UNIT 1 INTRODUCTION TO MANAGEMENT SYSTEMS

Structure

1.0 OBJECTIVES

The aim of this unit is to introduce us to international standards representing different management systems. After reading this, we shall become familiar with the following management systems standards. These standards are applicable to all industries including food industry.

a) ISO 9001:2000,

b) ISO 14001:2004,

c) OHSAS 18001:1999, and

d) ISO 27001:2005.

The following standards are applicable specifically to food industry.

a) ISO 22000

b) BRC Food

c) IFS

d) SQF

e) HACCP

1.1 INTRODUCTION

The management system of an organisation is a system to establish policy and objectives and to achieve those objectives**.** Management systems encompass all possible spheres of life, industrial and non-industrial. They include quality management, environmental management, food safety management, occupational health and safety management, information security management.

These management standards are prepared by International Organisation for Standardization (ISO). It is located in Switzerland (Geneva) and was established in 1947 to develop common international standards in many areas. Its members come from over 150 national standards bodies. The Bureau of Indian Standards, the National Standards Body (NSB) in India, is a member of ISO.

1.2 ISO 9001:2000 QUALITY MANAGEMENT SYSTEM-REQUIREMENTS

1.2.1 Introduction to ISO 9001

ISO 9001 is sweeping the world. It is rapidly becoming the most important quality management systems standard. Thousands of companies in over 100 countries have already adopted it, and many more are in the process of doing so. Why? Because it assists organisations, of all types and sizes, to implement and operate effective quality management systems. It saves money. Customers expect it and competitors use it.

ISO 9001 applies to all types of organisations. It doesn't matter what size they are or what they do. It can help both product and service oriented organisations achieve standards of quality that are recognized and respected throughout the world.

1.2.2 ISO 9000

The term ISO 9000 refers to a set of quality management standards. ISO 9000 currently includes three quality management systems standards: ISO 9000:2005, ISO 9001:2000 and ISO 9004:2000. ISO 9001:2000 presents requirements, while ISO 9000:2005 deals with fundamentals and vocabulary, and ISO 9004:2000 presents guidelines for performance improvements. All of these are system standards (not product standards).

ISO's purpose is to facilitate international trade by providing a single set of standards that people everywhere would recognize and respect.

The ISO 9000:2000 Standards apply to all kinds of organisations in all kinds of areas. Some of these areas include manufacturing, processing, servicing, printing, forestry, electronics, steel, computing, legal services, financial services, accounting, trucking, banking, retailing, drilling, recycling, aerospace, construction, exploration, textiles, pharmaceuticals, oil and gas, pulp and paper, petrochemicals, publishing, shipping, energy, telecommunications, plastics, metals, research, health care, hospitality, utilities, pest control, aviation, machine tools, food processing, agriculture, government, education, recreation, fabrication, sanitation, software development, consumer products, transportation,

design, instrumentation, tourism, communications, biotechnology, chemicals, engineering, farming, entertainment, horticulture, consulting, insurance, and so on.

These standards are explained in detail separately in this course.

1.3 ISO 14001:2004 ENVIRONMENTAL MANAGEMENT SYSTEM-REQUIREMENTS

1.3.1 Introduction to ISO 14001:2004

ISO 14001:2004 is an environmental management standard. It defines a set of environmental management requirements for environmental management systems. The purpose of this standard is to help all kinds of organisations to protect the environment, to prevent pollution and to improve their overall environmental performance.

This standard was first published as ISO 14001:1996 and was revised as ISO 14001:2004

Since it was first published in 1996, ISO 14001 has rapidly become the most important environmental standard in the world. Thousands of organisations use it, environmentalists support it, and governments actively encourage its use. ISO 14001 applies to all types of organisations. It doesn't matter what size they are or what they do.

1.3.2 How to Use ISO 14001

If you don't already have an Environmental Management System (EMS), you can use this ISO 14001 standard to establish one. And once you've established your EMS, you can use it to manage the environmental aspects of your organisation's activities, products and services, and to improve its overall environmental performance. Environmental performance is all about how well you manage and control your environmental aspects and the impact they have on the environment.

You can also use this standard to demonstrate that you are doing everything you can to protect the environment and improve your environmental performance. You can demonstrate your organisation's commitment in several ways:

1) You can simply announce to the world that your EMS complies with the ISO 14001 standard (if it actually does).
2) You can ask your customers or other interested parties to confirm that your EMS complies with the ISO 14001 standard.
3) You can ask an ISO 14001 registrar or external auditor to verify that your EMS complies with the ISO 14001 standard.

ISO 14001 expects organisations to comply with all of the requirements that make up the standard. No exceptions. According to ISO, every ISO 14001 requirement must be built into every EMS. However, the size and complexity of environmental management systems vary quite a bit.

How far you go is up to you. The size and complexity of your EMS, the extent of your documentation, and the resources allocated to it will depend on

many things. How you meet each of the ISO 14001 requirements, and to what extent, depends on many factors, including:

1) The size of your organisation.
2) The location of your organisation.
3) The scope of your organisation's EMS.
4) The content of your environmental policy.
5) The nature of your activities, products and services.
6) The environmental impact of your environmental aspects.
7) The legal and other requirements that must be met.

1.3.3 Your General Approach

If you don't already have an EMS, ISO 14001 suggests that you start with a review of your organisation's environmental status. Your environmental review should:

- Identify your organisation's environmental aspects. Study normal and abnormal operating conditions, as well as accidents, disasters, and emergency situations. Identify the environmental aspects associated with all operating conditions and situations.
- Clarify the legal and other requirements that apply to your organisation's environmental aspects. Legal requirements include national and international as well as local and regional laws and regulations. Other requirements include agreements that have been established with governments, customers, community groups and others as well as commitments, guidelines, principles, or codes of practice that influence how your environmental aspects ought to be handled.
- Examine your organisation's current environmental management policies, procedures, and practices. Pay special attention to your organisation's purchasing and contracting policies, procedures and practices.
- Define the scope of your EMS. When ISO 14001 asks you to define the scope of your EMS, it is asking you to define its boundary. You can choose to apply ISO 14001 to the entire organisation or only to a specific operating unit or facility. Once you've made this decision, you've defined the scope or boundary of your EMS. Henceforth, all activities, products and services that fall within this boundary must comply with the ISO 14001 standard.

Once you've considered the above factors, you can begin the development of your organisation's unique environmental management system.

But if you've already established an EMS and you simply need to update it to meet the new standard, you need to do a gap analysis. A gap analysis will compare your current EMS with ISO 14001:2004 standard.

This comparison will pinpoint the areas that fall short of the standard (the gaps). Once you know where to focus your attention, you can begin to make the changes that are needed to comply with the ISO 14001:2004 standard.

1.3.4 Application

This international standard specifies requirements for an environmental management system to enable an organisation to develop and implement a policy and objectives which take into account legal requirements and other requirements to which the organisation subscribes, and information about significant environmental aspects. It applies to those environmental aspects that the organisation identifies as those which it can control and those which it can influence. It does not itself state specific environmental performance criteria.

1.3.5 Structure and Interpretation

Clause/ Subclause No.	Clause/Subclause title	Clause/Subclause : Contents/Interpretation
--	Introduction	This discusses the need for implementation of this standard. The methodology PDCA on which the model is based is explained as follows : **Plan** : Establish the objectives and processes necessary to deliver results in accordance with the organisation's environmental policy. **Do** : Implement the processes. **Check** : Monitor and measure processes against environmental policy, objectives, targets, legal and other requirements, and report the results. **Act** : Take actions to continually improve performance of the environmental management system.
1.	Scope	Specifies basis of requirements and applicability criteria.
2.	Normative reference	No normative reference are cited.
3.	Terms and definitions	Twenty key terms are defined. The terms are as follows : 3.1 Auditor 3.2 Continual improvement 3.3 Corrective action 3.4 Document 3.5 Environment 3.6 Environmental aspect 3.7 Environmental impact 3.8 Environmental management system 3.9 Environmental objective 3.10 Environmental performance 3.11 Environmental policy 3.12 Environmental target 3.13 Interested party 3.14 Internal audit 3.15 Non-conformity 3.16 Organisation 3.17 Preventive action 3.18 Prevention of pollution 3.19 Procedure 3.20 Record

Clause/ Subclause No.	Clause/Subclause title	Clause/Subclause : Contents/Interpretation
4.	Environmental Management System requirements	---
4.1	General requirements	Requirement of establishing, documenting, implementing, maintaining and continually improving an environmental management system is stated. Requirement of defining and documenting the scope of the environmental management system is stated.
4.2	Environmental policy	Requirement to define the organisation's environmental policy within the defined scope of its environmental management system is stated. Requirement about the contents (including commitment to legal and other requirements) is stated. Requirement for a commitment to continual improvement and prevention of pollution. Requirement of documentation, implementation and maintenance of policy is stated. Requirement of communicating the policy to the concerned (including employees and those who work on behalf of the organisation) is stated. Requirement of making the policy available to the public is stated.
4.3	Planning	---
4.3.1	Environmental aspects	Requirement for establishing, implementing and maintaining a procedure to identify the environmental aspects of its activities, products and services within the defined scope of the environmental management system that it can control and those that it can influence is stated. Requirement for determining the significant environmental aspects is stated. Requirement for documenting and updating this information is stated.
4.3.2	Legal and other requirements	Requirement for establishing, implementing and maintaining a procedure to identify and have access to the applicable legal and other requirements is stated. Requirement of determining how these requirements apply to its environmental aspects is stated.
4.3.3	Objectives, targets and programs	Requirement of establishing, implementing and maintaining documented measurable environmental objectives and targets at relevant functions and levels within the organisation is stated. Requirement of establishing, implementing and maintaining a program for achieving organisational objectives and targets is stated.
4.4	Implementation and operation	---

Clause/ Subclause No.	Clause/Subclause title	Clause/Subclause : Contents/Interpretation
4.4.1	Resources, roles, responsibility and authority	Requirement of ensuring the availability of resources essential to establish, implement, maintain and improve the environmental management system is stated. Requirement of defining, documenting and communicating the roles, responsibilities and authorities is stated. Requirement of appointing a management representative is stated.
4.4.2	Competence, training and awareness	Requirement of ensuring that relevant personnel are competent on defined basis is stated. Requirement of identifying training needs associated with environmental aspects and environmental management system is stated. Requirement of establishing, implementing and maintaining a procedure to make persons aware of aspects associated with environmental management system is stated.
4.4.3	Communication	Requirement of establishing, implementing and maintaining a procedure for internal and external communication is stated.
4.4.4	Documentation	Requirement of maintaining the documents relevant to established environmental management system is stated.
4.4.5	Control of documents	Requirement of establishing, implementing and maintaining a procedure to control the documents relevant to established environmental management system is stated.
4.4.6	Operational control	Requirement of establishing, implementing and maintaining a procedure related to identified environmental aspects is stated.
4.4.7	Emergency preparedness and response	Requirement of establishing, implementing and maintaining a procedure for identifying, reviewing and responding to emergency situations and testing them is stated.
4.5	Checking	---
4.5.1	Monitoring and measurement	Requirement of establishing, implementing and maintaining a procedure for monitoring and measuring key characteristics of its operations including calibration/verification of equipments is stated.
4.5.2	Evaluation of compliance	Requirement of establishing, implementing and maintaining a procedure for evaluating compliance with legal and other requirements is stated.
4.5.3	Non-conformity, corrective action and preventive action	Requirement of establishing, implementing and maintaining a procedure for nonconformities and taking corrective and preventive actions is stated.
4.5.4	Control of records	Requirement of establishing, implementing and maintaining a procedure for maintaining relevant records is stated.
4.5.5	Internal audit	Requirement of establishing, implementing and

Clause/ Subclause No.	Clause/Subclause title	Clause/Subclause : Contents/Interpretation
		maintaining a procedure for planning, conducting, reporting and recording internal audits is stated.
4.6	Management review	Requirement of reviewing the organisation's environmental management system at planned intervals is stated.
Annex A	Guidance on the use of the standard	Clause by clause guidance is given for effective implementation of environmental management system.
Annex B	Correspondence with ISO 9001:2000	Two tables establish correspondence between ISO 14000:2004 and ISO 9001:2000 and vice versa.
Bibilo-graphy	Reference of standards	List of relevant standards is given *viz*. ISO 9000:2000, ISO 9001:2000, ISO 14001:2004 and ISO 19011:2002.

