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COURSE HANDBOOK

UNDERSTANDING ISO/IEC 17065:2013

IAS Training: Training that Reaches People

Rev 2

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Introduction

Course Development

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Course Description

This course is aimed at product/process/service certification body staff and accreditation body assessors:

- Who participate in the operation / assessment of a certification body quality system – in the conduct of their evaluations, certification decisions, and surveillance activities.
- Who participate in the management / assessment of the quality system.
- Who participate in the management / assessment of the certification body.

The certification of products, processes and services represents the most intensive conformity assessment activity of the following group:

- ISO/IEC 17025 (testing and calibration)
- ISO/IEC 17020 (inspection)
- ISO/IEC 17021 (system certification)

This course will provide information to certification body staff, accreditation body assessors, scheme owners and other interested parties who seek ways to better understand the requirements behind ISO/IEC 17065 – the standard used for the certification of products, processes, and services.

Course Learning Objectives

The course will assist you to:

- **understand** how certification schemes operate;
- **appreciate** the needs of scheme owners;
- **understand** how certification works within the global conformity assessment approaches;
- **understand** the requirements for impartiality;
- **identify** the standard quality system requirements for certification bodies;
- **appreciate** the contribution of testing and support to certification evaluation processes;
- **understand** the requirements for protection of marks of certification, and
- **understand** various approaches for surveillance.

Completing the Course

The course material is broken down into chapters. Within each chapter, specific objectives are listed as well as instructions on how to complete each chapter. Directions are provided to guide you through the readings, other reference materials, and work to be completed.

Course Content

The syllabus for this course is as follows.

Chapter 1 – Background and Principles of Certification (Annex A and ISO/IEC 17067)
- Introduction to the concepts behind certification
- Emphasis on conformity to market and regulatory needs
- Principles behind certification
- The components of certification schemes (scheme owners, certification bodies, applicants)
- Compatibility within the ISO/IEC family of conformity assessment disciplines

Chapter 2 – Certification process Overview
- Certification processes, a macro view
- ISO/IEC 17065 clauses mapped to certification processes
- Certification processes mapped to ISO/IEC 17065 clauses

Chapter 3 – Safeguarding Integrity in Certification (Clause 4 and part of Clause 5)
- Understanding impartiality
- Managing impartiality
- Safeguarding impartiality

Chapter 4 – Certification Body Organisation and Structure (Clauses 1 and 4, 5)
- Certification body scope of operations
- Evaluation processes
- Use of competent testing, calibration, and inspection services

Chapter 5 – Certification Body Resources (Clause 6 and part of Clause 7)
- Training, qualification and competence of staff
- Facilities and equipment requirements
- Competence of organisations used in outsourcing evaluation work

Chapter 6 – Certification Processes (part of Clause 4 and most of Clause 7)
- Application processes
- Evaluation processes
- Review processes
- Certification processes
- Control of marks of conformity
- Surveillance processes
- Enforcing conformant behaviours from applicants

Chapter 7 – Management System Requirements (Clause 8)
- QMS components (Options A and B)
- Document control and control of records
- Continual improvement – from identification to resolution
- Complaints and other Feedback
- Disputes and appeals
- Internal audit
- Management review

Supplier / Manufacturer / Applicant

This course is about the process of certification and it does not matter if a product, process or service is submitted for certification, the term “applicant” will be used to mean all of the following:

- applicant for certification;
- manufacturer using the process, or supplying the product, process or service that is the object of certification, and
- supplier of the product, process or service that is the object of certification.

Course Grading

The quiz is at the end of the course and will allow you to measure your acquired knowledge of Product Certification in relation to ISO/IEC 17065. Participant evaluation will be based on the result of the quiz. 70% is required in order to pass this course.

National Capacity Review

Participants will also make a formal presentation at the end of the training, on the conditions that exist in their own economy to allow the facilitator to estimate the capacity within that economy for the implementation of conformant certification programs. See Chapter 8.

Chapter 1 – Background and Principles

1.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **understand** how certification schemes operate;
- **understand** the principles behind ISO/IEC 17065; and
- **appreciate** the needs of scheme owners.

1.2 Completing the Chapter

Discussion Activity 1.1

Who are some of the stakeholders involved in product, process and service certification?

Discussion Activity 1.2

How important is impartiality to the success of a certification scheme?

Discussion Activity 1.3

What are the types of certification schemes that you may be most familiar with?

1.3 Establishing Public Confidence

1.3.1 Driving Forces

More than any other type of conformity assessment activity, product/process/service certification is primarily focused on the establishment of confidence in the certified products, processes or services. The users of goods and services that carry formal certification marks are much less interested in the process of certification than in its results.

Certification has traditionally been used to identify products deemed safe for sale within a jurisdiction or economy, and public confidence in the marks associated with certification has been based on evaluation and certification processes that met regulatory and market specifications. Conversely, users of testing and calibration services tend to be more involved in the processes that produce these primarily objective results. They may not work within the science of the tests, but they understand more than the general public and consumer.

As a result, the processes surrounding certification tend to involve more agencies and public sector bodies that may represent consumers and other users of certified products. Depending on the scheme within which certification is conducted; liability for the certification decisions may be much more than for other conformity assessment activities such as testing, inspection, management and other system certification activities that involve very little liability for those certification bodies.

No other conformity assessment activity is perceived to have so much bearing on the demonstrated performance of products, and this is the reason why certification requires such transparency and impartiality, and can be so expensive. Stakeholders and regulators expect and demand that all parts of the certification processes will successfully prevent the certification of unsafe, inappropriate, imprudent, unethical, and illegal goods and services.

1.3.2 Market and Regulator Involvement

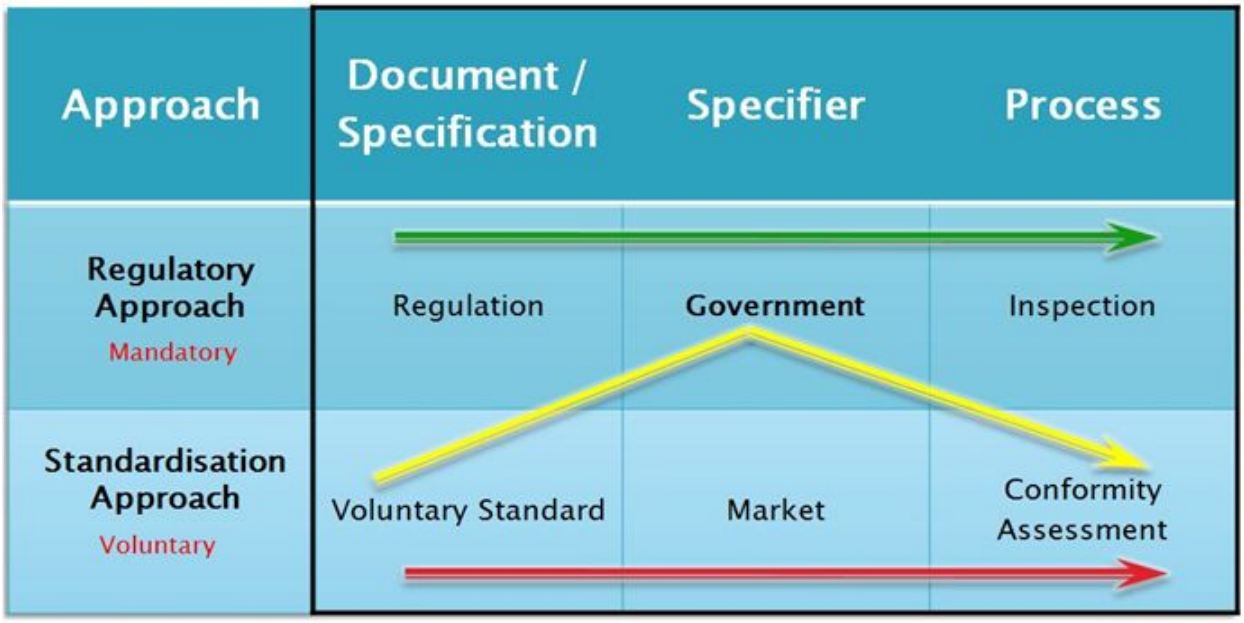
Due to the implied, if not actual, liability associated with certification, many agencies representing various stakeholders will involve themselves in the processes surrounding certification. Most do so as participants in the applicable certification schemes, sometimes as the scheme owners, and sometimes as scheme participants.

