Chapter no. 5 Various International Quality Standards

5.1 QMS-ISO 9001: 2000

ISO 9001 is part of this series and is the standard applicable for certifying quality management systems. The 1994 version of the standard was originally divided in three guidelines:

- ISO 9001 - Model for Quality Assurance in Design, Development, Production, Installation and Services
- ISO 9002 - Quality systems - Model for Quality Assurance in Production, Installation and Services
- ISO 9003 - Quality systems - Model for Quality Assurance in Final Inspection and Test

According to the scope of certification, the organization could decide which standard should be implemented.

However, at the same time ISO 9001 was adopted by many companies worldwide, it also received many criticisms: it was too bureaucratic, too operational, departments-focused, without a systemic approach…The concept of quality assurance stated by the ISO 9001:1994 in fact made it distant from management and closer to operational control. That's the reason the standard was revised in the year 2000… and what many people still don't know is that its new version– the ISO 9001:2000 - is totally focused on business and quality management (and less bureaucracy…).

The ISO 9001:2000 – "Quality Management System – Requirements" replaced the 1994 standards ISO 9001, 9002 and 9003 by unifying them. It presents requirements to the implementation of quality management systems. Its main objective is to achieve customer satisfaction by meeting their needs and also by providing conforming services/products and developing continual improvement.

 A Management system is the set of interrelated or interacting elements that allow an organization to establish policies and objectives and to achieve those objectives.

The coordinated activities to direct and control an organization with regard to quality are what we call a Quality Management System (QMS). Actually, it's the way things are done to satisfy the customer quality requirements. Remember that, as a generic standard, the ISO 9001 indicates "what to do" in a quality management system but not "how to do" it.

Figure 1 shows the QMS Model of ISO 9001:2000 and the interaction of its requirements, leading to customer satisfaction.
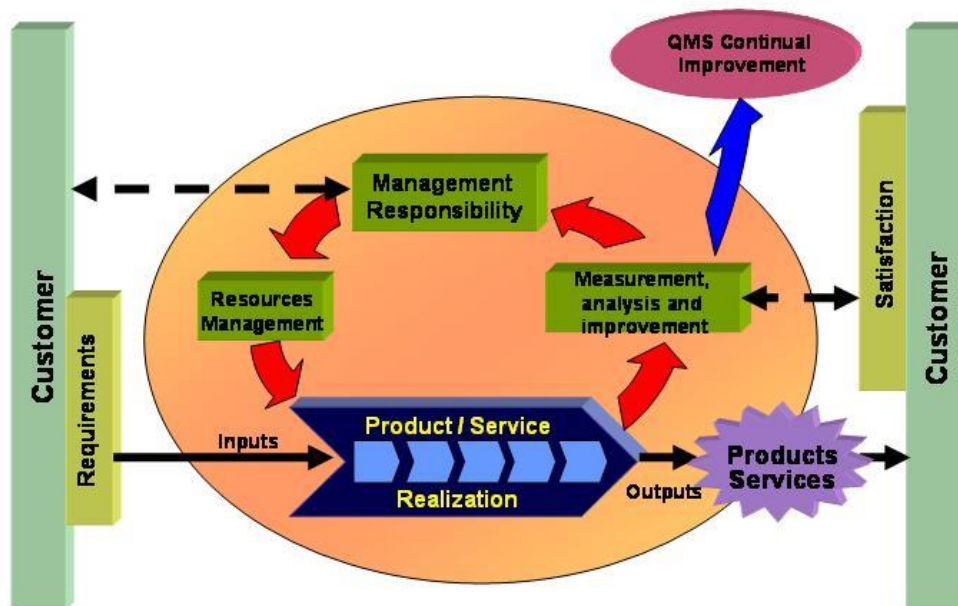
In order to achieve the objectives, the ISO 9001:2000 standard is based on eight principles:

- **Customer-focused organization:** organizations should understand customers' current and future needs, and exceed their expectations.
- **Leadership:** establish a unity of purpose and direction creating an internal environment where people can contribute to achieve the organization's expected results.
- **Involvement of people:** full involvement of employees enables their abilities to be used for the organization's benefit.
- **Process approach:** systematic identification and management of the various processes employed within an organization and the interactions among these processes in order to obtain the desired result.
- **Systemic approach:** managing a system of interrelated processes to a given objective contributes to efficiency. Integrating and aligning processes leads to better results.
- **Continual improvement:** should be a permanent objective of the organization, leading to improvements in the overall performance.
- **Factual approach to decision making:** effective decisions are based on the logical analysis of reliable data and information.
- **Mutually beneficial supplier relationships:** establishing relationships with suppliers to enhance the ability of both organizations to create value.