1.4 OHSAS 18001:2007 OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEMS REQUIREMENTS

1.4.1 Introduction to OHSAS 18001:2007

OHSAS 18001:2007 is an occupational health and safety management standard. It defines a set of Occupational Health and Safety (OH&S) management requirements for Occupational Health and Safety Management Systems (OHSMS).

OHSAS 18001:2007 was developed by the OHSAS Project Group, a consortium of 43 organisations from 28 countries. This consortium includes national standards bodies, registrars (certification bodies), OH&S institutes, and consultants.

This new OHSAS 18001:2007 standard was officially published during July of 2007. It cancels and replaces OHSAS 18001:1999. Since it was first published in 1999, OHSAS 18001 has rapidly become the most widely used international OH&S management standard. OHSAS 18001 applies to all types of organisations. It doesn't matter what size they are or what they do.

The purpose of OHSAS 18001 is to help organisations to manage and control their OH&S risks and to improve their OH&S performance. They can achieve this purpose by developing an OHSMS that complies with OHSAS 18001.

An OHSMS is a network of interrelated elements. These elements include responsibilities, authorities, relationships, functions, activities, processes, practices, procedures, and resources. These elements are used to establish OH&S policies, plans, programs and objectives.

Certainly the concept of an OHSMS is rather abstract. However, fortunately, you don't really have to completely grasp, absorb or memorize what it means. Simply by meeting all of the OHSAS 18001 requirements (Part 4), you will automatically establish an integrated OHSMS for your organisation.

1.4.2 How to Use 18001 OHSAS 18001:2007

If you don't already have an Occupational Health and Safety Management System (OHSMS), you can use this OHSAS 18001 standard to establish one. And once you've established your organisation's OHSMS, you can use it to manage and control your OH&S risks and to improve your OH&S performance.

OHSAS 18001 expects organisations to comply with all of the requirements that make up the standard. According to the standard, your OHSMS must comply with every OHSAS 18001 requirement (Part 4 of the standard).

However, the size and complexity of OHSMS vary quite a bit. How far you go is up to you. The size and complexity of your OHSMS, the extent of your documentation, and the resources allocated to your system will depend on many things. How you meet each of the OHSAS 18001 requirements, and to what extent, depends on many factors, including:

1) The size of your organisation.
2) The location of your organisation.
3) The nature of your organisation's culture.
4) The nature of your organisation's activities.
5) The nature of your organisation's legal obligations.
6) The nature and scope of your organisation's OHSMS.
7) The content of your organisation's OH&S policy.
8) The nature of your organisation's OH&S hazards.
9) The nature of your organisation's OH&S risks.

OHSAS 18001 is designed to be used for certification (registration) purposes. However, OHSAS 18001 does not require certification. You can be in compliance without being formally certified (registered). You can self-assess (self audit) your OHSMS and simply declare that it complies with the OHSAS 18001 standard (if it actually does).

If you wish to become certified, you need to ask a registrar to audit your OHSMS. If your system complies with OHSAS 18001, your registrar will issue a certificate that you can use to formally announce that your OHSMS is compliant.

1.4.3 PDCA Methodology

OHSAS 18001 uses what is called the Plan-Do-Check-Act (PDCA) methodology. It uses this methodology to organize the standard and you can use it to establish your OHSMS.

The PDCA methodology is used to organize OHSAS 18001 in the following way:

1) *PLAN*–Parts 4.1, 4.2, and 4.3 expect you to plan the establishment of your OHSMS.
2) *DO*–Part 4.4 expects you to implement your OHSMS.
3) *CHECK*–Parts 4.5 and 4.6 expect you to monitor, measure and report on the performance of your OHSMS.

4) *ACT*–Parts 4.5 and 4.6 expect you to improve your OHSMS.

You can also use a PDCA approach to help you establish your organisation's OHSMS. By taking the following four steps you will be using a PDCA approach:

1) *PLAN*–Plan your OHSMS.
2) *DO*–Establish your OHSMS.
3) *CHECK*–Evaluate your OHSMS.
4) *ACT*–Improve your OHSMS.

1.4.4 Your General Approach

The following material presents a brief OHSMS development plan. It summarizes the general approach you will take to develop your own unique OHSMS. It uses a PDCA approach and is taken directly from our OHSAS 18001. Translated into plain english. If you use our plain english standard to develop your organisation's OHSMS, you will automatically take the following steps:

1) Define the scope of your OHSMS.
2) Define your organisation's OHSMS policy.
3) Develop a methodology to identify hazards and assess risks.
4) Establish procedures to identify hazards and assess risks.
5) Identify your organisation's hazards and assess your risks.
6) Establish procedures to evaluate and select OH&S controls.
7) Evaluate the adequacy of your existing OH&S controls.
8) Select OH&S controls that reduce your OH&S risks.
9) Document the results of your control selection process.
10) Identify relevant legal and non-legal OH&S requirements.
11) Respect all relevant legal and non-legal OH&S requirements.
12) Establish unique OH&S objectives for your organisation.
13) Establish programs to achieve your OH&S objectives.
14) Appoint a member of top management to manage OH&S.
15) Ensure the competence of those who influence OH&S.
16) Identify your OH&S training and awareness needs.
17) Establish OH&S training and awareness procedures.
18) Implement OH&S training and awareness procedures.
19) Establish procedures to manage OH&S communications.
20) Establish procedures to manage OH&S participation.
21) Document your organisation's unique OHSMS.
22) Control your organisation's OH&S documents and records.
23) Implement controls to manage OH&S hazards and risks.

24) Establish an OH&S emergency management process.

25) Monitor and measure your organisation's OH&S performance.

26) Record the results of your OH&S monitoring and measuring.

27) Evaluate compliance with legal and non-legal requirements.

28) Record the results of your OH&S compliance evaluations.

29) Establish procedures to investigate OH&S incidents.

30) Establish non-conformity management procedures.

31) Perform regular internal audits of your OHSMS.

32) Review your OHSMS at planned intervals.

33) Update and improve your OHSMS.

Of course, you may already have an existing OHSMS. If this is true, you don't need to follow a detailed OHSMS development plan. You would probably find it easier and more efficient to use a gap analysis approach, instead.

A gap analysis would compare your existing OHSMS with the OHSAS 18001 requirements. Such a comparison would pinpoint the areas that fall short of the standard (the gaps). By focusing on filling your unique occupational health and safety gaps, you will soon comply with the OHSAS 18001 standard.

If you already have an existing OHSMS, a gap analysis is more targeted and efficient. It is more targeted and efficient because it takes an incremental approach and ignores areas that already comply with the standard.

1.5 ISO/IEC 27001:2005 INFORMATION TECHNOLOGY-SECURITY TECHNIQUES-INFORMATION SECURITY MANAGEMENT SYSTEM-REQUIREMENTS

1.5.1 ISO and IEC

ISO is the International Organisation for Standardization. It was set up in 1947 and is located in Geneva, Switzerland. Its purpose is to develop standards that support and facilitate international trade. IEC is the International Electrotechnical Commission. It was set up in 1906 and is also located in Geneva, Switzerland. Its purpose is to develop standards for all types of electrotechnologies. Both ISO and IEC are supported by national member bodies. These member bodies participate in the standards development process through technical committees.

1.5.2 ISO/IEC 27001 *vs*. BS 7799-2

ISO/IEC 27001:2005 was developed by ISO/IEC JTC 1, SC 27 (Joint Technical Committee 1, Subcommittee 27). JTC 1 is responsible for all kinds of information technology standards while SC 27 is specifically responsible for the development of standards related to IT security techniques.

ISO/IEC 27001:2005 was officially published on October 15, 2005. This new ISO 27001:2005 standard cancels and replaces the old BS 7799-2 standard (published in 2002 by BSI). The old BS 7799-2 information security standard is now obsolete and has been officially withdrawn.

1.5.3 Introduction to ISO/IEC 27001

ISO/IEC 27001 is an information security management standard. It defines a set of information security management requirements. These requirements are defined in sections 4, 5, 6, 7 and 8.

The purpose of ISO/IEC 27001 is to help organisations establish and maintain an *Information Security Management System (ISMS)*. ISO/IEC 27001 applies to all types of organisations. It doesn't matter what your organisation does or what size it is. ISO IEC 27001 can help your organisation meet its information security management needs and requirements.

ISO/IEC 27001 is designed to be used for certification purposes. In other words, once you've established an ISMS that meets both the ISO/IEC 27001 requirements and your organisation's needs, you can ask a registrar to audit your system. If your registrar likes what it sees, it will issue an official certificate that states that your ISMS meets the ISO/IEC 27001 requirements. According to ISO/IEC 27001, you must meet every requirement (specified in clauses 4, 5, 6, 7, and 8) if you wish to claim that your ISMS complies with the standard.

However, while you must meet every requirement, the size and complexity of information security management systems varies quite a bit. How you meet each of the ISO 27001 requirements, and to what extent, depends on many factors, including your organisation's:

- Size and structure
- Needs and objectives
- Security requirements
- Business processes

ISO/IEC 27001 also lists a set of control objectives and controls. These are listed in Annex. A (our Part 9) and come from the ISO/IEC 27002 (17799:2005) information security standard.

In addition to control objectives and controls, ISO 27002 also provides implementation guidance and other information. These last two items are not included in ISO 27001. As a result, you may find it helpful to also purchase the ISO/IEC 27002 (17799) standard.

While ISO/IEC 27001 expects you to meet every requirement, it does allow you to exclude selected Annex. A control objectives and controls if you can justify doing so. Briefly put, you may *exclude* or ignore Annex. A control objectives and controls whenever they address risks you can live with, and whenever doing so will not impair your ability and obligation to meet all relevant legal and security requirements.

More precisely, you may ignore or exclude selected control objectives and controls under the following circumstances:

- You may exclude selected control objectives and controls if they address security risks that you can accept and if you can show that your decision to accept these risks complies with your organisation's official risk acceptance criteria.
- You must also be able to justify your exclusion decision.
- You must also be able to show that accountable persons have accepted the associated risks.
- You may exclude selected control objectives and controls if you have used a risk assessment to identify your organisation's information security requirements and you believe that these requirements will, nevertheless, be met.
- You may exclude selected control objectives and controls whenever this does not impair your ability and responsibility to meet your organisation's information security requirements.
- You may exclude selected control objectives and controls if you can show that all applicable legal and regulatory requirements will, nevertheless, be met.
- You may exclude selected control objectives and controls whenever this does not impair your ability and responsibility to meet all applicable legal and statutory requirements.

1.5.4 The PDCA Model

ISO/IEC 27001 uses the *Plan-Do-Check-Act (PDCA)* model. ISO/IEC has used this model to organize the standard and you can use it to help you establish your Information Security Management System (ISMS). ISO/IEC uses this model in the following way:

- *PLAN*–Section 4 expects you to plan the establishment of your organisation's ISMS.
- *DO*–Section 5 expects you to implement, operate, and maintain your ISMS.
- *CHECK*–Sections 6 and 7 expect you to monitor, measure, audit, and review your ISMS.
- *ACT*–Section 8 expects you to take corrective and preventive actions and continually improve your ISMS.

Since ISO/IEC has used a PDCA model to organize the ISO/IEC 27001 standard, it is conveniently designed to facilitate system development. If you follow the five general steps (sections 4 to 8) that make up the standard, you'll automatically develop comprehensive ISMS.

