

## ISO/IEC 17065: 2012

### Conformity assessment - Requirements for bodies certifying products, processes and services

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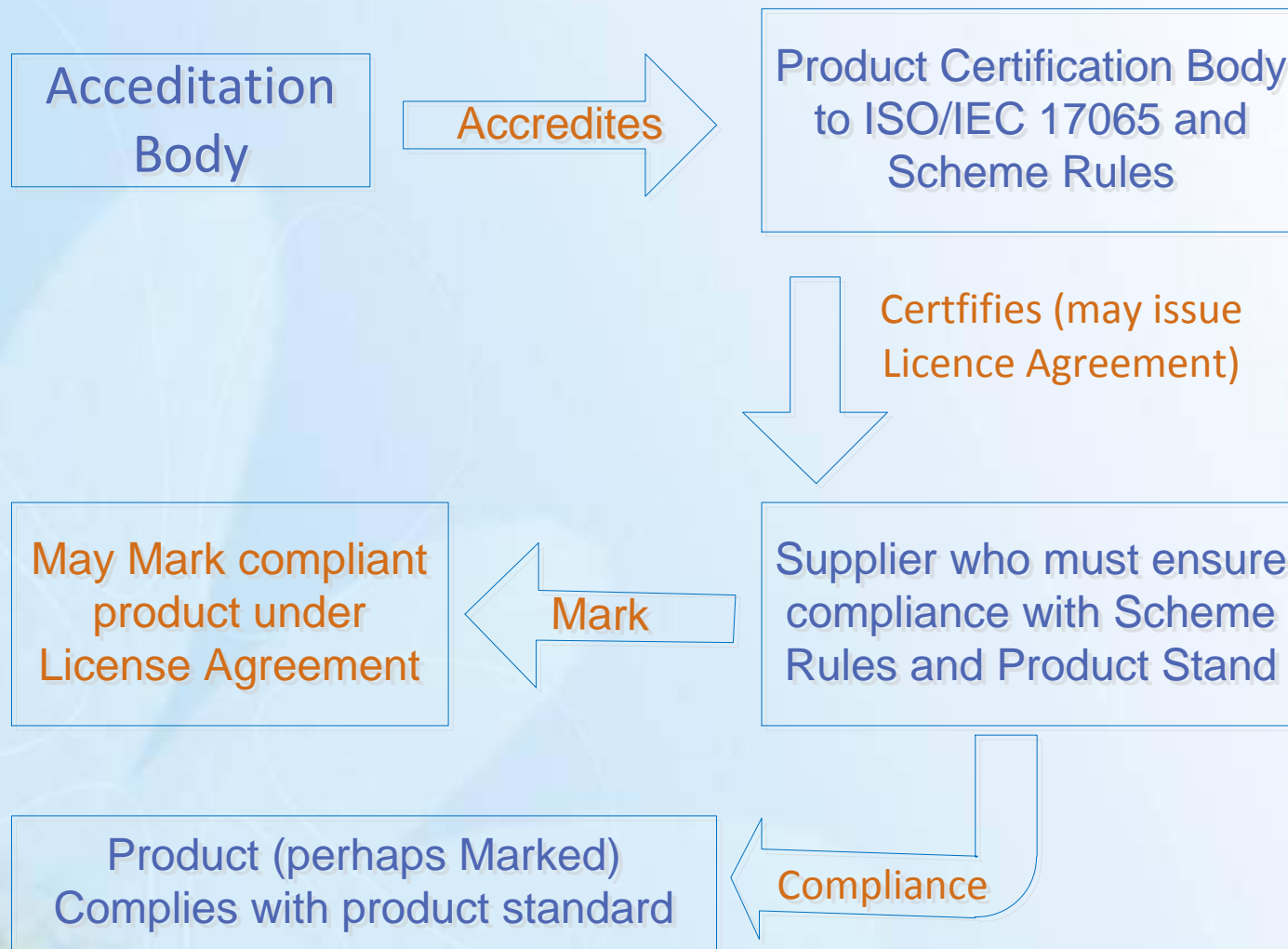
# Objectives of Product Certification

- In keeping with WTO principles, mandatory product certification may be applied to areas of significant concern relating to human or animal safety, health or the environment.
- Voluntary product certification is used for market differentiation.
- It improves acceptability of products by the market.

