UNIT 8 ISO 22000 AND ISO 17025

Structure

8.0 OBJECTIVES

After reading this unit, you will be able to:

- justify the need of food safety management system;
- explain the salient features of ISO 22000;
- describe good laboratory practices; and
- discuss ISO 17025 and its importance.

8.1 INTRODUCTION

Food safety is related to the presence of food-borne hazards in food at the point of consumption. As food safety hazards can occur at any stage of the food chain, adequate control throughout the food chain is essential. Thus, food safety is ensured through the combined efforts of all the parties participating in the food chain. An ideal food safety management system should be able to plan, implement, operate, maintain and update a food safety management system capable of providing products that, according to their intended use, are safe for the consumer; to demonstrate compliance with applicable statutory and regulatory food safety requirements; to evaluate and assess customer requirements and demonstrate conformity with those mutually agreed customer requirements that relate to food safety, in order to enhance customer satisfaction; to effectively communicate

food safety issues to their suppliers, customers and relevant interested parties' in the food chain; to ensure that the organization conforms to its stated food safety policy; to demonstrate such conformity to relevant interested parties, and to seek certification or registration of its food safety management system by an external organization, or make a self-assessment or self-declaration of conformity to a specific International Standard. That is the reason why International Standards are made – to ensure that food is safe to the consumer. Seafood is very popular and is exported as well as imported. Seafood being a very highly perishable commodity has a high percentage of food-borne hazards and requires stringent quality checkups and a fully fledged food safety management system.

8.1.1 Who Prepares Standards?

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for whom a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. International Standards are drafted in accordance with the rules given in the ISO/IEC directives; Part 2.The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote. ISO 22000 was prepared by Technical Committee ISO/TC 34, Food products.

8.2 WHAT DOES ISO 22000 OFFER?

You must remember that food safety is related to the presence of food-borne hazards in food at the point of consumption (intake by the consumer). As the introduction of food safety hazards can occur at any stage of the food chain, adequate control throughout the food chain is essential. Thus, food safety is ensured through the combined efforts of all the parties participating in the food chain. ISO 22000 specifies the requirements for a food safety management system that combine following generally recognized key elements to ensure food safety along the food chain, up to the point of final consumption. This International Standard has been aligned with ISO 9001 in order to enhance the compatibility of the two standards.

The salient points covered in this standard are:

- Interactive communication;
- System management;
- Pre-requisite programmes; and
- HACCP principles.

Communication along the food chain is essential to ensure that all relevant food safety hazards are identified and adequately controlled at each step within the food chain. This International Standard can be applied independently of other management system standards. Its implementation can be aligned or integrated with existing related management system requirements, while organizations may

utilize existing management system(s) to establish a food safety management system that complies with the requirements of this International Standard.

This International Standard integrates the principles of the Hazard Analysis Critical Control Point (HACCP) system and application steps developed by the *Codex Alimentarius Commission*. By means of auditable requirements, it combines the HACCP plan with pre-requisite programmes (PRPs). Hazard analysis is the key to an effective food safety management system, since conducting a hazard analysis assists in organizing the knowledge required to establish an effective combination of control measures. This International Standard requires that all hazards that may be reasonably expected to occur in the food chain, including hazards that may be associated with the type of process and facilities used, are identified and assessed. Thus, it provides the means to determine and document certain identified hazards needed to be controlled by a particular organization and why others need not. During hazard analysis, the organization determines the strategy to be used to ensure hazard control by combining the PRP(s), operational PRP(s) and the HACCP plan. To facilitate the application of this International Standard, it has been developed as an auditable standard. However, individual organizations are free to choose the necessary methods and approaches to fulfill the requirements of this International Standard. To assist individual organizations with the implementation of this International Standard, guidance on its use is provided in ISO/TS 22004. This International Standard is intended to address aspects of food safety concerns only. This International Standard allows an organization (such as a small and/or less developed organization) to implement an externally developed combination of control measures. The aim of this International Standard is to harmonize on a global level the requirements for food safety management for businesses within the food chain. It is particularly intended for application by organizations that seek a more focused, coherent and integrated food safety management system than is normally required by law.