1.5.5 Your General Approach

The following material presents a brief information security management system development plan. It summarizes the general approach you will take to develop your own unique ISMS. It uses a PDCA approach and is taken directly from our plain English version of the standard. If you use our plain english standard to develop your organisation's ISMS, you will automatically take the following steps:

1) Define the scope and boundaries of your ISMS.
2) Define your organisation's ISMS policy.
3) Define your approach to risk management.
4) Identify your organisation's security risks.
5) Analyze and evaluate your security risks.
6) Identify and evaluate your risk treatment options.
7) Select control objectives and controls to treat risks.
8) Prepare a detailed statement of Applicability.
9) Develop a risk treatment plan to manage your risks.
10) Implement your organisation's risk treatment plan.
11) Implement your organisation's security controls.
12) Implement your organisation's educational programs.
13) Manage and operate your organisation's ISMS.
14) Implement your organisation's security procedures.
15) Use procedures and controls to monitor your ISMS.
16) Use procedures and controls to review your ISMS.
17) Perform regular reviews of your organisation's ISMS.
18) Verify that your security requirements are being met.
19) Review your risk assessments on a regular basis.
20) Review your residual risks on a regular basis.
21) Review acceptable levels of risk on a regular basis.
22) Perform regular internal audits of your ISMS.
23) Perform regular management reviews of your ISMS.
24) Update your organisation's information security plans.
25) Implement ISMS improvements.
26) Take appropriate corrective actions.
27) Take appropriate preventive actions.
28) Communicate ISMS changes to interested parties.
29) Establish records that document your decisions.
30) Document your organisation's ISMS.
31) Protect and control your ISMS documents.
32) Establish records for your organisation's ISMS.
33) Maintain records for your organisation's ISMS.

Of course, you may already have existing ISMS. If this is true, you don't need to follow a detailed ISMS development plan. You would probably find it easier and more efficient to use a gap analysis approach, instead.

A gap analysis would compare your existing ISMS with the ISO/IEC 27001 requirements. Such a comparison would pinpoint the areas that fall short of the standard (the gaps). By focusing on filling your unique information security gaps, you will soon comply with the ISO/IEC 27001 standard.

If you already have an existing ISMS, a gap analysis is more targeted and efficient. It is more targeted and efficient because it ignores areas that already comply with the standard.

1.5.6 The Process Approach

ISO/IEC 27001 also uses a process approach. The process approach is a management strategy. When managers use a process approach, it means that they control their processes, the interaction between these processes, and the inputs and outputs that "glue" these processes together. It means that they manage by focusing on processes and on inputs and outputs. ISO/IEC 27001 suggests that you use a process approach to manage and control your ISMS processes.

In general, a process uses resources to transform inputs into outputs. In every case, inputs are turned into outputs because some kind of work or activity is carried out. And because the output of one process often becomes the input of another process, inputs and outputs are really the same thing.

ISO/IEC 27001 suggests that you structure every ISMS process using the Plan-Do-Check-Act (PDCA) model. This means that every process should be:

- Planned (PLAN)
- Implemented, operated, and maintained (DO)
- Monitored, measured, audited and reviewed (CHECK)
- Improved (ACT)

The PDCA model runs through every aspect of the ISO IEC 27001 standard. The standard not only recommends that the PDCA model be used to structure every ISMS process, it was also used to structure the standard itself. And since it was used to structure the standard, you will automatically use a PDCA approach as you use the standard to develop your own ISMS.

Check Your Progress Exercise 1

Note: a) Use the space below for your answers.
b) Check your answers with those given at the end of the unit.

1) Name any four standards applicable to an industry irrespective of its type.

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2) Name any six standards applicable to food industry.

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3) In ISO 14000: 2004 explain the meaning of environmental aspects.

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4) In OHSAS 18001:2007 explain how PDCA methodology is used in the structure of the standard.

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5) What is the purpose of implementing ISO 27001: 2005 in any industry?

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1.6 LET US SUM UP

This unit introduced us to international standards representing different management systems. They include quality management, environmental management, food safety management, occupational health and safety management, information security management.

All management system follow Plan-Do-Check-Act PDCA model. This means every process should be planed, implemented, operated and maintained (DO), monitored, measured, audited and reviewed (Check) and improved (Act).

It also describes the general approach, application, structure and interpretation of these standards.

1.7 KEY WORDS

Quality : Degree to which a set of inherent characteristics fulfils requirements.

Requirement : Need or expectation that is stated, generally implied or obligatory.

Quality Management System : Management system to direct and control an organisation with respect to quality.

Corrective Action : Action to eliminate the cause of a detected non-conformity or other undesirable situation.

Preventive Action : Action to eliminate the cause of a potential non-conformity or other undesirable potential situation.

Competence : Demonstrated ability to apply knowledge and skills.

Effectiveness : Extent to which planned activities are realized and planned results achieved.

Product : Result of a process.

Document : Information and its supporting medium.

Record : Document stating results achieved or providing evidence of activities performed.

Customer Satisfaction : Customer's perception of the degree to which the customer's requirements have been fulfilled.

Environment : The term *environment* refers to an organisation's natural and human surroundings. An organisation's environment extends from within the organisation itself to the global system, and includes air, water, land, flora, fauna, as well as human beings.

Environmental Aspect : An *environmental aspect* is a feature or characteristic of an activity, product, or service that affects or can affect the environment.

Environmental Impact : An *environmental impact* is a change to the environment. Such change can be positive or negative. Environmental impacts are caused by *environmental aspects*. Your environmental aspects can have a direct and decisive impact on the environment or contribute only partially or indirectly to a larger environmental change.

Environmental Management System (EMS) : An organisation's environmental management system (EMS) is one part of a larger management system. The EMS part of this larger management system is used to establish an environmental policy and to manage the environmental aspects of an organisation's activities, products and services.

Environmental Objective : An *environmental objective* is a specific environmental goal. Your organisation's environmental objectives must be consistent with its environmental policy.

Environmental Performance : *Environmental performance* is all about how well an organisation manages the environmental aspects of its activities, products and services and the impact they have on the environment. Your organisation's environmental performance can be improved by reducing its negative environmental impact or increasing its positive environmental impact.

Environmental Policy : An *environmental policy* statement expresses a commitment to the implementation and maintenance of an organisation's environmental management system and the improvement of its overall environmental performance.

Environmental Target : An *environmental target* is a detailed performance requirement. Environmental targets are derived from environmental objectives and are used to achieve these objectives. Targets can apply to specific areas or to the organisation as a whole.

Hazard : A *hazard* is any situation, substance, activity, event, or environment that could potentially cause injury or ill health shutdowns.

Hazard Identification : *Hazard identification* is a process that involves recognizing that an OH&S hazard exists and then describing its characteristics.

Incident : An *incident* is a work related event during which injury, ill health, or fatality actually occurs, or could have occurred.

Information Security : *Information security* is all about protecting and preserving information. It's all about protecting and preserving the confidentiality, integrity, authenticity, availability, and reliability of information.

Information Security Management System (ISMS) : An *Information Security Management System (ISMS)* includes all of the policies, procedures, plans, processes, practices, roles, responsibilities, resources and structures that are used to protect and preserve information. It includes all of the elements that organisations use to manage and control their information security risks. An ISMS is part of a larger *management system*.

Information Security Policy : An *information security policy* statement expresses management's commitment to the implementation, maintenance and improvement of its information security management system.

Risk : The concept of *risk* combines three ideas: it selects an event, and then combines its probability with its potential impact.

Statement of Applicability : A *Statement of Applicability* is a document that lists your organisation's information security control objectives and controls.

Threat : A *threat* is a potential event. When a *threat* turns into an actual event, it may cause an unwanted incident. It is unwanted because the incident may harm an organisation or system.

Vulnerability : A *vulnerability* is a weakness in an asset or group of assets. An asset's weakness could allow it to be exploited and harmed by one or more threats.

1.8 ANSWERS TO CHECK YOUR PROGRESS EXERCISE

Your answer should include following points:

Check Your Progress Exercise 1

1)
- ISO 9001: 2000
- ISO 14001: 2004
- OHSAS 18000: 2007
- ISO 27001: 2005

2)
- ISO 9001: 2000
- ISO 14001: 2004
- OHSAS 18000: 2007
- ISO 27001: 2005
- HACCP
- ISO 22000: 2005

3) An environmental aspect is a feature or characteristic of an activity, product, or service that affects or can affect the environment.

4) The PDCA methodology is used to organize OHSAS 18001 in the following way:

   i) *PLAN* - Parts 4.1, 4.2 and 4.3 expect you to plan the establishment of your OHSMS.

   ii) *DO* - Part 4.4 expects you to implement your OHSMS.

   iii) *CHECK* - Parts 4.5 and 4.6 expect you to monitor, measure and report on the performance of your OHSMS.

   iv) *ACT* - Parts 4.5 and 4.6 expect you to improve your OHSMS.

5) The purpose of ISO IEC 27001 is to help organisations establish and maintain an *Information Security Management System (ISMS)*. ISO IEC 27001 applies to all types of organisations. It doesn't matter what your organisation does or what size it is. ISO IEC 27001 can help your organisation meet its information security management needs and requirements.

1.9 SUGGESTED READING

http://www.iso.org

ISO 19011:2002 – *Guidelines for Quality and/or Environmental Management Systems Auditing*.

ISO 9000:2000 – *Quality Management Systems- Fundamentals and Vocabulary*.

ISO 9001:2000 – *Quality Management Systems- Requirement*.

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

ISO 10012:2003 – *Quality Assurance Requirements for Measuring Equipment*.

ISO 10013:1995 – *Guidelines for Developing Quality Manuals*.

UNIT 2 AUDITING

Structure

2.0 OBJECTIVES

After reading this unit, we shall be able to:

- define requirements of ISO 19011:2002;
- plan, implement and control of audit activities;
- explain the principles of auditing and auditor attributes; and
- state the audit reporting activity.

2.1 INTRODUCTION

ISO 19011: 2002 (Guidelines for quality and/or environmental management systems auditing), was published in October 2002 in response to demand for guidance on combined management system audits.

It offers comprehensive guidelines for quality and/or environmental management systems audit. The objective is that by using this document, organisations can save effort, time and expenditure by:

- Avoiding confusion over the objectives of the environmental or quality audit program.
- Ensuring audit reports follow the best format and contain all the relevant information.

- Securing agreement of the goals for individual audits within an audit program.
- Evaluating the competence of members of an audit team against appropriate criteria.
- Reducing duplication of effort when conducting combined environmental/ quality audits.

Whatever the reason for the audit (certification, internal review, contract compliance, etc.) it is intended that organisations can move efficiently through the process by applying these guidelines.

Getting a firm grasp of the audit process is therefore an extremely worthwhile exercise.

Within one single standard there are now four critical decision/support resources for the efficient planning, conducting and evaluation of quality and environmental audits:

- A clear explanation of the principles of management systems auditing.
- Guidance on the competence and evaluation of auditors.
- Guidance on the management of audit programs.
- Guidance on the conduct of internal or external audits.

At the core of the standard is a set of principles that will help anyone connected with an audit to perform it effectively. And because it focuses primarily on the underlying processes of audit management, it can also be adapted for use when auditing any management system.

The ISO 9000 and ISO 14000 series of International Standards emphasize the importance of audits as a management tool for monitoring and verifying the effective implementation of an organisation's quality and/or environmental policy. Audits are also an essential part of conformity assessment activities such as external certification/registration and of supply chain evaluation and surveillance.

This International Standard provides guidance on the management of audit programs, the conduct of internal or external audits of quality and/or environmental management systems, as well as on the competence and evaluation of auditors. It is intended to apply to a broad range of potential users, including auditors, organisations implementing quality and/or environmental management systems, organisations needing to conduct audits of quality and/or environmental management systems for contractual reasons, and organisations involved in auditor certification or training, in certification/registration of management systems, in accreditation or in standardization in the area of conformity assessment.

The guidance in this International Standard is intended to be flexible. As indicated at various points in the text, the use of these guidelines can differ according to the size, nature and complexity of the organisations to be audited, as well as the objectives and scopes of the audits to be conducted. Throughout this International Standard, supplementary guidance or examples on specific topics are provided in the form of practical help in boxed text. In some instances, this is intended to support the use of this International Standard in small organisations.

Clause 4 describes the principles of auditing. These principles help the user to appreciate the essential nature of auditing and they are a necessary prelude to clauses 5, 6 and 7.

Clause 5 provides guidance on managing audit programs and covers such issues as assigning responsibility for managing audit programs, establishing the audit program objectives, coordinating auditing activities and providing sufficient audit team resources.

