MINISTRY FOR FOREIGN AFFAIRS OF FINLAND

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HANDBOOK ON SELECTED MANAGEMENT SYSTEMS ACCORDING TO THE INTERNATIONAL STANDARDS

MANAGEMENT SYSTEMS FROM THE SERIES OF STANDARDS ISO 9000, ISO 14000 AND HACCP SYSTEM

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ACRONYMS

KSA	Kosovo Standardization Agency
FVA	Food and Veterinary Agency
BCC	Business Consultants Council
KAD	Kosovo Accreditation Directory
HACCP	Hazard Analysis and Critical Control Point
KIA	Kosovo Institute of Agriculture
IEC	The International Electro-technical Commission
ISO	International Organization for Standardization
CCP	Critical Control Point
PDCA	Plan, Do, Check, Act
QMS	Quality Management System
EMS	Energy Management System
EnMS	Environmental Management System
ESMS	Event Sustainability Management System (ESMS)
ISMS	Information Security Management System
SMSU	Food Safety Management System
UNDP	United Nations Development Programme

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INTRODUCTION

The handbook is part of the United Nations Development Programme (UNDP), "Aid for Trade" project in Kosovo[1] and is developed as part of the activity "Providing support in improving quality management levels in accordance with recognized international standards".

The aim of this activity is to assist the business community in obtaining relevant information on international quality standards. In addition, the project aims to support enterprises on improving export opportunities by providing guidelines on improving the quality management systems, and their business activities in accordance with recognized international standards ISO 9001 (Quality Management System), ISO 14001 (Environmental Management System) and HACCP (Hazard Analysis and Critical Control Points).

The handbook includes the aforementioned standards and provides information applicable to all sectors excluding HACCP that is applicable to enterprises dealing with production of food products.

Hence, the handbook will help enterprises understand the essence of the selected management systems standards, processes included within the quality management, environmental protection and food safety, identifying existing gaps in the establishment of effective management systems and certification of systems.

The handbook provides information on:

- Standards and their relevance
- The series of standards ISO 9001, ISO 14001 and HACCP principles and their background
- Management systems
- Fundamentals of ISO 9001, 14001 management systems
- Stages to develop and implement relevant systems
- Documentation required to set up systems
- The benefits related to the application of these systems
- Types of audits and management system certification process
- Relevant Kosovo institutions covering quality infrastructure.

1 For UNDP, all references to Kosovo on this document are made in the context of UN Security Council Resolution 1244 (1999).

1. ISO AND INTERNATIONAL STANDARDS

ISO stands for International Organization for Standardization.[2]

ISO history began in 1946, whereby delegates from 25 countries met at the Institute of Civil Engineering in London and decided to establish a new international organization "in order to facilitate, international coordination and unification of industrial standards". In February 1947 the new organization, ISO, officially began its operations.

ISO (International Organization for Standardization) is an independent, non-governmental membership organization and the world's largest developer of voluntary International Standards. Nowadays, it is a network of national standards institutes of 165 countries, coordinated by the Central Secretariat in Geneva, Switzerland. These national standards institutions constitute the ISO membership and at the same time represent ISO in their country. The organization has its Technical Management Board, responsible for the technical issues, managing more than 250 technical committees developing ISO standards.
ISO develops standards and guidelines to encourage accreditation and certification good practices.

To date, ISO developed over 20,000 international standards in different areas, and around *1,100 new ISO standards are published every year.*

WHAT ARE THE STANDARDS?

A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are in line with their purpose.

Under the definition of ISO/IEC[3] Guide 2:2004, *"the standard is a document established by consensus that provides rules, guidelines or characteristics for activities or their results"*.

ISO standards protect users and consumers, simplifying many aspects of their lives. Standards facilitate international trade, expand innovative progress in technology, share knowledge and provide management and conformity assessment best practices.

2 www.iso.org.

3 IEC - International Electro technical Commission

Standards are integral elements in consumer protection, helping to improve national legislation and certification schemes.

1.1 ISO STANDARDS

ISO standards provide solutions and benefits for almost all sectors and activities, including: agriculture, construction, mechanical engineering, manufacturing, distribution, transportation, services, information and communication technologies, medical devices, energy, environment, etc. These standards enable quality management and conformity assessment ensuring that products and services are safe, reliable and of a good quality.

Standards are not intended to replace legislative requirements; they are of voluntary and not of mandatory nature.

"Standards are strategic tools to help businesses predict periods of economic fluctuations and adapt to new conditions to ensure business sustainability"

For businesses, standards are strategic tools that help reduce costs by minimizing errors, reduce waste and increase productivity. They help enterprises access new markets, increase competitive advantages in developing countries and facilitate international trade.

Standards are based on consent (reconcilability) over definitions, measuring units, testing and other parameters and represent international expertise and best practices in respective fields.

Standards are reviewed at regular intervals to ensure that they are applicable to and appropriate for modern requirements.

ISO standards ensure quality, safety, environmental care, reliability, efficiency, effectiveness and interaction with low economic costs. They can be applied to products, services, processes, and to staff.

Every enterprise dedicated to its business activities, strives to provide quality, efficiency, sustainability and apply best practices. In this regard, standards can help ensure that your company is getting the best results by guiding continuation with further improvement and advancement of your business.

Why should your enterprise use ISO?	Benefits
International standards are strategic tools of guiding character that help your company facing some of the most challenging issues. Standards may be used to manage risks as well as improve your performance. They ensure efficient business processes, enable increased productivity and help your enterprise access to new markets. Standards help you apply best practices by providing the opportunity to prove the quality to your customers.	- Performance Improvement - Reorganizing enterprise processes - Efficient management of resources - Risk management - Promoting innovations - Improve customer satisfaction - Access to new markets - Ensuring business sustainability - Environmental benefits - reducing the negative impact on the environment

1.2 MANAGEMENT SYSTEM STANDARDS

Among thousands of standards, ISO is also known for developing a set of standards for management systems related to quality, environment, food safety, information security, energy, etc.

The series of Management System Standards	
ISO 9000	Quality Management System (QMS)
ISO 14000	Environmental Management System (EnMS)
ISO 22000	Food Safety Management System (FSMS)
ISO 20121	Event Sustainability Management System (ESMS)
ISO 27000	Information Security Management System (ISMS)
ISO 50001	Energy Management System (EMS)

ISO management system standards provide models to be implemented when we develop and operate a management system. Like all ISO standards, they are the result of consensus among international experts, sharing successful experiences and management practices.

These standards are comprehensive and can be applied to any organization, enterprise or institution, regardless of the sector, scope, form of organization or size.

The benefits of an effective management system include:

- Efficient management of resources
- Adequate risk management , and
- Higher customer satisfaction.

1.3 WHAT IS A MANAGEMENT SYSTEM

Management System refers to a systematic approach to managing processes, activities, resources - staff, infrastructure, working environment, etc.

A management system describes the set of processes and procedures that an enterprise needs to follow in order to fulfil its objectives.

It is clear that the size and type of enterprise will affect the composition of the Quality Management System (QMS), environmental, food safety systems etc. A micro enterprise with one individual will require a fairly simple management system. The larger the enterprise, the management of activities becomes more complex, and the there is a need for documenting the working procedures and maintaining the records to ensure that roles, duties and responsibilities assigned to the staff are clear to all of them. This process of collating the internal processes is known as management system.

1.3.1 SUCCESSFUL MANAGEMENT SYSTEM

Management system applied in an enterprise will prove successful only when a range of conditions are fulfilled and function properly, as in cases when:

- Management recognizes the commitment and duties, ensuring commitment and support for the establishment of a functional management system.
- The implementation process is properly planned and communicated to the staff.
- Staff, at all levels within the enterprise, is qualified, competent to perform tasks, trained and motivated to have a participatory role.
- Audit programs applied are effective, conducted periodically by qualified auditors, planned in the best manner, pro-active and based on arguments and evidence.
- The system is reviewed in continuity by management to ensure proper and efficient performance during the implementation.

2. ISO 9000 SERIES OF STANDARDS

ISO 9000 series of standards addresses the "Quality Management". This implies what an enterprise should do to meet: [4]

- Client requirements on the quality (focus on customer), and
- Applicable legal and regulatory requirements.

This standard of quality management system is intended to:

- Meet customers' requirements and achieve their satisfaction, and
- Achieve continuous improvement of enterprise performance in pursuit of the set goals.

ISO 9000 series of standards consists of the following standards:

ISO 9000 series of standards	
ISO 9000:2005	Quality management systems -- Fundamentals and vocabulary
ISO 9001:2008	Quality management systems -- Requirements
ISO 9004:2009	Managing for the sustained success of an organization - A quality management approach
ISO 19011:2011	Guidelines for management systems auditing

ISO 9000 family of standards is reviewed periodically. Version 2008 is currently in use, while in September of 2015 the latest version ISO 9001: 2015 is expected to be issued.

2.1 ISO 9000 - QUALITY MANAGEMENT SYSTEMS - FUNDAMENTALS AND VOCABULARY

ISO 9000:2005 describes fundamentals of quality management systems, which form the subject of the ISO 9000 family, and defines the vocabulary and terminology.

4 ISO - Selection and use of the ISO 9000 family of standards.

The standard is applicable to the following:

a) Businesses seeking advantage through the implementation of a quality management system;
b) Organizations seeking confidence from their suppliers that their product requirements will be satisfied;
c) Users of the products;
d) Those concerned with a mutual understanding of the terminology used in quality management (e.g. suppliers, customers, regulators);
e) Internal or external persons of the organization who assess the quality management system or audit it for conformity with the requirements of ISO 9001 (e.g. auditors, regulators, certification/registration bodies);
f) Internal or external persons of the organization who provide appropriate advice or training on the quality management system to the organization;
g) Developers of related standards.[5]

2.2. ISO 9001 - QUALITY MANAGEMENT SYSTEMS - REQUIREMENTS

ISO 9001 is the key standard from ISO 9000 series of standards. This standard specifies quality management system requirements (QMS).[6]

ISO 9001:2008 is the most successful global standard that addresses best practices in the implementation of quality management systems in an organization. ISO 9001 is a generic standard, it can be applied to any organization, enterprise or institution, regardless of their size, sector and area of engagement (from manufacturing activities to service delivery).

Creation of a culture of continuous improvement through the establishment of an efficient quality management system is the key to a successful enterprise.

According to ISO survey on management system standards certifications *"by the end of 2013, over 1,129,446 ISO 9001 certifications were issued, in 187 countries*

5 ISO 9000:2005, Quality management systems - Fundamentals and vocabulary.
6 ISO 9001:2008, Quality management systems - Requirements.

worldwide". "Certification with ISO 9001 standard is used in global supply chains to provide assurance about suppliers' ability to satisfy quality requirements and to enhance customer satisfaction in supplier-customer relationships".[7]

The enterprises that applied the principles of quality management use the more efficient way of working, better cost control, overall enhancement of performance, reliability and sustainability of the enterprise from the quicker and more efficient application of new work practices.