8.2.1 Scope

This International Standard specifies requirements for a food safety management system where an Organization in the food chain needs to demonstrate its ability to control food safety hazards in order to ensure that food is safe at the time of human consumption. This International Standard specifies requirements to enable an organization.

a) To plan, implement, operate, maintain and update a food safety management system aimed at providing products that, according to their intended use, are safe for the consumer,

b) To demonstrate compliance with applicable statutory and regulatory food safety requirements,

c) To evaluate and assess customer requirements and demonstrate conformity with those mutually agreed customer requirements that relate to food safety, in order to enhance customer satisfaction,

d) To effectively communicate food safety issues to their suppliers, customers and relevant interested parties in the food chain,

e) To ensure that the organization conforms to its stated food safety policy,

f) To demonstrate such conformity to relevant interested parties, and

g) To seek certification or registration of its food safety management system by an external organization, or make a self-assessment or self-declaration of conformity to this International Standard.

All requirements of this International Standard are generic and are intended to be applicable to all organizations in the food chain regardless of size and complexity. This includes organizations directly or indirectly involved in one or more steps of the food chain.

8.2.2 Normative References

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. ISO 9000:2000, Quality management systems - Fundamentals and vocabulary.

8.2.3 Terms and Definitions

All the terms used in the document of the standard are clearly defined in the terms and definitions given in ISO 9000 and the following apply. For the convenience of the users of this International Standard, some of the definitions in ISO 9000 are quoted with added notes that are applicable only to this special application, in the document of the Standard.

8.2.4 Food Safety Management System

a) General Requirements

The organization shall establish, document, implement and maintain an effective food safety management system and update it when necessary in accordance with the requirements of this International Standard. The organization shall define the scope of the food safety management system. The scope shall specify the products or product categories, processes and production sites that are addressed by the food safety management system. Ensure that food safety hazards are identified, evaluated and controlled so as not to harm the consumer; communicate appropriate information throughout the food chain regarding safety issues and evaluate periodically, and update when necessary, the food safety management system.

Documentation Requirements

The food safety management system documentation shall include:

1) Documented statements of a food safety policy and related objectives,

2) Documented procedures and records required by this International Standard, and

3) Documents needed by the organization to ensure the effective development, implementation and updating of the food safety management system.

b) Management responsibility

This is done through management commitment for implementation of the food safety management system and to continually improving its effectiveness.

- The top management shall define, document and communicate its food safety policy. Top management shall ensure that the food safety policy is appropriate to the role of the organization in the food chain.
- Top management shall ensure that planning of the food safety management system is carried out to meet requirements that support food safety, and the integrity of the food safety management system is maintained, when changes to the food safety management system are planned and implemented.
- Top management shall ensure that responsibilities and authorities are defined and communicated within the organization. All personnel shall have responsibility to report problems with the food safety management system to identified person(s).
- Top management shall appoint a food safety team leader who, irrespective of other responsibilities, shall have the responsibility and authority to manage a food safety team. There shall be both external communication as well as internal communication with the food safety team.
- Top management shall establish, implement and maintain procedures to manage potential emergency situations and accidents that can impact food safety and which are relevant to the role of the organization in the food chain.
- Top management shall review the organization's food safety management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness through review input as well as review output.

Resource management

- The organization shall provide adequate resources for the establishment, implementation, maintenance and updating of the food safety management system.
- The food safety team and the other personnel carrying out activities having an impact on food safety shall be competent and shall have appropriate education, training, skills and experience.
- The organization shall provide the resources for the establishment and maintenance of the infrastructure needed to implement the requirements of this International Standard.
- The organization shall provide the resources for the establishment, management and maintenance of the work environment needed to implement the requirements of this International Standard.

Planning for realization of safe products

The organization shall plan and develop the processes needed for the realization of safe products.

The organization shall implement, operate and ensure the effectiveness of the planned activities and any changes to those activities. This includes pre-requisite programmes – PRP(s) as well as operational PRP(s) and/or the HACCP plan.

The organization shall establish, implement and maintain PRP(s) which shall consider and utilize appropriate information [e.g. statutory and regulatory

requirements, customer requirements, recognized guidelines, *Codex Alimentarius* Commission (Codex) principles and codes of practices, national, international or sector standards]. The organization shall consider the following when establishing PRP programmes:

a) Construction and layout of buildings and associated utilities;

b) layout of premises, including workspace and employee facilities;

c) Supplies of air, water, energy and other utilities;

d) Supporting services, including waste and sewage disposal;

e) The suitability of equipment and its accessibility for cleaning, maintenance and preventative maintenance;

f) Management of purchased materials (e.g. raw materials, ingredients, chemicals and packaging), supplies (e.g. water, air, steam and ice), disposals (e.g. waste and sewage) and handling of products (e.g. storage and transportation);

g) Measures for the prevention of cross-contamination;

h) Cleaning and sanitizing;

i) Pest control;

j) Personnel hygiene; and

k) Other aspects as appropriate.