Clause 6 provides guidance on conducting audits of quality and/or environmental management systems, including the selection of audit teams.

Clause 7 provides guidance on the competence needed by an auditor and describes a process for evaluating auditors.

Where quality and environmental management systems are implemented together, it is at the discretion of the user of this International Standard as to whether the quality management system and environmental management system audits are conducted separately or together.

Although this International Standard is applicable to the auditing of quality and/or environmental management systems, the user can consider adapting or extending the guidance provided herein to apply to other types of audits, including other management system audits.

This International Standard provides only guidance; however, users can apply this to develop their own audit related requirements.

In addition, any other individual or organisation with an interest in monitoring conformance to requirements, such as product specifications or laws and regulations, may find the guidance in this International Standard useful.

2.2 CLAUSE 1 – SCOPE OF THE STANDARD

This International Standard provides guidance on the principles of auditing, managing audit programs, conducting quality management system audits and environmental management system audits, as well as guidance on the competence of quality and environmental management system auditors.

It is applicable to all organisations needing to conduct internal or external audits of quality and/or environmental management systems or to manage an audit program.

2.3 CLAUSE 2 – NORMATIVE REFERENCES

The following two standards are referred to in ISO 19011: 2002, which mainly focus on the fundamentals and vocabulary of the terms and words used in this standard.

ISO 9000:2000 – Fundamentals and vocabulary.
ISO 14050:2002 – Environmental management – vocabulary.

2.4 CLAUSE 3 – TERMS AND DEFINITIONS

There are fourteen terms defined in this section of the standard. These are given below in the Key Words section. However to clarify different types of audits, definition of audit, as given in the standard, is reproduced below.

Audit

Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

Note 1: Internal audits, sometimes called first-party audits, are conducted by, or on behalf of the organisation itself for management review and other internal purposes, and may form the basis for an organisation's self-declaration of conformity. In many cases, particularly in smaller organisations, independence can be demonstrated by the freedom from responsibility for the activity being audited.

Note 2: External audits include those generally termed second and third-party audits. Second-party audits are conducted by parties having an interest in the organisation, such as customers, or by other persons on their behalf. Third party audits are conducted by external, independent auditing organisation, such as those providing registration or certification of conformity to the requirements of ISO 9001 or ISO 14001.

Note 3: When a quality management system and an environmental management system are audited together, this is termed a combined audit.

Note 4: When two or more auditing organisations cooperate to a single audit, this is termed a joint audit.

2.5 CLAUSE 4 – PRINCIPLES OF AUDITING

Auditing is characterized by reliance on a number of principles. These make the audit an effective and reliable tool in support of management policies and controls, providing information on which an organisation can act to improve its performance. Adherence to these principles is a prerequisite for providing audit conclusions that are relevant and sufficient and for enabling auditors working independently from one another to reach similar conclusions in similar circumstances. The following principles relate to auditors.

a) **Ethical conduct:** *The foundation of professionalism*. Trust, integrity, confidentiality and discretion are essential to auditing.

b) **Fair presentation:** *The obligation to report truthfully and accurately*. Audit findings, audit conclusions and audit reports reflect truthfully and accurately the audit activities. Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and the auditee are reported.

c) **Due professional care:** *The application of diligence and judgment in auditing*. Auditors exercise care in accordance with the importance of the task they perform and the confidence placed in them by audit clients and other interested parties. Having the necessary competence is an important factor.

   Further principles relate to the audit, which is by definition independent and systematic.

d) **Independence:** *The basis for the impartiality of the audit and objectivity of the audit conclusions*. Auditors are independent of the activity being audited and are free from bias and conflict of interest. Auditors maintain an

objective state of mind throughout the audit process to ensure that the audit findings and conclusions will be based only on the audit evidence.

e) **Evidence-based approach:** *The rational method for reaching reliable and reproducible audit conclusions in a systematic audit process*. Audit evidence is verifiable. It is based on samples of the information available, since an audit is conducted during a finite period of time and with finite resources. The appropriate use of sampling is closely related to the confidence that can be placed in the audit conclusions.

The guidance given in the remaining clauses of this International Standard is based on the principles set out above.

2.6 CLAUSE 5 – MANAGING AN AUDIT PROGRAM

An audit program may include one or more audits, depending upon the size, nature and complexity of the organisation to be audited. These audits may have a variety of objectives and may also include joint or combined audits. (see Notes 3 and 4 to definition of audit in 3.1.).

An audit program also includes all activities necessary for planning and organizing the types and number of audits, and for providing resources to conduct them effectively and efficiently within the specified time frames.

An organisation may establish more than one audit program. The organisation's top management should grant the authority for managing the audit program.

Those assigned the responsibility for managing the audit program should:

a) establish, implement, monitor, review and improve the audit program, and

b) identify the necessary resources and ensure they are provided.

2.6.1 Audit Program Objectives and Extent

A. Objectives of an audit program

Objectives should be established for an audit program, to direct the planning and conduct of audits. These objectives can be based on consideration of:

a) management priorities,

b) commercial intentions,

c) management system requirements,

d) statutory, regulatory and contractual requirements,

e) need for supplier evaluation,

f) customer requirements,

g) needs of other interested parties, and

h) risks to the organisation.

B. Extent of an audit program

The extent of an audit program can vary and will be influenced by the size, nature and complexity of the organisation to be audited, as well as by the following:

a) the scope, objective and duration of each audit to be conducted;

b) the frequency of audits to be conducted;

c) the number, importance, complexity, similarity and locations of the activities to be audited;

d) standards, statutory, regulatory and contractual requirements and other audit criteria;

e) the need for accreditation or registration/certification;

f) conclusions of previous audits or results of a previous audit program review;

g) any language, cultural and social issues;

h) the concerns of interested parties; and

i) significant changes to an organisation or its operations.

2.6.2 Audit Program Responsibilities, Resources and Procedures

Audit program responsibilities

The responsibility for managing an audit program should be assigned to one or more individuals with a general understanding of audit principles, of the competence of auditors and the application of audit techniques. They should have management skills as well as technical and business understanding relevant to the activities to be audited. Those assigned the responsibility for managing the audit program should:

a) establish the objectives and extent of the audit program,

b) establish the responsibilities and procedures, and ensure resources are provided,

c) ensure the implementation of the audit program,

d) ensure that appropriate audit program records are maintained, and

e) monitor, review and improve the audit program.

2.6.3 Audit Program Resources

When identifying resources for the audit program, consideration should be given to:

a) financial resources necessary to develop, implement, manage and improve audit activities,

b) audit techniques,

c) processes to achieve and maintain the competence of auditors, and to improve auditor performance,

d) the availability of auditors and technical experts having competence appropriate to the particular audit program objectives,

e) the extent of the audit program, and

f) traveling time, accommodation and other auditing needs.

2.6.4 Audit Program Procedures

Audit program procedures should address the following:

a) planning and scheduling audits;

b) assuring the competence of auditors and audit team leaders;

c) selecting appropriate audit teams and assigning their roles and responsibilities;

d) conducting audits;

e) conducting audit follow-up, if applicable;

f) maintaining audit program records;

g) monitoring the performance and effectiveness of the audit program;

h) reporting to top management on the overall achievements of the audit program.

For smaller organisations, the activities above can be addressed in a single procedure.

2.6.5 Audit Program Implementation

The implementation of an audit program should address the following:

a) communicating the audit program to relevant parties;

b) coordinating and scheduling audits and other activities relevant to the audit program;

c) establishing and maintaining a process for the evaluation of the auditors and their continual professional development, in accordance with respectively 7.6 and 7.5;

d) ensuring the selection of audit teams;

e) providing necessary resources to the audit teams;

f) ensuring the conduct of audits according to the audit program;

g) ensuring the control of records of the audit activities;

h) ensuring review and approval of audit reports, and ensuring their distribution to the audit client and other specified parties; and

i) ensuring audit follow-up, if applicable.

2.6.6 Audit Program Records

Records should be maintained to demonstrate the implementation of the audit program and should include the following:

a) records related to individual audits, such as:

- audit plans,
- audit reports,

- non-conformity reports,
- corrective and preventive action reports, and
- audit follow-up reports, if applicable;

b) results of audit program review;

c) records related to audit personnel covering subjects such as:

- auditor competence and performance evaluation,
- audit team selection, and
- maintenance and improvement of competence.

Records should be retained and suitably safeguarded.

2.6.7 Audit Program Monitoring and Reviewing

The implementation of the audit program should be monitored and, at appropriate intervals, reviewed to assess whether its objectives have been met and to identify opportunities for improvement. The results should be reported to top management. Performance indicators should be used to monitor characteristics such as:

- the ability of the audit teams to implement the audit plan,
- conformity with audit programs and schedules, and
- feedback from audit clients, auditees and auditors.

The audit program review should consider, for example:

a) results and trends from monitoring,

b) conformity with procedures,

c) evolving needs and expectations of interested parties,

d) audit program records,

e) alternative or new auditing practices, and

f) consistency in performance between audit teams in similar situations.

Results of audit program reviews can lead to corrective and preventive actions and the improvement of the audit program.

2.7 CLAUSE 6 – AUDIT ACTIVITIES

This clause contains guidance on planning and conducting audit activities as part of an audit programme. Figure below provides an overview of typical audit activities. The extent to which the provisions of this clause are applicable depends on the scope and complexity of the specific audit and the intended use of the audit conclusions.

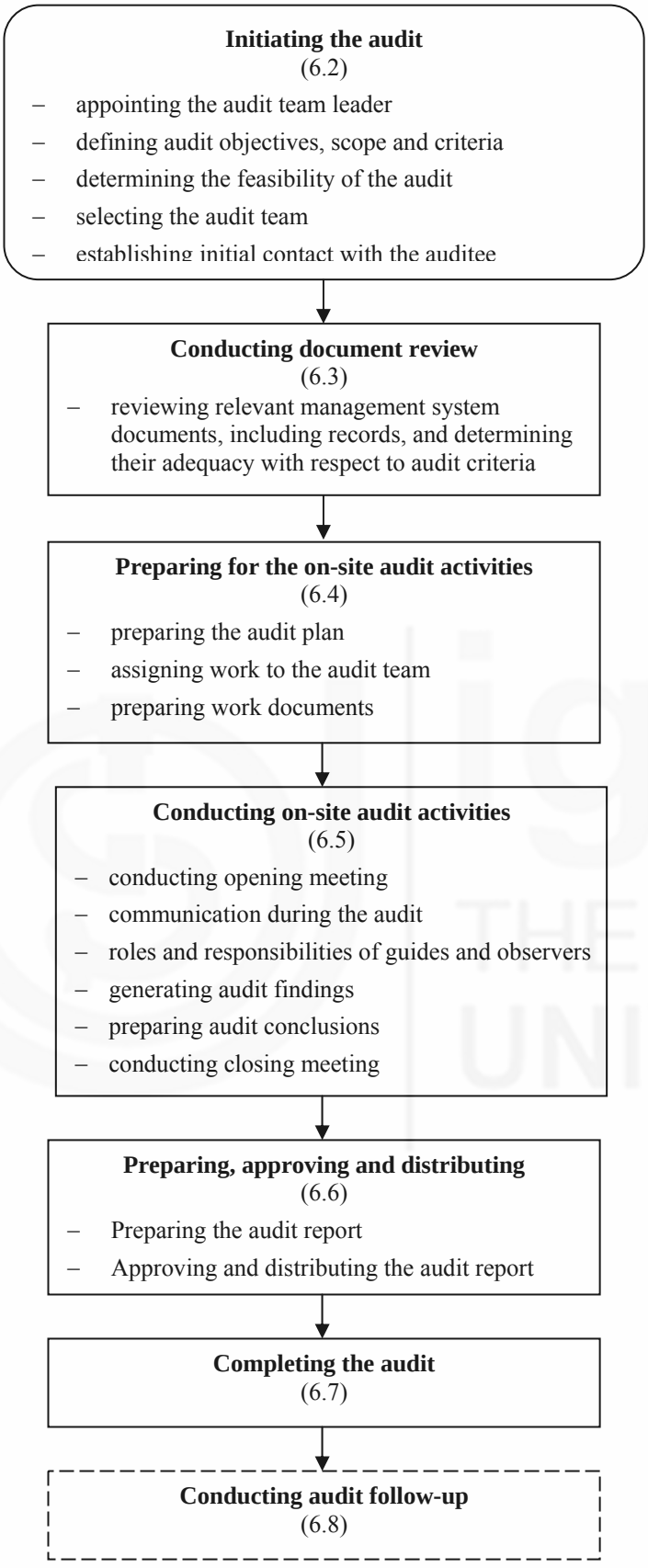

Fig. 1.1: Overview of typical audit activities

Note: The dotted lines indicate that any audit follow-up actions are usually not considered to be part of the audit. Numbers in bracket in the diagram refer to the clauses and sub-clauses of the standard.