There are generally four methods for stakeholders to participate in the accreditation or approval of certification schemes:

- As scheme owner;
- As a participant in the development of scheme requirements;
- As assessors of certification bodies within accreditation programs, and
- As reviewers and approvers in the accreditation of certification bodies.

1.3.3 From Specification to Assessment of Conformity

There are generally two approaches to allow stakeholders to establish specifications and then ensure they have been followed.



The green line at the top shows how a government develops a regulation, then specifies its use, and finally enforces it through inspection. An example is the current laboratory-licensing program used by the US FDA.

The red line at the bottom is an example of how ISO 9001 and ISO/IEC 17025 are normally delivered without any regulator specification – “by the market, from the market, and for the market”. These two standards were developed from within their own communities. Both were developed internationally and included the input of their clients and other stakeholders, including governments. They are delivered using voluntary conformity assessment techniques.

The yellow line in the middle represents how a government can specify a voluntary standard. ISO/IEC 17025, ISO/IEC 17065, and other technically-focused conformity assessment standards / guidelines are delivered today to organisations, which, if they wish to do business in some specific fields, must meet regulatory requirements for accreditation. These are now part of regulatory tool kits in the protection of the

health, welfare and safety of citizens of many nations around the world.

Each of the three components of either type of approach involves:

- writing something that can be used to determine acceptable behavior (standard or regulation),
- specifying the necessity for this behaviour (the market or some legislation), and
- determining how to evaluate performance against the specification (inspection or conformity assessment).

1.3.4 Third Party Certification Principles (Annex A to ISO/IEC 17065)

As stated above, the overall aim of certification is to give confidence to all interested parties that a product fulfils specified requirements. The value of certification is the degree of confidence and trust that is established by an impartial and competent demonstration of of specified requirements by a third-party. Parties that have an interest in certification include, but are not limited to:

- the clients of the certification bodies;
- the customers of the organisations whose products are certified;
- governmental authorities;
- non-governmental organisations, and
- consumers and other members of the public.

The principles for inspiring confidence are those listed below:

1.3.4.1 Impartiality

It is necessary for certification bodies and their personnel to be, and to be perceived as, impartial to give confidence in their activities and their outcomes.

Risks to impartiality include bias that may arise from:

a) self-interest (e.g. overdependence on a contract for service or the fees, or fear of losing the client or fear of becoming unemployed, to an extent that adversely affects impartiality in carrying out conformity assessment activities);

b) self-review (e.g. performing conformity assessment activity in which the certification body evaluates the results of other services it has already provided, such as consultancy);

c) advocacy (e.g. a certification body or its personnel acting in support of, or in opposition to, a given company, which is at the same time its client);

d) over-familiarity, i.e. risks that arise from a certification body or its personnel being overly familiar or too trusting instead of seeking evidence of conformity (in the product certification context, this risk is more difficult to manage because the need for personnel, with very specific expertise, often limits the availability of qualified personnel);

e) intimidation (e.g. the certification body or its personnel can be deterred from acting impartiality by risks from or fear of, a client or other interested party);

f) competition (e.g. between the client and a contracted person).

1.3.4.2 Competence

Competence of the personnel supported by the management system of the certification body is necessary to deliver certification that provides confidence.

1.3.4.4 Confidentiality and openness

1.3.4.4.1 General

Managing the balance between confidentiality (1.3.4.4.2) and openness (1.3.4.4.3) related requirements affects stakeholders' trust and their perception of value in the conformity assessment activities being performed.

1.3.4.4.2 Confidentiality

To gain access to the information needed to conduct effective conformity assessment activities, the certification body needs to provide confidence that confidential information will not be disclosed

All organisations and personnel have the right to have protected any proprietary information that they provide unless the law or the certification scheme applied for require disclosure of proprietary information (See ISO/IEC 17065, clause 4.5).

1.3.4.4.3 Openness

A certification body needs to provide access to, and disclosure of, appropriate and timely information about its evaluation and certification processes, and about the certification status (granting, maintaining, extending or the scope of, reducing the scope of, suspending, withdrawing or refusing certification) of any product, in order to gain confidence in the integrity and credibility of certification. Openness is a principle of access to, or disclosure of appropriate information.

1.3.4.4.4 Access to information

Any information held by the certification body on a product that is the subject of an evaluation and/or certification should, upon request, be made accessible to the person or organisation which contracted the certification body to undertake the certification activity.

1.3.4.5 Responsiveness to complaints and appeals

The effective resolution of complaints and appeals is an important means of protection for the certification body, its clients and other users of conformity assessment against errors, omissions or unreasonable behaviour. Confidence in conformity assessment activities is safeguarded when complaints and appeals are processed appropriately.

1.3.4.6 Responsibility

The client (applicant), not the certification body, has the responsibility for fulfilment of the certification requirements.

The certification body has the responsibility to obtain sufficient objective evidence upon which to base a certification decision. Based on a review of the evidence, it makes a decision to grant certification if there is sufficient evidence of conformity, or a decision not to grant certification if there is not sufficient evidence of conformity, or a decision not to maintain certification.

1.4 Certification Schemes

1.4.1 Third Party Certification Schemes (from ISO/IEC 17067)

There are many examples available to describe how regulatory agencies deliver inspections in support of their own regulations. Municipal building inspections and the FDA GMP programs are such examples.

In order to provide more transparency and confidence in the actual certifications, the use of third party certification schemes has largely overtaken this approach over the last 40 years or so for those products and services that are delivered to markets in a ready-to-use condition. In the building industry, third party certification of electrical panels and light fixtures to performance standards referenced in national building codes are examples.

Such an approach also allows regulatory agencies to concentrate on the actual requirements for certification and approval of certification bodies, and leave the conformity assessment work to others. In other words, these organisations become "scheme owners."

ISO/IEC Guide 67 (*Fundamentals of Product Certification*), soon to be ISO/IEC 17067 (*Fundamentals of product certification and guidelines for product certification schemes*), is a standard that can be used by scheme owners to guide their actions in the development of certification schemes. It may take some time, however, for many regulatory agencies to accept the approaches used in this standard as replacements for their own given their views regarding the regulatory responsibility to protect the health, safety and welfare of the citizens of their jurisdictions.

1.4.2 Third Party Certification Scheme Ownership

Scheme owners can be any of the following:

- product certification bodies;
- governments and regulators;
- non-government organisations;
- industry and retail associations, and
- consumer organisations.

Scheme owners establish requirements for the following non-exclusive list of aspects of third party certification schemes:

- pre-requisites for participation as a third party certification body;
- pre-requisites for the certification of conformant products, processes and services;
- scheme owner participation in the processes leading to either of the above;
- surveillance of products, processes and services for continued certification;
- sanctions to all other parties for failure to conform to their requirements, and
- supporting requirements such as cost recovery, legal liability, and conflict resolution.

In other words, the scheme owners own the scheme. They wish to influence the processes that define trust in the products, processes and services certified. **THE FOLLOWING IS IMPORTANT**: **Certification bodies must meet the needs of scheme owners in order to establish scheme owner trust in their certification processes.** Accreditation bodies accrediting certification bodies that conduct third party certification will work closely with scheme owners to establish confidence in their accreditations of these certification bodies.

1.4.3 Types of Third Party Certification Schemes (from ISO/IEC 17067)

1.4.3.1 General

The following examples do not represent all possible forms of product certification schemes. They may be used with many types of requirements and may utilize a wide variety of statements of conformity (Note 1 to ISO/IEC 17000 clause 5.2). **All types of product certification scheme involve selection, determination, review and attestation.** One or more determination activities should be selected from among those in Table 1 below considering the product and the specified requirements. The types of schemes referred to in Table 1 differ according to which surveillance activities (if applicable) are carried out. For scheme types 1a and 1b, no surveillance is required since the attestation relates only to the product items that have been subjected

to the determination activities. For the other scheme types, the following sections outline the way in which the different surveillance activities can be used and the circumstances to which they could be applicable.

1.4.3.2 Scheme Type 1a (Certification of specific samples only)

In this scheme, one or more samples of the product are subjected to the determination activities. The samples are representative of subsequent production items but these items are not covered by the attestation of conformity. A certificate of conformity or other statement (e.g. letter or completed data sheets) is issued for the product type, the characteristics of which are detailed in the certificate or a document referred to in the certificate. Subsequent production items cannot be described as “certified,” but could be referred to as being manufactured in accordance with the certified type.

1.4.3.3 Scheme Type 1b (Certification by lot number, such as aircraft type certification)

This scheme type involves the certification of a whole batch of products following selection and determination as specified in the scheme. The proportion to be tested would be based, for example, on the homogeneity of the items in the batch and the application of a sampling plan where appropriate. If the outcome of the determination is positive, all items in the batch may be described as certified and may have a mark of conformity affixed if that is included in the scheme.

