions compared to previous standard versions to accommodate the changing business environment of the modern world.

Organizations operate in a quite dynamic business environment, where they are supposed to monitor and revise their business strategies and tactics at regular intervals.

ISO 9001:2015 update takes care of it by including several terminologies, information restructuring, and importance to risk-based thinking in order to make it further applicable and relevant nowadays.

- For ISO 9001:2015 upgrade, organizations should review the current approach. Business leaders are required to engage with process owners and team members to understand the process change with respect to the proposed version. They should identify, manage, and control these modifications as quickly as possible so that there is a minimized impact.

Organizations that are already certified for ISO 9001 should upgrade to 2015 version because it widens the horizon of applicability and relevance. As per ISO norms, a transition period of three years is given to ISO 9001:2008 certified organizations. (The transition period will last until September 2018).

Organizations should apply the principles of quality management for enhancing the business in such a way that a sustainable business improvement can be obtained. It is the biggest benefit of ISO certification. ISO 9001:2015 is beneficial for small, medium and large organizations across industries, all over the world.

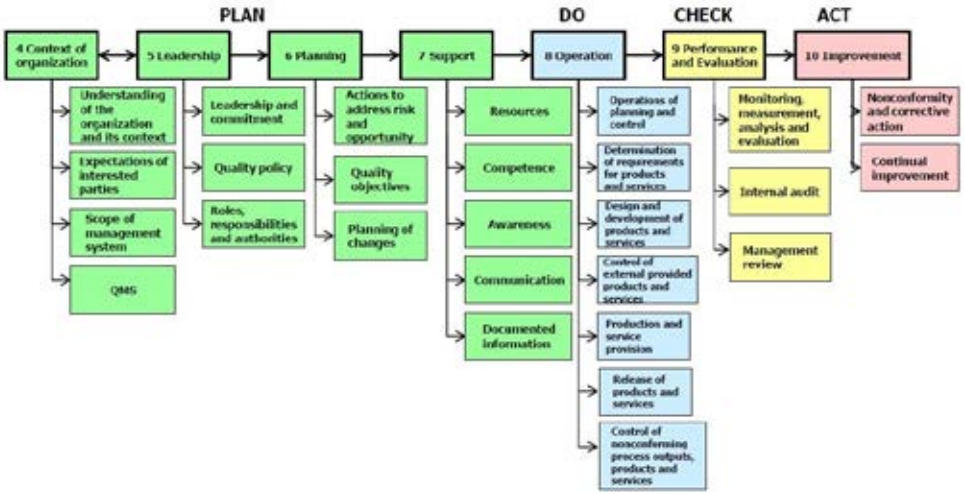

Figure 1: The general structure and organization of ISO 9001:2015.

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ISO 9001:2015 CLAUSES

General

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

The potential benefits to an organization of implementing a quality management system based on this International Standard are:

a) The ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

B) Facilitating opportunities to enhance customer satisfaction.

C) Addressing risks and opportunities associated with its context and objectives.

D) The ability to demonstrate conformity to specified quality management system requirements.

ISO 9001:2015 can be used by internal and external parties.

It is not the intent of the Standard to imply the need for:

- Uniformity in the structure of different quality management systems.
- Alignment of documentation to the clause structure of this International Standard.
- The use of the specific terminology of this International Standard within the organization.

The quality management system requirements specified ISO 9001:2015 Standard are complementary to requirements for products and services.

The Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise.

Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

In 9001:2015 Standard, the following verbal forms are used:

- "Shall" indicates a requirement.
- "Should" indicates a recommendation.
- "May" indicates a permission.
- "Can" indicates a possibility or a capability.

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Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.

Clauses 1 - 3

Scope

ISO 9001:2015 Standard specifies requirements for a quality management system when an organization:

a) Needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and

b) Aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of thE Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1: The terms "product" or "service" only apply to products and services intended for, or required by, a customer.

NOTE 2: Statutory and regulatory requirements can be expressed as legal requirements.

Normative References

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015, Quality management systems — Fundamentals and vocabulary.

Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

Clause 4 Context of the organization

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 results of its quality management system.

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.

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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:

a) The interested parties that are relevant to the quality management system;

b) The requirements of these interested parties that are relevant to the quality management system.

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

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 Referred To In 4.1.

B) The Requirements Of Relevant Interested Parties Referred To In 4.2.

C) The products and services of the organization.

The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the quality of its products and services and the enhancement of customer satisfaction.

Quality management system and its processes

1. The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

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 (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes.

D) Determine the resources needed for these processes and ensure their availability.

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E) Assign the responsibilities and authorities for these processes.

