Ch. 3 INTRODUCTION QUALITY STANDARDS

QMS- ISO 9001: 2000

As quality became a major focus of businesses throughout the world, various organizations developed standards and guidelines. Terms such as quality management, quality control, quality system, and quality assurance acquired different, and sometimes conflicting meanings from country to country, within a country, and even within an industry. As the European Community moved toward the European free trade agreement, which went into effect at the end of 1992, quality management became a key strategic objective. To standardize quality requirements for European countries within the common market and those wishing to do business with those countries, a specialized agency for standardization, the International Organization for Standardization, founded in 1946 and composed of representatives from the national standards bodies of 91 nations, adopted a series of written quality standards in 1987, which were revised in 1994, and again (significantly) in 2000. The most recent version is called the ISO 9000:2000 family of standards.

ISO 9000 is an international quality standard for goods and services. The term quality standard tends to be misleading. For example, ISO 9000 does not set any specifications for quality. Rather, it sets broad requirements for the assurance of quality and for management's involvement. The emphasis is on prevention rather than inspection and rework. In fact, this emphasis is placed not only on the production process but also on the product design process. The ISO 9000 approach is completely compatible with the total quality philosophy, though it is not as all encompassing. ISO 9000 is composed of three

standards:

ISO 9000:2000 Quality Management Systems – Fundamentals and Vocabulary

ISO 9001:2000 Quality Management Systems – Requirements

ISO 9004:2000 Quality Management Systems – Guidelines for Performance Improvements

9001:2000 made a giant leap in comparison, especially in the area of continual improvement, which has gone from receiving just cursory treatment to becoming a firm requirement. In addition, the standard now incorporates eight quality management principles that come directly from TQM.

They are:

1. Customer focus – understanding customer's needs, striving to exceed their expectations.

2. Leadership – establishing direction, unity of purpose, and a supportive work environment.

3. Involvement of people – ensuring that all employees at all levels are able to fully use their abilities for the organization's benefit.

4. Process approach – recognizing that all work is done through processes, and managing them accordingly.

5. System approach to management – expands on the previous principle in that achieving any objective requires a system of interrelated processes.

6. Continual improvement – as a permanent organizational objective, recognizing and acting on the fact that no process is so good that further improvement is impossible.

7. Factual approach to decision making – acknowledging that sound decisions must be based on analysis of factual data and information.

8. Mutually beneficial supplier relationships – to take advantage of the synergy that can be found in such relationships.

By design, as a result of ISO 9000, any organization supplying products or service is able to develop and employ a quality management system that is recognized by customers worldwide. Customers around the globe who deal with ISO 9000-registrered organizations can expect that purchased goods or services will conform to a set of recognized standards.

EMS-ISO 14001:2004:

The ISO 14000 family addresses various aspects of environmental management. It provides practical tools for companies and organizations looking to identify and control their environmental impact and constantly improve their environmental performance. ISO 14001:2004 focus on environmental management systems.

ISO 14001:2004 sets out the criteria for an environmental management system and can be certified to. It does not state requirements for environmental

performance, but maps out a framework that a company or organization can follow to set up an effective environmental management system. It can be used by any organization regardless of its activity or sector. Using ISO 14001:2004 can provide assurance to company management and employees as well as external stakeholders that environmental impact is being measured and improved.