1.4.3.4 Scheme Type 2 (Certification through continuing after-market testing)

The surveillance part of this scheme involves periodically taking samples of the product from the market and subjecting them to determination activities to check that items produced subsequent to the initial certification fulfill the specified requirements.

While this scheme may identify the impact of the distribution chain on conformity, the resources it requires can be extensive. Also, when significant nonconformities are found, effective preventative measures may be limited since the product has already been distributed to the market.

1.4.3.5 Scheme Type 3 (Certification through continuing production line testing)

The surveillance part of this scheme involves periodically taking samples of the product from the point of production and subjecting them to determination activities to check that items produced subsequent to the initial certification fulfill the specified requirements. The surveillance includes periodic assessment of the production process.

This scheme does not provide any indication of the impact the distribution channel plays on conformity. When serious nonconformities are found, the opportunity may exist to resolve them before widespread market distribution.

1.4.3.6 Scheme Type 4 (Certification through continuing comprehensive re-testing)

The surveillance part of this scheme involves periodically taking samples of the product from the point of production, from the market, or both, and subjecting them to determination activities to check that items produced subsequent to the initial certification fulfill the specified requirements. The surveillance also includes periodic assessment of the production process.

This scheme can both indicate the impact of the distribution channel on conformity and provide a pre-market mechanism to identify and resolve serious nonconformities. Significant duplication of effort may take place for those products whose conformity is not affected during the distribution process.

1.4.3.7 Scheme Type 5 (Certification through continued audit of the manufacturer and products)

The surveillance part of this scheme involves periodically taking samples of the product either from the point of production or from the market, or both, and subjecting them to determination activities to check that items produced subsequent to the initial certification fulfill the specified requirements. The surveillance includes periodic assessment of the production process, an audit of the quality system, or both.

1.4.3.8 Scheme Type 6 (Certification of processes and services)

This scheme is mainly applicable to certification of services and processes.

Although services are considered as being generally intangible, the determination activities are not limited to the evaluation of intangible elements (for instance effectiveness of an organisation's procedures, delays and responsiveness of the management). Tangible elements can also be taken into consideration and evaluated, for instance inspection of the cleanliness of vehicles for the quality of public transportation.

As far as processes are concerned, the situation is very similar. For example, the determination activities for welding processes can include testing and inspection techniques of the resultant welds.

For both services and processes, the surveillance part of this scheme should include periodic audits of the quality system and periodic assessment of the service or process.

1.4.3.9 Comparing Certification Scheme Types

This table (from ISO/IEC 17067) provides a quick comparison of the specific activities involved in each type of certification scheme. Note that **ALL** product certification schemes include, as a minimum, those activities in 1), 2), 3), and 4) below.

Table 1 — Building a product certification scheme

Conformity assessment activities[a] within product certification	Types of product certification schemes [b, c]							
	1a	**1b**	**2**	**3**	**4**	**5**	**6**	***N*[d]**
1) **Selection** including selection of normative documents and sampling as applicable,	x	x	x	x	x	x	x	
2) **Determination of characteristics,** as applicable, by:	x	x	x	x	x	x	x	
a) testing (ISO/IEC 17025)								
b) inspection (ISO/IEC 17020)								
c) design appraisal								
d) assessment of services or processes								
e) other determination activities, e.g. verification, audit								
3) **Review** Examining the evidence of conformity obtained during the determination stage to establish whether the specified requirements have been met	x	x	x	x	x	x	x	
4) **Attestation (decision on certification)** Granting, maintaining, extending, suspending, withdrawing certification	x	x	x	x	x	x	x	
5) **Licensing** Granting, maintaining, extending, suspending, withdrawing the right to use certificates, marks or other statements of conformity on products conforming to the specified requirements		x	x	x	x	x	x	
6) **Surveillance**, as applicable, by:								
a) testing or inspection of samples from the open market			x		x	x		
b) testing or inspection of samples from the factory				x	x	x		
c) quality system audits combined with random tests or inspections						x	x	
d) assessment of the production process or service				x	x	x	x	

[a] Where applicable, the activities can be coupled with initial audit and surveillance audit of the applicant's quality system (an example is given in ISO/IEC Guide 53) or initial assessment of the production process. The order in which the assessments are performed may vary and will be defined within the scheme.

[b] A product certification scheme includes at least the activities 1), 2), 3) and 4).

[c] An often used and well-tried model for a product certification scheme is described in ISO/IEC Guide 28; it is a product certification scheme corresponding to scheme type 5.

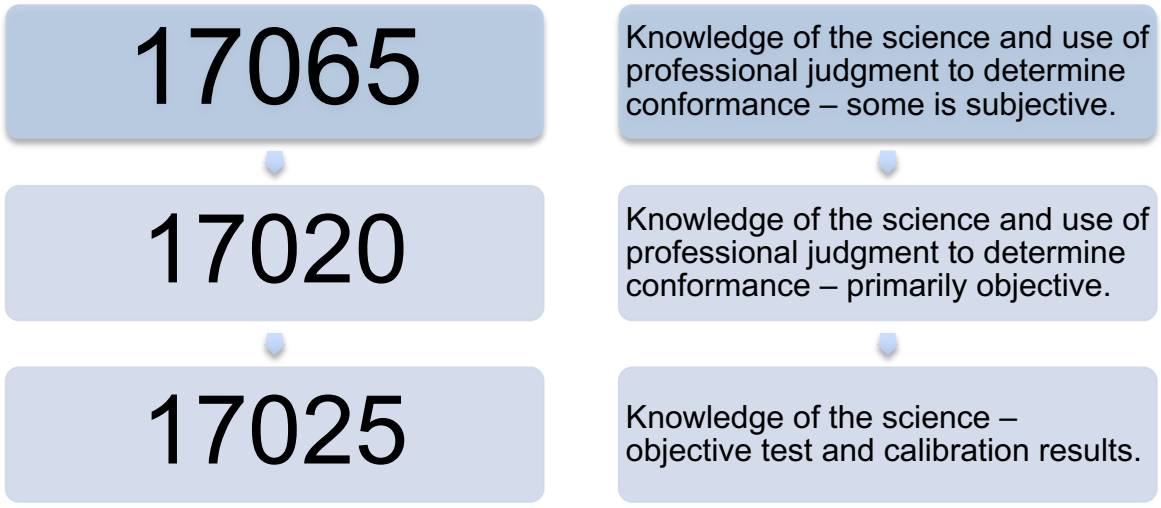
[d] The symbol *N* has been added to show an undefined number of possible other schemes, that can be based on different activities.

1.5 The Hierarchy of Conformity Assessment Standards

The following diagram shows the differences in the application of the three most-common technical conformity assessment standards. They differ in the amount of subjective effort is required to deliver the attestation associated with that conformity assessment activity.

ISO/IEC 17025 and ISO/IEC 17020 can both be used as technical specifications for the provision of inspection, testing, and calibration results to be used as part of the evaluation of the product, process or service.

ISO/IEC 17024 and ISO/IEC 17021 would be included in the evaluation if they applied to the process or service that is the object of certification assessment activities.



1.5.1 Common Elements of Conformity Assessment Standards

Most standards now produced within ISO/CASCO (those with the ISO/IEC nomenclature) follow the criteria set out in the Publicly Available Specifications (PAS) 17001 through 17005 that were once used to define the considerations. These specifications have now been incorporated into the ISO/IEC Directives:

- Impartiality;
- Confidentiality;
- Complaints and appeals;
- Disclosure of information, and
- Use of management systems in conformity assessment.

Because of these and other common approaches adopted, most 17000 series standards contain elements common to all of them that allow organisations to seamlessly incorporate conformity assessment standards in different disciplines.