F) Address the risks and opportunities as determined in accordance with the requirements of 6.1.

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.

2 To the extent necessary, the organization shall:

a) Maintain documented information to support the operation of its processes.

b) Retain documented information to have confidence that the processes are being carried out as planned.

Clause 5 Leadership

Leadership and commitment

General

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

a) Taking accountability for the effectiveness of the quality management system.

b) Ensuring 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.

c) Ensuring the integration of the quality management system requirements into the organization's business processes.

d) Promoting the use of the process approach and risk-based thinking.

e) Ensuring that the resources needed for the quality management system are available.

f) Communicating the importance of effective quality management and of conforming to the quality management system requirements.

g) Ensuring that the quality management system achieves its intended results.

h) Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system.

i) Promoting improvement.

j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE: Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.

Customer focus

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

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a) Customer and applicable statutory and regulatory requirements are determined, understood and consistently met.

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

c) Focus on enhancing customer satisfaction is maintained.

Policy

Developing 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.

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 quality management system conforms to the requirements of this International Standard.

b) Ensuring that the processes are delivering their intended outputs.

c) Reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management.

d) Ensuring the promotion of customer focus throughout the organization.

e) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Clause 6 Planning

Actions to address risks and opportunities

When planning for the quality management system, 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:

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a) Give assurance that the quality management system can achieve its intended results.

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 quality management system processes.

2) Evaluate the effectiveness of these actions.

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

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 clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

Quality objectives and planning to achieve them

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

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

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

a) What will be done.

b) What resources will be required.

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c) Who will be responsible.

d) When it will be completed.

e) How the results will be evaluated.

Planning of changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner.

The organization shall consider:

a) The purpose of the changes and their potential consequences.

b) The integrity of the quality management system.

c) The availability of resources.

d) The allocation or reallocation of responsibilities and authorities.

Clause 7 Support

Resources

General

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

The organization shall consider:

a) The capabilities of, and constraints on, existing internal resources.

b) What needs to be obtained from external providers.

People

The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

Infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

NOTE: Infrastructure can include:

a) Buildings and associated utilities.

b) Equipment, including hardware and software.

c) Transportation resources.

d) Information and communication technology.

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Environment for the operation of processes

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE: A suitable environment can be a combination of human and physical factors, such as:

a) Social (e.g. Non-discriminatory, Calm).

b) Psychological (e.g. Stress-Reducing, Burnout Prevention, Emotionally Protective).

c) Physical (e.g. Temperature, Heat, Humidity, Light, Airflow, Hygiene, Noise).

These factors can differ substantially depending on the products and services provided.

Monitoring and Measuring Resources

General

The organization shall determine and provide the resources needed to ensure valid and reliable results.

when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization shall ensure that the resources provided:

a) Are suitable for the specific type of monitoring and measurement activities being undertaken.

b) Are maintained to ensure their continuing fitness for their purpose.

The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

Measurement Traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards when no such standards exist, the basis used for calibration or verification shall be retained as documented information.

b) Identified in order to determine their status.

c) Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary

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.

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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 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 from customers or external providers).

Competence

The organization shall:

a) Determine the necessary competence of persons doing work under its control that affects the performance and effectiveness of the quality management system.

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.

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 quality management system, including the benefits of improved performance.

d) The implications of not conforming with the quality management system requirements.

Communication

The organization shall determine the internal and external communications relevant to the quality management system, including:

a) On what it will communicate.

b) When to communicate.

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c) With whom to communicate.

d) How to communicate.

e) Who communicates.

Documented information

General

The organization's quality management system shall include:

a) Documented information required by ISO 9001:2015.

b) Documented information determined by the organization as being necessary for the effectiveness of the quality management system.

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.

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) and media (e.g. Paper, Electronic).

c) Review and approval for suitability and adequacy.

Control of documented information

- Documented information required by the quality management system and by this International Standard 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 the quality management system shall be identified as appropriate, and be controlled.

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

NOTE: Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

Clause 8 operation

Operational planning and control

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, 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 and keeping 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.

NOTE "Keeping" implies both the maintaining and the retaining of documented information.

The output of this planning shall be suitable for the organization's operations.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled (see 8.4).

Requirements for products and services

Customer communication

Communication with customers shall include:

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.

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Determining the requirements related to products and services

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

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.

Review of requirements related to products and services

The organization shall ensure that it has the ability to meet therequirements 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 postdelivery 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.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues or advertising material.