2.7.1 Initiating the Audit

Appointing the audit team leader

Those assigned the responsibility for managing the audit program should appoint the audit team leader for the specific audit.

Where a joint audit is conducted, it is important to reach agreement among the auditing organisations before the audit commences on the specific responsibilities of each organisation, particularly with regard to the authority of the team leader appointed for the audit.

Defining audit objectives, scope and criteria

Within the overall objectives of an audit programme, an individual audit should be based on documented objectives, scope and criteria. The audit objectives define what is to be accomplished by the audit and may include the following:

a) Determination of the extent of conformity of the auditee's management system, or parts of it, with audit criteria;

b) Evaluation of the capability of the management system to ensure compliance with statutory, regulatory and contractual requirements;

c) Evaluation of the effectiveness of the management system in meeting its specified objectives; and

d) Identification of areas for potential improvement of the management system.

The audit scope describes the extent and boundaries of the audit, such as physical locations, organisational units, activities and processes to be audited, as well as the time period covered by the audit.

The audit criteria are used as a reference against which conformity is determined and may include applicable policies, procedures, standards, laws and regulations, management system requirements, contractual requirements or industry/business sector codes of conduct.

The audit objectives should be defined by the audit client. The audit scope and criteria should be defined between the audit client and the audit team leader in accordance with audit programme procedures. Any changes to the audit objectives, scope or criteria should be agreed to by the same parties.

Where a combined audit is to be conducted, it is important that the audit team leader ensures that the audit objectives, scope and criteria are appropriate to the nature of the combined audit.

Determining the feasibility of the audit

The feasibility of the audit should be determined, taking into consideration such factors as the availability of:

- sufficient and appropriate information for planning the audit,
- adequate cooperation from the auditee, and
- adequate time and resources.

Where the audit is not feasible, an alternative should be proposed to the audit client, in consultation with the auditee.

Selecting the audit team

When the audit has been declared feasible, an audit team should be selected, taking into account the competence needed to achieve the objectives of the audit. If there is only one auditor, the auditor should perform all applicable duties of an audit team leader. Clause 7 contains guidance on determining the competence needed and describes processes for evaluating auditors. In deciding the size and composition of the audit team, consideration should be given to the following:

a) audit objectives, scope, criteria and estimated duration of the audit;

b) whether the audit is a combined or joint audit;

c) the overall competence of the audit team needed to achieve the objectives of the audit;

d) statutory, regulatory, contractual and accreditation/certification requirements, as applicable;

e) the need to ensure the independence of the audit team from the activities to be audited and to avoid conflict of interest;

f) the ability of the audit team members to interact effectively with the auditee and to work together;

g) the language of the audit, and an understanding of the auditee's particular social and cultural characteristics; these issues may be addressed either by the auditor's own skills or through the support of a technical expert.

The process of assuring the overall competence of the audit team should include the following steps:

- identification of the knowledge and skills needed to achieve the objectives of the audit; and
- selection of the audit team members such that all of the necessary knowledge and skills are present in the audit team.

If not fully covered by the auditors in the audit team, the necessary knowledge and skills may be satisfied by including technical experts. Technical experts should operate under the direction of an auditor.

Auditors-in-training may be included in the audit team, but should not audit without direction or guidance.

Both the audit client and the auditee can request the replacement of particular audit team members on reasonable grounds based on the principles of auditing described in clause 4. Examples of reasonable grounds include conflict of interest situations (such as an audit team member having been a former employee of the auditee or having provided consultancy services to the auditee) and previous unethical behaviour. Such grounds should be communicated to the audit team leader and to those assigned responsibility for managing the audit programme, who should resolve the issue with the audit client and auditee before making any decisions on replacing audit team members.

2.7.2 Conducting Document Review

Prior to the on-site audit activities the auditee's documentation should be reviewed to determine the conformity of the system, as documented, with the audit criteria. In some situations, this review may be deferred until the on-site activities commence if this is not detrimental to the effectiveness of the conduct of the audit.

If the documentation is found to be inadequate, the audit team leader should inform the audit client for resolution of document review concerns.

Preparing for the on-site audit activities

The audit team leader should prepare an audit plan to provide the basis for the agreement among the audit client, audit team and the auditee regarding the conduct of the audit. The plan should facilitate scheduling and coordination of the audit activities.

The audit plan should cover the following:

a) The audit objectives;

b) The audit criteria and any reference documents;

c) The audit scope, including identification of the organisational and functional units and processes to be audited;

d) The dates and places where the on-site audit activities are to be conducted;

e) The expected time and duration of on-site audit activities, including meetings with the auditee's management and audit team meetings;

f) The roles and responsibilities of the audit team members and accompanying persons;

g) The allocation of appropriate resources to critical areas of the audit. The audit plan should also cover the following, as appropriate:

h) Identification of the auditee's representative for the audit;

i) The working and reporting language of the audit where this is different from the language of the auditor and/or the auditee;

j) The audit report topics;

k) Logistic arrangements (travel, on-site facilities, etc.);

l) Matters related to confidentiality; and

m) Any audit follow-up actions.

Assigning work to audit team

The audit team leader, in consultation with the audit team, should assign to each team member responsibility for auditing specific processes, functions, sites, areas or activities. Such assignments should take into account the need for the independence and competence of auditors and the effective use of resources, as well as different roles and responsibilities of auditors, auditors-in-training and technical experts. Changes to the work assignments may be made as the audit progresses to ensure the achievement of the audit objectives.

Preparing work documents

The audit team members should review the information relevant to their audit assignments and prepare work documents as necessary for reference and for recording audit proceedings. Such work documents may include:

- checklists and audit sampling plans, and
- forms for recording information, such as supporting evidence, audit findings and records of meetings.

2.7.3 Conducting on Site Activities

Conducting the opening meeting: An opening meeting should be held with the auditee's management or, where appropriate, those responsible for the functions or processes to be audited. The purpose of an opening meeting is:

a) to confirm the audit plan,

b) to provide a short summary of how the audit activities will be undertaken,

c) to confirm communication channels, and

d) to provide an opportunity for the auditee to ask questions.

Communication during the audit

Depending upon the scope and complexity of the audit, it can be necessary to make formal arrangements for communication within the audit team and with the auditee during the audit.

During the audit, the audit team leader should periodically communicate the progress of the audit and any concerns to the auditee and audit client, as appropriate. Evidence collected during the audit that suggests an immediate and significant risk (e.g. safety, environmental or quality) should be reported without delay to the auditee and, as appropriate, to the audit client. Any concern about an issue outside the audit scope should be noted and reported to the audit team leader, for possible communication to the audit client and auditee.

2.7.4 Roles and Responsibilities of Guides and Observers

Guides and observers may accompany the audit team but are not a part of it. They should not influence or interfere with the conduct of the audit.

When guides are appointed by the auditee, they should assist the audit team and act on the request of the audit team leader.

Collecting and verifying information

During the audit, information should be collected by appropriate sampling and should be verified. Only information that is verifiable may be audit evidence. Audit evidence should be recorded.

Generating audit findings

Audit evidence should be evaluated against the audit criteria to generate the audit findings. Audit findings can indicate either conformity or non-conformity with audit criteria. When specified by the audit objectives, audit findings can identify an opportunity for improvement. The audit team should meet as needed to review the audit findings at appropriate stages during the audit.

Audit findings indicating either conformity or non-conformity with the audit criteria and their supporting audit evidence should be recorded. Non-conformities may be graded. They should be reviewed with the auditee to obtain acknowledgement that the audit evidence is accurate, and the non-conformities are understood.

2.7.5 Preparing Audit Conclusions

The audit team should confer prior to the closing meeting:

a) to review the audit findings, and any other appropriate information collected during the audit, against the audit objectives,

b) to agree on the audit conclusions, taking into account the uncertainty inherent in the audit process,

c) to prepare recommendations, if specified by the audit objectives, and

d) to discuss audit follow-up, if included in the audit plan.

Conducting the closing meeting

A closing meeting, chaired by the audit team leader, should be held to present the audit findings and conclusions in such a manner that they are understood and acknowledged by the auditee, and to agree, if appropriate, on the timeframe for the auditee to present a corrective and preventive action plan. Participants in the closing meeting should include the auditee, and may also include the audit client and other parties. If necessary, the audit team leader should advise the auditee of situations encountered during the audit that may decrease the reliance that can be placed on the audit conclusions.

2.7.6 Preparing, Approving and Distributing the Audit Report

Preparing the audit report

The audit team leader should be responsible for the preparation and contents of the audit report. The audit report should provide a complete, accurate, concise and clear record of the audit, and should include or refer to the following:

a) The audit objectives;

b) The audit scope, particularly identification of the organisational and functional units or processes audited and the time period covered;

c) Identification of the audit client;

d) Identification of audit team leader and members;

e) The dates and places where the on-site audit activities were conducted;

f) The audit criteria;

g) The audit findings; and

h) The audit conclusions.

Approving and distributing the audit report

The audit report should be issued within the agreed time period. If this is not possible, the reasons for the delay should be communicated to the audit client and a new issue date should be agreed.

The audit report should be dated, reviewed and approved in accordance with audit programme procedures. The audit report should then be distributed to recipients designated by the audit client.

Completing the audit

The audit is completed when all activities described in the audit plan have been carried out and the approved audit report has been distributed.

2.8 CLAUSE 7 – COMPETENCE AND EVALUATION OF AUDITORS

Confidence and reliance in the audit process depends on the competence of those conducting the audit. This competence is based on the demonstration of the personal attributes and the ability to apply the knowledge and skills gained through the education, work experience, auditor training and audit experience.

2.8.1 Personal Attributes

An auditor should be:

a) ethical, i.e. fair, truthful, sincere, honest and discreet;

b) open-minded, i.e. willing to consider alternative ideas or points of view;

c) diplomatic, i.e. tactful in dealing with people;

d) observant, i.e. actively aware of physical surroundings and activities;

e) perceptive, i.e. instinctively aware of and able to understand situations;

f) versatile, i.e. adjusts readily to different situations;

g) tenacious, i.e. persistent, focused on achieving objectives;

h) decisive, i.e. reaches timely conclusions based on logical reasoning and analysis; and

i) self-reliant, i.e. acts and functions independently while interacting effectively with others.

2.8.2 Knowledge and Skills

Auditors should have knowledge and skills in the following areas:

a) Audit principles, procedures and techniques.

b) Management system and reference documents.

c) Organisational situations.

d) Applicable laws, regulations and other requirements relevant to the discipline.

e) Specific knowledge and skills of the relevant management system to comprehend the technological context in which the audit is being conducted.

Education, work experience, auditor training and audit experience

Auditor, audit team leaders

Should have the established level of education, work experience, auditor training and audit experience so as to conduct the audits effectively and identify the non-conformities to report to the management for improvement.

Auditor evaluation

The evaluation of auditors and audit team leaders should be planned, implemented and recorded in accordance with audit programme procedures to provide an outcome that is objective, consistent, fair and reliable. The evaluation process should identify training and other skill enhancement needs.

The evaluation of auditors occurs at the following different stages:

- the initial evaluation of persons who wish to become auditors;
- the evaluation of the auditors as part of the audit team selection process; and
- the continual evaluation of auditor performance to identify needs for maintenance and improvement of knowledge and skills.

Check Your Progress Exercise 1

Note: a) Use the space below for your answers.
b) Check your answers with those given at the end of the unit.