These common elements generally include the following:

- Organisation requirements;

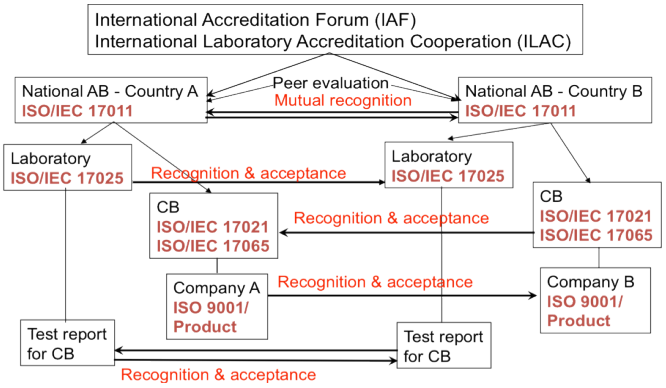
- Management system requirements, including:
  - Technical and management system responsibilities (including both authorities and accountabilities);
  - Conflict of interest requirements;
  - Confidentiality requirements;
  - Impartiality requirements, and
  - Personnel training and qualification requirements.
- Document control;
- Control of records;
- Feedback, including complaints;
- Disputes and appeals (where applicable);
- Handling of non-conformances through to corrective action (as appropriate);
- Handling of potential non-conformances and opportunities for improvement through to preventive action (as appropriate);
- Internal audit, and
- Management review

1.5.2 Common Structure of Conformity Assessment Standards

The resulting commonality in structure is apparent in most of the documents issued by ISO/CASCO.

Informative Preliminary	Title page Table of contents Foreword Introduction (including relationship to other standards)
Normative General	Title Scope Normative references
Normative Technical	Terms and definitions Principles Requirements Structural requirements Resource requirements (including Human resources) Process requirements (including operational functions) Management system requirements Normative annexes
Informative supplementary	Any further explanations that are not part of the normative process Informative annexes Bibliography Indexes

This commonality enhances the interoperability of these standards and promotes mutual recognition around the world. This diagram demonstrates how mutual recognition allows certifications, inspection results, and test and calibration results to be acceptable in other nations. Note that there are currently no IAF endorsed schemes, rather they are considered equivalent, “equally reliable” per IAF PR004.



Chapter 2 – Overview of Certification

2.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **appreciate** the overall approach to certification;
- **understand** how product (process/service) certification works within the global conformity assessment approaches;

2.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 2.1

What are the five steps in the certification of products, processes and services?

Discussion Activity 2.2

What are the common elements that appear in ISO/IEC standards?

Discussion Activity 2.3

What types of requirements are contained in 17065 that may not be present in the other standards used in the evaluation process?

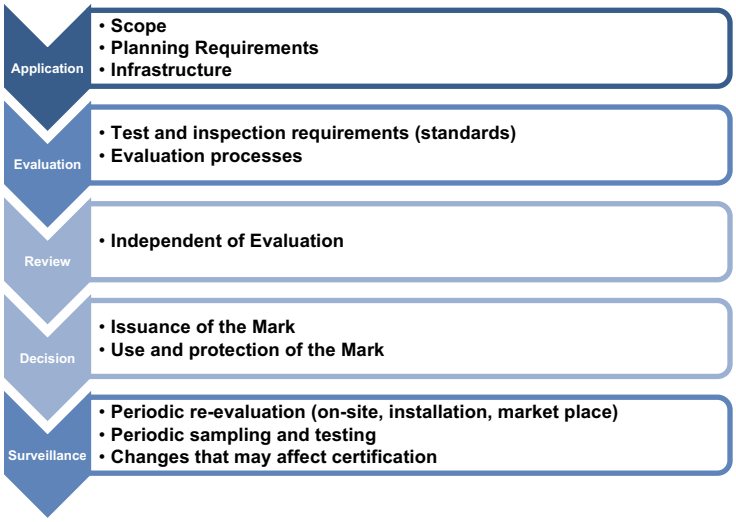
2.3 Certification is different than Testing or Inspection

2.3.1 General Certification Processes

ISO/IEC 17065 articulates the process of certification to contain the following 5 steps.

These five steps underpin all certification processes and therefore, the management system that supports them, in ISO/IEC 17065, is geared towards allowing the certification body to issue certificates that enhance trust in the safety and performance of the products examined.

The first diagram below shows the placement of wording within ISO/IEC 17065 that can apply to specific certification process components and is the basis for the structure of this course. The second diagram lists the process components discussed in each of the clauses.



2.3.2 Certification Processes within ISO/IEC 17065

PROCESS COMPONENT ***CLAUSE REFERENCE***

2.3.2.1 Application for Certification

SCOPE

CB Scope

- ..... CB scope of operations 1, 4.1.1
- ..... CB structure 4.3, 5.1

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- ..... People 6.1
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2.3.2.2 Evaluation of Conformance

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Review processes

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- .....

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CLAUSE REFERENCE	*PROCESS COMPONENT*
Foreword	-
Introduction	-
1. Scope	Scope
2. Normative references	-
3. Terms and definitions	-
4. General requirements	
4.1 Legal and contractual matters	
4.1.1 Legal responsibility	Scope
4.1.2 Certification agreement	Planning
4.1.3 Use of license, certificates and marks	Planning
4.2 Management of impartiality	Planning
4.3 Liability and financing	Scope
4.4 Non-discriminatory conditions	Planning
4.5 Confidentiality	Management System
4.6 Publicly available information	Planning
5. Structural requirements	
5.1 Organisational structure and top management	Scope
5.2 Mechanism for safeguarding impartiality	Planning
6. Resource requirements	
6.1 Certification body personnel	
6.1.1 General	Infrastructure
6.1.2 Management of competence for certification personnel	Infrastructure
6.1.3 Contract with personnel	Infrastructure
6.2 Resources for evaluation	Infrastructure
6.2.1 Internal resources	Infrastructure
6.2.2 External resources	Infrastructure
7. Process requirements	
7.1 General	Planning
7.2 Application	Planning
7.3 Application review	Planning
7.4 Evaluation	Evaluation
7.5 Review	Technical Review
7.6 Certification decision	Decision
7.7 Certification documentation	Decision
7.8 Directory of certified products	Decision
7.9 Surveillance	Surveillance
7.10 Changes affecting certification	Surveillance
7.11 Termination, reduction, suspension or withdrawal of certification	Surveillance
7.12 Records	Management System
7.13 Complaints and appeals	Management System

CLAUSE REFERENCE	PROCESS COMPONENT
8. Management system requirements	
8.1 Options	Management System
8.2 General management system documentation (Option A)	Management System
8.2.1 Control of documents (Option A)	Management System
8.2.2 Control of records (Option A)	Management System
8.2.3 Management review (Option A)	Management System
8.2.4 Internal audits (Option A)	Management System
8.2.5 Corrective actions (Option A)	Management System
8.2.6 Preventive actions (Option A)	Management System

Chapter 3 – Integrity in Certification

3.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **understand** the management system requirements for impartiality, and
- **understand** the ways in which ISO/IEC 17065-conformant bodies manage and safeguard impartiality.

3.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 3.1

How can a CB ensure that the decision to certify a product, process or service is taken impartially?

Discussion Activity 3.2

What are the minimum set of processes a CB must have to ensure real and perceived impartiality in its processes?

3.3 Understanding Impartiality

The concept of Impartiality is the following:

> *Decisions made for certification are **based solely on the defined merits or criteria related to the object of certification (product, service or process)**, or its operation, or some other aspect related to it. Only those things can be used in the certification decision – nothing else, and certainly nothing related to the decision maker.*

Conflict of interest is the notion that something other than those defined merits or criteria are influencing the decisions related to that thing. People or organisations are deemed to be in conflict of interest when they are associated with any condition or organisation that might have an interest in influencing the outcome of the decisions.

Simple conflict of interest is deemed to exist whenever more than one relationship connects two parties. When this occurs, it is not possible to ensure that one relationship is not being influenced by the dynamics of the other. For example, if a friend of a landlord rents an apartment from that landlord, can either the friendship or the landlord-tenant relationship be influenced by the other relationship between these two people? The most precise answer to this question is: It **cannot be established** that either of these relationships **does not influence** the other. It is **not certain** that either one **will influence** the other, but there is very little to prevent them from doing so.

Impartiality in certification is more difficult to understand than simple conflict of interest considerations. It is not possible to simply identify and declare the existence of more than one relationship between parties. There may not be any, but because of the possibility of small amounts of influence being applied that may skew the evaluation or certification, all possible aspects of conditions that may jeopardize or compromise impartiality must be dealt with in a clear and transparent manner.

Failure to do so will adversely affect the integrity of the certification scheme and its certified products, processes and services, and may significantly reduce the trust placed in the certification body and its stakeholders.

3.4 Detailed Impartiality Requirements

ISO/IEC 17065 References

4.2 Management of impartiality

4.2.1 Certifications shall be impartial

4.2.2 CBs shall operate impartially without commercial or financial pressures that may compromise impartiality.

4.2.3 CBs shall identify risks to impartiality on an ongoing basis, including its related bodies and any relationships of its staff.