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

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

Design and development of products and services

General

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

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Design and development planning

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

a) The nature, duration and complexity of the design and development activities.

b) The required process stages, including applicable design and development reviews.

c) The required design and development verification and validation activities.

d) The responsibilities and authorities involved in the design and development process.

e) The internal and external resource needs for the design and development of products and services.

f) The need to control interfaces between persons involved in the design and development process.

g) The need for involvement of customers and users in the design and development process.

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 to demonstrate that design and development requirements have been met.

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.

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.

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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.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

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.

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.

Control of Externally Provided Processes, Products and Services

General

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 customers by external providers on behalf of the organization.

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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.

Type and extent of control

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

The organization shall:

a) Ensure that externally provided processes remain within the control of its quality management system.

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.

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.

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Production and service provision

Control of production and service provision

The organization shall implement production and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

a) The availability of documented information that defines:

1) The characteristics of the products to be produced, the services to be provided, or the activities to be performed.

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.

Identification and traceability

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

Property belonging to customers or external providers

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

NOTE: A customer's or external provider's property can include material, components, tools and equipment, premises, intellectual property and personal data.

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4 Preservation

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

NOTE: Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization shall consider:

a) Statutory and regulatory requirements.

b) Potential undesired consequences associated with its products and services.

c) Nature, use and intended lifetime of its products and services.

d) Customer requirements.

e) Customer feedback.

NOTE: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

Control of changes

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

Release of products and services

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

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.

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.

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The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected 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 nonconforming outputs are corrected

The organization shall retain documented information that:

a) Describes the nonconformity.

b) Describes the actions taken.

c) Describes any concessions obtained.

d) Identifies the authority deciding the action in respect of the nonconformity.

Clause 9 Performance evaluation

Monitoring, measurement, analysis and evaluation

General

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 analysed and evaluated.

The organization shall evaluate the performance and the effectiveness of the quality management system.

The organization shall retain appropriate documented information as evidence of the results.

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.

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Analysis and evaluation

The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.

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 quality management system.

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 quality management system.

NOTE Methods to analyse data can include statistical techniques.

Internal audit

The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

a) Conforms to:

   1) The organization's own requirements for its quality management system.

   2) The requirements of this International Standard.

b) Is effectively implemented and maintained.

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 of the implementation of the audit programme and the audit results.

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Management review

General

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.

Management review inputs

The management review shall be planned and carried out taking into consideration:

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 the quality management system, 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 (see 6.1).

f) Opportunities for improvement.

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

Clause 10 Improvement

General

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

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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 the quality management system.

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

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 consequences0

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 analysing 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.

2 The organization shall retain documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions taken.

b) the results of any corrective action.

Continual Improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

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.

Structure and terminology

The clause structure (and some of the terminology of the ISO 9001:2015 edition, in comparISOn with the previous

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edition (ISO 9001:2008), have been changed so as to improve alignment with other management systems standards.

There is no requirement in the ISO 9001:2015 for its structure and terminology to be applied to the documented information of an organization's quality management system.

The structure of clauses is intended to provide a coherent presentation of requirements, rather than a model for documenting an organization's policies, objectives and processes. The structure and content of documented information related to a quality management system can often be more relevant to its users if it relates to both the processes operated by the organization and information maintained for other purposes.

There is no requirement for the terms used by an organization to be replaced by the terms used in ISO 9001:2015 to specify quality management system requirements. Organizations can choose to use terms which suit their operations (e.g. using "records", "documentation" or "protocols" rather than "documented information"; or "supplier", "partner" or "vendor" rather than "external provider").

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Chapter 5

MAJOR DIFFERENCES BETWEEN ISO 9001:2008 & ISO 9001:2015

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Chapter Objectives

- To present the main differences between ISO 9001:2008 and ISO 9001:2015
- To comment on the considerable differences between ISO 9001:2008 and ISO 9001:2015
- To underline the focus of ISO 9001:2015
- To indicate the different terminology of ISO 9001:2015

WHAT ARE THE MAIN DIFFERENCES BETWEEN ISO 9001:2008 AND ISO 9001:2015

ISO 9001:2015 Has Ten Clauses Instead of Eight

ISO 9001:2015 has ten clauses instead of eight. The following table shows the relationship of the ISO 9001:2008 clauses to those in the new version.

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ISO 9001:2008	ISO 9001:2015
0. Introduction	0. Introduction
1. Scope	1. Scope
2. Normative reference	2. Normative reference
3. Terms and definitions	3. Terms and definitions
4. Quality management system	4. Context of the organisation
5. Management responsibility	5. Leadership
	6. Planning
6. Resource management	7. Support
7. Product realisation	8. Operation
8. Measurement, analysis and improvement	9. Performance evaluation
	10. Improvement

Table 2: Clauses revisions.