1) What is the purpose of following ISO 19011:2002?

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2) List five principles of auditing.

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3) List factors influencing the audit program objectives.

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4) List the procedures which form the audit program.

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5) List the records related with audit program.

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6) List the elements of audit report.

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7) What are the personal attributes required for the role as an auditor?

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2.9 LET US SUM UP

This unit explains us about the fundamentals of auditing for quality and/or environmental systems. By using this document, organisations save effort, time and expenditure. There are five principles that are followed by auditors. (a) Ethical conduct (b) Fare presentation (c) Due Professional care (d) Independence (e) Evidence – based approach.

A typical audit activity follows seven steps: i) Initiating the audit ii) Conducting document review iii) Preparing for on-site audit activities iv) Conducting on-site audit activities v) Preparing, approving and distributing the audit report. vi) Completing the audit vii) Conducting audit follow up.

It also describes that confidence and reliance in audit process depends on competence of auditors; that is based on demonstration of perusal attributes and ability to apply the knowledge and skills gained through education, work experience, and for training and audit experience.

2.10 KEY WORDS

Audit	**:**	Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.
Audit Criteria	**:**	Set of policies, procedures or requirements.
Audit Evidence	**:**	Records, statements of fact or other information, which are relevant to the audit criteria and verifiable.
Audit Findings	**:**	Results of the evaluation of the collected audit evidence against audit criteria.
Audit Conclusion	**:**	Outcome of an audit, provided by the audit team after consideration of the audit objectives and all audit findings.
Audit Client	**:**	Organisation or person requesting an audit.
Auditee	**:**	Organisation being audited.
Auditor	**:**	Person with the competence to conduct an audit.
Audit Team	**:**	One or more auditors conducting an audit, supported if needed by technical experts.
Technical Expert	**:**	Person who provides specific knowledge or expertise to the audit team.
Audit Programme	**:**	Set of one or more audits planned for a specific time frame and directed towards a specific purpose.
Audit Plan	**:**	Description of the activities and arrangements for an audit.
Audit Scope	**:**	Extent and boundaries of an audit.
Competence	**:**	Demonstrated personal attributes and demonstrated ability to apply knowledge and skills.

2.11 ANSWERS TO CHECK YOUR PROGRESS EXERCISE

Your answer should include following points:

Check Your Progress Exercise 1

1) a) Avoiding confusion over the objectives of the environmental or quality audit program.

   b) Ensuring audit reports follow the best format and contain all the relevant information.

c) Securing agreement of the goals for individual audits within an audit program.

d) Evaluating the competence of members of an audit team against appropriate criteria.

e) Reducing duplication of effort when conducting combined environmental/quality audits.

2) a) **Ethical conduct:** The foundation of professionalism.

b) **Fair presentation:** The obligation to report truthfully and accurately.

c) **Due professional care:** The application of diligence and judgment in auditing.

d) **Independence:** The basis for the impartiality of the audit and objectivity of the audit conclusions.

e) **Evidence-based approach:** The rational method for reaching reliable and reproducible audit conclusions in a systematic audit process.

3)
- management priorities,
- commercial intentions,
- management system requirements,
- statutory, regulatory and contractual requirements,
- need for supplier evaluation,
- customer requirements,
- needs of other interested parties, and
- risks to the organisation.

4)
- planning and scheduling audits;
- assuring the competence of auditors and audit team leaders;
- selecting appropriate audit teams and assigning their roles and responsibilities;
- conducting audits;
- conducting audit follow-up, if applicable;
- maintaining audit program records;
- monitoring the performance and effectiveness of the audit program; and
- reporting to top management on the overall achievements of the audit program.

5) a) audit reports,

b) nonconformity reports,

c) corrective and preventive action reports,

d) follow-up audit report,

e) auditor competence and performance evaluation,

f) audit team selection, and

g) maintenance and improvement of competence.

6)
- the audit objectives;
- the audit scope, particularly identification of the organisational and functional units or processes audited and the time period covered;
- identification of the audit client;
- identification of audit team leader and members;
- the dates and places where the on-site audit activities were conducted;
- the audit criteria;
- the audit findings; and
- the audit conclusions.

7)
- ethical, i.e. fair, truthful, sincere, honest and discreet;
- open-minded, i.e. willing to consider alternative ideas or points of view;
- diplomatic, i.e. tactful in dealing with people;
- observant, i.e. actively aware of physical surroundings and activities;
- perceptive, i.e. instinctively aware of and able to understand situations;
- versatile, i.e. adjusts readily to different situations;
- tenacious, i.e. persistent, focused on achieving objectives;
- decisive, i.e. reaches timely conclusions based on logical reasoning and analysis; and
- self-reliant, i.e. acts and functions independently while interacting effectively with others.

2.12 SUGGESTED READING

http://www.iso.org

ISO 19011:2002 – *Guidelines for Quality and/or Environmental Management Systems Auditing*.

ISO 9000:2000 – *Quality Management Systems- Fundamentals and Vocabulary*.

ISO 10012:2003 – *Quality Assurance Requirements for Measuring Equipment*.

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

ISO 10013:1995 – *Guidelines for Developing Quality Manuals*.

UNIT 3 STANDARDIZATION AND ACCREDITATION

Structure

3.0 OBJECTIVES

After studying this unit, we should be able to:

- describe the functioning of various national and international organisations working for standardization;

- state Certification and Accreditation as tools for Conformity Assessment; and
- narrate the purpose of key standards and concerned organisations.

3.1 INTRODUCTION

- **The History of Standardization goes back to the Period of Dawn of Civilization**

The wheel, the language and culture itself are the artifacts of standardization activity. Standardization has contributed immensely to the development of various tools, techniques and technologies in different sectors of industrial and non-industrial activities in every country.

Standardization, as an organized activity, is defined as the activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context.

In particular, the activity consists of the processes of formulating, issuing and implementing standards.

- **Standards in the Present Context, Play an Important Role in Trade and Commerce**

Play an important role in trade and commerce within and between all countries of the world. These standards are developed by many bodies, at sub-national, national, regional and international levels, a significant number of which prepare their documents by consensus processes.

Standards at National Level, in India, are formulated and issued by the Bureau of Indian Standards, the National Standards Body in India (BIS) (erstwhile Indian Standards Institution). The Bureau of Indian Standards was set up under the Bureau of Indian Standards Act, 1986. The standards formulated by BIS are generally voluntary in nature unless made mandatory under any applicable regulation.

- **The Standardization Activity all Over the World Grew as an Outcome of Globalization**

Opening of different national frontiers and minimization of trade barriers. At the international level, the voluntary standardization process is essentially coordinated under the auspices of the International Organisation for Standardization (ISO), and the International Electro technical Commission (IEC).

ISO and IEC form the specialized system for worldwide standardization. National Bodies that are members of ISO or IEC, participate in the development of standards through technical committees established by respective organisations to deal with particular fields of activity. Other international organisations, governmental and non-governmental in liaison with ISO an IEC also take part in the work of ISO and IEC. BIS, as the National Standards Body of India (NSB), is represented on ISO and IEC.

- **One of the Effective Means of Implementing the Standards**

One of the effective means of implementing the standards and for the benefits of standardization to percolate through the society, is through third party

certification and accreditation systems, being operated at, both, national and international level.

Certification is third party attestation related to products, processes, systems or persons. Any particular organisation engaged in manufacturing or providing services to a customer can approach a conformity assessment body (also referred to as certification body) seeking certification of compliance with different applicable system standards formulated by ISO. Certification activities involve the audit of an organisations management system and provides an assurance that the organisation has implemented the system. There are a number of CABs operating at this level.

- **Conformity Assessment Bodies (CABs**)

Also need to demonstrate that they have competency, consistency and impartiality of audit and certification processes in respect of management systems they certify. Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks is under taken through accreditation by accreditation bodies operating at National and International level.

- **The International Conformity Assessment Scenario**

Therefore functions in three tiers *viz*., Accreditation bodies, Conformity Assessment Bodies and the organisations seeking certification of compliance with different applicable standards. Both accreditation bodies and conformity assessment bodies have their forums at international level. There are standards which govern the functioning of various organisations which form part of international conformity assessment scenario.

3.2 INTERNATIONAL ACCREDITATION FORUM (IAF)

3.2.1 IAF an Organisation

The International Accreditation Forum, Inc. (IAF) is the world association of Conformity Assessment Accreditation Bodies and other bodies interested in conformity assessment in the fields of management systems, products, services, personnel and other similar programs of conformity assessment. Its primary function is to develop a single worldwide program of conformity assessment, which reduces risk for business and its customers by assuring them that accredited certificates may be relied upon. Accreditation assures users of the competence and impartiality of the body accredited. IAF members accredit certification or registration bodies that issue certificates attesting that an organisation's management, products or personnel comply with a specified standard (called conformity assessment).

3.2.2 Role of IAF

The primary purpose of IAF is two-fold. Firstly, to ensure that its accreditation body members only accredit bodies that are competent to do the work they undertake and are not subject to conflicts of interest. The second purpose of the IAF is to establish mutual recognition arrangements, known *as Multilateral Recognition Arrangements* (MLA), between its accreditation body members which reduces risk to business and its customers by ensuring that an accredited

certificate may be relied upon anywhere in the world. The MLA contributes to the freedom of world trade by eliminating technical barriers to trade. IAF works to find the most effective way of achieving a single system that will allow companies with an accredited conformity assessment certificate in one part of the world, to have that certificate recognised else where in the world. The objective of the MLA is that it will cover all accreditation bodies in all countries in the world, thus eliminating the need for suppliers of products or services to be certified in each country where they sell their products or services. Certified once - accepted everywhere.

3.2.3 IAF Membership

Accreditation body membership of IAF is open to organisations that conduct and administer programs by which they accredit bodies for certification/registration of quality systems, products, services, personnel, environmental management systems of similar programs of conformity assessment.

These organisations must declare their intention to join the IAF Multilateral Recognition Agreement (MLA) recognising the equivalence of other members' accreditations to their own. IAF Association Members are organisations or associations that represent a similar group of entities internationally or within an economy or region. These entities are associated with programs by IAF Accreditation Body Members supporting IAF objectives.

IAF Members may grant Special Recognition status to organisations that share a common objective with the Corporation. Organisations granted Special Recognition status may be represented and participate at any IAF Members meeting but are not eligible to vote.

Special Recognition status may also be granted to Regional groupings where the implementation of the IAF's multilateral recognition arrangement is promoted. Therefore Regional groups of Accreditation Bodies that operate a Regional Multilateral Recognition Arrangement based upon the equivalence of accreditations to IAF MLA, are eligible for Special Recognition status in IAF.

3.2.4 IAF Programs

IAF operates a range of programs to ensure the continued competence of accredited certification/registration bodies and the consistent application of international conformity assessment standards.

IAF has programs to:

- Develop guidance, rules and procedures for the operation of accreditation, certification/registration and mutual recognition programs resulting in "Certified once, accepted everywhere"
- Ensure that all accreditation body members operate to the highest standards of competence and probity, and only accredit bodies that have demonstrated that they are competent and impartial.
- Harmonise accreditation procedures and their implementation based on international standards and guides, and IAF guidance on their application.
- Develop guidance, rules and procedures for the operation of specific sector conformity assessment schemes to meet the needs of specific industries.

- Develop guidance, rules and procedures for the operation of compliance programs to satisfy regulatory or government requirements.
- Exchange information between accreditation bodies.
- Cooperate in the training of assessors and other personnel.
- Contribute to the work of ISO and other relevant international bodies.
- Liaise with the regional groups of accreditation bodies.
- Liaise with other relevant bodies such as ILAC, ISO and industry groups.
- Assist emerging accreditation bodies in low and medium income economies.

3.2.5 IAF Charter

The IAF Charter sets out the aims and principles under which IAF functions. The International Accreditation Forum, Inc. (IAF) is an international association of organisations that have agreed to work together on a worldwide basis to achieve common trade facilitation objectives. IAF is a major world forum for developing the principles and practices for the conduct of conformity assessment that will deliver the confidence needed for market acceptance. IAF acts through the accreditation of those bodies that certify or register management system, products, personnel and/or inspection.