4.2.4 The CB shall demonstrate how it eliminates or minimizes identified risks

4.2.5 Top management shall be committed to impartiality.

4.2.6 The CB, and its subcontractors, shall not:

a) be involved in the design or other business aspect of the product object of certification
b) be involved in the design or other business aspect of the process object of certification
c) be involved in the design or other business aspect of the service object of certification
d) provide consultancy to its clients;
e) provide management system consultancy to any client whose certification requirements include the evaluation of their management system.

4.4 Non-discriminatory conditions

4.4.1 The policies and procedures under which the CB operates, and the administration of them, shall be non-discriminatory. Procedures shall not be used to impede or inhibit access by applicants, other than as provided for in this International Standard.

4.4.2 The CB shall make its services accessible to all applicants whose activities fall within the scope of its operations.

4.4.3 Access to the certification process shall not be conditional upon the size of the client or membership of any association or group, nor shall certification be conditional upon the number of certifications already issued. There shall not be undue financial or other conditions.

NOTE A CB can decline to accept an application or maintain a contract for certification from a client when fundamental or demonstrated reasons exist, such as the client participating in illegal activities, having a history of repeated non-compliances with certification/product requirements, or similar client-related issues.

4.4.4 The CB shall confine its requirements, evaluation, review, decision and surveillance (if any) to those matters specifically related to the scope of certification.

5.2 Mechanism for safeguarding impartiality

5.2.1 The CB shall have a mechanism for safeguarding its impartiality. The mechanism shall provide input on the following:

a) the policies and principles relating to the impartiality of its certification activities;
b) any tendency on the part of a CB to allow commercial or other considerations to prevent the consistent impartial provision of certification activities;
c) matters affecting impartiality and confidence in certification, including openness.

NOTE 1 Other tasks or duties (e.g. taking part in the decision-making process) can be assigned to the mechanism, provided these additional tasks or duties do not compromise its essential role of ensuring impartiality.

NOTE 2 A possible mechanism can be a committee established by one or more certification bodies, a committee implemented by a scheme owner, a governmental authority or an equivalent party.

NOTE 3 A single mechanism for several certification schemes can satisfy this requirement.

NOTE 4 If the CB also provides management systems certification, a committee that fulfills ISO/IEC 17021:2011, 6.2, can also fulfill this subclause (5.2) providing that all the requirements of 5.2 have been met.

5.2.2 The mechanism shall be formally documented to ensure the following:

a) a balanced representation of significantly interested parties, such that no single interest predominates (internal or external personnel of the CB are considered to be a single interest, and shall not predominate);
b) access to all the information necessary to enable it to fulfil all its functions.

5.2.3 If the top management of the CB does not follow the input of this mechanism, the mechanism shall have the right to take independent action (e.g. informing authorities, accreditation bodies, and stakeholders). In taking appropriate action, the confidentiality requirements of 4.5 relating to the client and CB shall be respected.

Input that is in conflict with the operating procedures of the CB or other mandatory requirements should not be followed. Management should document the reasoning behind the decision to not follow the input and maintain the document for review by appropriate personnel.

5.2.4 Although every interest cannot be represented in the mechanism, a CB shall identify and invite significantly interested parties.

NOTE 1 Such interested parties can include clients of the certification body, customers of clients, manufacturers, suppliers, users, conformity assessment experts, representatives of industry trade associations, representatives of governmental regulatory bodies or other governmental services, and representatives of non-governmental organisations, including consumer organisations. It can be sufficient to have one representative of each interested party in the mechanism.

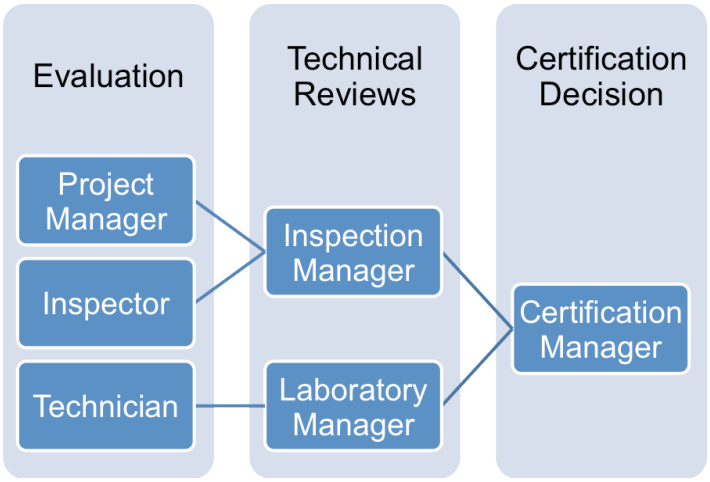
NOTE 2 These interests can be limited, depending on the nature of the certification scheme.

3.5 Demonstrating Impartiality in Decision Processes

Rock solid demonstrations of impartiality require the CB to ensure that its own staff are not involved in any aspect of ownership, design, manufacture, or other relationship as regards the object of certification or its manufacturer / supplier.

It requires that all sub-contracted organisations that participate in the evaluation processes also are visibly free of such conflicts.

ISO/IEC 17065, cl 7.6.2 requires that all persons involved in the review and decision must be independent of the evaluation.



ISO/IEC 17065 References

7.6.2 The decision(s) of at least one person is required and must be based on the relevant evaluation information and must be person(s) independent of the evaluation.

Chapter 4 – Organisation and Structure

4.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **understand** the organisational structure needed to conduct certification, and
- **understand** the main tort legal requirements for certification bodies.

4.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 4.1

Are there requirements for evaluation that go beyond simple testing and inspection? What are they?

Discussion Activity 4.2

What are the types of considerations that must be contained in an agreement between a CB and an Applicant?

Discussion Activity 4.3

How can a CB demonstrate conformance to the 17065 liability requirements?

4.3 Detailed Certification Scope Requirements

ISO/IEC 17065 References

1 Scope

CBs need not offer all types of products, processes and services certification.

4.4 Detailed Organisational Requirements

ISO/IEC 17065 References

4.1 Legal and contractual matters

The CB shall be a legal entity.

Government CBs are deemed to be legal entities.

4.5 Detailed Requirements for Agreement with the Applicant

ISO/IEC 17065 References

4.1.2 Certification Agreement

The CB enters into a legally enforceable agreement with the applicant on these issues.

a) the client always fulfils the certification requirements (see 3.7), including implementing appropriate changes when they are communicated by the CB (see 7.10);

b) if the certification applies to ongoing production, the certified product continues to fulfill the product requirements (see 3.8);

c) the client makes all necessary arrangements for

   1) the conduct of the evaluation (see 3.3) and surveillance (if required), including provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and client's subcontractors;
   2) investigation of complaints;
   3) the participation of observers, if applicable;

d) the client makes claims regarding certification consistent with the scope of certification (see 3.10)

e) the client does not use its product certification in such a manner as to bring the CB into disrepute and does not make any statement regarding its product certification that the CB may consider misleading or unauthorized;

f) upon suspension, withdrawal, or termination of certification, the client discontinues its use of all advertising matter that contains any reference thereto and takes action as required by the certification scheme (e.g. the return of certification documents) and takes any other required measure;

g) if the client provides copies of the certification documents to others, the documents shall be reproduced in their entirety or as specified in the certification scheme;

h) in making reference to its product certification in communication media such as documents, brochures or advertising, the client complies with the requirements of the CB or as specified by the certification scheme.

i) the client complies with any requirements that may be prescribed in the certification scheme relating to the use of marks of conformity, and on information related to the product;

   NOTE: See also ISO/IEC 17030, ISO/IEC Guide 23 and ISO Guide 27.

j) the client keeps a record of all complaints made known to it relating to compliance with certification requirements and makes these records available to the CB when requested, and

   1) takes appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification;

   2) documents the actions taken;

   NOTE Verification of item j) by the CB can be specified in the certification scheme.

k) the client informs the certification body, without delay, of changes that may affect its ability to conform with the certification requirements.

NOTE Examples of changes can include the following:

- the legal, commercial, organisational status or ownership,
- organisation and management (e.g. key managerial, decision-making or technical staff),
- modifications to the product or the production method,
- contact address and production sites,
- major changes to the quality management system.

4.6 Detailed Organisational Structure Requirements

ISO/IEC 17065 References

5.1 Organisational Structure and Top Management

5.1.1 CB activities are managed so as to safeguard impartiality.

5.1.2 The CB describes its organisational structure, responsibilities and authorities of its people and the lines of authority with respect to related bodies within its own legal entity.