All relevant information needed to conduct the hazard analysis shall be collected, maintained, updated and documented. Records shall be maintained. A food safety team shall be appointed. The food safety team shall have a combination of multi-disciplinary knowledge and experience in developing and implementing the food safety management system. Records shall be maintained that demonstrate that the food safety team has the required knowledge and experience.

All raw materials, ingredients and product-contact materials shall be described in documents to the extent needed to conduct the hazard analysis. The characteristics of end products shall be described in documents to the extent needed to conduct the hazard analysis. The intended use, the reasonably expected handling of the end product, and any unintended but reasonably expected mishandling and misuse of the end product shall be considered and shall be described in documents to the extent needed to conduct the hazard analysis. The existing control measures, process parameters and/or the rigorousness with which they are applied, or procedures that may influence food safety, shall be described to the extent needed to conduct the hazard analysis.

The food safety team shall conduct a hazard analysis to determine which hazards need to be controlled, the degree of control required to ensure food safety, and which combination of control measures is required.

When identifying the hazards, consideration shall be given to each of the food safety hazards identified; the acceptable level of the food safety hazard in the end product shall be determined whenever possible. The determined level shall take into account established statutory and regulatory requirements, customer food safety requirements, the intended use by the customer and other relevant data. The justification for, and the result of, the determination shall be recorded.

A hazard assessment shall be conducted to determine, for each food safety hazard identified whether its elimination or reduction to acceptable levels is essential to the production of a safe food, and whether its control is needed to enable the defined acceptable levels to be met. Each food safety hazard shall be evaluated according to the possible severity of adverse health effects and the likelihood of their occurrence. The methodology used shall be described and the results of the food safety hazard assessment shall be recorded. The selection and categorization shall be carried out using a logical approach. Based on the hazard assessment, an appropriate combination of control measures shall be selected which is capable of preventing, eliminating or reducing these food safety hazards to defined acceptable levels.

The HACCP plan shall be documented and shall include the following information for each identified critical control point (CCP).

- For each hazard that is to be controlled by the HACCP plan, CCP(s) shall be identified for the control measures identified.
- A monitoring system shall be established for each CCP to demonstrate that the CCP is in control.
- The system shall include all scheduled measurements or observations relative to the critical limit(s).
- If necessary, the HACCP plan and the procedures and instructions specifying the PRP(s) shall be amended.
- Verification planning shall define the purpose, methods, frequencies and responsibilities for the verification activities.
- The organization shall establish and apply a traceability system that enables the identification of product lots and their relation to batches of raw materials, processing and delivery records.
- The organization shall ensure that when critical limits for CCP(s) are exceeded, or there is a loss of control of operational PRP(s), the products affected are identified and controlled with regard to their use and release.
- The organization shall handle non-conforming products by taking action(s) to prevent the nonc-onforming product from entering the food chain.

Validation, verification and improvement of the food safety management system

The food safety team shall plan and implement the processes needed to validate control measures and/or control measure combinations, and to verify and improve the food safety management system. The organization shall provide evidence that the specified monitoring and measuring methods and equipment are adequate to ensure the performance of the monitoring and measuring procedures. The organization shall conduct internal audits at planned intervals to determine whether the food safety management system is adequate. The food safety team shall systematically evaluate the individual results of planned verification. The food safety team shall analyse the results of verification activities, including the results of the internal audits and external audits. Top management shall ensure

that the food safety management system is continually updated through communication, management review, internal audit, evaluation of individual verification results, analysis of results of verification activities, validation of control measure combinations, corrective actions and food safety management system updating.

Check Your Progress 1

Note: a) Use the space given below for your answers.

b) Check your answers with those given at the end of the unit.

1) What is ISO?

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2) Who does the work of preparation of International standards?

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3) Which committee prepared ISO 22000?

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4) What is PRP?

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5) Name two components under documentation requirements?