ISO 9001 is an international reference that provides a set of requirements on what an enterprise must undertake to manage the processes that affect the quality of its products or services. This standard addresses how an enterprise applies and controls its processes and activities in order to acquire confidence from third parties. Also, the standard addresses the belief that the enterprise may, at any time and steadily, offer services or products that meet the quality requirements of its customers and the requirements of applicable regulatory and legal requirements. The ISO 9001: 2008 QMS is based on the fulfilment of requirements set up by chapters 4-8 of the standard, such as:

ISO 9001 standard requirements	
Chapter 4	Overall requirements of the quality management system as well as necessary documentation requirements
Chapter 5	Enterprise management responsibilities
Chapter 6	Human resources, infrastructure and working environment management
Chapter 7	Production realization or service delivery process
Chapter 8	Continuous measurement, analysis and improvement

2.3 ISO 9004 - MANAGING FOR THE SUSTAINED SUCCESS OF AN ORGANIZATION - A QUALITY MANAGEMENT APPROACH

ISO 9004 provides a systematic approach to quality improvement and serves as a guiding document to manage and achieve sustainable success of the enterprise. This standard is recommended as a guide for enterprises and their management

7 ISO survey of Management System Standard Certification – 2013

that are in search of continuous improvement.[8] ISO 9004: 2009 is not intended for certification or contractual use; it rather provides guidance for enterprises to support sustainable success with a quality management approach. This is applicable to any organization, regardless of size, sector and type of activity. This standard can be used independently or in conjunction with ISO 9001 or together with other standards of management systems.

ISO 9004 achieves this through the application of quality management principles addressing the needs of all stakeholders, including employees, shareholders, suppliers and the local community - not only consumers, who are the focus of ISO 9001.

ISO 9004 is built upon ISO 9001's customer focus, broadening the scope of quality management and enabling users to identify opportunities for continuous improvement and application of innovations in leadership and management, preparation of proper strategies, rational use of resources, improvement of processes and management systems.[9]

2.4 QUALITY MANAGEMENT SYSTEM ACCORDING TO ISO 9001

According to ISO 9001, "The organization shall establish, document, implement and maintain a quality management system and must continually improve its effectiveness in accordance with the requirements of this international standard".

QMS introduces the methods of managing and controlling enterprise activities related to fulfilment of customer requirements. *QMS can be seen as a complex system consisting of all parts and components of an enterprise dealing with the quality of processes and products.*

Quality management is key to overcoming difficult times and achieving long-term success credence to the consumer.

QMS provides a structure, including relevant documentation processes enabling control and management of products and services offered in order to meet the quality and security foreseen requirements continuously.

8 ISO 9004:2009 Managing for the sustained success of an organization - A quality management approach

9 Achieving excellence, BSI, March 2012

ISO 9001 is a standard of quality management. Consequently, quality management implies what the enterprise does to:

- ensure that its products or services satisfy customer quality requirements;
- be in full compliance with all legal requirements and specifications applicable to its products and services.

The purpose of all the above is to help the enterprise increase its customers satisfaction and ensure sustainability through continuous performance improvement.

In general, QMS includes your organizational structure together with planning, processes, resources and documentation you use to achieve your quality goals, to meet the needs of your customers and ensure your quality management system improvement, and consequently, improving your products or services.

Quality management in your enterprise helps create competitive advantages to build confidence of your clients and to satisfy a greater number of customers as well as to save money and increase profits (see item 2.8 of the handbook).

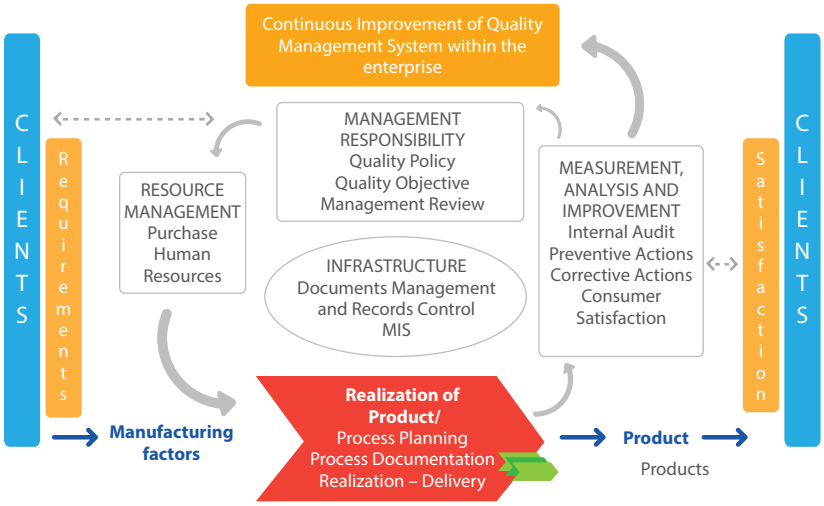
Many enterprises may be unorganized and have inadequate working systems. According to ISO 9001 QMS affects business activities of the enterprise through the simplification of internal processes, enhancement and improvement of communication and efficiency.

In order for QMS to be effective and operational, it should be integrated along with the existing operating system of the enterprise and adapt to each other, by working as a whole functional system.

QMS is a strategic tool that helps the enterprise to focus on understanding customer needs and improve client communication. In addition, QMS contributes to the achievement of enterprise objectives, affects the efficiency (by reducing losses in manufacturing), ensures continuous increase of product quality, and to establishing a team spirit affecting staff performance and efficiency.

When stating that the built system is "in compliance with ISO 9001", one understands that QMS is in accordance with the requirements specified in international standard ISO 9001, current edition.

QUALITY SYSTEM Model ACCORDING TO ISO 9001



The table below shows the problems that a manufacturing enterprise may face prior to applying the QMS, and their tackling, following the establishment and application of a QMS under ISO 9001.

Documentation required by ISO 9001 is explained in item 2.6, implementation stages in item 2.7 and benefits from the application of this system in item 2.8.

Problems with no quality system	Improvements / adjustments following the QMS establishment
Staff duties and responsibilities not clearly defined - work overload and low productivity	Functional organizational structure - clearly defined duties and responsibilities - high productivity. The organizational chart defines the functions and relevant authorities as well as the tasks assigned to each position within the enterprise.
Unsafe final product as a result of not implementing controls during production	Safe final products - standard checks during the manufacturing process as well as adequate maintenance of records.

Generation of excess waste during production	Improvement of production process - Reducing the amount of waste as a result of improving internal processes through corrective actions and following instructions for each step in the manufacturing process.
Inefficient employees - unchecked professional competence	Annual training and qualification plan - efficient, motivated and competent employees with verified knowledge. Maintaining adequate records of professional and academic advancement for each employee.
Non-standardized work processes - uncertainty in performing activities	Standardization of business processes with relevant instructions and procedures.

2.4.1 PRINCIPALS OF QUALITY MANAGEMENT UNDER ISO 9001

The family of ISO 9001 quality management system is built on eight principles of quality management.

These principles set to implement QMS should be used by senior executives of the enterprise to successfully lead and manage the enterprise, to run and check systematically its activities. This would help senior management to review the needs of all stakeholders (customers, shareholders, staff, suppliers etc.); and would ensure maintaining the consistency with other management disciplines.

Following these principles enables the maintenance of a management system and the establishment of a mechanism to continuously improve the management system performance.

Customer focus	Any organization depends on its customers and therefore should understand their needs and meet their requirements and strive to exceed their expectations.
Leadership	Leaders provide clear enterprise goals and direction. They should create and maintain effective internal communication and adequate internal environment in which staff may be involved in achieving the enterprise objectives.
Involvement of personnel	The personnel is the essence of any enterprise, so their involvement enables use of their skills for the benefit of the enterprise.
Process approach	Efficiency is better achieved when relevant activities and resources are managed as processes. Processes are the foundation upon which the QMS of an enterprise is built.
System approach to management	Identification, understanding, implementation and management of connected processes as a system, contributes towards achieving the enterprise efficiency and effectiveness.
Continual improvement	Continual improvement of the enterprise overall performance should be its permanent objective. This is accomplished through the use of quality policy and objectives, data analysis, audit results, corrective and preventive actions and management review.
Factual approach to decision making	Effective decisions are based on analysis of data and information. Decision making and implementation of actions based on factual analysis should be balanced with the experience and intuition of leaders.
Mutually beneficial supplier relationships	An enterprise and its suppliers are interdependent. Establishment of relationships through clear and open communication will provide mutual benefit and balance short term gains to the benefit of long-term relationships.

2.5 WHAT IS THE QUALITY?

General explanation says that quality refers to all the characteristics of a product or service required by customers.

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

Given the above expression of Aristotle, one understands that in order for the quality to become a habit it should be deeply involved in the culture of doing business. Namely, the establishment of a QMS enables change and setting up a work culture focused on delivery, continuous quality measurement and product or service alignment with required technical characteristics or by the customer itself.

William A. Foster quote, "*Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skilful execution; it represents the wise choice of many alternatives*".[10]

Change is a continuous process and not a momentary act. It requires leadership, commitment, determination, flexibility and engagement to enable and lead the enterprise toward quality based culture transformation. Establishing a quality system requires establishing a planning culture in the business and implementing corrective actions.

The Institution of quality culture is the equivalent of transformational change across organizations.[11] Setting up an environment that supports a culture of quality within an enterprise, requires a systematic and well-structured process. Successful quality initiatives require ongoing commitment of enterprise leaders, resource commitment and support from all staff for remedial transformation of enterprise structure, personnel and internal processes by providing and enhancing value for both customers and enterprise itself.

At QMS, emphasis is placed on the development of quality and continuous improvement. QMS aims to include the structure of the company, its culture and working environment through the use of management to associate the mission, objectives, quality culture and doing business. It also assists in the implementation of good working practices, in pursuit of continuous quality improvement.

10 William A. Foster, quotes on quality, http://www.quotes.net/quote/44042/

11 Abraham, M., Crawford, J., Fisher, T. (1999), Key factors predicting effectiveness of cultural change and improved productivity in implementing total quality management, International Journal of Quality & Reliability Management ,Vol.16, No. 2, pp.112-132.

2.5.1 QUALITY FROM THE BUSINESS PERSPECTIVE

Quality management aims to enhance business processes in continuity in order to ensure compliance with customer requirements, legal requirements and enterprise benefits[12.] One can also see the enterprise as a system consisting of many linked processes, where a change in any of the processes has complex impact in the overall work system and consequences in many aspects of doing business.

One of the most important things to the success of an enterprise is focusing on raising the quality in general and quality management system in particular.

In quality management, process improvement initiatives are often set in unbalanced relations, on the one hand commitments or investments, and on the other hand the benefits of the actions taken. Sometimes, a single change or improvement of a process will bring many benefits. Other times, some changes in a process must come together to produce an effect that provides result[13], and this often makes enterprise leaders to lose patience and stop engagement in activities that ensure continuous improvement. However, there are many reasons why an enterprise should invest in quality management.

It is quite difficult, if not impossible, that an enterprise remains constantly in a high position in the market without making constant changes to maintain its competitive position. *The moment we cease to work towards achieving the highest quality, negative impact on the enterprise will be immediate, resulting in less quality. To maintain quality, continuous control, monitoring and review of enterprise processes functioning is required.*[14]

A commitment to quality helps improve the efficiency of decision-making, in optimized use of available resources and improve customer support capabilities by building credibility and consequently customer loyalty (which helps reduce the sale costs). Simultaneously, commitment to quality also allows the development of an effective system of internal communication that helps in maintaining the current number of employees by reducing operational costs.

12 Sid Kemp, PMP., (2006), Quality Management Demystified.

13 Ibid.

14 Ibid.

If our competitors are focused on providing quality effectively, we will remain behind very quickly, especially in market share.[15] Therefore, to maintain competitiveness capability an organization should invest in building an effective quality system. Economic benefit emerges from the improvements in organization`s overall value and stability.

