CHAPTER 1
Introduction to International Organization for Standardization (ISO)

1.1 History of ISO

ISO is an independent, non-governmental international organization with a membership of 164 national standards bodies.

Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.

Because 'International Organization for Standardization' would have different acronyms in different languages (IOS in English, OIN in French for *Organisation internationale de normalisation*), our founders decided to give it the short form ISO. ISO is derived from the Greek isos, meaning equal. Whatever the country, whatever the language, it is always ISO.

The ISO story began in 1946 when delegates from 25 countries met at the Institute of Civil Engineers in London and decided to create a new international organization 'to facilitate the international coordination and unification of industrial standards'. On 23 February 1947 the new organization, ISO, officially began operations.

Since then, they have published over 22663 International Standards covering almost all aspects of technology and manufacturing.

Today they have members from 164 countries and 782 technical committees and subcommittees to take care of standards development. More than 135 people work full time for ISO's Central Secretariat in Geneva, Switzerland.

These members play a vital role in how ISO operates, meeting once a year for a General Assembly that decides their strategic objectives. The Central Secretariat in Geneva, Switzerland, coordinates the system and runs day-to-day operations, overseen by the Secretary General.

The General Assembly

The General Assembly is the overarching organ and ultimate authority of the Organization. It is an annual meeting attended by the members and principal officers.

The ISO Council

The ISO Council is the core governance body of the Organization and reports to the General Assembly. It meets three times a year and is made up of 20 member bodies, the ISO Officers and the Chairs of the Policy Development Committees CASCO, COPOLCO and DEVCO. The Council has direct responsibility over a number of bodies reporting to Council:

- The President's Committee advises Council on matters decided by Council.
- Council Standing Committees address matters related to finance (CSC/FIN), strategy and policy (CSC/SP), nominations for governance positions (CSC/NOM), and oversight of the Organization's governance practices (CSC/OVE).
- Advisory Groups provide advice on matters related to ISO's commercial policy (CPAG) and Information Technology (ITSAG).
- CASCO (Committee on Conformity Assessment) - provides guidance on conformity assessment
- COPOLCO (Committee on Consumer Policy) - provides guidance on consumer issues
- DEVCO (Committee to support Developing Countries) - provides guidance on matters related to developing countries

Membership to the Council is open to all member bodies and rotates to make sure it is representative of the member community.

Technical Management Board (TMB)

The management of the technical work is taken care of by the Technical Management Board, which reports to Council. This body is also responsible for the technical committees that lead standard development and any strategic advisory boards created on technical matters.

1.2 Types of Standards

What are standards?

International Standards make things work. They give world-class specifications for products, services and systems, to ensure quality, safety and efficiency. They are instrumental in facilitating international trade.

ISO has published 22663 International Standards and related documents, covering almost every industry, from technology, to food safety, to agriculture and healthcare. ISO International Standards impact everyone, everywhere.

While there are many different kinds of ISO standards, only a select few of them can be *certified*. Certification is a process that takes place outside ISO, where a company's program is reviewed by an independent party to confirm it meets ISO standards. While certification is not done by ISO, accredited certification organizations, who use ISO's standards on certification, are available to audit internal programs and business practices. After review, these third-party agencies will certify whether a company meets the ISO criteria.

There are various types of ISO certification are available such as listed below:

- ISO 9001:2015- Quality Management System
- OHSAS 18001 – Occupational Health & Safety Management System
- ISO 37001 – Anti-bribery management systems
- ISO 31000 – Risk Management
- ISO 27001 – Information Security Management System
- ISO 10002 – Compliant Management System
- ISO 14001:2015 – Environment Management System
- ISO 26000 – Social Responsibility
- ISO 28000 – Security Management
- ISO 22008 – Food Safety Management
- SA 8000 – Social accountability
- EnMS EN 16001 ISO 50001 – Energy Management
- SO/IEC 17025 – Testing and calibration laboratories
- SO 13485 – Medical devices
- ISO 639 – Language codes
- ISO 4217 – Currency codes
- ISO 3166 – Country codes
- ISO 8601 – Date and time format
- ISO 20121 – Sustainable events
- SO/IEC 27001 – Information security management

Most commonly used Standards

ISO 9001:2015- Quality Management System

ISO 9000 lays out the criteria for a quality management system that will help a business continue to improve quality and customer relations. It's a set of standardized tools and practices to identify areas of improvement, and is internationally viewed as the best practice for quality management.

ISO 22000 - Food Safety Management

ISO 2200 sets out what an organization needs to do to ensure their food is safe for public consumption. It contains guidelines that can be used at all points in the industry, no matter the size of the business.