5.1.3 Person(s) having overall responsibilities for the following are identified:

- Operational policies
- Implementation of policies
- Finances
- Certification activities
- Certification requirements
- Evaluation
- Review
- Certification decisions
- Delegation of authority to committees
- Contracts
- Provision of adequate resources.
- Responsiveness to complaints and appeals.
- Competence of personnel
- Management system

5.1.4 The CB has formal rules for the operation of its committees involved in certification. They are free from influence, but the CB can fire them.

4.7 Detailed Liability and Financing Requirements

ISO/IEC 17065 References

4.3 Liability and financing

4.3.1 The CB shall have adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations.

4.3.2 The CB shall have the financial stability and resources required for its operations.

Chapter 5 – Certification Body Resources

5.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **understand** the requirements for competence of all persons involved in the certification process.

5.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 5.1

Do the competence requirements for CB staff differ from those of subcontractors? Why?

Discussion Activity 5.2

What are the types of competence required by the 17065?

Discussion Activity 5.3

Why does 17065 require the use of binding, enforceable employment contracts when this is not a requirement of 17025?

Discussion Activity 5.4

How can a 17065-conformant body ensure that technically competent and impartial people create the scheme information they publish?

Discussion Activity 5.5

How can traceability of measurement influence the safety of a certified product, process or service? Provide three examples.

5.3 Detailed Competence Requirements

ISO/IEC 17065 References

6.1 CB personnel

The CB shall have access to a sufficient number of personnel to cover its operations.

Personnel shall be competent for the functions they perform.

Personnel shall keep confidential all information obtained or created during the performance of the certification activities, except as required by law or by certification scheme.

6.1.2 Management of Competence

6.1.2.1 The CB shall manage competencies of personnel involved in the certification process to:

- determine the criteria for the competence of personnel for each function
- identify training needs as necessary
- demonstrate that personnel have the required competencies
- formally authorize personnel
- monitor the performance of the personnel

6.1.2.2 Records of personnel shall be maintained to include:

- name and address;
- employer(s) and position held;
- educational qualification and professional status;
- experience and training;
- the assessment of competence;
- performance monitoring;
- authorizations held within the certification body;
- date of most recent updating of each record.

6.1.3 Personnel Contracts

The CB shall implement signed contracts with personnel which they commit themselves to:

- comply with the rules defined by the certification body,
- declare any prior and/or present association with:
  - a supplier or designer of products, or
  - a provider or developer of services, or
  - an operator or developer of processes

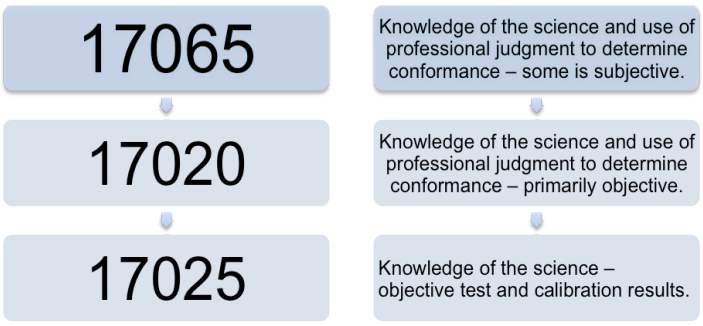
Certification bodies shall use this information as input to identifying risks to impartiality

7.1.3 Scheme information is to be formulated by technically competent and impartial persons.

5.4 Acquisition of Competent External Support

From understanding the hierarchy of standards involved in the certification of products, processes, and services, it is easy to appreciate the importance of competence in the production of the inspection reports, test reports and calibration certificates that support accredited certification.

Most scheme owners, whether or not their program conforms to ISO/IEC Guide 67 (soon to be 17067), rely on scheme CBs to make use of accredited organizsations for inspection, testing, and calibration.



5.5 Detailed Competence Requirements for Evaluation

ISO/IEC 17065 References

6.2 Resources for Evaluation

6.2.1 Internal resources

CB must meet the requirements of relevant evaluation standards when it evaluates using its own resources.

6.2.2 External resources (Outsourcing)

Only competent (normally accredited) bodies can be used for outsourcing such things as evaluation activities

Use of applicant evaluation facilities must be such that they are managed in a manner that provides confidence in the results, and that records are available to justify the confidence.

CB is responsible for all activities outsourced, including:
- impartiality of staff in subcontractor
- the qualification and selection of subcontractors
- undertake corrective or legal action for breaches of the evaluation contract
- allow the applicant to review outsourcing

6.2.2.2 Where evaluation activities are outsourced to non-independent bodies (e.g. client laboratories), the CB shall ensure that the evaluation activities are managed in a manner which provides confidence in the results, and that records are available to justify the confidence.

6.2.2.3 The CB shall have a legally binding contract with the body that provides the outsourced service, including provisions for confidentiality and conflict of interest as specified in 6.1.3, item c).

7.4.2 The CB assigns people who meet the requirements of 6.2.1 (competence in evaluation).

Chapter 6 – Certification Processes

6.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **understand** the components of the certification decision;
- **understand** the requirements for protection of marks of certification, and
- **understand** the requirements for changes to certification
- **understand** certification surveillance requirements
- **appreciate** the contribution of testing and inspection to support evaluation processes.

6.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 6.1

Are there any differences in evaluation requirements if a product is being resubmitted for certification following an initial failure to meet the requirements of the certification scheme? What are they?

Discussion Activity 6.2

What tools are available to allow a CB to suspend or withdraw a certification?

Discussion Activity 6.3

What types of changes can affect the certification of a product, process, or service? Who implements them and how are these changes implemented?

Discussion Activity 6.4

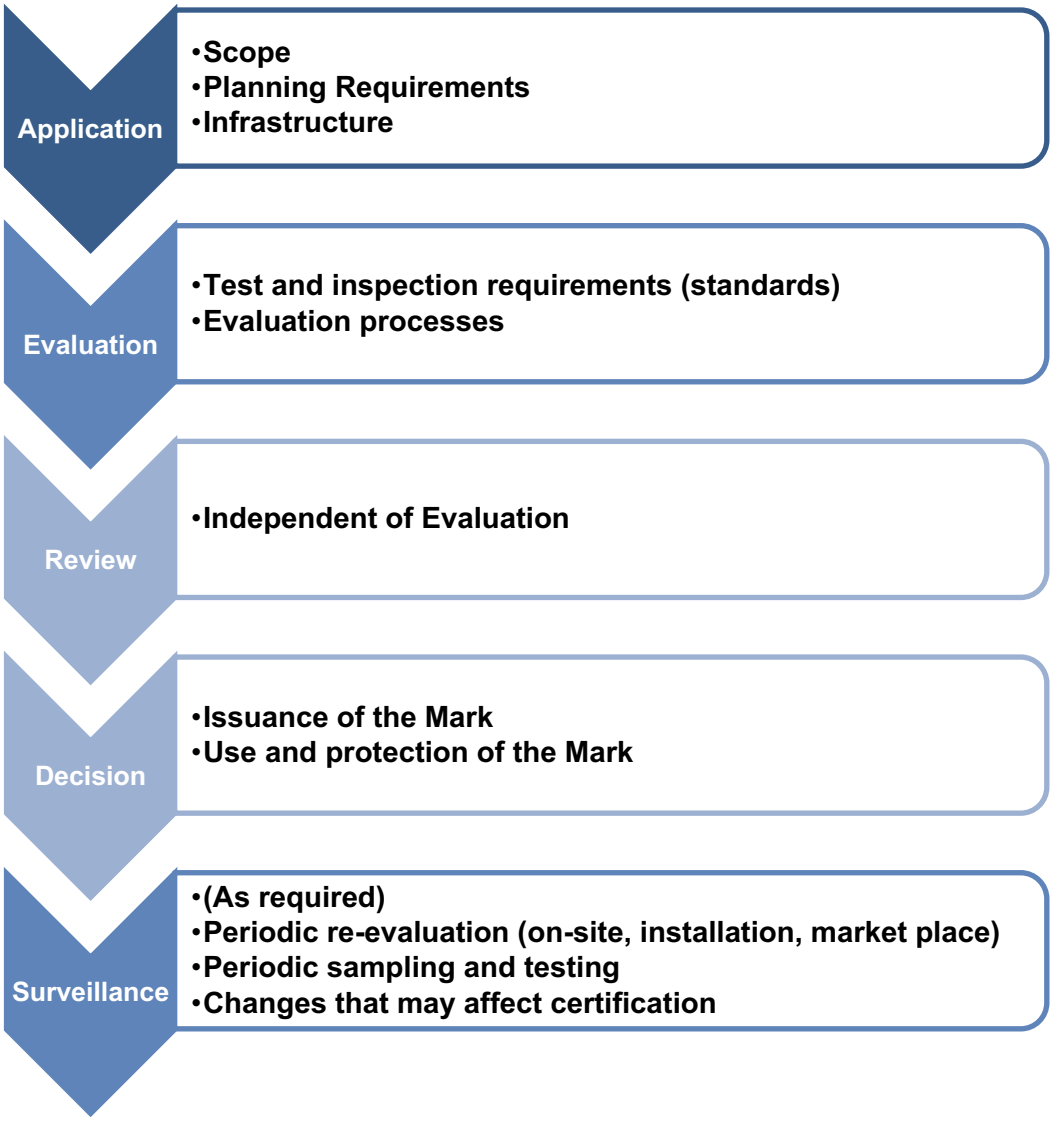
What are the requirements for the protection of the marks of certification? Which organisation is responsible for enforcing them?