2.5.2 QUALITY FROM THE PERSPECTIVE OF PROCESSES FLOW

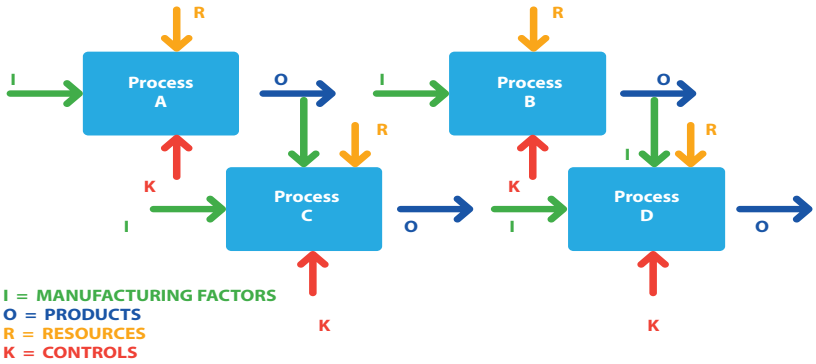
A "Process" can be defined as a "set of interrelated or interacting activities, which transforms inputs into outputs".
The question is what follows the workflow in an enterprise? The answer is simple, the processes! In a manufacturing enterprise, the process shows how a product is built. Each process has a few elements that constitute it. The key elements are as follows:

Production factors (inputs)	represent ingredients, raw materials or components that go into a process and become part of the production (output).
Process	input transformation activity to produce results - work through the use and combination of resources.
Products/services (outputs)	Final results of a process such as final products or services.

Often outputs can also serve as inputs that represents processes linkage. "*The quality of the Business Process' output is essential for the corporation since it directly impacts the company's profit, the customers' satisfaction, and the company's reputation*".[16]

15 Ibid.

16 Knapper, Rico; Poodratchi, Daniel; and Job, Lennart, "Process Quality? A business process perspective on quality of service", (2012), ECIS 2012 Proceedings. Paper 209.



Identification of key processes within an enterprise is usually done by using the flowchart. According to "Business Charts & Graphs", *Flowchart shows a visual representation of the sequence of steps and decisions necessary to perform a process.*[17]

For an enterprise to conduct activities effectively and efficiently, it must identify, develop and manage many related activities. Under ISO 9001, *"The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach". At the same time, it represents the central point of a Quality Management System, as it allows individual control of internal processes and enables the linkage between individual processes enabling their chain interaction and building of a functional system".*

Therefore, the process approach implies the identification, establishment and application of a system of processes within an enterprise, together with the interactions of these processes and their management.

17 Graphs & charts vocabulary

Identifying, understanding and managing interrelated processes as a system contributes to the organization`s effectiveness and efficiency in achieving its defined objectives

ISO 9001:2008 promotes the PDCA methodology[18] on processes known as the *Shewhart cycle. This can be used as a basic tool to ensure continuous improvement and as a basis for QMS application*. This represent Shewhart / Deming PDCA model (Plan, Do, Check, Act) - A model for continuous quality improvement.

PLAN: Set the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies (develop plan to achieve them!).
DO: Implement the processes!
CHECK: Monitor and measure processes and product against policies, objectives and requirements!
ACT: Take actions to continually improve process performance and achievement of objectives.

As a conclusion, the organizational structure and processes have a strong influence on organizational culture and the acquisition of the concept of quality, within the enterprise, that cannot be instantly changed by leadership. *"Culture change is driven by a change in performance and guided and influenced by policies, practices, skills, and procedures that are implemented and further reinforced"*.[19] This is provided through leadership commitment by pledging sufficient resources and by establishing a system of rewards within the enterprise.

18 PDCA – Plan, Do, Check, Act

19 Appelbaum S. H., Mitraud, A., Gailleur, J., Iacovella, M., Gerbasi, R., & Ivanova, V. (2008). The Impact Of Organizational Change, Structure And Leadership On Employee Turnover: A case study, Journal of Business Case Studies. 4(1), 21-38.

2.6 DOCUMENTATION REQUIRED BY ISO 9001

SMC ensures a structure, including the documentation and processes, enabling provision of products and services in a controlled, measured and managed manner to consistently fulfil the specified technical requirements as well as requirements of customers.

To establish the quality system a package of documents must be prepared. Initially it is necessary to categorize the required documentation to develop an effective SMC and completely in harmony with the requirements of internationally recognized standard ISO 9001: 2008 and the scope requirements.[20]

The main components of an effective SMC in terms of the requirements for the Standard regarding the documentation are grouped as follows:

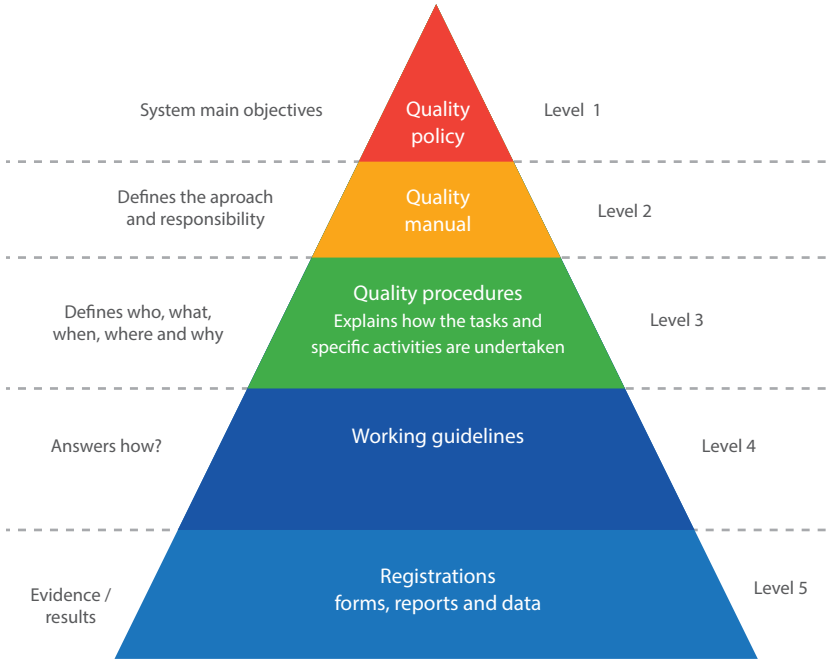
- Mandatory documentation;
- General implied documentation (according to specifications and scope of the enterprise);
- Documentation required by the legislation of the country concerned.

Furthermore, entire usual packages of abovementioned documents are divided into appropriate levels that consist of:

Level I - quality policy and objectives,
Level II - quality manual,
Level III - procedures,
Level IV - work instructions and
Level V - registrations such as forms, reports, data, etc.

20 Jay Schlickman, (2003), ISO 9001:2000 Design of Quality Management System

Implementation pyramid of the levels of documents within SMC according to ISO 9001: 2008



The level and volume of the QMS documentation depends on the enterprise type and size. The smaller the enterprise, the simpler the construction of the system; and the larger the enterprise, the system becomes more complex and demanding. For example, a service provider with one person does not need to develop a procedure for human resources management. Instead, it should demonstrate a commitment for ongoing professional development.

SMC is highly oriented to people and their participation, implying that the quality culture is an integral and essential part of an enterprise and encourages the involvement of the entire staff in its implementation and monitoring.

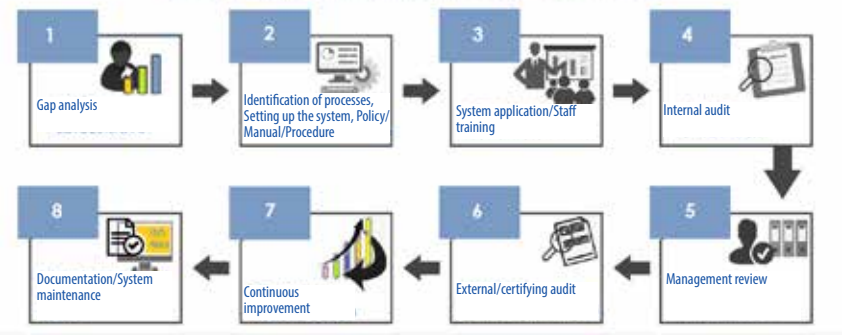
2.7 QMS IMPLEMENTATION STAGES BY ISO 9001

Starting from the commitment of the owners and of the senior management towards continuous improvement, the enterprises must apply structural

changes and be subject to restructuring processes, development of skills, provide ongoing training to the staff and a set of measures that reflects technological advances and request of customers.

Several activities are needed to set up an effective system of quality management, which are divided into various stages of implementation:

Quality Management System ISO 9001 implementation phases



For the purpose of setting up the QMS, it is proposed to initially establish the quality team within the enterprise. The team will meet at agreed intervals to prepare the work plan, to set up and document the QMS as well as to implement and maintain the system in practice.

The team should be comprised of members who know the processes that are occurring in the enterprise and have the knowledge to assist in development and maintenance of QMS.

1. GAP ANALYSIS

First step is to purchase the referring standard ISO 9001:2008 at the Kosovo Standardization Agency (KSA). It commences by analysing the requirements of the standard. Afterwards starts the process of realization of the gap analysis. This represents the standard method of data collection and enterprise assessment to identify and assess the key processes of the enterprise whether they are in compliance with the QMS or not according to ISO 9001: 2008. In order to apply, a checklist is prepared according to the clauses of the standard or since the approach process is now at the centre of ISO methodology, the list is prepared by the processes.
QMS processes within an enterprise can be:

- Quality management process
- Process of management commitment and internal communications
- Process of resource management and training
- Process of product management
- Processes of monitoring, measuring and analysing
- Process of managing relations with customers
- Process of purchasing goods
- Process of continuous improvement, etc.

The focus at this stage is in data collection, collection of evidence and in identifying gaps in the current system of enterprise management in accordance with the principles and criteria required by the ISO 9001: 2008 standard.

2. SETTING UP THE SYSTEM

Management should appoint a member to the position of quality manager who must ensure the proper functioning of the system, its maintenance and continuous improvement.
The team lead by the quality manager drafts the processes chart and undertakes all activities to pursue the establishment of the QMS documentation and its implementation in practice.
The following documentation is drafted when setting up the system:

- Drafting of quality policy that represents the company's commitment in fulfilling the requirements of clients and utilizing the opportunity for continuous quality improvement that the policy provides
- Setting (corrective) objectives and quality indicators
- Six documented mandatory procedures required by the referring standard:

- Control of documents,
- Control of registrations
- Internal audits,
- Nonconformity,
- Preventive actions and
- Corrective actions, as well as other procedures required according to the needs of the enterprise.

- Detailed instructions for special functions
- Preparation of necessary documents for the enterprise to provide effective planning, operation and control of its processes.

Registrations must be legible, easily identifiable and reversible. The registrations include forms, various reports such as the management review report, audit report, supplier's assessment, training reports, maintenance, calibration of equipment, control activities during the production process, etc.

3. SYSTEM APPLICATION AND TRAINING

Once the system is set, documented procedures must be followed to commence the implementation in practice. It is precisely the use of various forms and reports that you have compiled during the drafting of documentation that makes possible the implementation of the activities as described in the procedure.
Work on implementation of the work plan for implementation of activities. Continuously monitor the progress and provide support of management to overcome the potential obstacles along the way. The management of your enterprise should play an active role in this stage to ensure that all stages of the project regarding the QMS implementation and the deadlines are met.
To make this a successful stage, it is important that your employees understand the benefits from the implementation of QMS according to ISO 9001 (see section 2.8.1 of this manual). Internal communication and training is the key for a successful implementation.
Training and education within the enterprise is conducted with the aim that all personnel are adequately prepared to correctly implement the relevant functions. Continuous training is a very important activity in ensuring the quality of work, as it ensures the competence of personnel in carrying out the relevant function.