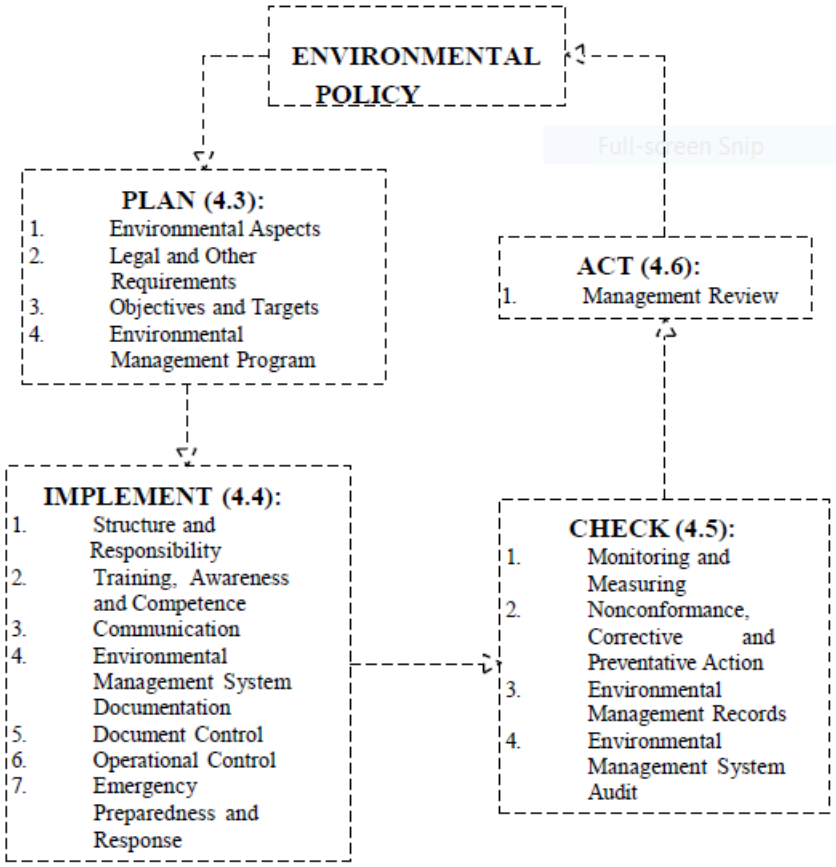
The benefits of using ISO 14001:2004 can include:

- Reduced cost of waste management
- Savings in consumption of energy and materials
- Lower distribution costs
- Improved corporate image among regulators, customers and the public

The Generalized Strategic Planning process in the preceding figure follows the "plan-implement-check-act" cycle. ISO 14001 is based upon the same concept. One additional concept is highlighted within ISO 14001. The additional concept is "continual improvement". The "continual improvement" concept is aimed at improving on a regular basis the overall environmental management system. How do you improve the environmental management system? ISO 14001 requires that you evaluate the organization's interactions/impacts with the environment. Following this evaluation each impact is ranked based upon its significance. The most significant interactions/aspects

are then addressed within the frame of the environmental management system for that cycle. Under the "continual improvement" concept the organization is attempting yo continually reduce its interaction/impact upon the environment.

What does a "plan-implement-check-act" cycle look like under ISO 14001?



Introduction to HACCP (Hazards Analysis Critical Control Point)

HACCP stands for 'Hazard Analysis Critical Control Point'.

HACCP is a system which looks for and prevents potential problems before they happen.

HACCP may be used by food companies to make sure they do not break the law by putting consumers at risk when producing food.

It is a structured approach to risk assessment and is one means of satisfying the risk assessment requirement of UK hygiene legislation.

What does it involve?

Identifying points during the production of a product where potential hazards may occur.

• Analysing the risk of the hazard points happening including the scale of consequence if they do.

• Deciding which points are critical to consumer safety.

• Implementing controls, monitoring production and taking action if necessary.

• Reviewing the HACCP plan whenever the food operation is altered, and on a regular basis, e.g. annually, even if no alterations have been made

Qualities of the HACCP system

HACCP is:

• systematic – all the potential hazards are identified before there is a problem;

• efficient – it concentrates the control effort at the stages where the risk is potentially the highest;

• on the spot – the processes can be controlled immediately by the food business.

History of HACCP

Hazard Analysis and Critical Control Point (HACCP) was developed in the 1960s in the United States to ensure food safety for the first manned National Aeronautics and Space Administration space missions (NASA).

NASA required a ‘zero defect’ program to guarantee safety in the foods astronauts consumed in space.