Discussion Activity 6.5

Who decides on the necessity for surveillance? What are the major components of continued surveillance?

6.3 Processes involved in Certification

This diagram shows the five principal steps involved in certification and the type of scheme will have a good deal of influence on the scope and complexity of each of these steps



6.4 General Process Requirements

ISO/IEC 17065 References

7.1 General

7.1.1 The CB shall operate one or more certification scheme(s) covering its certification activities.

NOTE 1: The elements of such schemes can be coupled with surveillance of production, or with the assessment and surveillance of the client's management system, or both.

NOTE 2: General guidance on the development of schemes is given in ISO/IEC 17067, in combination with ISO/IEC Guide 28 and ISO/IEC Guide 53.

7.1.2 The requirements against which the products of a client are evaluated shall be those contained in specified standards and other normative documents.

NOTE Guidance for developing normative documents suitable for this purpose is contained in ISO/IEC 17007.

7.1.3 If explanations are required as to the application of these documents (see 7.1.2) for a specific certification scheme, they shall be formulated by relevant and impartial persons or committees, possessing the necessary technical competence, and shall be made available by the CB upon request.

6.5 Detailed Application Requirements

ISO/IEC 17065 References

4.6 Publicly available information

CB maintains (through publications, electronic media or other means), and make available upon request, the following:

a) information about (or reference to) the certification scheme(s), including evaluation procedures, rules and procedures for granting, for maintaining, for extending or reducing the scope of, for suspending, for withdrawing or for refusing certification;

b) a description of the means by which the CB obtains financial support and general information on the fees charged to applicants and to clients;

c) a description of the rights and duties of applicants and clients, including requirements, restrictions or limitations on the use of the certification body's name and certification mark and on the ways of referring to the certification granted;

d) information about procedures for handling complaints and appeals.

7.2. Application

Onus is on the CB to acquire the requisite information based on the descriptions provided.

7.3 Application Review

The CB is to ensure the application documentation is complete and contains info on the:

- product, process or service to be certified;
- a defined scope of certification;

- the means for the CB to conduct the evaluation, and
- the means (competence and capacity) to conduct the certification.

When the CB is accepting new work the application identifies:

- the object of certification, and
- the specifications for certification, or
- the applicable scheme.

Where the work is new, the CB must maintain records demonstrating its justification to undertake the new work.

If the CB lacks any competence for the work it declines the application.

If the work is based on previous certifications, any changes in approach from the previous one are to be justified.

6.6 Detailed Evaluation Requirements

ISO/IEC 17065 References

7.4.3 Required information is available for the evaluation.

7.4.4 The evaluation makes use of resources identified in 6.2, using the plan developed in 7.4.1 and against the requirements given in the certification scheme.

7.4.5 The CB is responsible for all evaluation results used for the certification, regardless of which body (internal or outsourced) conducted the tests and inspections.

7.4.6 The CB keeps the applicant informed of any issues discovered during the evaluation and offers the decision to the applicant to continue (7.4.7) if issues are non-conformances to certification requirements.

7.4.8 The evaluation process is repeated if the client agrees to continue following discovery of non-conformances.

6.7 Detailed Review Requirements

ISO/IEC 17065 References

7.6.2 The decision(s) of at least one person is required and must be based on the evaluation information received and must be person(s) independent of the evaluation.

6.8 Detailed Certification Decision Requirements

ISO/IEC 17065 References

7.4.9 Results of the evaluation are reported. The report can contain opinions on the conformance of the object of certification with respect to the actual requirements.

7.5 Review A person reviews the report, and is independent of all evaluation activities. (See diagram above.)

Review is documented separately unless the same person is both reviewer and certification authority.

7.6 Certification Decision

The CB is responsible for the certification decision.

The decision(s) of at least one person is required and must be based on the evaluation information received and must be person(s) independent of the evaluation.

Those making the decision are under contract to the CB or one of its divisions.

The CB notifies the applicant of the reasons for any adverse decision.

Resumption of the certification work following an adverse decision can be done by following the original process.

7.7 Certification documentation

7.7.1 This is to include:

- Particulars of the CB
- Effective date of certification.
- Particulars of the applicant
- Scope of certification, objects certified, standards of certification, the applicable scheme.
- Effective term of certification and its expiry
- Other information required by the scheme.

7.7.2 The formal certification documentation shall include the signature or other defined authorization of the person(s) of the CB assigned such responsibility.

> **NOTE** The name and title of an individual whose agreement to be responsible for certification documentation is on record at the CB is an example of a “defined authorization” other than a signature.

7.7.3 Certification is granted only when

- The decision is made, and
- All certification requirements are met, and
- The applicant has signed the certification agreement.

7.8 Directory of certified products

The CB shall maintain information on certified products which contains at least the following:

a) identification of the product;
b) the standard(s) and other normative document(s) to which conformity has been certified;
c) identification of the client.

The parts of this information that need to be published or made available upon request in a directory (through publications, electronic media or other means) are stipulated by the relevant scheme(s). As a minimum, the CB shall provide information, upon request, about the validity of a given certification.

> **NOTE:** Where the CB provides the information to a scheme, the scheme directory would satisfy this requirement.

6.9 Detailed Requirements Regarding the Use of a Mark

ISO/IEC 17065 References

4.1.3 Use of license, certificates and marks of conformity

4.1.3.1 The CB controls ownership, use and display of licenses, certificates, marks of conformity. See ISO/IEC Guide 23 (1982 edition).

NOTE 1: Guidance on the use of certificates and marks permitted by the CB can be obtained from ISO/IEC Guide 23.

NOTE 2: ISO/IEC 17030 provides requirements for the use of third-party marks.

4.1.3.2 Incorrect references to certification or misleading use of licenses, certificates or marks shall be dealt with by suitable action.

NOTE: Such actions are addressed in ISO Guide 27 and can include corrective actions, withdrawal of certificate, publication of the transgression and, if necessary, legal action.

7.9.1 Surveillance. When a certification mark is authorized, surveillance shall be established to include periodic surveillance of marked products to ensure fulfilment of certification requirements.

4.6 Public Information. CB to provide a description of the rights and duties of applicants and clients, including requirements, restrictions or limitations on the use of the certification body's name and certification mark and on the ways of referring to the certification granted.

6.10 Detailed Surveillance Requirements

ISO/IEC 17065 References

7.9 Surveillance

7.9.1 The CB establishes surveillance sufficient to allow continuing demonstration of conformance to requirements as defined in the applicable scheme.

Any evaluation or re-evaluation that is part of surveillance is to be done as per the original evaluation.

If a certification mark has been authorised for use directly on a product (or packaging), surveillance shall include periodic review of marked products to ensure ongoing fulfilment of certification requirements.

Process and service certifications are also to be supported by periodic surveillance.

6.11 Detailed Change Requirements

ISO/IEC 17065 References

7.10.1 Changes affecting certification.

Certification scheme changes are to be applied to the object of certification by the applicant. This activity may be covered by the original certification agreement.

NOTE: Contractual arrangements with clients can be necessary to ensure implementation of these requirements. A model of a license agreement for the use of certification, including the aspects related to a notice of changes, as far as applicable, is given in ISO/IEC Guide 28:2004, Annex E.

7.10.2 The CB shall consider other changes affecting certification, including changes initiated by the client, and shall decide upon the appropriate action.

NOTE Changes affecting certification can include new information related to the fulfillment of certification requirements obtained by the CB after certification has been established.

