

## ISO STANDARDS IN FORCE: NEEDS AND OPPORTUNITIES

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### Abstract

*The work comprises in the first part a description of the concept of quality. Before submitting in detail the ISO standards, The International Organization for Standardization is presented, namely a short history, its work and why developing these ISO standards.*

*Reference is made to ISO 9001 [1]- Quality Management Systems, specifically its objectives, the purpose of the quality management system, the basic principles of ISO 9001, the structure of documents of the quality management system (QMS), compatibility with other management systems, the requirements of a QMS and also its implementation benefits. In the case of the ISO 14000 series of standards[2] is presented a brief history of their development. More attention is given to the ISO 14001 - Environmental Management Systems.*

*In describing the standard ISO 18001[3] are exposed particular elements of the security system to work, in comparison with those for quality and environment and opportunities and benefits of implementing safety and health management systems.*

*For ISO 22000:2005 - Food Safety Management Systems[4] reference is made to the principles of food safety management system (HACCP), developing a HACCP plan, the range of application of the standard and its benefits. The paper also relate to the implementation of these standards in Romania.*

Keywords: food, control, analysis, standards, quality

## 1. INTRODUCTION

The purpose of the paper is to highlight the need for raising the quality of products and services, environmental standards, labor safety and food safety in Romania by implementing ISO - SREN to improve quality of life and align it to the one existing in highly developed states of the European Union and worldwide.

## 2. CONCEPT OF QUALITY

### 2.1. Quality - definition, general concept

Quality is all the properties and characteristics of a product / service that gives its ability to satisfy the needs expressed or implied.

Quality control: operational techniques and activities with the character used to fulfill the quality conditions.

Quality assurance means all the actions planned to give adequate confidence that a product or service will satisfy the conditions as specified.

Quality policy: objectives, general guidelines of an organization, in terms of quality, as they are official expressed by the business company management at the highest level.

Quality Management: part of the overall management function that determines and implements quality policy.

### 2.2. Quality Planning

Part of quality management, focused on setting quality objectives and specifying necessary operational processes and related resources to meet the quality objectives.

Quality Plan refers to:

- Product realization planning involves identifying, classifying and determining the importance of quality characteristics, and setting goals, conditions and constraints on quality;
- Planning and operational management consists in preparations to be made to implement the quality system, including organization and planning;

- Develop plans and establish quality measures for quality improvement.

### 2.3. Quality Control

Part of quality management, focused on fulfilling quality requirements. Quality control has a direct impact on the development of systems to ensure that products and services are produced and supplied in purpose to satisfy our clients.

This must be closely related to the interpretation and implementation of quality plans. Not all activities matter for the quality control compartment monitoring the quality of products, some of them entering the direction of other groups or departments. For example, analysis of customer requirements and defining quality standards are not usually the responsibility of the design compartment. Therefore the need of integrating the activities of all departments of the organization in an integrated system of quality management.

### 2.4. The concept of quality management system

Quality Management System (QMS) in organizations is to integrate all the elements that influence the quality of a product or service offered by a company.

Functional areas and activities included in the QMS approach are: marketing and market prospecting, analyzing customer requirements and regulatory requirements, client communication, design and development, supply, planning processes realizing the products, realizing the products / services, checking, testing, examination, storage products, delivery and distribution.

### 3. THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

The International Organization for Standardization, abbreviated - ISO is an international confederation of establishing norms in all areas except electricity and electronics that are the IEC (International

Electrotechnical Commission) and Telecommunications ITU (International Telecommunication Union). These three organizations are united in the WSC (World Standards Cooperation).

The organization represents over 150 countries, where each country has one representative. The official languages are English and French.

ISO standards are adopted, translated and distributed in Romania by ASRO - Standardization Association in Romania which participates through its specialists in the international technical committees of ISO.

## 4. ISO 9000 FAMILY

### 4.1. General

The ISO 9000 family of standards represents an international consensus on good quality management practices. It consists of standards and guidelines relating to quality management systems and related supporting standards.

ISO 9000 introduces users to the Quality Management Principles as well as the use of the process approach to achieve continual improvement.