IAF promotes the worldwide acceptance, of certificates of conformity issued by inspection, certification and/or registration bodies accredited by an Accreditation Body Member of IAF, and seeks to add value for all stakeholders through what IAF does, and through their programs.

IAF brings together, on a worldwide basis, partner accreditation bodies and representatives of stakeholder groups that seek to facilitate global trade through the acceptance of accredited certificates of conformity.

IAF develops and/or recognizes appropriate processes and practices for the conduct of conformity assessment worldwide, and ensures their universal application by IAF Accreditation Body Members and their accredited certification, registration and/or inspection bodies.

IAF consults widely with stakeholders in developing their programs, and works to deliver the best possible standard of conformity assessment in order to provide IAF's stakeholders with a value-added outcome.

IAF influences world trade through linking, and working, with other key international organisations and industry groups.

3.3 INTERNATIONAL LABORATORY ACCREDITATION COOPERATION (ILAC)

3.3.1 The International Laboratory Accreditation Cooperation (ILAC)

First started as a conference in 1977 with the aim of developing international cooperation for facilitating trade by promotion of the acceptance of accredited test and calibration results. In 1996, ILAC became a formal cooperation with a charter to establish a network of mutual recognition agreements among

accreditation bodies that would fulfil this aim. The ILAC Arrangement is the culmination of 22 years of intensive work.

On 2 November 2000, 36 laboratory accreditation bodies, full members of the International Laboratory Accreditation Cooperation (ILAC), from 28 economies worldwide signed an 'arrangement' in Washington, DC to promote the acceptance of technical test and calibration data for exported goods.

The arrangement came into effect on 31 January 2001. The 'ILAC Arrangement' provides significant technical underpinning to international trade. The key to the Arrangement is the developing global network of accredited testing and calibration laboratories that are assessed and recognised as being competent by ILAC Arrangement signatory accreditation bodies. The signatories have, in turn, been peer-reviewed and shown to meet ILAC's criteria for competence. Now that the ILAC Arrangement is in place, governments can take advantage of it to further develop or enhance trade agreements. The ultimate aim is increased use and acceptance by industry as well as government of the results from accredited laboratories, including results from laboratories in other countries. In this way, the free-trade goal of ‘product tested once and accepted everywhere, can be realised.

3.3.2 ILAC's Role

ILAC is an international cooperation between the various laboratory accreditation schemes operated throughout the world. ILAC first started as a conference in 1977 with the aim of developing international cooperation for facilitating trade by promotion of the acceptance of accredited test and calibration results.

ILAC was formalised as cooperation in 1996 when 44 national bodies signed a Memorandum of Understanding (MoU) in Amsterdam. This MoU provided the basis for the further development of the Cooperation and the eventual establishment of a multilateral recognition agreement between ILAC member bodies.

On 2 November 2000, 36 laboratory accreditation bodies, full members of the International Laboratory Accreditation Cooperation (ILAC), from 28 economies worldwide, signed an “arrangement” in Washington, DC to promote the acceptance of technical test and calibration data for exported goods.

Over 40 laboratory accreditation bodies have signed the multi-lateral, mutual recognition arrangement (the “ILAC Arrangement”) to promote the acceptance of accredited test and calibration data. This “ILAC Arrangement” provides significant technical underpinning to international trade.

The key to the Arrangement is the developing global network of accredited testing and calibration laboratories that are assessed and recognised as being competent by ILAC Arrangement signatory accreditation bodies. The signatories have, in turn, been evaluated by their peers (against the requirements of ISO/IEC 17011) and shown to meet ILAC’s criteria for competence. Now that the ILAC Arrangement is in place, governments can take advantage of it to further develop or enhance trade agreements.

The ultimate aim is increased use and acceptance by industry as well as government of the results from accredited laboratories, including results from

laboratories in other countries. In this way, the free-trade goal of "a product tested once and accepted everywhere" can be realised.

As part of its global approach, ILAC also provides advice and assistance to countries that are in the process of developing their own laboratory accreditation systems. These developing systems are able to participate in ILAC as associate members, and access the resources of ILAC's more established members.

In conjunction with ILAC, specific regions have also established their own accreditation co-operations, notably in Europe (EA) and the Asia-Pacific (APLAC). These regional co-operations work in harmony with ILAC and are represented on ILAC's board of management. ILAC is encouraging the development of such regional co-operations in other parts of the globe.

Hence, ILAC is the world's principal international forum for the development of laboratory accreditation practices and procedures, the promotion of laboratory accreditation as a trade facilitation tool, the assistance of developing accreditation systems, and the recognition of competent test facilities around the globe.

3.3.3 ILAC Mutual Recognition Arrangement

The ILAC Arrangement supports international trade by promoting international confidence and acceptance of accredited laboratory data. Technical barriers to trade, such as the re-testing of products each time they enter a new economy would be reduced.

3.4 QUALITY COUNCIL OF INDIA (QCI)

3.4.1 Introduction

QCI is setup as an Autonomous body by the Government of India, (Ministry of Commerce and Industry, Department of Industrial Policy and Promotion being the nodal Ministry) to establish and operate National Accreditation Structure for conformity assessment bodies. QCI is also assigned the task of monitoring and administering the National Board for Quality Promotion and oversee effective functioning of the National Information and enquiry services. Indian Industry is represented on QCI by three premier industry associations ASSOCHAM, CII and FICCI.

3.4.2 Main Objectives of the QCI

a) To establish National Accreditation Boards, suitable for the country and in accordance with the relevant international standards and guidelines for:

   i) Bodies certifying Quality Management Systems, Environment Management Systems, Products and carrying out third party inspection.

   ii) Registration of Quality Management Personnel and Training Organisations.

   iii) Testing and Calibration Laboratories

b) To raise quality consciousness in the country through National Board for Quality Promotion including conducting seminars, study tours and using

other forms of promotion, by promoting business excellence through quality award schemes, competitions etc.

c) To ensure effective functioning of a National Information and Inquiry Service on Standards and Quality.

d) To promote, coordinate, guide and implement a national quality initiative for building confidence in Indian products and services and for improving the competitiveness of the Indian Industry.

e) To enter into arrangements with similar foreign agencies and develop procedures for exchange and transfer of technologists and technologies, study tours, training in specialised areas of quality technology, conducting of joint projects, providing technical assistance in the establishment of quality consciousness and for other matters consistent with the aims and objectives of Society.

f) To encourage industrial/applied research and development in the field of quality and dissemination of its results in relevant publications including professional and trade journals.

g) To facilitate up-gradation of testing and calibration facilities and laboratories and to encourage the development of a national laboratory accreditation system for global recognition and for acceptability of measurement and test results.

h) To raise the level of training for personnel engaged in quality activities including the assessors and trainees.

i) To develop and operate an appeal mechanism to deal with unresolved complaints.

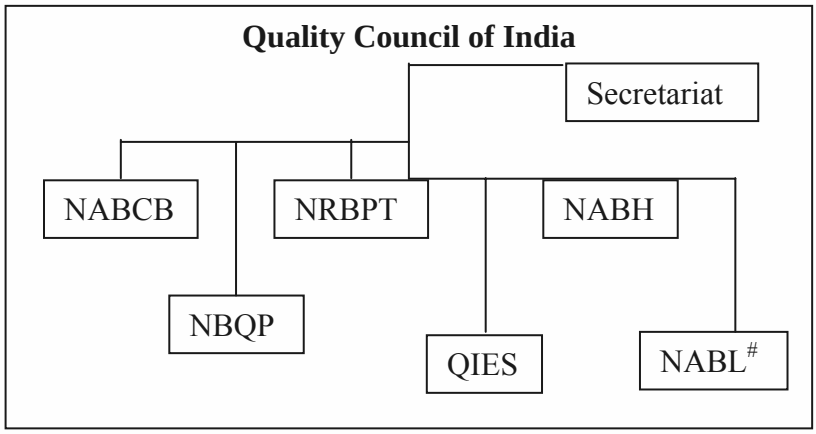
3.4.3 Structure of QCI

With a view to achieve the objectives of QCI, a two-tier structure has been formulated.

Quality Council of India is the top level body responsible for formulating the strategy, general policy and related issues, constitution and monitoring of various components of QCI including the accreditation boards to ensure a transparent accreditation system, monitoring the progress of activities and appeal mechanisms set by the respective Boards.

Second level bodies are the executive bodies (board/committees) that implement the strategy, policy and operational guidelines set by the Quality Council of India with a view to achieve international acceptance and recognition of various components including the accreditation systems.

Each Board has a Chairman and a representative voluntary group of stakeholders who monitor the activities and progress of their respective Boards. Each Board has a panel of trained Assessors who evaluate applicants by review of documents and/or by site visits. Respective Boards grant accreditation based on the recommendation made by the evaluation committees, after review of the reports of assessors.



NABCB - National Accreditation Board for Certification Bodies
NRBPT - National Registration Board for Personnel and Training
NABH - National Accreditation Board for Hospitals & Healthcare
Providers NABL - National Accreditation Board for Testing and Calibration Laboratories
NBQP - National Board for Quality Promotion
QIES - Quality Information and Enquiry Services

Currently functioning as an independent autonomous body under the Department of Science and Technology

3.5 NATIONAL ACCREDITATION BOARD FOR TESTING AND CALIBRATION LABORATORIES (NABL)

3.5.1 National Accreditation Board for Testing and Calibration Laboratories

NABL is an autonomous body under the aegis of Department of Science & Technology, Government of India, and is registered under the Societies Act. NABL has been established with the objective to provide Government, Industry Associations and Industry in general with a scheme for third-party assessment of the quality and technical competence of testing and calibration laboratories. Government of India has authorised NABL as the sole accreditation body for Testing and Calibration laboratories.

In order to achieve this objective, NABL provides laboratory accreditation services to laboratories that are performing tests/calibrations in accordance with ISO/IEC 17025 and ISO 15189:2003 for medical laboratories. These services are offered in a non-discriminatory manner and are accessible to all testing and calibration laboratories in India and abroad, regardless of their ownership, legal status, size and degree of independence.

NABL has established its Accreditation System in accordance with ISO/IEC 17011:2004, which is followed internationally. In addition NABL has to also comply with the requirements of APLAC MR001, which requires the applicant and the accredited laboratories to take part in recognized Proficiency Testing Programs in accordance with ISO/IEC Guide 43. An applicant laboratory has to satisfactorily participate in at least one Proficiency Testing program, while

the accredited laboratories are expected to cover the major scopes of accreditation in a cycle time of four years. Towards this objective, NABL has been conducting Proficiency Testing with the help of selected accredited laboratories as nodal laboratories in different fields. The performance remains confidential between NABL and each participating laboratory by using laboratory code numbers. In case of unsatisfactory performance, laboratory is expected to investigate and take the necessary corrective actions. In case of repeated failure or gross failure indicated by Z factor, En ratio etc., scope of accreditation is reduced by NABL.

NABL also satisfies the requirements of APLAC MR001. NABL had undergone the first peer evaluation by a 4 member team of APLAC in July 2000, based on which NABL qualified as an APLAC MRA (Mutual Recognition Arrangement) Partner as well as a Signatory to ILAC Arrangements. NABL was reassessed in July 2004 and as stated earlier the signatory status of NABL within APLAC MRA has been confirmed for further four years i.e. October 2008. This distinction has brought additional responsibility on NABL and its accredited laboratories. Annual Surveillance are carried out to ensure that the accredited laboratories are continuing to comply the accreditation criteria. NABL and its accredited laboratories are also required to meet the new challenges arising out of requirements such as satisfactory participation in a recognized Proficiency Testing Program and the requirement of estimating the Uncertainty in Measurements even by the testing laboratories. NABL has already published the revised guideline on Estimation of Uncertainty in Measurement for Calibration Laboratories. NABL also conducts One-Day Awareness Programs on key issues such as Uncertainty in Measurement, Proficiency Testing, Validation etc., at different parts of India so that applicant and accredited laboratories can take the appropriate action.

The users have access to information regarding accredited laboratories through web-based directory of NABL accredited laboratories.