ISO/IEC 27000 - Information Security Management Systems

ISO/IEC 27000 contains the family of standards used to keep informational assets safe. Businesses that manage personal data, customer data, finances or intellectual property use these standards to ensure this information remains protected.

ISO 31000 - Risk Management

Risk is a part of every business decision. ISO 31000 provides a framework for managing these risks, with best practices for identifying risks and consequences.

SO/IEC 17025 – Testing and calibration laboratories

ISO/IEC 17025 enables laboratories to demonstrate that they operate competently and generate valid results, thereby promoting confidence in their work both nationally and around the world. It also helps facilitate cooperation between laboratories and other bodies by generating wider acceptance of results between countries. Test reports and certificates can be accepted from one country to another without the need for further testing, which, in turn, improves international trade.

ISO 3166 – Country codes

The purpose of ISO 3166 is to define internationally recognised codes of letters and/or numbers that we can use when we refer to countries and subdivisions. However, it does not define the names of countries – this information comes from United Nations sources (Terminology Bulletin Country Names and the Country and Region Codes for Statistical Use maintained by the United Nations Statistics Divisions).

Using codes saves time and avoids errors as instead of using a country's name (which will change depending on the language being used) we can use a combination of letters and/or numbers that are understood all over the world.

For example, all national postal organizations throughout the world exchange international mail in containers identified with the relevant country code. Internet domain name systems use the codes to define top level domain names such as '.fr' for France, '.au' for Australia. In addition, in machine readable passports, the codes are used to determine the nationality of the user and when we send money from one bank to another the country codes are a way to identify where the bank is based.

Definitions and Terms used in ISO

1. Continual improvement: In the context of ISO 22000, the term continual improvement refers to an ongoing need to improve the effectiveness of a food safety management system (FSMS). The effectiveness of any FSMS can be continually improved through the use of communications, management reviews, internal audits, corrective actions, system updates, verification research, and validation studies.
2. Control measure: Control measures are actions or activities that are used to manage and control food safety hazards. Control measures must be capable of preventing or eliminating food safety hazards or reducing them to an acceptable level.
3. Corrections: A correction is any action that is taken to eliminate nonconformity. In the context of the ISO 22000 standard, a correction is any action that is taken to deal specifically with potentially unsafe products (nonconforming products).
   Corrections may include the following types of actions: Reprocessing or further processing of potentially unsafe products, assigning them to a different use, or simply destroying them.
   In the context of this standard, a correction is not the same as a corrective action. Corrections are carried out in order to deal immediately with unsafe products, while corrective actions are designed to prevent recurrence by addressing causes. Corrective actions often take a longer term perspective and tend to take a more systemic approach.
4. Corrective actions: Corrective actions are steps that are taken to eliminate the causes of an existing nonconformity. The corrective action process includes causal analysis and is designed to prevent recurrence.
5. Critical control point (CCP): A critical control point (CCP) is the point (or step) at which a control measure must be applied. It is a point that is critical or essential to safety. It is the point where a control measure can be used to prevent or eliminate a food safety hazard or to reduce it to an acceptable level.