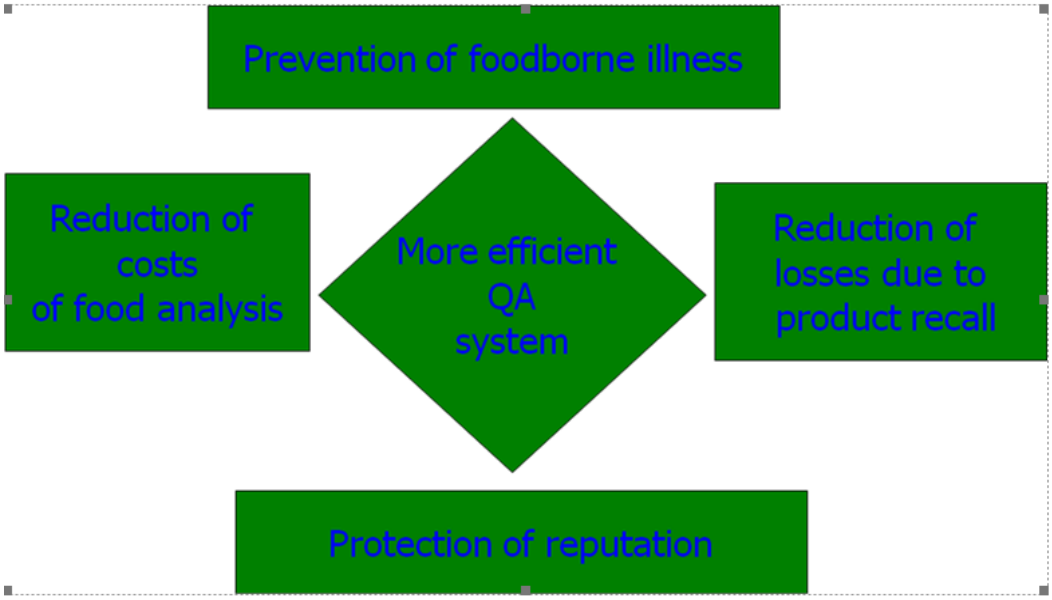
Since then, HACCP principles have been defined and endorsed in international food standards (Codex Alimentarius Commission), and in European and UK legislation.
Indonesia → SNI 1998

Pillsbury presented the HACCP system at a national food protection conference in 1971

HACCP Concept

- ASSURING FOOD SAFETY
- Emphasizing from end-product testing to preventive control of critical aspects of producing safe foods
- Identifying potential food safety problems
- Determining how and where these can be controlled or prevented
- Describing what to do and training the personnel
- Implementation and recording
- It is important to always remember that the establishment of effective HACCP programs involves primarily the application of good common sense and preventive considerations to address situations before they become problems.
- The emphasis is on prediction rather than reaction, on getting the process right initially rather than correcting it after problems have occurred.

The objectives of application of the HACCP system



Guidelines for the application of HACCP system:

- Assemble the HACCP team
- Describe product
- Identify intended use
- Construct flow diagram
- On-site verification of flow diagram
- List all potential hazards, conduct a hazard analysis and determine control measures
- Determine CCPs
- Establish critical limits for each CCP
- Establish a monitoring system for each CCP
- Establish corrective actions
- Establish verification procedures
- Establish record keeping and documentation

The 7 principles of HACCP

1. Conduct a hazard analysis
2. Determine the CCPs
3. Establish critical limit(s)
4. Establish a monitoring system
5. Establish corrective actions
6. Establish verification procedures
7. Establish documentation

Hazard analysis

The first step involves identifying any hazards that must be prevented, eliminated or reduced to acceptable levels.

All potential hazards, from the receipt of raw materials through to release of the finished product, must be considered.

A hazard must be controlled if it is likely to occur, and/or likely to result in an unacceptable risk to consumers.

Determine the Critical Control Point (CCP)

Identifying the Critical Control Point (CCP) at the steps or at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels.

Establish critical limits

A critical limit is a maximum or minimum value to which a biological, chemical or physical limit must be controlled at a CCP.

This is set in order to prevent, eliminate or reduce a hazard to an acceptable level.

Critical Control Point (CCP) monitoring

A planned series of observations or measurements need to be taken to assess whether a CCP is within critical limits.

This also helps to produce an accurate record for future use in verification.

Corrective actions

Corrective actions, are procedures to be followed when a hazard is identified in the food production.

The aim is to correct and eliminate the cause of the hazard and bring CCP back under control.

The cause of problem must be identified to prevent future recurrence.

Establishing corrective actions when monitoring procedures at CCP is not under control.

Verification procedures

Verification procedures are those activities, other than monitoring CCPs, that verify the HACCP plan and show the system is operating according to the plan.

This is usually completed annually or when a system fails or there is a significant change in the product or process.

Establishing procedures, which shall be carried out regularly to verify that the measure outlines in the above paragraphs

Record keeping procedures

Documentation and record keeping help to demonstrate the effective implementation of the previous principles of HACCP.

This records could be of the development of the HACCP plan, CCP monitoring, corrective actions or verification activities.

Four different types of HACCP records include:

1. HACCP plan and support documentation used in developing the plan.
2. Records of CCP monitoring.
3. Records of corrective actions.
4. Records of verification activities.