Prepare training packages such as:

- Introduction to series of ISO 9000 standards
- Information about the requirements of ISO 9001 standard
- Implementation of quality management system according to ISO 9001
- Preparation of procedures and work instructions
- Setting the objectives and key performance indicators (KPI)
- Internal audit and the auditor's role.

4. INTERNAL AUDIT

The enterprise should perform internal controls in planned intervals to determine whether the QMS coincides with the requirements of referring standard and whether the system is effectively being implemented.

Internal audits are conducted at least once a year and must be planned in advance. To conduct a successful audit, the internal auditor must prepare a checklist that is compiled either from clauses of standard or according to approach to the processes.

5. MANAGEMENT REVIEW

Senior management should review the QMS of enterprise in planned intervals to ensure the continuity of the system for compliance and efficiency. This is accomplished by organizing meetings for management review, which must be held at least once a year.

During the meeting, the topics that must be reviewed are those related to the QMS, such as:

- Review of the quality policy
- Analysis of clients feedback
- Discussion of possible impacts to the QMS on organizational changes or other new legal provisions
- Analysis of the results of performed audits in the prior period such as internal as well as those performed by the certification body
- Analysis of non-compliance identified during the year as well as the result of corrective actions related to them
- Analysis of the actions followed by the previous reviews conducted by senior management
- Setting the improvement (quality) objectives for the next period
- Analysis of the needs for additional resources for strengthening the implementation of QMS.

At the end of the review, the quality manager prepares a review report (minutes) in which are presented the analysis and assessments for each of the abovementioned points, drawn conclusions from the management review meeting and any decisions and actions related to improvement of QMS efficiency.

6. EXTERNAL/CERTIFYING AUDIT

Following the positive results that derived from internal audit and management review, it is now the time to choose a certifying body. Quality team contacts the certification body (see section 4.1.1 of this manual as well as 4.3.1 for the certification process). The certification body is an independent entity that sends the auditor and issues an ISO 9001 certificate. Business relationship with the certification body will be long-term relationship, since the system is verified every year whether it is functional or not. It is suggested to contact the accredited certification bodies. Check whether the selected certification body is qualified/accredited to audit and certify the enterprises in your business category!

Certification audit for ISO 9001 is similar to your internal audits.
Once you are certified, celebrate and promote your success.

7. CONTINUOUS IMPROVEMENT & 8. DOCUMENTATION / SYSTEM MAINTENANCE

Your efforts will not stop after certification. You should use the tools and control the activities that are described in ISO 9001 standard to maintain and improve the established system. Your quality system according to ISO 9001 is designed to improve continuously.

According to ISO 9001 standard, section 8.5.1 *"the enterprise must continually improve the effectiveness of the quality management system through the use of quality policy, quality objectives, internal audit results, data analysis, corrective and preventive actions and management review",* and you will begin to see performance improvements in your enterprise!

As part of continuous maintenance and improvement, it is expected from you to review your QMS documentation such as procedures, manual, etc. for their consistency. Once your QMS is matured, use the current version of ISO 9004 that provides guidelines (see section 2.3 of this manual) to help your enterprise to ensure the sustainability of activities and continuous improvement.

2.8 BENEFITS FROM SYSTEM IMPLEMENTATION BY ISO 9001

Literature gives different explanations on the benefits of the enterprise from the effective implementation of the system, whether real or potential. Benefits include: improved performance of the supply chain, reducing the time of presentation in the market, improvement of organizational performance and reliability, as well as establishing business sustainability.

In long terms of enterprise development, the implementation of this system also brings benefits such as increased organizational flexibility[21]*, and greater enterprise innovation*[22] by helping the enterprise maintaining its competitive capabilities on the market.

2.8.1 HOW CAN ISO 9001 HELP YOUR BUSINESS SUCCEED

From the establishment of a QMS based on ISO 9001 your company can draw many benefits. *This can be seen also in the aspect of motivations that encourage an enterprise to apply the QMS. The benefits can be divided into external and internal.*[23]

Internal benefits deal with internal purposes of improvement such as productivity, efficiency, internal communications, optimizing the use of resources, etc. *The external benefits are related to the image of the enterprise, namely the advantages and opportunities created in the enterprise promotion and marketing of the products or services*[24].

Internal benefits	External benefits
Increases efficiency, economization and profitability	Provides competitive advantage on national and international level
Greater focus on your business objectives and client expectations	Strengthens the image of the enterprise
Sets the principle of continuous improvement of processes as part of corporate culture through corrective and preventive actions	Provides enterprise acceptability from consumers in the internal and external market
Provides traceability and ease of evaluation	Offers reliability in the provided product or service

21 Han,S.B. (2008), Relationship Between Firm Performances and Profitability, Northeast Decision Sciences Institute Proceedings, March 28-30.

22 Prajogo, D.I., Sohal, A.S. (2003), The Relationship between TQM Practices, Quality Performance, and Innovation Performance - An Empirical Examination, International Journal of Quality & Reliability Management, Vol. 20, No 8, pp. 901-918.

23 Urban, Wieslaw, (2012), ISO 9001 as a Tool for Supporting Strategic Advantages, Transformations in business and Economics, Vol.11,No3 (27), pp.57-71

24 Ibid.

Increases motivation of employees, team spirit and strengthens the internal communication	Increases performance, raises the authority and credibility to the clients, suppliers and partners
Helps in clarifying the tasks, roles and responsibilities of employees	Enables better relationships with strategic partners
Optimal use of available resources	Increases market share
Increases efficiency of processes and reduces costs	Encourages work focused on customer demand - builds loyalty

3. ISO 14000 SERIES OF STANDARD

ISO 14000 standards series addresses various aspects of environmental management. It provides practical tools for enterprises and organizations that seek to identify and control their impact on environment to continuously improve their environmental performance.

ISO 14000 standards series for environmental management are designed to provide practical work tools to assist enterprises in implementing the supporting actions for sustainable development.

ISO 14001: 2004 and ISO 14004: 2004 are focused on environmental management systems (EMS). The other standards of this series have a special focus on environmental aspects such as analysis of lifecycle, communication and auditing.

ISO 14000 standards series consists of the following standards:

ISO 14000[25] Standards Series	
ISO 14001:2004	Environmental management systems - Requirements with guidance for use
ISO 14004:2004	Environmental management systems - General guidelines on principles, systems and support techniques
ISO 19011:2011	Guidelines for auditing management systems
ISO 14006:2011	Environmental management systems - Guidelines for incorporating eco-design

25 ISO 14000 standards series has numerous standards. We have selected these standards as they directly impact the enterprises. Other standards of this series focus on specific aspects of the environment. For more visit the website www.iso.org

ISO 14020:2000	Environmental labels and declarations - General principles
ISO 14031:1999	Environmental management - Environmental performance evaluation – Guidelines
ISO 14040:2006	Environmental management - Life cycle assessment - Principles and framework
ISO 14050:2009	Environmental management - Vocabulary

ISO 14000 standards series were published for the first time in 1996 and revised lastly in 2004.

3.1 ENVIRONMENTAL MANAGEMENT SYSTEMS - REQUIREMENTS WITH GUIDANCE FOR USE

Always according to the ISO, ISO 14001:2004 standard specifies criteria for an environmental management system and is certifiable.

ISO 14001 does not specify requirements for environmental performance, but provides a framework that an enterprise or organization can follow to establish an efficient environmental management system. This standard can be used by any company regardless of its activity, sector or size.

According to ISO 14001:2004, section 3.5 defines the **Environment** as *"Surroundings in which an organization operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelation".*[26]

The standard in question provides a structure for management of important environmental aspects over which an enterprise can be expected to have control and can affect.

Usage of ISO 14001: 2004 can provide security for enterprise management and employees, and for external parties, that the impact on the environment is being measured, monitored and improved continuously.

ISO 14001:2004 standard on environmental management system (EMS) is based on the fulfilment of a set of requirements. Requirements for environmental management systems are presented in Chapter 4 of the standard, under six main sections, as shown below.

26 ISO 14001:2004, Environmental management systems - Requirements with guidance for use.

Requirements by ISO 14001 Standard	
Section 4.1	General requirements
Section 4.2	Environmental policy
Section 4.3	Planning
Section 4.4	Implementation and operations
Section 4.5	Checking
Section 4.6	Management review

In the scope of EMS establishment, the scope of ISO 14001 should be defined. It should include all factors of production, products / services, activities, enterprise products and services. At the same time it includes all the staff and management to undertake their duties with appropriate responsibility in taking care of the environment, as well as all locations where the enterprise operates.

According to the ISO survey on certification with standards of management systems *although the certification of conformity with the standard is not an ISO 14001 requirement, at the end of 2013, at least 301,647 certificates were issued in 171 countries.*[27]

3.2 ISO 14004 - QUALITY MANAGEMENT SYSTEM – GENERAL GUIDELINES ON PRINCIPLES, SYSTEMS AND SUPPORT TECHNIQUES

ISO 14004 is presented as a supporting tool for environmental management developed by ISO, which supplemented ISO 14001, by providing additional guidance and explanations.

ISO 14004: 2004 provides guidance for establishing, implementing, maintaining and improving environmental management system and its coordination with other management systems such as ISO 9001.[28]

Whereas ISO 14001 contains only requirements that can be clearly audited regarding the environmental aspects, ISO 14004 provides additional general guidelines on various issues related to environmental management system.

27 Research of ISO Standards Certification for Quality Management - 2013.

28 ISO 14004:2004, Quality management system – General guidelines on principles, systems and support techniques.

3.3 ENVIRONMENTAL MANAGEMENT SYSTEM BY ISO 14001

According to ISO 14001: 2004, the Environmental Management System represents the part of the general management system of an enterprise that includes organizational structure, planning of activities, responsibilities, practices, procedures, processes and resources for developing, implementing, reviewing environmental policy and management of environmental aspects.

In order to achieve the environmental objectives in preventing or minimizing the impact on the environment, the EMS promotes the application of best available techniques and practices whenever they are appropriate and when they appear economically reasonable.

Establishment of an EMS helps in shifting the enterprise from being reactive to proactive, by anticipating and preventing negative effects on the environment and human health.

EMS is a system that defines the roles and responsibilities within the enterprise to identify the environmental aspects in order to prevent environmental pollution.

An implemented EMS proves that the company is committed to undertake appropriate steps to reduce the environmental impact (within its capabilities and the level of applied technology).[29]

According to ISO 14001:2004, section 3.6 defines the **Environmental Aspect** as the *"Element of an organization's activities, products or services that can interact with the environment"*. Whereas section 3.7 defines the **Environmental Impact** as *"Any change in the environment, whether adverse or beneficial, entirely or partially resulting from an organization's activities, products or services."*

The enterprise should identify environmental aspects that may have a significant negative impact on the environment, in order to implement appropriate activities in assisting with controlling, prevention or reduction of environmental impact. Environmental aspects represent one of the most important requirements of ISO 14001 standard during the establishment and implementation of EMS. If they are clearly addressed, they enable accurate identification of environmental impact from the enterprise activities and effective implementation of established EMS.