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8.3 BACKGROUND HISTORY OF ISO 17025

The first edition (1999) of ISO/IEC 17025 was produced as the result of extensive experience in the implementation of two standards *viz.* ISO/IEC Guide 25 and EN 45001. It contained all of the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a management system, are technically competent and are able to generate technically valid results.

Accreditation bodies that assess and recognize the competence of testing and calibration laboratories should use ISO/IEC 17025 Standard as the basis for their accreditation. Clause 4 of ISO/IEC 17025 specifies the requirements for sound management and Clause 5 technical requirements for competence of the laboratory for the type of tests and/or calibrations it undertakes. Testing and calibration laboratories that comply with this International Standard will therefore also operate in accordance with ISO 9001.

The acceptance of testing and calibration results between countries should be facilitated, if laboratories comply with this International Standard and if they

obtain accreditation from bodies which have entered into mutual recognition agreements with equivalent bodies in other countries using this international standard. With this objective, the Bureau of Indian Standards adopted the ISO/IEC 17025 and this standard is designated as IS/ISO/IEC 17025:2005. For the purpose of implementation, this standard is described under five sections. They are:

1) Scope,
2) Normative References,
3) Terms and Definitions,
4) Management Requirements, and
5) Technical Requirements.

8.3.1 Scope of ISO 17025

It covers all types of testing and calibration in various fields performed using standard methods, non-standard methods and laboratory-developed methods. This International Standard is applicable to all organizations performing tests and/or calibrations. These include, for example first-, second-, and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification. This International Standard is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories.

Guidelines for establishing accreditation body

Guidance for establishing applications for specific fields, especially for accreditation bodies are available in the form of a standard- ISO/IEC 17011, which is given in Annex-B of IS/ISO/IEC 17025. If a laboratory wishes accreditation for part or all of it's testing and calibration activities, it should select an accreditation body that operates in accordance with ISO/IEC 17011. NABL (National Accreditation Board for Testing and Calibration Laboratories) is such a national accreditation body, whereas, APLAC (Asia Pacific Laboratory Accreditation Cooperation), ILAC (International Laboratory Accreditation Cooperation) etc. are international accreditation bodies.

8.3.2 Terms and Definitions

Vocabulary, terms and definitions of laboratory accreditation

ISO/IEC 17000 gives details about the terms, definitions and principles of laboratory accreditation procedure as contained in IS/ISO/IEC 17025. Consequently, this standard is known as Vocabulary of International Metrology (VIM).

8.3.3 Management Requirements

For the purpose of implementing, demonstrating and monitoring IS/ISO/IEC standard in a laboratory, the management of the lab shall establish and operate certain facilities, procedures and records called management requirements.

The laboratory or the organization, of which it is part, shall be an entity that can be held legally responsible. It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition. The management system shall cover all work carried out by the lab such as in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities. If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.

The laboratory shall:

a) Have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures;

b) Have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

c) Have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

d) Have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;

e) Define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;

f) Specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;

g) Provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration and with the assessment of the test or calibration results;

h) Have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;

i) Appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;

j) Appoint deputies from key managerial personnel for supervision of all technical requirements; and

k) Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

8.3.4 Management System

The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programmes, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to and implemented by the appropriate personnel.

The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers; the management's statement of the laboratory's standard of service; the purpose of the management system related to quality; a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and the laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system. Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness. Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

The quality manual shall include or make reference to the supporting procedures including technical procedures. The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual. Top management shall ensure that the integrity of the management system is maintained.

8.3.5 Document Control

a) General

Documents are items relating to policy, procedures, specifications, memoranda, software, drawings etc. in any form such as soft, hard copy, electronic, digital and analog, photo, drawing etc.

b) Document approval and issue

All documents issued to personnel in the laboratory as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and shall be readily available to preclude the use of invalid and/or obsolete documents.

The procedure(s) adopted shall ensure that:

- authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;
- documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;
- invalid or obsolete documents are promptly removed from all points of issue or use; obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

c) Document changes

These shall be reviewed and approved; shall suitably identify all new and altered documents; shall define and identify procedures and authorities responsible for amendment and shall establish procedure used to change computerized documents; shall also establish and maintain procedures for review of requests, tenders and contract.

d) Subcontracting of tests and calibrations

The test calibrations and sub-contracting should be given to an approved laboratory which complies with IS/ISO/IEC 17025. Notify the details of subcontractor and get consent from client in writing. Should have a Policy and procedure for purchase and supplies, storage use and documentation; cooperate with customer to clarify doubts, monitor lab's performance and ensure confidentiality**.** Have a policy and procedure for customer complaint along with records of complaint redressed and these shall be documented.