Basically, the first three clauses in ISO 9001:2015 are the same as those in ISO 9001:2008, but there are considerable differences between ISO 9001:2008 and ISO 9001:2015 from the fourth clause and beyond. The last seven clauses are now arranged according to the PDCA cycle.

Clauses 4, 5, 6 and 7 of ISO 9001:2015 come under PLAN, clause 8 comes under DO, clause 9 comes under CHECK and clause 10 is covered by ACT.

You can see **Figure 3:** PDCA Cycle in correlation to ISO 9001 CLAUSES

The reason for correlating the seven clauses with the PDCA cycle, is because ISO 9001:2015 strives to give additional momentum to the continuous and systematic improvement of processes within organizations.

ISO 9001:2015 Has a High Level Structure (HLS)

As a result of the new arrangement in ten clauses, ISO 9001:2015 now has the same unambiguous structure as all standardised management systems, known as a 'High Level Structure' (HLS).

The core elements of ISO 9001, ISO 14001, ISO 22000, OHSAS 18001, etc. are therefore all the same from now on. This has made the integration of various management systems much simpler. If, for example, an organization wishes to implement ISO 14001 in addition to ISO 9001, the parts that cover the same topic can easily be seen in the standards.

ISO 9001:2015 Puts more focus on Input and Output

there is more emphasis in ISO 9001:2015 on measuring and properly assessing the input and output of processes. According to ISO 9001:2015, the organization must closely monitor which articles, information and specifications are involved in the production process.

Risk-based thinking is at the core of ISO 9001:2015

Risk-based thinking has a very important place in ISO 9001:2015. Organizations are now strongly encouraged to use risk analysis in order to decide which challenges they identify in the management of the business processes.

Formal risk analysis, familiar to many organizations via HACCP techniques, is now standard for everyone. To emphasize their dominance, the concept of 'risk' occurs forty-eight times in ISO 9001:2015, compared with only three times in ISO 9001:2008.

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The addition of risk-based thinking has made the 'preventive measures' of ISO 9001:2008 redundant. These preventive measures no longer appear in ISO 9001:2015.

Context of the organisation is considered important in ISO 9001:2015

ISO 9001:2015 requires an organization to construct its quality management system from now on from the specific context within which it is active. This means, among other things, that, as an organization, you have to take into account the needs and expectations of interested parties and that you evaluate and deal with internal and external strategic questions. A clear understanding of the expectations of all the parties concerned, must be displayed.

ISO 9001:2015 and the engagement of interested parties

in ISO 9001:2008, customers were often named as being the only interested party. This concept has been extended in ISO 9001:2015, therefore suppliers, personnel, shareholders, legislative bodies, society, internal customers, and so on are now included as interested parties, in addition to customers.

These interested parties' (changing) requirements and standards, should be taken into account and anticipate them in the features of the organizations' products and services.

Leadership and commitment in ISO 9001:2015

ISO 9001:2015 also places more emphasis on leadership and management commitment. It requires greater involvement by top managers and business leaders in controlling the quality management system.

This way, ISO 9001:2015 is intended to encourage integration and harmonization with business processes and business strategies. The top management now has to take more responsibility for the effectiveness of the quality management system.

Because ISO 9001:2015 pays more attention to risk management, interested parties and the context of the organization, the quality management system also fits in better with the needs of the top management.

The quality management system is now more than ever a mean for being strategically successful by addressing the needs of interested parties and by managing opportunities and threats.

The 'management representative' of ISO 9001:2008 was a member of the management committee who had the responsibility and authority for steering the quality management system along the right lines, no longer exists. The idea behind the change is that quality is a matter for everyone and for all levels within the organization.

Documented Information

ISO 9001:2015 no longer requires obligatory documented procedures or a quality manual. Instead, there is now the term 'documented information' in practically all clauses of ISO 9001:2015.

The information can be in any format and come from various sources and media. Diverse forms of evidence or documentation are therefore possible.

There is no longer any mention of 'records' neither, but of 'retaining documented information'.

Different Terminology in ISO 9001:2008 and ISO 9001:2015

The following table is a brief summary of a number of important changes to the terminology compared with ISO 9001:2008.

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ISO 9001:2008	ISO 9001:2015
Products	Products and services
Documentation, quality manual, documented procedures, records, instructions	Documented information
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider

Table 3. Terminology Revisions.

This is an indicative list of the differences between ISO 9001:2008 and ISO 9001:2015, comparing the basic differences.