7.10.3 The CB reviews any changes to the object of certification initiated by the applicant. This may include re-evaluation, review, and decision processes and conducted in accordance with the processes used for the initial certification (clauses 7.4 through 7.8). Exclusions of any of these steps shall be justified by the CB.

6.12 Detailed Requirements for Withdrawal and Suspension

ISO/IEC 17065 References

7.11 Termination, reduction, suspension or withdrawal of certification.

7.11.1 Substantiated non-conformance with certification requirements may lead to one or more of the following:

- Increased surveillance or other changes of certification requirements.
- Reduction of scope to remove non-conforming variants.
- Suspension pending remedial action.
- Withdrawal of certification.

7.11.2 Processes in 7.5 (Review) and 7.6 (Decision) shall be followed. No one involved in the evaluation that resulted in the discovery of the non-conformance may participate in these two processes.

7.11.3 If applicant terminates certification, or if certification is suspended or withdrawn, the CB shall issue notifications to ensure the market is not mislead with respect to the status of certification and the integrity of its mark is protected.

7.11.4 The CB appoints persons to undertake discussion with the applicant on how to lift the suspension and reinstate certification.

7.11.5 Evaluations, reviews and decisions to reinstate certification follow the original processes in 7.4 – 7.7, 7.9, and 7.11.3.

7.11.6 If certification is reinstated, the CB shall issue notifications to ensure the market is not misled with respect to the status of certification and the integrity of its mark is protected.

Chapter 7 – Management System Requirements

7.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **identify** the standard management system requirements for certification bodies;

7.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 7.1

Why are CBs required to deal with appeals when laboratories do not have such a requirement?

Discussion Activity 7.2

Are the continual improvement requirements in 17065 much different than 17025?

Discussion Activity 7.3

How can a CB, that is itself certified to ISO 9001, demonstrate conformance to the requirements of ISO/IEC 17065?

Discussion Activity 7.4

If a CB that is itself certified to ISO 9001 has their 9001 certificate suspended, will that automatically affect their accreditation as a CB? Does suspension of the accreditation automatically affect their certification?

7.3 Detailed Management System Requirements

ISO/IEC 17065 References

8. Management System Requirements (Options)

Option A - The CB defines and implements a quality system based on ISO/IEC 17065

Option B - The CB defines and implements a quality system based on ISO 9001, but which also meets the requirements of 17065, specifically clauses 8.2 through 8.8, inclusive.

8.2 General Management System (Option A)

8.2.1 CB defines and implements an appropriate management system.

8.2.2 Top management provides evidence of its commitment the management system

8.2.3 CB appoints a management representative.

8.2.4 The management system is documented and all documentation is referenced or referred to in the overall documented management system.

8.2.5 All personnel have access to the management system documentation (and related information above) that is applicable to their responsibilities.

7.4 Detailed Requirements for Document Control and Control of Records

ISO/IEC 17065 References

8.3 Control of documents (Option A)

8.3.1 CB controls documents (internal and external)

8.3.2 The procedures include:

- documental approval;
- review and update of documents;
- identification of changes and the current status of documents;
- availability of documents;
- documents are legible and identifiable;
- external documents are controlled; and
- preventing the unintended use of obsolete documents.

8.4 Control of records (Option A)

8.4.1 The CB shall establishes procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfilment of this International Standard.

8.4.2 The CB establishes procedures for retaining records (see 7.12) for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements.

7.5 Detailed Requirements for Complaints and Appeals

ISO/IEC 17065 References

7.13 Complaints and appeals

7.13.1 The CB shall have a documented process to receive, evaluate and make decisions on complaints and appeals. The CB shall record and track complaints and appeals, as well as actions undertaken to resolve them.

7.13.2 Upon receipt of a complaint or appeal, the CB shall confirm whether the complaint or appeal relates to certification activities for which it is responsible and, if so, shall address it.

7.13.3 The CB shall acknowledge receipt of a formal complaint or appeal.

7.13.4 The CB shall be responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision.

7.13.5 The decision resolving the complaint or appeal shall be made by, or reviewed and approved by, person(s) not involved in the certification activities related to the complaint or appeal.

7.13.6 To ensure that there is no conflict of interest, personnel (including those acting in a managerial capacity) who have provided consultancy (see 3.2) for a client, or been employed by a client, shall not be used by the CB to review or approve the resolution of a complaint or appeal for that client within two years following the end of the consultancy or employment.

7.13.7 Whenever possible, the CB shall give formal notice of the outcome and the end of the complaint process to the complainant.

7.13.8 The CB shall give formal notice of the outcome and the end of the appeal process to the appellant.

7.13.9 The CB shall take any subsequent action needed to resolve the complaint or appeal.

7.6 Detailed Requirements for Continual Improvement

ISO/IEC 17065 does not provide any indication of the methods to identify nonconformities, potential nonconformities, or opportunities for improvement. It uses the term "nonconformity in only three places: 7.4 (evaluation), 7.11 (suspension), and 8.7 (corrective action). Its terms for determining the necessity for doing more than simple remediation (correction, prevention, improvement) are not very clear. It only starts considering a continual improvement program within a certification body under the aegis of corrective action.

ISO/IEC 17065 References

8.7 Corrective actions (Option A)

8.7.1 The CB shall establish procedures for identification and management of nonconformities in its operations.

8.7.2 The CB shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence.

8.7.3 Corrective actions shall be appropriate to the impact of the problems encountered.

8.7.4 The procedures for corrective actions shall define requirements for the following:

a) identifying nonconformities (e.g. from complaints and internal audits);
b) determining the causes of nonconformity;
c) correcting nonconformities;
d) evaluating the need for actions to ensure that nonconformities do not recur;
e) determining and implementing the actions needed in a timely manner;
f) recording the results of actions taken;
g) reviewing the effectiveness of corrective actions.

8.8 Preventive actions (Option A)

8.8.1 The CB shall establish procedures for taking preventive actions to eliminate the causes of potential nonconformities.

8.8.2 Preventive actions taken shall be appropriate to the probable impact of the potential problems.

8.8.3 The procedures for preventive actions shall define requirements for the following:

a) identifying potential nonconformities and their causes;
b) evaluating the need for action to prevent the occurrence of nonconformities;
c) determining and implementing the action needed;

d) recording the results of actions taken;
e) reviewing the effectiveness of the preventive actions taken.

NOTE The procedures for corrective and preventive actions do not necessarily have to be separate.

7.7 Detailed Requirements for Internal Audit and Management Review

ISO/IEC 17065 References

8.6 Internal audits (Option A)

8.6.1 The CB shall establish procedures for internal audits to verify that it fulfils the requirements of this International Standard and that the management system is effectively implemented and maintained.

NOTE ISO 19011 provides guidelines for conducting internal audits.

8.6.2 An audit program shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits.

8.6.3 Internal audits shall normally be performed at least once every 12 months, or completed within a 12-month time frame for segmented (or rolling) internal audits. A documented decision-making process shall be followed to change (reduce or restore) the frequency of internal audits or the time frame in which internal audits shall be completed. Such changes shall be based on the relative stability and ongoing effectiveness of the management system. Records of decisions to change the frequency of internal audits, or the time frame in which they will be completed, including the rationale for the change, shall be maintained.

8.6.4 The CB shall ensure that:

a) internal audits are conducted by personnel knowledgeable in certification, auditing and the requirements of this International Standard;
b) auditors do not audit their own work;
c) personnel responsible for the area audited are informed of the outcome of the audit;
d) any actions resulting from internal audits are taken in a timely and appropriate manner;
e) any opportunities for improvement are identified.

8.5 Management review (Option A)

8.5.1 General

8.5.1.1 The CB's top management shall establish procedures to review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfillment of this International Standard.

8.5.1.2 These reviews shall be conducted at least once a year. Alternatively, a complete review broken up into segments shall be completed within a 12-month time frame. Records of reviews shall be maintained.

8.5.2 Review inputs

The input to the management review shall include information related to the following:

a) results of internal and external audits;
b) feedback from clients and interested parties related to the fulfillment of this International Standard;

NOTE Interested parties can include scheme owners.

c) feedback from the mechanism for safeguarding impartiality;
d) the status of preventive and corrective actions;
e) follow-up actions from previous management reviews;
f) the fulfillment of objectives;
g) changes that could affect the management system;
h) appeals and complaints.

8.5.3 Review outputs

The outputs from the management review shall include decisions and actions related to the following:

a) improvement of the effectiveness of the management system and its processes;
b) improvement of the CB related to the fulfillment of this International Standard;
c) resource needs.