Shall identify authority, policy and procedure for corrective actions and keep a record of all corrective action. Lab shall identify opportunities for improvement, develop action plans for improvement, implement and monitor the same for better quality of tests/ calibration. Lab shall establish a documentation procedure for identification, collection, indexing, accessing, filing, storage, maintenance and disposal of quality system and technical records. Lab shall conduct internal audit as per pre-determined schedule by auditors independent of the activity audited and as decided by the quality manager, which shall cover quality management system and testing and calibration system as contained in IS/ISO/ IEC 17025**.** Top management shall conduct review of the quality management system and testing and calibration activities as per the pre-determined schedule, with a view to ensure effectiveness of QMS and for introducing changes or improvements to better compliance with IS/ISO/IEC 17025.

8.3.6 Technical Requirements

Technical requirements of the Food safety management system are condensed in simplified version below:

The raw material quality, the process monitoring as per HACCP, The Good Manufacturing Practice, the SSOP (Standard Sanitation Operation Procedures), Personal hygiene etc. depend heavily on monitoring certain physical, chemical or microbiological parameters. Consequently, the success of all the above processes and procedures will depend on the facilities of the laboratory in the plant. In fact the laboratory shall have all test methods and testing equipments in tune with the following requirements.

i) *Use of approved methods / Standard Operating Procedures (SOPs)*

All the methods used by the lab shall be methods approved by national or international agencies, like BIS (Bureau of Indian Standards), EU(European Union) Norms, US FDA(Food and Drug Authority), US EP, Codex, AOAC (Association of Official Analytical Chemists), APHA (American Public Health Association) etc.

ii) *Use only calibrated instruments for measurements*

In case of measurements like volume, weight, time, temperature, pressure etc., the measuring instruments shall be subjected to periodic calibration with reference to national or international standards, before they are used for actual measurements. In case of weights and measures, the Legal Metrology Department and in case of other physical measurements calibration with reference to the standards whose accuracy can be traced back to the standards maintained at National Physical Laboratory, New Delhi or the international standards kept at Paris.

iii) *Use of CRM as standards*

All labs will be using various chemical standards for estimation of several chemical parameters by different methods like titration, chromatography, spectrophotometry etc. All such standards shall be Certified Reference Materials (CRM) or certified analytical reagents with traceability to NIST standards. This will ensure accuracy and reproducibility of test results.

iv) *Accreditation of labs by National / International agencies*

All labs attached to food processing plants must be accredited by qualified assessors appointed by agencies like National Accreditation Board for Laboratories or International Laboratory Accreditation Conference to ensure that these labs have necessary facilities in terms of equipments, chemicals including certified reference materials, qualified personnel etc. and necessary methodology to perform stipulated tests so that the results generated by the lab are dependable as well as acceptable to the consumers.

v) *Participation in proficiency testing programmes*

Laboratories interested in generating dependable results shall undergo proficiency testing in appropriate testing fields under the guidance of nodal laboratories authorized by ILAC or NABL. The relevant testing fields for seafood testing laboratories are microbiology, biochemical, organoleptic and chemical residues. A list of authorized nodal laboratories including CIFT is available with NABL, New Delhi on request. Proficiency testing involves preparation of homogenized test samples and testing the same in the nodal lab to ensure homogeneity followed by testing the same samples in participating laboratories. The results obtained by the participating labs are compared with the results of the nodal lab to arrive at a rating for each of the participating labs, which will indicate the accuracy and authenticity of the analytical results generated by that lab. CIFT is a nodal laboratory identified by NABL and under supervision of CIFT, several laboratories including EIA laboratories and MPEDA laboratories had undergone proficiency testing.

vi) *Inter Laboratory Calibration (ILC)*

This is again a procedure for checking the accuracy and capability of a testing laboratory in comparison with the results of a reputed laboratory. For purpose of ILC, the European Union and Export Inspection Council of India have identified CIFT as a competent lab for testing antibacterial substances, antibiotics, total volatile basic nitrogen, lead, cadmium, mercury and microbiological parameters.

vii) *Calculation of Uncertainty for all analysis and measurements*

Every measurement or analysis involves use of equipments, chemicals and manual work. Based on accuracy of the equipment, purity of chemicals and efficiency of the analyst, the result of any analysis or measurement will be varying from individual to individual and laboratory to laboratory. These variations from the true value are known as uncertainty. Uncertainty of measurement generally comprises of many components. Some of these components may be evaluated from the statistical distribution of the results of a series of measurements and can be characterized by experimental standard deviations. The other components contributing to deviations from true value also can be characterized by standard deviations, and can be evaluated from assumed probability distributions based on experience or other information.