TRANSITION FROM ISO 9001:2008 TO ISO 9001:2015

In case a company is already ISO 9001 certified, the following steps are recommended in order to comply with ISO 9001:2015 (deadline September 2018):

Familiarize yourself with the new document

While some things have indeed changed, many remain the same.

Baseline measurement

Undertake a baseline measurement within the organization. Make a complete overview of the current status of the existing quality management system and the organization's operation of business. Then, identify any organizational gaps which need to be addressed to meet the new requirements.

Plan of approach

Draw up a plan based on the baseline measurement. In correlation to the specific plan, the company can take the time to make any adjustments needed and to implement improvements step by step.

Implementation

Implement the adjustments in accordance with the plan of approach. It is crucial to incorporate measurement points and milestones.

Training

Provide appropriate training and awareness for all parties that have an impact on the effectiveness of the organization.

Auditing and process analysis

Measure whether the changes have had the desired effect. Measure the input and output of the processes you consider to be important because they are critical or risky, for example.

Certification

Communicate with your certification body about transitioning to the new version.

Communication with interested parties

Show your interested parties not just the certificate, but also show them the results with pride. Let them see how well your organization manages its processes and continuously improves them.

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Chapter 6

THE IMPACT OF ISO 9001:2015 ON ISO 22000 AND FOOD SAFETY MANAGEMENT SYSTEMS

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Chapter Objectives

To present how ISO 9001 Management System is the basis on which ISO 22000 is structured and the relevant implications on the latter.

Introduction

Quality Management System (QMS) ISO standards have been created for all major sectors of manufacturing to answer an important need: A systematic application to improve and control the quality and the safety of consumer products. However the food and beverage industry has its own toolkit for quality (e.g., Safe Quality Foods Program, or SQF, and Global Food Safety Initiative(GFSI) and hazard analysis critical control points approach (HACCP). It even has its own standard (ISO 22000). However, the industry must embrace and apply the new concepts embodied in the ISO 9001:2015 revision to meet the challenges of ensuring quality in the 21st century, where the use of integrated and sophisticated systems of software and engineering technology applications have become the norm for achieving quality and consumer safety.

DEFINITION OF ISO 22000

ISO 22000 food safety management system; address what an organization needs to demonstrate its ability to control food safety hazards in order to ensure that food is safe at the time of human consumption and it can be used by any organization regardless of its size or position in the food

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chain (ISO, 2017).

IMPACT OF ISO 9001: 2015 ON ISO 22000

High level structure

the latest revision of ISO 9001 (ISO 9001:2015) follows the same overall structure as other ISO management systems (known as High-Level Structure), which makes it easier for anyone using multiple systems (e.g., ISO 9001 and ISO 22000), these changes have led to the decision by ISO to review ISO 22000:2005, to bring ISO 22000 in line with new ISO "high level structure" for management system standard.

Risk-based thinking

The concept of risk has always been implicit in ISO 9001 Standard and the 2015 revision makes it more explicit, building it into the whole management system:

- Risk-based thinking is already part of the process approach (4.4 Quality management system and its processes)
- Risk-based thinking makes preventive action part of the company's routine (6.1 Actions to address risks and opportunities)

ISO 22000 doesn't dictate any particular method of risk assessment or risk management, apart from addressing this concept on the already mentioned two levels, organizational and operational levels. However, the standard requires you to describe and retain as documented information the methodology used when conducting a risk assessment.

The PDCA cycle

The recently updated ISO 22000 requires that in addition to the organizational Plan-Do-Check-Act (PDCA) cycle, also known by the Deming Cycle wheel or Shewhart cycle, and following the high level structure, another PDCA cycle must coexist covering the operational processes within the food safety system. Your system includes two PDCA cycles at operational and organizational levels, and communication between them is established and maintained at all times.

Documentation

ISO 9001:2015 requires information to be maintained or retained, and no requirements for documented information. However, it is expected that due to the nature of Food Safety Management Systems some documented procedures could be required by future ISO 22000. ISO 9001:2015 does not require any longer a Quality Management Manual, which is in line with ISO 22000:2005 that doesn´t include a requirement for a food safety manual.

Terminology

ISO 9001:2015 also places more emphasis on leadership and management commitment. It requires greater involvement by top managers and business leaders at different level in controlling the quality management system.

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Chapter 7

CASE STUDIES: EUROPEAN FOOD COMPANIES THAT HAVE IMPLEMENTED ISO 9001 QUALITY SYSTEMS

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Chapter Objectives

- To present statistical data regarding the implementation of ISO 9001 Standard within Europe per sector for a period of time
- To present a short overview of the implementation of the ISO Standard in the food sector

STATISTICAL DATA FOR ISO 9001

ISO 9001 Standard is used successfully all over the world, by all types and size companies. In 2013 alone, over one million certificates to the standard were issued across 187 countries, and many other companies and organizations have used the standard without seeking certification.