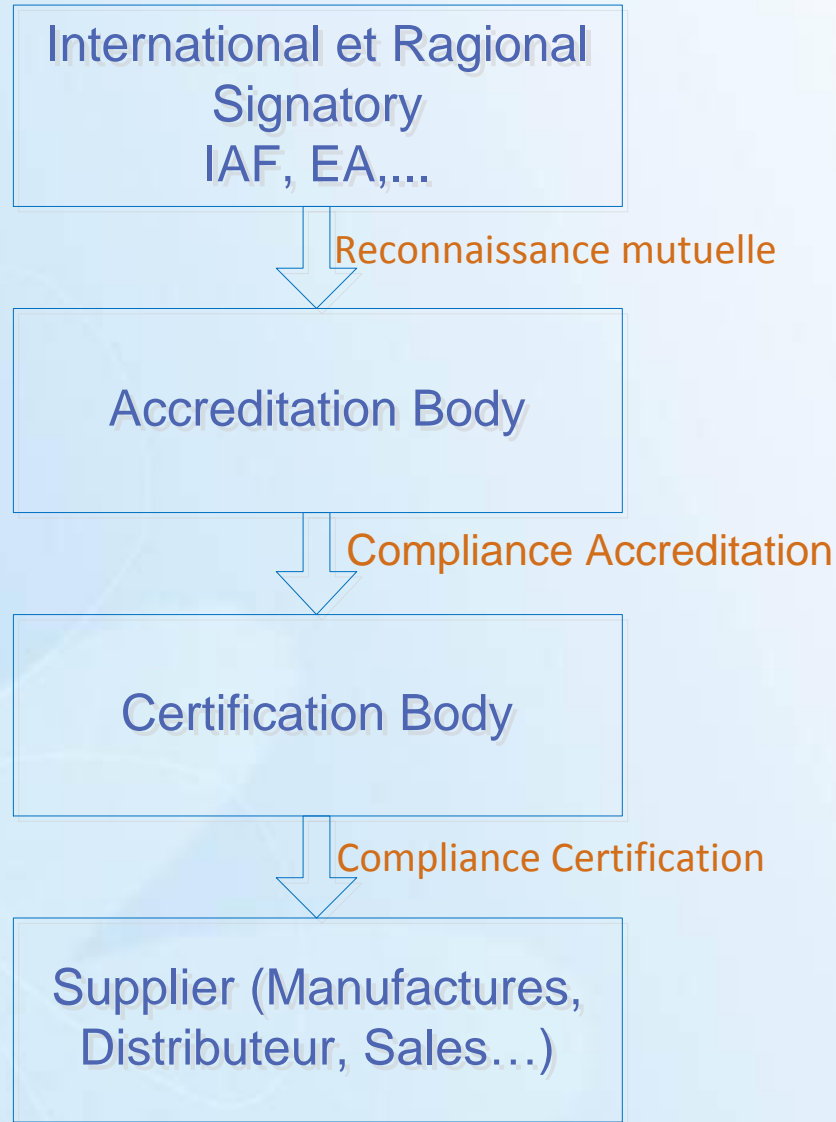
# Objectives of Product Certification cont.

- Three fundamental purposes :
  - Address concerns of consumers, users and all interested parties by instilling confidence that the product fulfills specified requirements.
  - Demonstrate third party (independent) oversight.
  - Not require excessive resources thus raising costs beyond market expectations beyond market expectations.
- Product certification is most successful when it delivers the appropriate level of confidence utilising cost effective resources.

# Accredited Certification



# Accredited Certification



# Factors for mutual recognition

- PAC members respect each others work.
- Mandatory mutual recognition only where IAF/Regional body has endorsed a scheme and/or standard e.g. ISO/IEC 17021; (No scheme); ISO 9001
- Equally reliable –ISO/IEC Guide 65 or ISO/IEC 17065 as applicable
- Equivalent - ISO/IEC Guide 65 or ISO/IEC 17065; a scheme and standard

- Conformity assessment – Requirements for bodies certifying products, processes and services.
- Enables a PCB to demonstrate that it operates in a competent and reliable manner.
- Certification results in the issue of formal certification documentation.
- Certification may result in a licence to use a mark.



- ISO/IEC 17065 identifies requirements that enable PCBs to demonstrate that they are competent and reliable.
- Product can mean tangible products, products, or products resulting from processes or services (Refer ISO/IEC 17065 Annex B).
- ISO/IEC 17065 notes that general guidance for developing schemes is described in ISO/IEC 17067.



# Transition Guide 65 to ISO / IEC 17065

## Legal and financial requirements :

ISO /IEC 17065	Guide 65	Comments
4.1.1 Legal responsibility	4.2 d	
4.3.1 Responsibility and finance - Insurance	4.2 h	a professional liability insurance is mandatory.
4.3.2 Responsibility and finance – financial stability	4.2.i	
4.4 Non-discriminatory conditions	4.1.1/ 4.1.2/ 4.1.4	

# Transition Guide 65 to ISO / IEC 17065

## Contractuel requirements :

ISO /IEC 17065	Guide 65	Comments
4.1.2 Certification agreement	4.2.g/ 8.1.2/ 8.2.1	All contracts with all clients in force must be updated as soon as it lacks a requirement.
4.1.3 Use of license, certificates and marks of conformity	14	Precised on each certification program