These principles are presented in the standard as general topics, divided in subtopics. Topics 0 to 3 refer to Introduction, Objective, Normative Reference and Terms and Definitions, respectively. Requirements are presented from items 4 to 8, as shown in the table below:

ISO9001:2000	
4. Quality management system	
4.1 General requirements	The organization shall identify critical processes and elaborate controlled procedures, including a quality manual
4.2 Documentation requirements	
5. Management responsibility	
5.1 Management commitment	Top management shall demonstrate its commitment to the QMS, establishing policies, objectives and plans and ensuring the achievement of customers and legal requirements. The organization shall define responsibilities and authorities and establish an effective internal communication system.
5.2 Customer focus	
5.3 Quality policy	
5.4 Planning	
5.5 Responsibility, authority and communication	
5.6 Management Review	
6. Resource management	
6.1 Provision of resources	Top management must identify where resources are needed and provide them in a timely manner, including human resources, infrastructure and continual education.
6.2.Human Resources	
6.3 Infrastructure	
6.4 Work Environment	
7. Product realization	
7.1 Planning of product realization	The organization shall identify, plan and implement processes under controlled conditions to realize the services/products. Purchased products should meet the organization's specifications. Customer requirements must be identified and assured during the process.
7.2.Customer-related processes	
7.3 Design and development	
7.4 Purchasing	
7.5 Production and service operations	
7.6 Control of measuring and monitoring devices	

8. Measurement, analysis and improvement	
8.1 General requirements	The organization must implement methods tomonitor, measure and analyze processes and customer satisfaction. Non-conformities must be identified and corrective actions taken. Continual improvement and preventive action should be pursued.
8.2. Measurement and monitoring	
8.3 Control of nonconformity	
8.4 Analysis of Data	
8.5 Improvement	

Companies wishing to implement a QMS are expected to meet these requirements and present evidences of the maintenance of the system.

In a general way, the main **benefits** of the implementation of a QMS based on ISO 9001:2000 requirements are:

- Better integration and more effective management of related processes and departments
- Process standardization
- Better control of documents and records
- Cost reduction
- Effective monitoring of processes
- Higher level of top management involvement to the system
- Focus on customer satisfaction enhancement
- Continual improvement

The implementation of a QMS based on ISO 9001:2000 requirements is a very good opportunity to improve the quality of internal processes and achieve the expected results of clinical laboratories.

5.2 EMW-ISO 14001: 1996

The organization shall establish and maintain an environmental management system, the requirements of which are described in the whole of clause 4.

Top management shall define the organization's environmental policy and ensure that it:

a) is appropriate to the nature, scale and environmental impacts of its activities, products or services;

b) includes a commitment to continual improvement and prevention of pollution;

c) includes a commitment to comply with **relevant** environmental legislation and regulations, and with other requirements to which the organization subscribes;

d) provides the framework for setting and reviewing environmental objectives and targets;

e) is documented, implemented and maintained and communicated to all employees;

f) is available to the public.

The organization shall establish and maintain (a) procedure(s) to identify the environmental aspects of its activities, products or services that it can control and over which it can be expected to have an influence in order to determine those which have or can have significant impacts on the environment.

The organization shall ensure that the aspects related to these significant impacts are considered in setting its environmental objectives.

The organization shall keep this information up-to-date.

The organization shall establish and maintain a procedure to identify and have access to legal and other requirements to which the organization subscribes,

1 Objectives and targets

The organization shall establish and maintain documented environmental objectives and targets, at each relevant function and level within the organization.

When establishing and reviewing its objectives,

An organization shall consider the legal and other requirements,

Its significant environmental aspects, its technological options and its financial, operational and business requirements, and the views of interested parties. The objectives and targets shall be consistent with the environmental policy, including the commitment to prevention of pollution.

2.Environmental management program(s)

The organization shall establish and maintain (a) program(s) for achieving its objectives and targets. It shall include

a) designation of responsibility for achieving objectives and targets at each relevant function and level of the organization;

b) the means and time-frame by which they are to be achieved.

If a project relates to new developments and new or modified activities, products or services, program(s) shall be amended where relevant to ensure that environmental management applies to such projects.

3 Structure and responsibility

Roles, responsibility and authorities shall be defined, documented and communicated in order to facilitate effective environmental management.

Management shall provide resources essential to the implementation and control of the environmental management system. Resources include human resources and specialized skills, technology and financial resources.

4 Structure and responsibility

The organization's top management shall appoint (a) specific management representative(s) who, irrespective of other responsibilities, shall have defined roles, responsibilities and authority for

ensuring that environmental management system requirements are established, implemented and maintained in accordance with this International Standard;

Reporting on the performance of the environmental management system to top management for review and as a basis for improvement of the environmental management system

5 Training, awareness and competence

The organization shall identify training needs. It shall require that all personnel whose work may create a significant impact upon the environment, have received appropriate training.

It shall establish and maintain procedures to make its employees or members at each relevant function an level aware of

a) the importance of conformance with the environmental policy and procedures and with the requirements of the environmental management system;

b) The significant environmental impacts, actual or potential, of their work activities and the environmental benefits of improved personal performance;

c) Their roles and responsibilities in achieving conformance with the environmental policy and procedures and with the requirements of the environmental management system, including emergency preparedness and response requirements;

d) The potential consequences of departure from specified operating procedures.