Success with ISO 9001 can take many forms: for some enterprises, it is all about attracting and maintaining new clients, while others see it as the blueprint for internal improvement and efficiency.

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According to the International Organization for Standardization, the Top 10 countries for ISO 9001 certificates in all sectors, for the year 2015 are as seen below. For Europe, Italy, Germany and the U.K. are the top countries with 132.870, 52.995 and 40.161 Certificates respectively.

ISO 9001 - Quality Management Systems - Requirements

ISO

Overview

Year	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
TOTAL	46571	70364	127348	162700	223299	271846	343641	407674	510349	561766	497919	660132	773843	896905	951486	980322	1063751	1076525	1009845	1017279	1022877	1036321	1034180
Africa	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Central and South America	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
North America	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Europe	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
East Asia and Pacific	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Central and South Asia	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Middle East	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Regional share - in %

Year	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
TOTAL	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Africa	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Central and South America	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
North America	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Europe	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
East Asia and Pacific	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Central and South Asia	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Middle East	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Annual growth - absolute numbers

Year	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
TOTAL	23793	56984	35352	60598	48548	71795	64033	102675	51417	-63847	162213	113711	123062	54581	28836	83429	12774	-66680	7434	5598	13444	-2141
Africa	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Central and South America	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
North America	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Europe	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
East Asia and Pacific	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Central and South Asia	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Middle East	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Annual growth - in %

Year	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
TOTAL	51%	81%	28%	37%	22%	26%	19%	25%	10%	-11%	33%	17%	16%	6%	3%	9%	1%	-6%	1%	1%	1%	-0.2%
Africa	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Central and South America	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
North America	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Europe	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
East Asia and Pacific	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Central and South Asia	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Middle East	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Number of countries / economies

Year	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
TOTAL	60	75	95	112	125	140	148	153	161	159	149	154	161	170	174	176	178	178	179	184	187	188	201
Africa	3	7	12	18	21	27	28	29	31	31	25	29	35	36	38	41	44	43	43	43	47	48	51
Central and South America	6	9	15	19	23	28	29	30	33	33	30	29	27	30	33	33	33	33	33	33	33	34	36
North America	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Europe	30	34	36	38	42	42	46	47	48	47	47	48	48	49	49	49	49	49	49	49	49	49	50
East Asia and Pacific	13	13	15	16	18	20	22	22	22	21	21	22	24	25	25	23	22	23	25	27	27	25	29
Central and South Asia	2	3	4	6	6	7	7	9	11	11	10	10	11	13	13	14	14	14	13	14	14	14	14
Middle East	3	6	10	12	12	13	13	13	13	13	13	13	13	14	14	14	14	14	13	13	14	14	14

Top 10 countries for ISO 9001 certificates - 2015

1	China	292559
2	Italy	132870
3	Germany	52995
4	Japan	47101
5	United Kingdom	40161
6	India	36305
7	United States of America	33103
8	Spain	32730
9	France	27844
10	Romania	20524

Furthermore, for the same year (2015) the Industrial Sector "Food Products, Beverages and Tobacco" is among the top 10 sector as for awarded Certificates for ISO 9001, while for 2016 there has been an increase of 18.3%, since 31.469 were awarded.