NABL website is updated continuously with respect to status of accredited laboratories and their scope of accreditation. The list of laboratories which are either suspended or their scope of accreditation is partially or fully withdrawn is also available for the benefit of the users. The laboratories will be able to acquire the necessary NABL documents through the website thereby eliminating postal delays. Suggestions are welcome from users of the website for further improvement.

3.5.2 Why do Laboratories get Accreditation?

The concept of Laboratory Accreditation was developed to provide a means for third-party certification of the competence of laboratories to perform specific type(s) of testing and calibration.

Laboratory Accreditation provides formal recognition of competent laboratories, thus providing a ready means for customers to find reliable testing and calibration services in order to meet their demands.

Laboratory Accreditation enhances customer confidence in accepting testing/ calibration reports issued by accredited laboratories.

The globalisation of Indian economy and the liberalisation policies initiated by the Government in reducing trade barriers and providing greater thrust to

exports makes it imperative for Accredited Laboratories to be at international level of competence.

3.5.3 Benefits of Accreditation

Formal recognition of competence of a laboratory by an Accreditation body in accordance with international criteria has many advantages:

1) Potential increase in business due to enhanced customer confidence and satisfaction.
2) Savings in terms of time and money due to reduction or elimination of the need for re-testing of products.
3) Better control of laboratory operations and feedback to laboratories as to whether they have sound Quality Assurance System and are technically competent.
4) Increase of confidence in Testing/Calibration data and personnel performing work.
5) Customers can search and identify the laboratories accredited by NABL for their specific requirements from the directory of Accredited Laboratories.
6) Users of accredited laboratories will enjoy greater access for their products, in both domestic and international markets, when tested by accredited laboratories.

3.5.4 Scope of Accreditation

NABL Accreditation is currently given in the following fields:

a) Testing Laboratories

- Biological
- Chemical
- Electrical
- Electronics
- Fluid-Flow
- Mechanical
- Non-Destructive
- Photometry
- Radiological
- Thermal

b) Calibration Laboratories

- Electro-Technical
- Mechanical
- Fluid Flow
- Thermal and Optical
- Radiological

c) Medical Laboratories

- Clinical Biochemistry
- Clinical Pathology

- Haematology and Immuno haematology
- Microbiology and Serology
- Histopathology
- Cytopathology
- Genetics
- Nuclear Medicine (in-vitro tests only)

3.5.5 Procedure for Accreditation

A laboratory may apply for accreditation from as little as one to as many tests / calibrations provided it is performing these in accordance with NABL criteria. Classification of the Testing Laboratories has been done on the basis of basic fields of testing. The laboratories doing inter-disciplinary testing of products, for e.g. textiles, plastics, building materials, metallurgical products, shall have to apply in relevant field(s) separately depending upon to which field(s) the test(s) belongs.

The accreditation granted to a laboratory shall remain valid for a period of 2 years subject to satisfactory periodical (annual) surveillance. Laboratory also has an option to widen the scope of accreditation in terms of specific tests and calibrations.

3.6 ISO/TS 22003:2007 FOOD SAFETY MANAGEMENT SYSTEM-REQUIREMENT FOR BODIES PROVIDING AUDIT AND CERTIFICATION OF FOOD SAFETY MANAGEMENT SYSTEMS

3.6.1 The International Organisation for Standardization (ISO) Published ISO/TS 22003:2007

The International Organisation for Standardization (ISO) published ISO/TS 22003:2007 a technical specification (TS) in the ISO 22000 series, which gives requirements for the auditing and certification of Food Safety Management Systems (FSMS).

ISO/TS 22003:2007 provides information, criteria and guidance for carrying out ISO 22000:2005 auditing and certification, and will be useful for certification bodies, the accreditation bodies that approve them, suppliers wishing to have their FSMS certified, their customers and food sector regulators.

3.6.2 ISO 22000

ISO 22000 can be applied to organisations ranging from feed producers and primary producers to food manufacturers, transport and storage operators, as well as sub-contractors to retail and food service outlets. Related organisations, such as producers of equipment, packaging material, cleaning agents, additives and ingredients, are also affected by the prospective standard.

Comprising 10 clauses, two annexes and a bibliography, ISO TS 22003 covers topics such as resource requirements, competence of management and personnel (including auditors and those involved in decisions related to certification), process requirements and requirements for certification bodies.

It closely follows the requirements established by ISO 17021:2006 - Conformity assessment - Requirements for bodies providing audit and certification of management systems, which places rigorous requirements for competence and impartiality on the bodies that offer audit and certification to management system standards.

3.7 ISO GUIDE 65: GENERAL REQUIREMENTS FOR BODIES OPERATING PRODUCT CERTIFICATION SYSTEMS

3.7.1 Certification of a Product

Certification of a product (a term used to include a process or service) is a means of providing assurance that it complies with specified standards and other normative documents. This Guide specifies general requirements, the observance of which is intended to ensure that certification bodies are competent to operate third-party certification systems in a consistent and reliable manner, thereby facilitating their acceptance on a national and international basis and also furthering international trade.

3.7.2 The Certification System

The certification system used by the certification body may include one or more of the following, which could be coupled with production surveillance or assessment and surveillance of the supplier's quality system or both.

a) Type testing or examination;

b) Testing or inspection of samples taken from the market or from supplier's stock or from a combination of both;

c) Testing and inspection of every product or of a particular product, whether new or already in use;

d) Batch testing or inspection; and

e) Design appraisal.

3.8 ISO/IEC 17020:1998 GENERAL CRITERIA FOR THE OPERATION OF VARIOUS TYPES OF BODIES PERFORMING INSPECTIONS

International standard ISO 17020: 1998 (General Criteria for the operation of various types of bodies performing inspection) was prepared by the European committee for standardization (CEN) and the European committee for electrotechnical standardization (CENEELEC) as EN 45004, and was adopted under a special fast track procedure by the ISO committee on conformity assessment. The ISO committee on conformity assessment (CASCO) chose EN 45004 to meet a perceived market for an international consensus based normative document on requirements for inspection bodies, replacing ISO/IEC Guide 39: 1988 (General requirements for the acceptance of inspection bodies, and ISO/IEC guide 57: 1991 (Guidelines for the presentation of inspection results).

This standard specifies general criteria for the competence of impartial bodies performing inspection irrespective of the sector involved. It also specifies independence criteria.

This standard is intended for the use of inspection bodies and their Accreditation bodies as well as other bodies concerned with recognizing the competence of inspection bodies.

3.9 ISO/IEC 17021:2006 – CONFORMITY ASSESSMENT-REQUIREMENTS FOR BODIES PROVIDING AUDIT AND CERTIFICATION OF MANAGEMENT SYSTEMS

ISO/IEC 17021:2006 contains principles and requirements for the competence, consistency and impartiality of the audit and certification of management systems of all types (e.g. quality management systems or environmental management systems) and for bodies providing these activities. Certification bodies operating to this International Standard need not offer all types of management system certification.

Certification of management systems is a third-party conformity assessment activity. Bodies performing this activity are therefore third-party conformity assessment bodies.

The standard covers Principles (Clause 4), general requirements (Clause 5), structural requirements (Clause 6), resource requirements (Clause 7), information requirements (Clause 8), process requirements (Clause 9) and management system requirements for certification bodies (Clause 10).

Clause 4 describes the principles on which credible certification is based. These principles are prelude to clauses 5 to 10. These principles underpin all the requirements in this international standard but such principles are not auditable requirements in their own right.

3.10 ISO 17025:2005 GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES

An Introduction

ISO/IEC 17025:2005 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.

It is applicable to all organisations 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.

ISO/IEC 17025:2005 is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When a laboratory does not undertake one or more of the activities covered by ISO/IEC 17025:2005, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

ISO/IEC 17025:2005 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. ISO/IEC 17025:2005 is not intended to be used as the basis for certification of laboratories.

Compliance with regulatory and safety requirements on the operation of laboratories is not covered by ISO/IEC 17025:2005.

Check Your Progress Exercise 1

Note: a) Use the space below for your answers.
b) Check your answers with those given at the end of the unit.

1) What is the purpose of IAF?

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2) Explain the role of ILAC in the field of international standardization.

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3) Give six examples of laboratories to whom NABL accreditation is applicable.

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4) List the six wings of QCI.

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5) Briefly explain the standard ISO TS 22003: 2007.

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3.11 LET US SUM UP

This unit explains us about the various national and international organisations working for standardization. IAF basically develops a single worldwide program of conformity assessment, which reduces risk for business and its customers by assuring them that accredited certificates may be relied upon. ILAC is an international cooperation between the various laboratory accreditation schemes operated throughout the world. NABL has been established with scheme for third party assessments of the Quality and Technical complaints of testing and calibration laboratories. QCI is top level body responsible for monitoring and administrating the National Board for Quality Promotion and oversee effective functioning of the National information and enquiry services. ISO 22003 gives requirements for the auditing and certification of food safety management systems. ISO/IEC 17025:2005 is for use by laboratories in developing their management system for quality, administrative and technical operations.

3.12 KEY WORDS

Certification : Third-party attestation related to products, processes, systems or persons.

Attestation : Issue of a statement based on a decision following review that fulfillment of specified requirements have been demonstrated.

Standardization : Activity of establishing, with regard to actual or potential problems, provisions for common and repeated

use, aimed at the achievement of the optimum degree of order in a given context.

Note: In particular, the activity consists of the processes of formulating, issuing and implementing standards.

A standard : A document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

Note: Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

Accreditation : Attestation by third party assessment body.

Requirement : Stated, implied or obligatory need of a specific customer or generic groups.

3.13 ANSWERS TO CHECK YOUR PROGRESS EXERCISE

Your answer should include following points:

Check Your Progress Exercise 1

1) The primary purpose of IAF is two-fold. Firstly, to ensure that its accreditation body members only accredit bodies that are competent to do the work they undertake and are not subject to conflicts of interest. The second purpose of the IAF is to establish mutual recognition arrangements, known as Multilateral Recognition Arrangements (MLA), between its accreditation body members which reduces risk to business and its customers by ensuring that an accredited certificate may be relied upon anywhere in the world.

2) ILAC is the world's principal international forum for the development of laboratory accreditation practices and procedures, the promotion of laboratory accreditation as a trade facilitation tool, the assistance of developing accreditation systems, and the recognition of competent test facilities around the globe, through international cooperation between the various laboratory accreditation schemes operated throughout the world.

   The key to the "ILAC Arrangement" ("signing of multi-lateral, mutual recognition arrangement by over 50 laboratory accreditation bodies") is the developing global network of accredited testing and calibration laboratories that are assessed and recognised as being competent by ILAC Arrangement signatory accreditation bodies. The signatories have, in turn, been evaluated by their peers (against the requirements of ISO/IEC 17011) and shown to meet ILAC's criteria for competence.

   The ultimate aim is increased use and acceptance by industries as well as governments of the results from accredited laboratories. In this way, the free-trade goal of "a product tested once and accepted everywhere" can be realised.

3) • Biological
   • Chemical
   • Electro-Technical
   • Radiological
   • Microbiology and Serology
   • Genetics

4) NABCB - National Accreditation Board for Certification Bodies
   NRBPT - National Registration Board for Personnel and Training
   NABH - National Accreditation Board for Hospitals and Healthcare
   Providers NABL - National Accreditation Board for Testing and Calibration Laboratories
   NBQP - National Board for Quality Promotion
   QIES - Quality Information and Enquiry Services

5) ISO TS 22003:2007 is a technical specification (TS) in the ISO 22000 series, which gives requirements for the auditing and certification of Food Safety Management Systems (FSMS). It closely follows the requirements established by ISO 17021:2006 - Conformity assessment - Requirements for bodies providing audit and certification of management systems.

   It provides information, criteria and guidance for carrying out ISO 22000:2005 auditing and certification. Comprising 10 clauses, two annexes and a bibliography, it covers topics such as resource requirements, competence of management and personnel, process requirements and requirements for certification bodies.

3.14 SUGGESTED READING

ISO: www.iso.org

ISO/TC 176: www.tc176.org

ISO/TC 176 Subcommittee 2: www.iso.org/tc176/sc2

www.bis.org.in