#### Standards from the ISO 9000 family [1]

Standard	Title	Edition
ISO 9000:2005	Quality management systems – Fundamentals and vocabulary	3rd
ISO 9001:2008	Quality management systems – Requirements	4th
ISO 9004:2000	Quality management systems – Guidelines for performance improvements	2nd

### 4.2. ISO 9001:2008 - Quality Management Systems (QMS) [1]

#### Objective

Is to establish requirements for the management system of an organization that wants to demonstrate the ability to consistently provide a product / service according to customer requirements and legal requirements and to increase customer satisfaction through

effective application of the system including continuous improvement of the system.

### ***The purpose of the quality management system [1]***

- Provides a proactive, systemic and logic approach to issues of quality;
- Highlight an organization's ability to consistently provide products/services that satisfy customer and applicable regulatory requirements;
- To increase customer satisfaction through implementation of the system;

### ***Basic principles of ISO 9001***

By 2000, it was in force the family of standards adopted in 1994, which included 4 basic standards: ISO 9001, ISO 9002, ISO 9003 and ISO 9004, considering that between them there were some nonconformities, ISO has revised the ISO standards family in 2000, eliminated ISO 9002, ISO 9003 and ISO 9004, remaining only a single standard, namely ISO 9001:2000. In broad terms, it keeps the principles of the 1994 standard to which were added 8 new principles:

- Customer focus
- Style of leadership
- Involvement of people
- Management by processes
- Systemic Approach to Management
- Continuous Improvement
- Decisions based on facts
- Mutually beneficial relations between suppliers.

### ***Structure of QMS documentation***

There is not a universal "recipe" for the document structure of a QMS, however, is considered adequate the following pyramid structure:

- Level I:
  - The company's Quality Manual
- Level II:
  - Operational manual that includes procedures for the QMS items
  - Quality Plans
- Level III:

- Work Instructions
- Level IV:
  - Records relating to QMS.

### ***General Requirements***

If the previous edition of this standard has presented a radical shift in the quality systems approach, passing the quality assurance of the quality management, this new edition clarifies the standard requirements, clarification based on eight years of experience of implementing the standard in the world . Also, changes were introduced to correlate it with the requirements of ISO 14001.

ISO 9001 contains requirements for a Quality Management System which presumes:

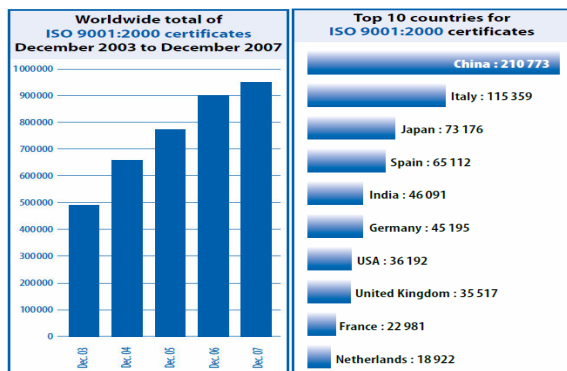
- Identification of processes and relationships between them;
- Documentation of the Quality Management System through ISO 9001 Quality Manual, system procedures, procedures and work instructions;
- Establish methods of preparation, checking and approving documents, conditions of distribution or withdrawal of documents;
- Establish rules which modify documents and data;
- Setting rules on external documents.

### ***Advantages of ISO 9001***

ISO 9001 is one of the factors that facilitate the international trade in goods and services, proof is a number of countries that have adopted this standard and hundreds of thousands of companies that have obtained ISO 9001 certification.

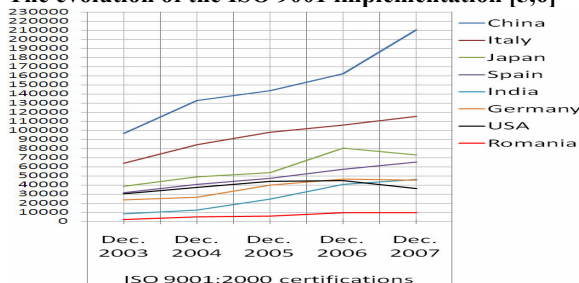
The fact that a company has obtained ISO certification is not simply obtaining an internationally recognized certificate, but as is the firm that uses some working practices, is aware of its obligations relating to its purpose in itself, meet customer requirements and is, of In fact, a general recommendation based on process and organization performance.