29 Ken Whitelaw, ISO 14001 Environmental Systems Handbook, Second Edition, 2004.

Understanding the environmental aspects and their impact is a key factor in successful implementation of EMS according to ISO 14001

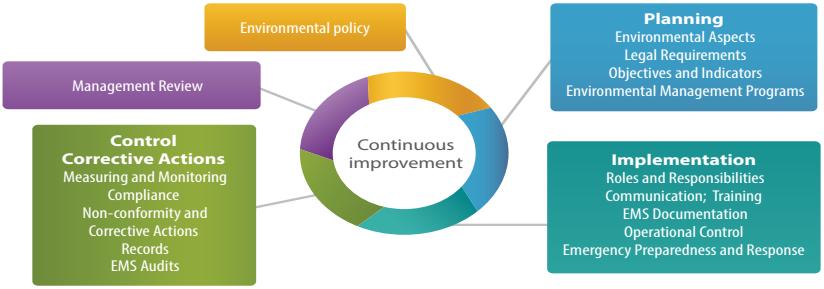
Environmental Aspects and environmental Impacts are closely related to each other. Their relationship can be described in such a way that environmental aspects are presented as "CAUSES" while environmental Impacts as "EFFECTS". It is well known that one cause can create one or more effects, depending on the circumstances and the relevant conditions.

According to ISO 14001:2004, Annex A 3.1, environmental aspects are grouped into eight groups as follows:

Air emissions
Wastewater discharge
Land pollution
Use of raw materials and natural resources
Use of energy
Emitted energy, eg heat, radiation, vibration.
Residues and waste
Other local issues

PDCA methodology

ISO 14001:2004 promotes PDCA (Plan → Do →Check → Act) methodology for processes, the same as ISO 9001: 2008. These two methodologies are considered to be consistent with each other, since PDCA approach is applicable in almost all processes.



The table below presents the problems that a manufacturing enterprise may face before implementing the EMS and their addressing after establishing and implementing the EMS according to ISO 14001.

Documentation required by ISO 14001 is explained in section 3.4, the implementation phases in section 3.5 and benefits from the application of this system in section 3.6.

Problems before establishment of EMS system	Improvements / adjustments after the establishment of EMS
Enterprise has problems in meeting the growing legal requirements, since the violations (environmental pollution from the enterprise activity) can result in fines up to lawsuits.	Compliance with legal requirements as a result of establishment of a proper system for monitoring and addressing the requirements and legal changes that have an impact on enterprise. Enterprise regularly communicates the appropriate information to employees and stakeholders. Reduction of the need for inspections within the enterprise by inspectors and significant reduction of the possibility of imposing fines and lawsuits.
Continuous pressure on enterprises from the market, standards and legal requirements to develop and enhance the activities of the enterprise in a sustainable manner.	Modern system for protection of environmental impact resulting in manufacturing activities with minimal effects/ impacts on the environment - standard controls of enterprise operations and activities to monitor the gas emissions and adequate maintenance of registrations. E.g. the enterprise applies wastewater treatment systems and efficient equipment resulting in stopping the pollution (*from discharge of contaminated water in the manufacturing process*), conserving energy and reduction of costs.
Enterprise generates more waste and residues during production by causing economic losses and environmental pollution.	Improvement of manufacturing process - Reducing the amount of waste as a result of improving internal processes through preventive / corrective actions and reuse of waste through recycling programs.

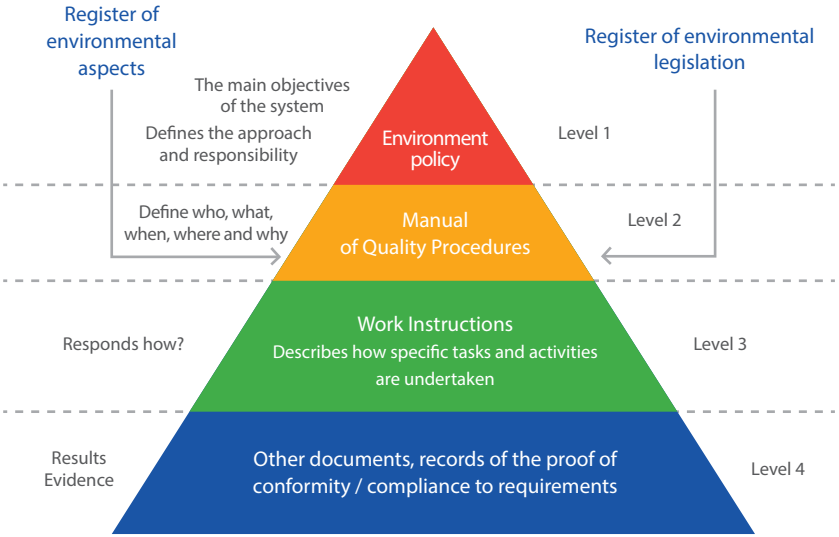
Inefficient employee - unchecked professional competence. Employees incapable of controlling the impact on the environment while performing their activities.	Training and qualification plan - Efficient employees, motivated, competent and capable of meeting environmental responsibilities. Keeping adequate records of professional and academic progress for each employee.
Due to its complex activity and emissions of various pollutants (excessive emission of gases in nature, maximum energy utilization, discharge of untreated wastewater in the environment, etc.), the enterprise must react to avoid damage through various programs in order to improve the situation.	The enterprise has established an effective process of readiness for emergencies and reactions by focusing mainly on the prevention of incidents and their impacts on the environment, by not having a need to react to avoid damages. As a result, it contributes in reducing the risk, reducing the impact on the environment, reducing injuries, protecting the health of employees and community and reducing the loss of assets.

3.4 REQUIRED DOCUMENTATION BY ISO 14001

ISO 14001:2004 Standard, in section 4.4.4 provides the requests for required documentation. Documentation of environmental management system should include:

- environmental policy, objectives and indicators,
- description of the scope of the environmental management system,
- description of the main elements of the environmental management system and their interaction, as well as referral of documents associated with them,
- documents (including records) required by this International Standard, and
- documents (including records) defined by the enterprise that are necessary to ensure planning, operation and effective control of the processes dealing with important environmental aspects of the enterprise.

Implementation pyramid of document levels within EMS according to ISO 14001:2004



3.5 EMS IMPLEMENTATION PHASES ACCORDING TO ISO 14001

In order to set up an EMS according to ISO 14001, an enterprise needs to pursue separate activities in various phases.

The table below presents the steps to building a functional EMS according to ISO 14001.

Activities for EMS implementation according to ISO 14001	
1	Contact with KSA - (Kosovo Standardization Agency) to ensure ISO 14001 standard
2	Analysis of the ISO 14001 standard requirements
3	Establishing quality and environmental protection team for within the enterprise
4	Conducting of the gap analysis
5	Drafting the work plan for building EMS
6	Drafting the environmental policy and assigning the scope of system
7	Identifying and determining environmental aspects and impacts triggered by the activities of the enterprise
8	Identification of legal requirements and other requirements affecting the enterprise
9	Identification of objectives and key performance indicators related to environmental aspects
10	Drafting the environmental manual
11	Drafting of procedures, instructions, forms and other supporting documentation
12	Training of the enterprise personnel regarding the EMS and ISO 14001
13	Conducting the EMS internal audit
14	Organizing of management review for EMS
15	Realization of external certification audit for certification of system established by international certification bodies.
16	Continuous improvement through monitoring, measurement, analysis, corrective actions
17	Maintenance of documentation and environmental management system

3.6 BENEFITS FROM SYSTEM IMPLEMENTATION ACCORDING TO ISO 14001

Benefits from establishing an EMS according to ISO 14001 are numerous and among other things, they can be grouped as benefits in the field of ethics, economy, and in legal and commercial field, as shown on the table below:

Benefits	Explanation of benefits
Ethics	Improved environmental performance through the establishment of the EMS. As human beings we have to take care about the world we live in, for ourselves and for the coming generations.

Economy	Optimize the use of resources and competitive advantage. Preservation of resources and non-generation of the waste from products or reduction of energy usage, which means that we reduce the expenditures. Provides guidance to recycle and reuse the products.
Legal	Reduction of risk towards legal obligations by minimizing the impact on the environment as a result of improved compliance with legal requirements. Governments are increasingly adopting laws to control the environment pollution and how we interact with the environment. Therefore we need the systems to ensure that we are in compliance with the laws, otherwise we can be fined and harm our reputation. It helps to prevent the environmental risk.
Commercial	Consolidated enterprises are increasingly taking responsibility for their impact on the environment and they expect their suppliers and subcontractors to do the same. In some cases without the testimony of an environmental management system, you will not be able to sell your products. On the other hand, new market opportunities can be opened for your enterprise by being able to demonstrate good environmental practices. Develops the trust factor between the organization and the public.

3.6.1 HOW CAN ISO 14001 HELP YOUR BUSINESS SUCCEED

A functional and certified EMS can help an enterprise in many aspects as:

Benefits for the business from EMS implementation	
⇑	Managing risk in complex responsibility issues
⇑	Provision of safety for affected parties
⇑	Achieving customer satisfaction
⇑	Planning and achievement of a continuous improvement
⇑	Savings in energy and materials consumption
⇑	Reduction of waste management costs
⇑	Reduction of total expenditure
⇑	Promotion of a positive enterprise image with the institutions, clients and the public
⇑	Highest reliability that meets legal requirements
⇑	Better access to finances

4. AUDITS AND CERTIFICATION OF THE MANAGEMENT SYSTEM

4.1 AUDITS

One of the core features of a QMS or an EMS is the assurance of its implementation, which assures the consumers that an appropriate quality or environmental management system is being implemented.

Audits are a vital part of the operation management system as they allow the enterprise to see on what level the achievements fulfil their objectives and demonstrate compliance with the standard. Although the performance of product / service providers without such assurances may be satisfactory, there is less risk of unsatisfactory results when the systematic management is being implemented, including the implementation of an efficient audit process and undertaking of adequate corrective actions.

In order to help the control regarding these standards, ISO has developed ISO 19011: 2011 by providing specific guidance on internal and external audits of management system.[30]

4.1.1 TYPES OF AUDITS

Audits can be:

- First party audits (internal) - an enterprise audits its own system. This service can be performed also by a service provider or external auditor to assess the compliance of the system with the requirements of the referring standard.
- Second party audits ("external" audits) an enterprise audits its suppliers. This service is performed by an agency / certification body or other client to assess the activities of its service / products providers. Notification and behaviour procedures for audit are official and require more planning and preparation.
- Third party audits ("external - certification" audits) performed by an independent certification entity / body accredited by an internationally recognized scheme, to prove that the QMS or EMS of product or service provider meets the requirements defined by the referring standard. These audits are more official.

30 ISO 19011:2011, Guidelines for auditing management systems.

4.1 ACCREDITATION

Accreditation - *formal recognition by an independent body, generally known as an accreditation body that a certification body operates according to international standards.*

Accreditation is a procedure by which an authoritative body gives formal recognition to a certification body or person to prove that it is competent to carry out specific tasks such as the provision of relevant certificates issued by them (certificates of management systems, products and personnel and other attestations of testing and inspection, etc.). *In relation to ISO 9001 or ISO 14001, accreditation means that an organ, certification body is authorized to certify an enterprise which has successfully met the requirements of the referring standard.*

Some of the important Kosovo, European and international accreditation institutions are:

- Kosovo Accreditation Directorate (KAD)
- The United Kingdom Accreditation Service - UKAS
- Italian National Accreditation Body - ACCREDIA
- ANSI-ASQ National Accreditation Board (ANAB)
- Turkish Accreditation Agency - TURKAK
- Joint Accreditation System of Australia and New Zealand - JAS-ANZ
- Dubai Accreditation Centre - DAC.