Thus uncertainty can be defined as the parameter, associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurement.

For all the parameters measured/analyzed by the laboratory there shall be calculated values of uncertainty, which shall be less than 3%.

viii) *Record Keeping*

The lab shall keep all the records relating to production and quality assurance as per HACCP, SSOP, GMP etc. and these records shall be available for review and audit for at least three years. Generally, the records insisted are those outlined in HACCP plan form (CCP monitoring records, corrective action records and calibration records.), Hygiene and sanitation monitoring records, GMP records, ETP (Effluent Treatment Plant) records, raw material and finished product testing records. All these records shall be supported with appropriate procedures and schedule for ensuring as well as to counter check their adequacy.

GLP is relatively new area and CIFT has implemented several programmes for achieving good laboratory practices. Conducting proficiency testing, inter-laboratory calibration etc. for testing laboratories and laboratories attached to factories are being done periodically. CIFT is also giving the much needed assistance for equipping the labs for accreditation from agencies like NABL, BIS etc.

ix) *Qualified and certified personnel- Good Personnel Policy*

All major events in a food manufacture like sanitation, hygiene, processing and quality checks heavily relay on modern methods in science and technology. However all the production and quality checks are performed

by specific personnel, whose knowledge and skill will ultimately decide the safety of the product. So the personnel required for all these activities shall be suitably qualified and certified for the job assigned to them. The laboratory personnel shall also undergo periodic training to update their skills in tune with developments in the field. Any lacuna in this respect will amount to compromising on safety of the products.

Check Your Progress 2

Note: a) Use the space given below for your answers.

b) Check your answers with those given at the end of the unit.

1) What does Clause 5 of ISO/IEC 17025 specify?

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2) What do documents stand for?

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3) What is SOP?

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4) What is CRM?

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8.4 LET US SUM UP

Food safety hazards can occur at any stage of the food chain. Adequate control throughout the food chain is essential to ensure food safety. Food safety is ensured through the combined efforts of all the parties participating in the food chain. An ideal food safety management system should be able to plan, implement, operate, maintain and update a food safety management system aimed at providing products that, according to their intended use, are safe for the consumer. In this unit, we were able to find the justification for the need of a food safety management system. The unit explains in detail the salient features of the International standard ISO 22000 as well as ISO 17025. The unit also clearly spells the details of Good Laboratory Practice. All these ensure food safety and quality especially for highly perishable commodities such as fish.

8.5 GLOSSARY

Accreditation : Authorization.

Calibration : Standardization of measuring instrument.

Coherent : Consistent.

Environment	**:**	Set of conditions.
Normative	**:**	Relating to standards.
Prerequisite	**:**	Precondition.
Rigorousness	**:**	Strict.
Sewage	**:**	Waste matter from homes.
Statutory	**:**	Constitutional.
Sufficiently	**:**	Adequately.

8.6 SUGGESTED FURTHER READING

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8.7 REFERENCES

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Surak, J.G. 2007. ISO 22000: *Requirements for Food Safety Management Systems.* http://www.asq.org/qic/display-item/index.html?item=20317. Retrieved on 28 February.

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8.8 ANSWERS TO CHECK YOUR PROGRESS

Check Your Progress 1

1) International Organization for Standardization.

2) The work of preparing International Standards is normally carried out through ISO technical committees.

3) ISO 22000 was prepared by Technical Committee ISO/TC 34, Food products.

4) Prerequisite programmes.

5) a) Documented statements of a food safety policy and related objectives.

   b) Documented procedures and records required by this International Standard.

Check Your Progress 2

1) Technical requirements for competence of the laboratory for the type of tests and/or calibrations it undertakes.

2) Documents are items relating to policy, procedures, specifications, memoranda, software, drawings etc. in any form such as soft, hard copy, electronic, digital and analog, photo, drawing etc.

3) Standard Operating Procedures.

4) Certified reference materials.