6. Critical limit: A critical limit is a criterion or boundary that is used to distinguish between what is acceptable (safe) and what is unacceptable (unsafe). A critical limit is a value of a parameter or variable.
   Critical limits (values) are used to ensure that a process produces safe food products. When critical limits are violated or exceeded, products are deemed to be potentially unsafe.
   Critical limits are established at critical control points (CCPs). They are used to determine whether or not a CCP is still under control. Whenever critical limits are violated or exceeded, CCPs are out of control and the associated products are considered to be potentially unsafe.
7. End product: An end product is a finished product. It requires no further processing or transformation. However, an end product for one organization could be an ingredient or raw material for another (customer) organization.
8. Food chain: The food chain consists of the entire sequence of stages and operations involved in the creation and consumption of food products. This includes every step from initial production to final consumption. It includes the production, processing, distribution, storage, and handling of all food and food ingredients.
   The food chain also includes organizations that do not directly handle food. These include organizations that produce feed for animals that produce food and organizations that produce feed for animals that will be used as food. It also includes organizations that produce materials that will eventually come into contact with food or food ingredients.
9. Food safety: The basic food safety concept is this: food will not harm the consumer so long as intended use guidelines are followed when it is prepared or eaten. Conversely, food is potentially harmful whenever it has been exposed to hazardous agents and intended use guidelines have not been followed.
10. Food safety hazard: A food safety hazard is an agent or condition that could potentially cause an adverse human health effect. Agents are either in or on food and can be biological, chemical, or physical. Furthermore, the condition of the food itself can also be hazardous. Food safety hazards can also be found in or on animal feed and feed ingredients. Since these may be transferred to food through the consumption of animal products, they can also cause adverse human health effects.
    Organizations that do not directly handle food and feed may also compromise food safety. These include producers of packaging materials, cleaning agents, and other products that eventually come into contact with food or feed. If such products have been exposed to hazardous agents and they come into contact with food or feed, adverse human health effects can occur.
11. Food safety hazard analysis: A food safety hazard analysis is done in order to determine which hazards need to be controlled, how much control is needed, and which combination of control measures should be used in order to make sure that food is safe.
12. OPRPs:- are operational prerequisite programs.
13. HACCP:- is hazard analysis critical control point.
14. Food safety management system (FSMS): A food safety management system (FSMS) is a network of interrelated elements that combine to ensure that food does not cause adverse human health effects. These elements include programs, plans, policies, procedures, practices, processes, goals, objectives, methods, controls, roles, responsibilities, relationships, documents, records, and resources. A FSMS is often one part of a larger management system.
15. Food safety policy: A food safety policy statement formally defines an organization's commitment to food safety. It expresses, in general terms, what top management intends to do about food safety and describes the direction the organization wishes to take.
    More precisely, a food safety policy statement should express an organization’s commitment to the implementation and ongoing maintenance of its food safety management system (FSMS). The food safety policy should drive the establishment of the FSMS and should also encourage people to update and improve its overall effectiveness.

16. Food safety record: A food safety record is a document that contains objective evidence which shows how well food safety activities are being performed or what kind of results are being achieved. It always documents what has happened in the past.
17. HACCP: HACCP stands for Hazard Analysis and Critical Control Point. HACCP is a methodology and a management system. It is used to identify, prevent, and control food safety hazards.
18. HACCP plan: An HACCP plan is a written document that describes how you plan to manage and control your organization's food safety hazards.
19. Internal audit: An internal audit is a systematic evidence gathering process that is carried out in order to determine how well a food safety management system (FSMS) meets a set of expectations.
    According to section 8.4.1 of this standard, your internal audits should determine how well your FSMS complies with both, the ISO 22000 requirements as well as your organization's own requirements and arrangements. In addition, section 8.4.1 expects internal auditors to evaluate how well the FSMS has been implemented and how well it is being updated and improved.
20. Management review: The purpose of a management review is to evaluate the overall performance of an organization's food safety management system and to identify improvement opportunities.
    These reviews are carried out by the organization's top managers and are done on a regular basis.
21. Nonconforming products: In the context of ISO 22000, nonconforming products are products that are potentially unsafe. They are potentially unsafe because they were produced or manufactured during a period when critical limits were violated or exceeded or when an organization has lost control of a prerequisite program (PRP) or an operational prerequisite program (OPRP).
22. Operational prerequisite programs (programmes): Operational prerequisite programs (OPRP's) are prerequisite programs (PRPs) that are essential. They are essential because a hazard analysis has shown that they are necessary in order to control specific food safety hazards.
23. Prerequisite programs (programmes): Prerequisite programs (PRPs) are the conditions that must be established throughout the food chain and the activities and practices that must be performed in order to establish and maintain a hygienic environment. PRPs must be suitable and be capable of producing safe end products and providing food that is safe for human consumption
24. Procedure: Procedures control processes or activities. A well-defined procedure controls a logically distinct process or activity, including the associated inputs and outputs. Such a procedure defines the work that should be done, and explains how it should be done, who should do it, and under what circumstances. In addition, it explains what authority and what responsibility has been allocated, which supplies and materials should be used, and which documents and records must be used to carry out the work. While procedures may be documented or undocumented, ISO usually expects them to be documented.
25. Traceability system: Traceability is the ability to identify and trace the history, location, and application of products and materials. A traceability system records and follows the trail as products and materials come from suppliers and are processed and distributed as end products.
26. Update: An update is an immediate or planned activity. Its purpose is to ensure that the most recent information is being applied.
27. Validation: Validation is a process that is used to ensure that food safety control measures are capable of being effective. The validation process uses evidence to determine whether control measures are capable of controlling food safety hazards and ensuring that end products are safe.
28. Verification: Verification is a process that uses objective evidence to confirm that specified requirements have been met. In the context of this ISO 22000 standard, you are expected to verify that your food safety management system (FSMS) has been implemented.