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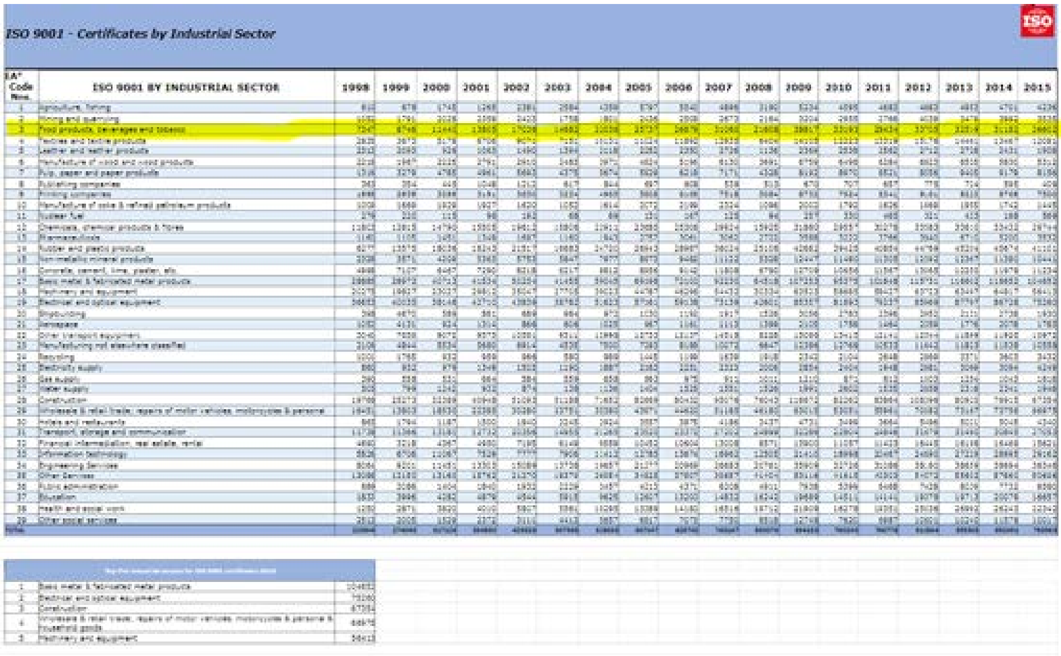
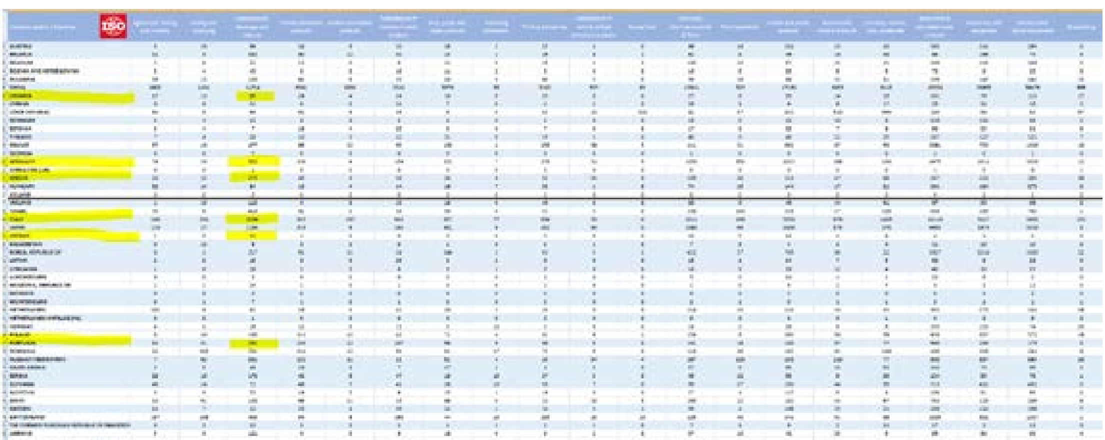


ISO 9001 - Certificates by Industrial Sector

EA* Code Nos.	ISO 9001 BY INDUSTRIAL SECTOR	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015

The industrial sectors per country regarding the ISO 9001:2008 & ISO 9001:2015 can be observed in the following table. (Highlighted the participating countries as well as Jordan).



According to the ISO Survey of Management System Standard Certifications 2015, A total of 1,036,321 **ISO 9001** certificates were issued (including 4190 issued to the 2015 version published in September 2015) a slight decrease of 0.2% on previous year (2014).

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For 2016, a total of 1,106,356 valid certificates were reported for ISO 9001 (including 80,596 issued to the 2015 version) an increase of 7% for 2015.

The number of Certificates and Sites covered by ISO 9001:2008 and ISO 9001:2015 implemented by European Countries, in total can be seen in the table below:

ISO 9001 - Quality Management Systems - Requirements

Number of certificates and sites per country

Countries	Certificates		Sites	
	ISO 9001:2008	ISO 9001:2015	ISO 9001:2008	ISO 9001:2015
ALBANIA	279	0	294	0
ANDORRA	30	0	36	0
ARMENIA	27	0	22	0
AUSTRIA	4330	140	3613	115
AZERBAIJAN	243	0	209	0
BELARUS	3656	1	206	1
BELGIUM	3522	40	2336	2
BULGARIA	5385	56	4130	8
CROATIA	2524	5	1980	1
CYPRUS	820	2	100	0
CZECH REPUBLIC	10620	28	10073	10
DENMARK	1858	7	1715	0
ESTONIA	1119	12	1237	10
FINLAND	2872	24	1037	8
FRANCE	27598	246	47135	63869
GEORGIA	85	0	57	0
GERMANY	52347	648	22219	165
GIBRALTAR (UK)	27	0	28	0
GREECE	6178	9	4666	20
HUNGARY	5769	20	3868	5
ICELAND	75	0	60	0
IRELAND	2273	50	1841	43
ITALY	131718	1152	163239	1180
KOSOVO	9	0	0	0
LATVIA	1114	1	572	1
LIECHTENSTEIN	68	4	12	0
LITHUANIA	1231	7	796	0
LUXEMBOURG	249	3	272	0
MALTA	507	0	77	0
MOLDOVA, REPUBLIC OF	130	0	103	0
MONACO	46	1	84	0
MONTENEGRO	84	0	66	0
NETHERLANDS	10250	131	5972	12
NORWAY	2458	9	381	0
POLAND	10664	17	7804	3
PORTUGAL	7475	23	4373	7
ROMANIA	20504	20	3528	1062
RUSSIAN FEDERATION	9069	15	2028	6
SAN MARINO, REPUBLIC OF	49	0	19	0
SERBIA	2505	7	2519	3
SLOVAKIA	5675	8	4708	5
SLOVENIA	1481	0	899	0
SPAIN	32526	204	49092	166
SWEDEN	4313	3	4378	1
SWITZERLAND	12003	215	6096	9
THE FORMER YUGOSLAV REPUBLIC OF MACE	361	2	266	0
TURKEY	8533	5	5509	1
UKRAINE	1051	1	844	0
UNITED KINGDOM	39950	211	30645	59

A SHORT OVERVIEW OF THE IMPLEMENTATION OF THE ISO STANDARD IN THE FOOD SECTOR

As already mentioned, ISO 9001 is widely adopted by many manufacturing companies, including food manufacturing companies.

This is an expected outcome, because of the level of awareness of most consumers in terms of food product quality and safety that has enabled them to apply quality management systems. According to a survey conducted by ISO, in 2016, there were 31, 469 companies engaged in the field of food, beverage, and tobacco products, Certified with ISO 9001.

Therefore, the results of a survey conducted by Kafetzopoulos, D., Gotzamani, K., Psomas using quantitative data collection that were measured on a seven-point modified Likert scale, findings, showed a positive and significant relationship between the combined effective implementation of ISO 9001 - and ISO 22000 standards- and competitive performance of certified food companies.

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Keywords (Index)

-A-

Accreditation

-B-

Business Process

Business Strategy

-C-

Certification

Certified Company

Clause

Competitive performance

Continual Improvement

Customer Focus

Customer Needs

-D-

Decision Making

-E-

Engagement of people

Evidence-based decision making

-F-

Focused Leadership

Food Sector

Flowchart

-H-

-I-

Innovation

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Improvement

ISO 9001

ISO 22000

-L-

Leadership

Likert scale

-M-

Monitoring

-O-

Organization

-P-

Performance

Plan-do-check-act (PDCA) cycle

Process Approach

Process Capability

-Q-

Quality assurance (QA)

Quality control (QC)

Quality management (QM)

Quality Principles

Quality tools

Quality Management System

-R-

Relationship Management

Risk

-S-

Scope

Standard

Supplier

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System Approach

-T-

Total quality management (TQM)

Training

-V-

Vocational Training

Glossary

HACCP: A system which identifies, evaluates, and controls hazards which are significant for food safety.

Likert scale: is a psychometric scale commonly involved in research that employs questionnaires. It is the most widely used approach to scaling responses in survey research, such that the term is often used interchangeably with rating scale. **Plan-do-check-act (PDCA) cycle:** A four-step process for quality improvement.

Quality: In technical use, quality can have two meanings: 1. the characteristics of a product or service that bear on its ability to satisfy stated or implied needs; 2. a product or service free of deficiencies.

Quality assurance (QA): All the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfil requirements for quality.

Quality control (QC): The operational techniques and activities used to fulfill requirements for quality.

Quality management (QM): The application of a quality management system in managing a process to achieve maximum customer satisfaction at the lowest overall cost to the organization while continuing to improve the process.

Quality tool: An instrument or technique to support and improve the activities of process quality management and improvement.

Total quality management (TQM): A management approach to long-term success through customer satisfaction, based on all members of an organization participating in improving processes, products, services and the culture in which they work.

Abbreviations

GFSI: Global Food Safety Initiative

HACCP: Hazard Analysis & Critical Control Point

PDCA : Plan-Do-Check-Act

QA: Quality Assurance

QC: Quality Control

QM: Quality Management

QMSs: Quality Management Principles

QMSs: Quality Management Systems

TQM: Total Quality Management

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