### ISO 9001 implemented standards situation



Country	ISO 9001:2000 certifications				
	Dec. 2003	Dec. 2004	Dec. 2005	Dec. 2006	Dec. 2007
China	96715	132926	143823	162259	210733
Italy	64120	84485	98028	105799	115359
Japan	38751	48989	53771	80518	73176
Spain	31836	40972	47445	57552	65112
India	8367	12558	24660	40967	46091
Germany	23598	26654	39816	46458	45195
USA	30294	37285	44270	44883	36192
:					
Romania	2052	5183	6097	9426	9633

### The evolution of the ISO 9001 implementation [5,6]



## 5. ISO 14000 STANDARDS FAMILY

ISO 14000 standards are general standards for environmental management systems designed to control the impact of the organization processes over the environment.

### 5.1. Development history of ISO 14000 standards [2]

In 1992 the first standard was developed in environmental management, entitled "Specification for environmental management systems, British Standards Institute (BSI - BS 7750)

In 1993, at the Advisory's Group on Environment recommendations was established The Technical Committee ISO / TC 207 "Environmental Management". At its first meeting agreed to develop international environmental standards in two main purposes:

- To harmonize existing standards, ensuring a uniform system of reference in this area, to facilitate international trade;
- To provide organizations a tool to lead to improving their environmental performance and measure progress.

In 1994 came the second version of the standard "Specification for environmental management systems", BS 7750, stating that in implementing an environmental management system is important the prevention and not the detection of harmful effects of processes and their results against the environment.

First ISO 14000 series standards were published in 1996. It started with ISO 14001, which is the basis for certification of environmental management.

### 5.2. ISO 14001:2004 - Environmental Management Systems (EMS) [2]

ISO 14001 may be applicable to any organization wishing to implement and maintain an environmental management system to ensure compliance with stated environmental policy, to obtain certification from an international body to an international standard and to make a self assessment and declaration of conformity to standards.

#### General Requirements

In accordance with ISO 14001 any organization that wants to certify the environmental management system must [2]:

- Establish an appropriate environmental policy;
- Identify environmental issues arising from the activities, its products or services existing or planned earlier, to determine significant environmental impact;
- To identify priorities and establish appropriate environmental objectives and targets;

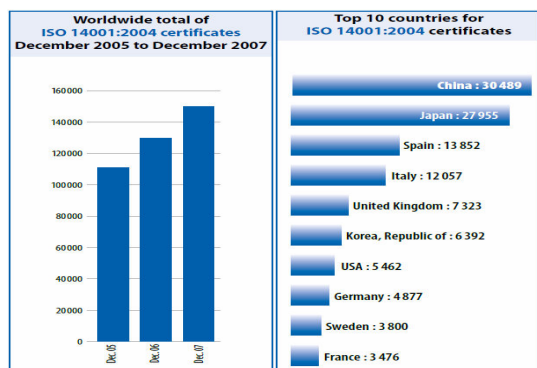
- Establish a structure and a timetable for policy implementation and fulfilling the objectives and targets;
- To be able to adapt to changes.

**Benefits of an EMS implementation[5,6]**

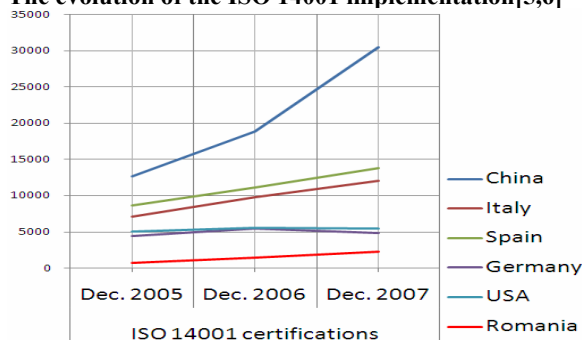
- Collate all relevant environmental activity leads to reduction of environmental risks;
- Improving environmental performance through the organization;
- Increase the public trust, government agencies, the banks, insurers and customers;
- Cost savings through systematic thinking and proactive action.
- Easy integration into a quality management system.