4.2 CERTIFICATION

Means that an **independent, external body** has audited the management system of an enterprise and verifies that the system is in compliance with the requirements specified in the referring standard.

Certification is the activity through which a third and independent party proves officially that a product, process or service is in compliance with the defined requirements of the standard.

Certification of standards for management system is not mandatory. Certification is not a mandatory requirement of the implementation of ISO 9001 or ISO 14001[31], and is not the only way to demonstrate the compliance with the standards. You can still benefit from the implementation of these standards, without having to be certified.

31 ISO 9001for small businesses. What needs to be done, Third Edition, 2010.

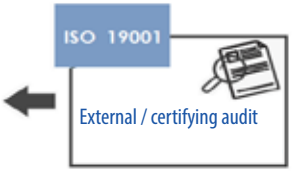
Certification - act by an independent audit body which proves that the product, service or system in question meets the specific requirements of the referring standard.

If you are looking to be certified in one or more of management system standards, you should contact an external certification body. ISO does not perform certification.

4.2.1 CERTIFICATION PROCESS

The certification process of management system includes the following stages:

- Selection of certification body
- Pre-auditing
- Initial visit and review of documentation
- Certifying audit
- Corrective actions following the audit
  - Verification of actions
- Decision of certification
- Issuance of the certificate, registered in the public list
- Supervisory audit at certain time intervals



There are many institutions that provide certification services, including the ones in the following table:

Certification bodies	
SGS	http://www.sgs.com
TUV	http://www.tuv.com
BVQI	http://www.bureauveritas.com
GlobalGROUP	http://www.globalgroup.net
Lloyd's	http://www.lrqa.com
DNV GL	http://www.dnvba.com

4.3 WHAT DOES IT MEAN "IN COMPLIANCE WITH ISO 9001 OR ISO 14001"

CONFORMITY ASSESSMENT

According to ISO, conformity assessment includes a set of processes that show that your product or service or system meets the requirements of a referring standard.

Conformity assessment has a number of benefits:

- Provides increased confidence of customers and other parties.
- Provides your enterprise with a competitive advantage.
- Assist regulators to ensure that the health, safety or environmental conditions are met.

The main forms of conformity assessment are tests, certifications and inspections.

5. FOOD SAFETY

Along with the development of international free trade and with global technological advances, methods of processing, manufacturing and distribution of food did sophisticate as well. Food sector enterprises are applying advances in biotechnology increasingly. Unfortunately, in parallel with the use of new technologies in food production, the use of pesticides as well as various additives has increased as well. This has led to an increase of international trade in food products and in the speed of transactions, but also in increase of concerns about food safety and quality.

Regarding the food that we consume, we may not have information of its origin or under what conditions it is manufactured. Since the food is very sensitive, these developments at the same time have also brought increased risks from borne diseases which are one of the most worrying problems of public health. Precisely this has prompted the reaction of the international community in finding the global solutions in regulating this sector through establishment of international standards on food.

The Codex Alimentarius Commission was established in 1963 by the Food and Agriculture Organization (FAO) of United Nations and the World Health Organization (WHO). The main goals of this program are that through the de-

velopment of standards, guidelines and codes of international harmonized practice on food, provide health protection of consumers and ensure fair practices in food trade. The Commission also promotes the coordination of work for all food standards undertaken by international governmental and nongovernmental organizations.

As a result, the Commission has prepared the general principles of Food Hygiene, which ensures the basis for food hygiene and places a solid foundation for development of an effective HACCP system.[32] By realizing that international standards are needed to ensure the security of the global supply chain in the food sector, ISO has been working in this direction by developing the ISO 22000 series of standards that addresses the food safety management. The consequences of unsafe food can be serious and the standards of food safety management are intended to help organizations to identify and control food safety hazards.

ISO 22000 standards series contains a number of standards in which each standard focuses on various aspects of food safety management.

5.1 ISO 22000: 2005 FOOD SAFETY MANAGEMENT SYSTEMS - REQUIREMENTS FOR ANY ORGANIZATION IN THE FOOD CHAIN

This international standard specifies requirements for the food safety management system. The enterprise needs to show its ability to control the food safety hazards by providing safe food.

ISO 22000 combines the following elements that are generally accepted to provide food safety along the food chain to the point of final consumption:[33]

- Interactive communication;
- System management;
- Prerequisite programs;[34]
- HACCP principles.[35]

In this handbook we will focus on the elaboration of HACCP as one of the most widespread scientific methods in the world in the food chain.

32 HACCP – Hazard Analysis and Critical Control Point

33 ISO 22000:2005, Food safety management systems - Requirements for any organization in the food chain

34 See section 5.2.7 Prerequisite conditions for HACCP implementation

35 ISO 22000:2005, Food safety management systems.

HACCP establishes a system for identifying and assessing health hazards at all phases of the process of food manufacturing, processing and distribution.

5.2 INTRODUCTION TO HACCP

Food safety requires special treatment. Consumers currently not only require higher quality, hygiene and health standards in the products that they buy, but they also require the provision of origin of products, verification of production methods, certification of products and systems. HACCP is one of the most popular international systems that provide food safety.

The main objectives of the food industry are: provision of safe production and supply of quality and healthy foods.

These targets can be achieved by establishing a proper systemic and organizational structure according to the requirements of ISO 9001 that are the basis of quality management system and establishing HACCP system within the enterprise, through:

- Control of the activities,
- Identification of work processes
- Establishing procedures and
- Allocating resources (human, infrastructural and financial).

Safety of the products is one of the universal core values. Establishment of a positive culture regarding the food safety through the establishment of HACCP system is a preventative approach in order to provide safe food.

5.2.1 HACCP BACKGROUND

HACCP has its origin in the United States since 1960's when Pillsbury Co. made an effort to enable a "zero defect" program, which would ensure food safety for food supply for astronauts for the space missions that were led by the American Space Agency - NASA.

The general program as it was implemented in Pillsbury, has placed the food safety in a corporate culture. It changed the system of analysing and controlling food safety by the application of proactive measures in reactive and preventive measures.

Since then, thanks to the success shown, HACCP principles are defined and accepted in international food standards (Codex Alimentarius), as well as in European legislation.

5.2.2 HACCP SYSTEM – CONCEPT, DEFINITION AND GOAL

HACCP is *"a system that identifies, assesses and controls the hazards which are significant for food safety"*.[36]
This system provides a guarantee of food safety through preventive controls of critical aspects of food manufacturing all the way to the final product testing.

The purpose of a HACCP system is to identify potential problems of food safety and determine the control and / or prevent them.

Product description and intended use, process flow diagrams, hazard analysis, establishment of critical control points and verification activities represent main aspects of HACCP plan.

HACCP is a risk management process based on the scientific method[37] and for this reason this activity requires a systematic approach in hazard analysis and undertaking of preventive measures, raising the competence of personnel, provision of sufficient resources and control as well as internal and external verifications (such as audits) to consistently assure that a food enterprise is in fact producing safe food for consumption.

Rather than relying solely on the final product testing and in inspection activities, HACCP is a very effective tool to assess potential risks and establish a control system through critical control points, which focuses on the prevention of risks.

HACCP as a methodology is designed to identify specific steps of the process or processing requirements that eliminate, hinder or decrease to an acceptable level an identified hazard.

In HACCP, the emphasis is on being proactive - prediction, prevention and reaction, in realization of the process from the beginning in appropriate manner rather than correcting it after the problems emerge.

36 General rules of food hygiene, CAC/RCP 1-1969, Rev. 4-2003.

37 Pierson, MD (1997). The importance of prerequisites programs. Advancement of food safety 1 (2) 34-35. Sydney.

Food safety has two main elements:

- Health Safety (safe and healthy food)
- Quality (quality food)

HACCP system provides more effective protection of consumers' health in food production process.

HACCP system is now a universally accepted method for provision of food safety. It can be applied for any food activity in micro, small, medium and large enterprises, such as:

- food processing centres
- hotel enterprises, hotel kitchens, restaurants
- commercial kitchens/cafeteria
- packaging enterprises, and
- distribution enterprises, such as supermarkets.

5.2.3 TYPES OF HAZARDS OF HACCP

HACCP focuses on hazards rather than on pollutants because many potentially dangerous agents can be usually detected in small amounts in food and may not be harmful; it is their concentrations that can cause the hazard.

HACCP is a systematic approach for food safety. Implementation of HACCP requires addressing the hazards and focuses on three types of food safety hazards that are likely to cause illness or injury if they are not controlled:

- microbiological,
- chemical and
- physical

Types of HACCP Hazards	
Biological hazards	Include pathogenic bacteria, viruses, natural toxins or parasites. Microbiological risks are the main risks since they pose the main threat to the public health. This type of risk is mainly caused by contaminated ingredient, unsatisfactory hygiene, poisoning and inadequate heating or cooling.
Chemical hazards	Usually result from pollution by agricultural chemicals (e.g., fertilizers, pesticides), industrial chemicals (e.g., cleaners, lubricants, fats), natural toxins or allergenic compounds (e.g. proteins, peanuts, gluten), heavy metals, and food chemicals (e.g., preservatives, acids, various food additives).
Physical hazards	Include foreign objects such as glass, metal, wood, insects, and stone.

5.2.4 LEGISLATION OF EUROPEAN COMMUNITY IN RELATION TO FOOD

European Community (EC) legislation covers all stages of production, processing, distribution and placing on the market the food intended for human consumption. Below are presented the main EC regulations regarding the food hygiene and safety.

EU legislation regarding food hygiene and safety	
Regulation EC/178/2002	of the European Parliament and of the Council dated 28 January 2002 sets general principles and requirements of food legislation, establishes the European Food Safety Authority (EFSA) and defines the procedures relating to food safety, especially the possibility of tracking the foods and their ingredients throughout all stages of production, processing and distribution.
Regulation EC/852/2004	dated 29 April 2004 on the hygiene of ingredients.
Regulation EC/853/2004	Simultaneously, this regulation recommends the inclusion of HACCP in food production and in the entire food chain.
Regulation EC/854/2004	Defines specific hygiene rules for food of animal origin.

Regulation EC/882/2004	Defines specific rules for organization of official controls on products of animal origin for human consumption.
Directive 2004/41/ EC	on official controls performed to ensure the verification of compliance with the legislation on feed and food, animal health and animal welfare rules.
EU Regulation 1169/2011	abrogates certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/ EC, 21 April 2004.

5.2.5 KOSOVO FOOD LEGISLATION

Law on Food No. 03 / L-016, published in the Official Gazette is the legislative basis on the food sector in Kosovo is the. The Law on Food is largely in accordance with Regulation of the European Parliament and Council No.187 / 2002.

Kosovo Legislation from Food Hygiene Package includes:

- Regulation No. 10/2011 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Regulation No. 11/2011 on hygiene of food stuffs.
- Regulation No. 12/2011 laying down specific rules on hygiene of food of animal origin.
- Regulation No. 13/2011 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption.