Personnel performing the tasks which can cause significant environmental impacts shall be competent on the basis of appropriate education, training and/ or experience

6 Communication

With regard to its environmental aspects and environmental management system, the organization shall establish and maintain procedures for

a) internal communication between the various levels and functions of the organization;

b) receiving, documenting and responding to relevant communication from external interested parties.

c) The organization shall consider processes for external communication on its significant environmental aspects and record its decision.

7 Environmental management system documentation

The organization shall establish an maintain information, in paper or electronic form, to

a) describe the core elements of the management system and their interaction;

b) provide direction to related documentation

8 Nonconformance and corrective and preventive action

The organization shall establish and maintain procedures for defining responsibility and authority for handling and investigating nonconformance, taking action to mitigate any impacts caused, and for initiating and completing corrective and preventive action.

Any corrective or preventive action taken to eliminate the causes of actual and potential nonconformance's shall be appropriate to the magnitude of problems and commensurate with the environmental impact encountered.

The organization shall implement and record any changes in the documented procedures resulting from corrective and preventive action.

Six Sigma certification-

Six Sigma was developed by Bill Smith in 1986. Then an engineer at Motorola aimed to help improve the company's devices which didn't meet the quality standards at the time. He based the approach on statistical and quality control methods taught by Walter Shewhart, Ronald Fisher, and Edwards Deming.

Six Sigma/lean six sigma is a set of tools and techniques used by companies to improve production processes, eliminate defects, and guarantee quality. The Lean **Six Sigma certification** helps in validating professionals who are skilled in identifying risks, errors, or defects in a business process and removing them.

Philosophy: The philosophical perspective of Six Sigma views all work as processes that can be defined, measured, analyzed, improved, and controlled. Processes require inputs (x) and produce outputs (y). If you control the inputs, you will control the outputs. This is generally expressed as $y = f(x)$.

Set of tools: The Six Sigma expert uses qualitative and quantitative techniques or tools to drive process improvement. Such tools include statistical process control (SPC), control charts, failure mode and effects analysis , and process mapping. Six Sigma professionals do not totally agree as to exactly which tools constitute the set.

Benefits-

1. Analytical Thinking and Innovation

As part of the Fundamental to Lean Six Sigma workshop, there is a crucial focus on two key elements. From an analytical thinking point of view, lean and six sigma methodologies provide a toolbox to help break down complex problems into manageable components.

This approach enables clear identification of root causes which lead to focused improvements resulting in improved business processes and performance.

2.Critical Thinking and Analysis

The methodology focuses on the core analysis and evaluation of data to identify the root cause(s) before jumping to any solution.

3. Complex Problem-Solving

At the heart of Lean Six Sigma is a mindset that pushes us to continually find better ways to create more customer value through continuous improvement. The only way to do this is through continuous problem-solving.

One of the core benefits of the best Lean Six Sigma Certification programs is a structured learning approach which maps out how to become lean certified with a combination of both theory and real-world practise.

4. Leadership and Social Influence

As with any project management role, leading your team and managing stakeholders will be critical to your success. Lean is not just about tools and methods – the ability to manage change is vital, and a skill everyone needs to practice to learn.

It is difficult and building your understanding of change management and team dynamics will help build your leadership capability and the influence you have on your team and the wider business.

5. Reasoning, Problem-Solving and Ideation

Companies in the hospitality industry rely heavily on customer loyalty, which is why there are so many travel-based rewards, loyalty, and incentive programs. When customer loyalty is earned, profits are bolstered, especially in an industry that is highly competitive, seasonally profitable, and depends upon the leisure time and disposable income of its customers. When hospitality companies are able to anticipate the needs of guests and deliver them in a cost-effective and profitable way, that earned customer satisfaction translates to customer loyalty, which in turn increases the profits and success of the company overall. When processes are improved upon and perfected all over the world in a consistent way with Six Sigma, a traveler can expect the same services and amenities from Denver to Dubai. In the age of easily accessible digital media, hospitality services rely heavily on both online reviews and social media. This is why it is imperative that mistakes are prevented. Using tools from the Six Sigma Toolbox, hospitality professionals are able to statistically decrease mistakes. This is critically important to the online reputation and presence of a hospitality organization.

What are Brand Standards Audits?

- **Brand Standard Auditing** is a methodology that involves a certified field auditor conducting an audit specialized to your needs. They are designed to protect your set brand standards that distinguish your company.

- The auditors enter your locations, either announced or unannounced, and follow the observation and interaction guidelines that you compose in consultation with our experienced staff. After going through a two-step quality control process, the results are then published to our exclusive system and made available to your designated and approved executives.

- Brand Standard Auditing can be used to verify a franchisee's adherence to corporate policy, proper food and safety regulations, facility and equipment code, and more. These types of audits can be conducted in almost any industry.