**ISO 14001 implemented standards situation**

Country	ISO 14001 certifications		
	Dec. 2005	Dec. 2006	Dec. 2007
China	12683	18842	30489
Italy	7080	9825	12057
Spain	8620	11125	13852
Germany	4440	5415	4877
Romania	752	1454	2269



**The evolution of the ISO 14001 implementation[5,6]**



**6. ISO 18001 STANDARD**

**6.1. ISO 18001:2005 - Systems management of labor protection [3]**

**General**

Occupational health and safety – through the OHSAS 18001 series [3] was designed to help organizations to formulate policies and objectives in occupational health and safety purposes.

18001 series includes specifications with guidelines for implementing a OHSAS 18001 system.

**Specific elements of the OHSAS system**

- The mandatory risk assessment;
- Develop program management system will be in accordance with the general rules of labor protection;
- Foundation of the Committee of Safety and Health at Work is required for unity with more than 50 employees;
- Staff training should include: general introductory training, training in the workplace and regular training;

**Benefits of OHSAS implementation**

- Shift the focus of the post factum inspection, on preventive actions;
- Improving company image;
- A management system more flexible, efficient and low cost;
- Meet requirements simultaneously for: market competitiveness, environmental protection, safety at work;

**7. ISO 22000 STANDARD**

**7.1. ISO 22000:2005 - Food Safety Management Systems [4]**

**General**

HACCP is a food safety system based on prevention.

HACCP is based on the Food Code (Codex Alimentarius) developed by the UN Food and Agriculture Organization and World Health Organization.

**Principles of HACCP / ISO22000**

- Identification of risks in all stages of production;

- Measuring the probability of (re) appearance;
- Identify preventive measures;
- Determine operational items that can be controlled to eliminate or minimize the likelihood of recurrence (critical control points - CCP);
- Determining values and critical limits that must be maintained to ensure control of the CCP;
- Establish a system for monitoring the CCP with the tests / inspections planned;
- Determine if corrective action when the process is out of control;
- Develop procedures to confirm that the HACCP system (ISO 22000) are working effectively;
- Determination of documentation and records needed to apply the HACCP principles.

#### ***Developing a HACCP plan[4]***

In order to develop a HACCP system and its application of the principles the following steps must be respected:

- Designation of HACCP team;
- Product description, method of processing and distribution;
- Description of intended use;
- Design diagrams of production processes;
- Hazard Analysis;
- Determine the critical control points;
- Establish critical limits;
- Develop monitoring procedures;
- Develop corrective actions;
- Develop verification procedures;
- Develop documentation and record keeping;

#### ***Range of application***

ISO 22000 standard specifies requirements for a food safety management system, when an organization in the food chain needs to demonstrate its capability to control food safety hazards in order to ensure that food is safe when consumed.

The standard is applicable to all organizations regardless of size, which are involved in all aspects of the food chain and want to implement systems that lead to the consistent production of safe products.

#### ***Benefits of implementing a HACCP system***

- Ensures quality hygiene;
- Achieve a reduction of rejects and complaints;
- Extends the period of validity of products;
- Get customers increased self;
- To improve their company image;
- Can attract prospective investors in expanding business;

## **8. CONCLUSION**

Implementation of ISO standards is a must for all world states, to the UE states really an obligation.

Implementation of these standards leads to the development of product / service quality, thus increasing the chances that they will be sold more easily and safely considering the global market demands.

The graphics submitted show how these standards were implemented in different countries.

To mention that Romania has positive started the implementation action of these standards in a relatively short time.

## **9. REFERENCES**

- [1] SR EN ISO 9001:2008 Quality Management Systems (QMS);
- [2] SR EN ISO 14001:2004 Environmental Management Systems (EMS)
- [3] SR EN ISO 18001:2005 Systems management of labor protection
- [4] SR EN ISO 22000:2005 Food Safety Management Systems
- [5] [www.consultanta-certificare.ro](http://www.consultanta-certificare.ro)
- [6] [www.iso.org](http://www.iso.org)