5.2.6 ADVANTAGES AND OBJECTIVE OF IMPLEMENTATION OF HACCP SYSTEM

Implementation of HACCP enables businesses to build a cost-effective system for controlling food safety through the processes of production, storage and distribution for sale and service to the final customer since it focuses on identifying and preventing hazards from poisoned food, based on scientific facts.

HACCP preventive approach not only improves the food safety management but also complements other quality management systems such as ISO 9001.

Although the main HACCP goal is food safety, through the implementation of an effective HACCP system other benefits results as well.

HACCP main benefits are:

- Avoiding consumer poisoning
- Preventing food-borne diseases
- Increasing standards of food safety and quality
- Demonstrating compliance with legal requirements
- Saving money in the long run for business
- Organizing the process of safe food production
- Organizing the staff in promoting teamwork and increasing efficiency
- Providing legal defence in court
- Demonstrating compliance with the requirements of the product
- Reducing the risk of product withdrawal from the market
- Increasing the trust of customers
- Reducing costs by reducing residues in production and reprocessing
- Reducing cost regarding food analysis
- Allowing more effective supervision and simplification of inspections as a result of maintaining documents and records, since record keeping allows investigators to see the compliance with laws on food safety.
- Ensuring consistently the quality products
- Reducing competition barriers in international trade.

5.2.7 PREREQUISITE CONDITIONS FOR HACCP IMPLEMENTATION

Before implementing the HACCP system, food enterprises must already operate with good manufacturing practices (GMP) and good hygiene practices (GHP) by already having installed the necessary prerequisite programs (PRP).

Prerequisite conditions (PRP) for HACCP are necessary practices and requirements which the company must meet prior and during the implementation of HACCP. Good manufacturing practices and hygiene are essential for food safety as shown on the general principles of food hygiene codex and other codes of practice.

Basic sanitary requirements of food manufacturing facilities are known as Good Manufacturing Practices (GMP). These practices are defined as universal steps or procedures that control the operating conditions in a food enterprise by enabling favourable conditions for safe food manufacturing. Prereq-

uisite Programs, GMP and GHP deal with creating favourable conditions for: manufacturing facilities, hygiene in facilities, operations control, personal hygiene, training, repairs and maintenance, transportation, information about the product, and consumer awareness. GMP and GHP are prerequisites for HACCP. Prerequisite programs are the foundation of HACCP plans. They alone are insufficient for the food safety. Therefore, after establishing the necessary prerequisite program, HACCP implementation is advised to enable control of the phases of key manufacturing processes or service provision.

GMP and GHP will simplify the HACCP plans and consequently will minimize the number of CCP.

Just like the GMP is the basis of an effective program of HACCP, the HACCP is also a critical system for food safety that supports other quality systems such as ISO 9001, etc.

5.2.8 SEVEN PRINCIPLES OF HACCP SYSTEM

HACCP has 7 principles upon which the food safety system is based. A system based on HACCP principles enables the identification and control of hazards before they pose a threat to public health.

1. HAZARD ANALYSIS

Hazard analysis enables identification of possible hazards associated with food through the entire food chain starting from supply of raw materials, manufacturing process, all the way to its distribution and their impact on food safety.
The main risks to be considered at each step are poisoning from biological, physical and chemical aspects (refer to the types of hazards).

2. IDENTIFYING THE CRITICAL CONTROL POINTS (CCP)

CCP is a step at which the control can be applied and is essential to prevent or eliminate a food safety hazard that threatens food safety or reduces it to an acceptable level.
They are often identified by the use of flowchart. Examples are the cooking process (cooking, baking, etc.), pasteurization, freezing, packaging etc.
It is important to identify all hazards during the operation to ensure food safety. But we should be careful in excessive monitoring because the focus might be lost and the main business operations might be limited.

3. ESTABLISHING CRITICAL LIMITS FOR EVERY CONTROL POINT

Set upper and lower limits which should not be exceeded to ensure that CCPs are under control, thus preventing the risk of contamination. These restrictions allow you to identify when a CCP is out of control. For example, regarding the food that must be cooked this would mean setting the minimum cooking temperature and time required to eliminate the harmful germs.

4. ESTABLISHING A SYSTEM FOR MONITORING CRITICAL CONTROL POINTS – (CCP)

When CCPs are identified, it is important to ensure that they are monitored at regular time intervals to ensure that they are within the critical limits and to ensure that there cannot any situation that could threaten food safety is avoided.

For example, these procedures can include instructions on how, when and who should control the temperature and time of cooking, baking, etc.

5. ESTABLISHING CORRECTIVE ACTIONS DURING MONITORING

The monitoring process of the system enables identification of an occurring problem. In the event when the CCP has failed to prevent the problem, then the corrective actions are placed. It should be clear to those who monitor and work with the system what corrective measures need to be taken. For example, continuing cooking, baking, if a specific minimum temperature is not reached.

6. ESTABLISHING VERIFICATION PROCEDURES TO CONFIRM THAT THE HACCP SYSTEM WORKS EFFICIENTLY

It is necessary to check the system periodically to ensure that all changes to the system and business requirements are taken into account. Simultaneously, we should test the measuring devices for weight, temperature, time, etc. to verify that data through the control points are correct.

7. CREATING AND IMPLEMENTING THE SYSTEM DOCUMENTATION IN ACCORDANCE WITH THESE PRINCIPLES

For implementation of a hygiene management system, documents as well as records must be drafted and maintained which prove that the controls are conducted.

HACCP procedures are documented. The way of documentation and record keeping depends on the nature and size of the activity. They should be sufficient to enable the enterprise to verify the implementation and maintenance of HACCP.[38]

Examples of documentation are reports on:

- Hazard Analysis
- Defining the CCP
- Establishing critical limits
- Modifications of the HACCP plan

38 Official Gazette of the Republic of Albania, MAFCP Instruction no. 20, dated 25.11.2010, For the implementation of prior programs of good hygiene practices, good manufacturing practices and procedures based on hazard analysis and critical control points (HACCP) in food establishments.

Examples of records are:

- CCP monitoring activities
- Deviations and associated corrective actions
- Verification actions

5.2.9 HACCP DEVELOPMENT PHASES

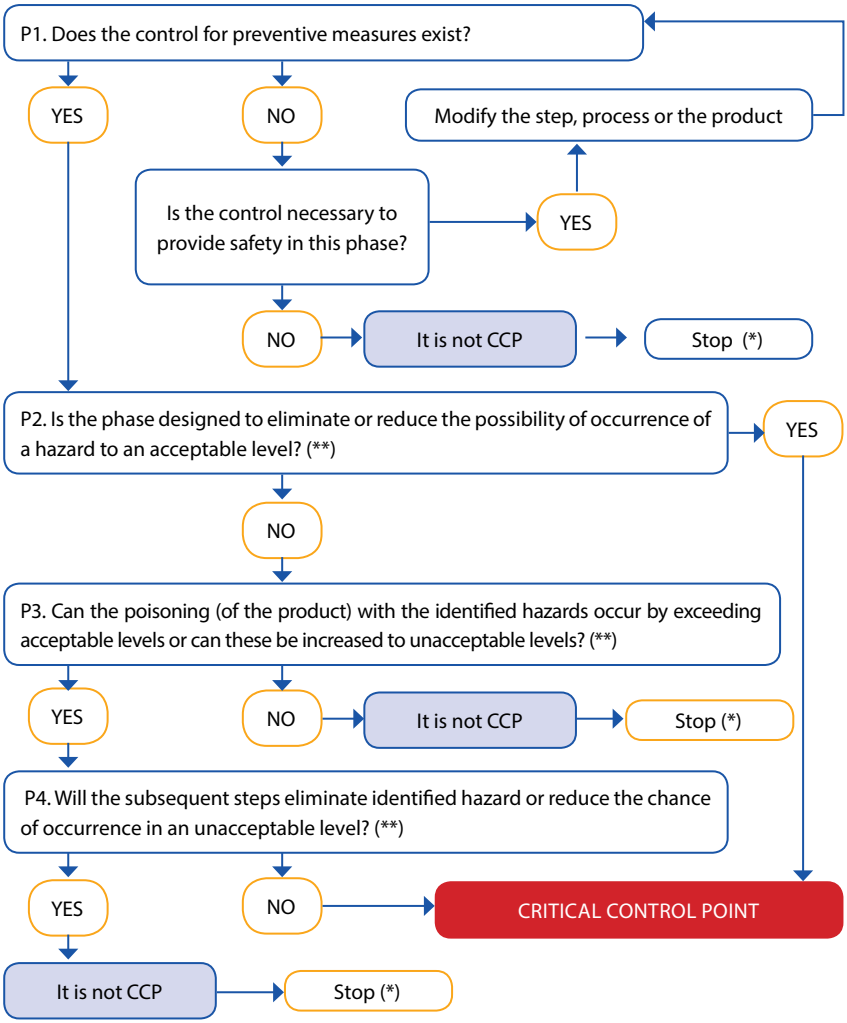
There are twelve steps required to develop a HACCP plan and these are designed to ensure that the seven principles are applied correctly.

Principle 1, which includes performing of a hazard analysis, requires that the first five tasks are addressed in a logical and fair manner so that all hazards associated with the food product are identified.

Phase 1	Selection of HACCP team
Phase 2	Product desciption
Phase 3	Description of the expected use of the product
Phase 4	Drafting processes flow chart
Phase 5	Field verification of process chart
Phase 6	Hazard analysis - Identification of hazards in the manufacturing phases and determination of control measures **- PRINCIPLE 1**
Phase 7	Determination of Critical Control Points (CCP) - implementation of the decision "tree" - **PRINCIPLE 2**
Phase 8	Establishing critical limits for each CCP - **PRINCIPLE 3**
Phase 9	Establishing the system (procedures) for monitoring of each CCP - **PRINCIPLE 4**
Phase 10	Determination of corrective actions - **PRINCIPLE 5**
Phase 11	Determination of verification procedures for the HACCP system - **PRINCIPLE 6**
Phase 12	Establishing the system records and documentation - **PRINCIPLE 7**

5.3 DECISION-MAKING TREE FOR IDENTIFYING CCP

EXAMPLE OF DECISION-MAKING TREE FOR IDENTIFYING CCP



(*) Continue to the next hazard identified in the described process.

(**) Acceptable and unacceptable levels must be defined within the overall objectives in identifying the CCPs of HACCP plan.

5.4 INTERCONNECTION OF HACCP AND ISO 9001 SYSTEMS

If the question is whether there is a difference between ISO 9001 and HACCP, simply said, ISO 9001 is a quality system and HACCP is food safety system. In the food industry, HACCP and ISO 9001 can be applied separately or together, as they complement each other.

In international practice, it is enterprises are advised to combine HACCP and ISO 9001, since it is proven that the combination of the two standards improves both the systems and provides industry and regulators with a measure of responsibility, safety and identification elements along the food chain that can be critical for safety issues and food quality. The combination of these two systems enables manufacturers to control the quality aspects that can have an effect on food safety. Furthermore, the combined use of quality management system according to ISO 9001 and HACCP system provides an efficient system and program for documentation, prevention and self-correction of food quality and safety, by meeting legal regulations, customer requirements for quality, food safety and standards for food processors.

6. KOSOVO RELEVANT INSTITUTIONS

Below are presented some Kosovo agencies, institutes and laboratories whose activities are control of standardization, accreditation, inspection and testing.

6.1 KOSOVO STANDARDIZATION AGENCY (KSA)

Kosovo Standardization Agency (KSA) is a body for managing, organizing and controlling the standardization activity in Kosovo. KSA was established in April 2005 in accordance with the Law on Standardization 2004/12 and Administrative Instruction 2005/15.

KSA is a national body that adopts standards, harmonizes them and as a result it aims to stimulate economic development by creating a basis for competitiveness in the region and beyond.

KSA provides information to stakeholders regarding each Kosovo standard.

Contact:
Kosovo Standardization Agency
str. "Ismail Hajdaraj" n.n, Lagja e Spitalit, Prishtinë/Priština
Tel: 038 512 779
Fax: 038 512 798
Email: aksinfo@rks-gov.net
http://aks.rks-gov.net/

6.2 KOSOVO ACCREDITATION DIRECTORY (KAD)

Kosovo Accreditation Directory (KAD) is a accreditation body for evaluation of technical competence of conformity assessment bodies in accordance with international standards. These bodies conduct activities such as: testing, calibration, certification and inspection whether voluntarily or mandatory in public or private sectors.

KAD's mission is to provide to all stakeholders accreditation on the basis of the rules set in the laws, standards and in principles of accreditation.

Contact:
Kosovo Accreditation Directory, Ministry of Trade and Industry,
Str. Muharrem Fejza n.n, Lagja Spitalit, Prishtinë/Priština
Tel: 038 512 792
E-mail: drejtoriaakreditimitekosoves@gmail.com
http://www.dak-ks.org/

6.3 KOSOVO METROLOGY AGENCY (KMA)

Kosovo Metrology Agency (KMA) is the only Kosovo institution that is responsible for establishing and managing metrology system including measurements related to precious metals.
KMA with its laboratories performs verification, testing and calibration of measuring instruments such as: electric meters, measuring tools of mass (scales and weights), thermometers, volume-meters in fuel selling stations, and performs quality control of precious metal works. In regard to the measuring tools for verification, testing and calibration, KMA has authorized entities dealing with servicing and preparation of measuring tools for verification, testing or calibration.

Contact:
Kosovo Metrology Agency
Str.„Muharrem Fejza“ n.n. Lagja Spitalit, Prishtinë/Priština
Tel: 038 512 121
http://www.mti-ks.org/sq/Agjencia-e-Metrologjise-se-Kosoves

6.4 FOOD AND VETERINARY AGENCY (FVA)

Food and Veterinary Agency develops and implements national policies in the field of food quality and safety, as well as in sectors of animal health and their welfare.
FVA is the highest food and veterinary authority responsible to protect the life and health of the people by providing high level of food safety, including animal feed, animal health, animal welfare and food quality of plant and animal origin.

Contact:
Food and Veterinary Agency, Industrial Zone, Fushë Kosovë/Kosovo Polje
Tel: 038 551918
Fax: 038 551962
Email: infoauv@ks-gov.net
http://www.auv-ks.net

6.5 KOSOVO INSTITUTE OF AGRICULTURE (KIA)

Kosovo Institute of Agriculture is a specialized institution for agricultural research, physical and chemical testing and quality control of agricultural inputs, food and preservation of living environment. KIA is located in Peja/Peč.

The main tasks of the KIA are support for the agricultural research, provision of advisory services, research services, performing analyses on all aspects of agriculture. KIA has laboratory for testing chemical residues in agricultural crops.

Among other KIA tasks also include technical and scientific support for technical departments of MAFRD, research of varieties of agricultural crops in Kosovo agro-ecological conditions, evaluation of manufacturing qualities and land improvement in Kosovo, researching, identifying and inventorying harmful biological agents (pests, pathogens, bad meadows etc.) in Kosovo, etc.

Contact:
Kosovo Institute of Agriculture, Pejë/Peč
Tel: 039 431 635

6.6 BUSINESS CONSULTANTS COUNCIL (BCC)

Business Consultants Council is an association of leading business services providers in Kosovo and recognized by local and international partners for its professionalism, standards of excellence and customer care.
BCC is committed to serve in the interests of its members, by supporting their efforts to ensure a better quality of service for their customers.

Contact:
Business Consultants Council
Str. Sylejman Vokshi 19/2, ground floor, Prishtinë/Priština
Tel: 038 712 369
E-mail: info@bcc-ks.org
http://www.bcc-ks.org/

7. FREQUENTLY ASKED QUESTIONS

WHAT IS AN ISO STANDARD?

A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are suitable to their purpose.

ARE THE STANDARDS MANDATORY?

ISO standards are voluntary. Although voluntary, ISO standards may become a requirement in the market. Often the market in which we operate or in which we intend to export may have requirements regarding the use of standards that are internationally recognized and used, such as European and international standards. So, if national legal regulation refers to the standard, then the use of standards becomes mandatory.

WHICH ENTERPRISES CAN GET CERTIFIED?

Management standards are comprehensive standards, and can be applied in any organization or enterprise, whether manufacturing or service enterprises regardless of the sector, scope, shape of organization or their size.

WHICH ISO STANDARDS FROM 9000 AND 14000 SERIES ARE INTENDED FOR CERTIFICATION?

Any enterprise can apply for certification according to the requirements of ISO 9001 for quality management systems and ISO 14001 for environmental management systems. Other standards of these series, i.e. ISO 9000 and ISO 9004 or ISO 14004 are guiding standards and are not intended for certification.

IS HACCP INTERNATIONALLY RECOGNIZED?

Yes, HACCP principles are adopted worldwide. HACCP is increasingly becoming an important element in the trade process of food products. HACCP is now universally recognized as the best method for managing food hazards.

WHAT STANDARDS ARE RELEVANT FOR MY ENTERPRISE?

ISO 9001 standard for quality management systems is applicable in all sectors without any discrimination. In the wood processing industry and in the construction sector where the impact on the environment may be greater, it is required to implement ISO 14001 (environmental management system). In agriculture and especially in food processing it is used ISO 9001 in combination with

HACCP system (Hazard analysis and critical control points) or the establishment of the food safety management system according to ISO 22000 standard.

HOW LONG DOES THE PROCESS OF ESTABLISHING A MANAGEMENT SYSTEM LAST?

Usually it cannot be given a fixed period of establishment and implementation of a management system in an enterprise, since it depends on the type of system, scope, number of employees and complexity of enterprise processes.

DO YOU HAVE TO CONTRACT A CONSULTANT FOR ESTABLISHMENT OF MANAGEMENT SYSTEMS ACCORDING TO ISO 9001, ISO 140001?

This handbook describes the phases, required documentation and the course of implementing these management systems to enable commencing the establishment of systems in your enterprises. However, experienced consultants and field experts (internationally licensed and preferably certified in CMC) can accelerate the development of your management system by implementing effective strategies and appropriate solution with a reasonable cost.

For more information about qualified consultants contact BCC - Business Consultants Council (see point 6.6 for contact information).

HOW MUCH DOES A MANAGEMENT SYSTEM OR HACCP SYSTEM COST?

Management systems according to ISO 9001, ISO 14001 and HACCP system are not offered in the same form for all enterprises. The cost of establishing the system depends on the number of business processes and the number of employees. It is therefore difficult to provide a real cost. A possibility to ensure a calculation of an approximate cost is to contact the specialized consultants through BCC (see point 6.6 for contact information).

HOW TO PURCHASE A STANDARD?

KSA provides information for each standard that is adopted. The written request is sent to KSA via mail or e-mail with the full title of the standard, or by visiting KSA offices (see point 6.1 for contact information).

WHAT IS THE DIFFERENCE BETWEEN CERTIFICATION AND ACCREDITATION?

In simple terms, accreditation is as certifying a certification body for the services it provides. Accreditation should not be used as an alternative for certification.

8. BIBLIOGRAPHY

- Abraham, M., Crawford, J., Fisher, T. (1999), Key factors predicting effectiveness of cultural change and improved productivity in implementing total quality management, International Journal of Quality & Reliability Management ,Vol.16, No. 2, pp.112-132.
- Appelbaum S. H., Mitraud, A., Gailleur, J., Iacovella, M., Gerbasi, R., & Ivanova, V. (2008). The impact of organizational change, structure and leadership on employee turnover: A case study, Journal of Business Case Studies. 4(1), 21-38.
- BSI Director Achieving excellence, March 2012.
- CERCO Working group on Quality – SWG A (1999). Good reasons for implementing a Quality Management System in European NMAs
- Codex Alimentarius Commission, General Principles Of Food Hygiene, CAC/RCP 1-1969, Rev. 4-2003.
- Codex Alimentarius Food Hygiene Basic Texts. Food and Agricultural Organization of the United Nations, World Health Organization, Rome, Fourth Edition, 2009.
- Dictionary of Business Charts & Graphs. (Flowchart).
- Official Gazette of the Republic of Albania, MAFCP Instruction no. 20, dated 25.11.2010, For the implementation of prior programs of good hygiene practices, good manufacturing practices and procedures based on hazard analysis and critical control points (HACCP) in food establishments.
- Han,S.B. (2008), Relationship between Firm Performances and Profitability, Northeast Decision Sciences Institute Proceedings, March 28-30.
- http://aks.rks-gov.net/
- http://ec.europa.eu/food/food/biosafety/hygienelegislation/comm_rules_en.htm
- http://www.auv-ks.net/
- http://www.codexalimentarius.org/
- http://www.dak-ks.org/
- http://www.iso.org/iso/
- https://www.fsai.ie/food_businesses/haccp/benefits_of_haccp.html
- ISO - Environmental Management (2009).
- ISO - International Organization for Standardization - www.iso.org.
- ISO - Selection and use of the ISO 9000 family of standards 2009.
- ISO 14001:2004, Environmental management systems — Requirements with guidance for use.
- ISO 14004:2004, Environmental management systems -- General guidelines on principles, systems and support techniques.

- ISO 19011:2011, Guidelines for auditing management systems.
- ISO 22000:2005, Food safety management systems.
- ISO 22000:2005, Food safety management systems -- Requirements for any organization in the food chain.
- ISO 9000:2005, Quality management systems — Fundamentals and vocabulary.
- ISO 9001 for Small Businesses. What to do, (2010), Edition 3.
- ISO 9001:2008, Quality management systems — Requirements.
- ISO 9004:2009, Managing for the sustained success of an organization -- A quality management approach.
- Jay Schlickman, (2003), ISO 9001:2000 ISO 9001:2000 Quality Management System design.
- Ken Whitelaw, ISO 14001 Second edition, (2004), ISO 14001 Environmental Systems Handbook.
- National Council for European Integration (May, 2013), Report of the Thematic Roundtable on Agriculture, Rural Development, Forestry, Fisheries and Food Safety, Kosovo 2020.
- Knapper, Rico; Poodratchi, Daniel; and Job, Lennart, "Quality of Process? A Business Process Perspective on Quality of Service" (2012). ECIS 2012 Proceedings. Paper 209.
- Pierson, MD (1997). The importance of pre-requisite programs. Advancing Food Safety 1 (2) 34-35. Sydney.
- Prajogo, D.I., Sohal, A.S. (2003), The relationship between TQM practices, quality performance, and innovation performance: An empirical examination, International Journal of Quality & Reliability Management, Vol. 20, No 8, pp. 901-918.
- Sid Kemp, PMP., (2006), Quality Management Demystified.
- The ISO Survey of Management System Standard Certifications – 2013.
- Urban, Wieslaw, (2012), ISO 9001 as a tool for supporting strategic advantages, Transformations in business and Economics, Vol.11, No.3 (27), pp.57-71.
- William A. Foster, quotes on Quality. http://www.quotes.net/quote/44042.

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