# Transition Guide 65 to ISO / IEC 17065

## Impartiality, confidentiality and transparency requirements:

ISO /IEC 17065	Guide 65	Comments
4.2 Management of impartiality	4.2.a/4.2.e/4.2m/4.2.o	
4.5 Confidentiality	4.10	
4.6 Publicly available information	4.8.1.b/4.8.1.c/8.1.1/8.1.3/4.8.1.d/4.8.1.e/4.8.1.f	More accurate
5.2 Mechanism for safeguarding impartiality	4.2.e	More accurate

# Transition Guide 65 to ISO / IEC 17065

## Structural requirements:

ISO /IEC 17065	Guide 65	Comments
5.1 Organisation and management	4.2.e/4.2.l/4.5.3d/ 4.5.3.e/4.2.c/4.2.n	more accurate

# Transition Guide 65 to ISO / IEC 17065

## Resource requirements:

ISO /IEC 17065	Guide 65	Comments
6.1.1 General : CB personal	4.2.j/5.1.1//4.10.1	By personal means persons working for the CB and persons working under individual contracts or as part of a formal agreement placing them under the authority and subject to the rules of the CB (including committee members ).
6.1.2 Management of competence for personnel involved in the certification process	4.5.3.i/5.2.1/5.1.2/ 4.5.3.c/5.2.3	More accurate
6.1.3 Contract with the personnel	5.2.2	All current contracts with all CB personnel must be updated.

# Transition Guide 65 to ISO / IEC 17065

## Resource requirements (cont'd):

ISO /IEC 17065	Guide 65	Comments
6.2.1 Internal resources	4.3	The CB must identify if the resources (internal / external) conduct tests or inspections or audits of systems management activities. If this is the case, it must comply with ISO / IEC 17065 but also the requirements that will be applicable as defined in ISO / IEC 17025/17020/17021. The CB must list the resources and requirements that are applicable, argue restraint selection and implementation.
6.2.2 External resources (outsourcing)	4.4	



# Transition Guide 65 to ISO / IEC 17065

## Process requirements :

ISO /IEC 17065	Guide 65	Comments
7.1 General	1.1/1.2/4.1.3/4.3/8 .1.3	
7.2 Application	8.2	
7.3 Application review	9.1	In particular, the results of the review of the application must be recorded.
7.4 Evaluation	9.2/9.3/9.4/4.3/10/ 4.4/11.b	More accurate
7.5 Review		Now required step in the process: the CB certification process must be completed and CB must define the skills accordingly.
7.6 Certification decision	4.2.b/12.2/4.2.f/12 .1	



# Transition Guide 65 to ISO / IEC 17065

## Process requirements (Cont'd) :

ISO /IEC 17065	Guide 65	Comments
7.7 Certification documentation	12.3	<p>Particular, the conditions for issuing the certificate (7.7.3) must be recorded.</p> <p>The certification document shall list the documents constituting the program or specify the document listing all documents / standards. If the relevant standard (s) test is (are) cited (s) in the product requirements, it is not necessary to (s) mentioned in the certification document.</p> <p>The applicable version of the program for issuing the certification document must be explicit.</p> <p>All certification documents in force must be updated as it lacks a requirement in connection with § 7.10.</p>

# Transition Guide 65 to ISO / IEC 17065

## Process requirements (Cont'd) :

ISO /IEC 17065	Guide 65	Comments
7.8 Directory of certified products	4.8.1.g	Precised on each certification program
7.9 Surveillance	13	
7.10 Changes affecting certification	6/12.4/13.2	The CB must identify the consequences for certification and indicate to clients what he planned to do for each change.

# Transition Guide 65 to ISO / IEC 17065

## Process requirements (Cont'd) :

ISO /IEC 17065	Guide 65	Comments
7.11 Termination, reduction, suspension or withdrawal of certification	4.5.3.l/4.6.1/4.6.2.a/4.6.2.b	The termination must be provided in particular in the rules of the CB.
7.12 Records	4.9	
7.13 Complaints and appeals	4.2.p/4.5.3.m/7	

# Transition Guide 65 to ISO / IEC 17065

## Management system requirements :

ISO /IEC 17065	Guide 65	Comments
8.1 Options	4.2.k	More presice : two options for implantation a management system : option A (requirements of ISO 17065 from 8.2 to 8.8 or option B requirements of ISO 9001)
8.2 General management system documentation (Option A)	4.2.l/4.5.3.h/5.1.2/ 4.8.2	
8.3 Control of documents (Option A)	4.8.2/4.5.3.g/4.5.3 .l.2	

# Transition Guide 65 to ISO / IEC 17065

## Management system requirements (cont'd) :

ISO /IEC 17065	Guide 65	Comments
8.4 Control of records (Option A)	4.9	
8.5 Management review (Option A)	4.5.3.f/4.7.2	
8.6 Internal audits (Option A)	4.5.3.n/4.7.1	In particular, the competences of the internal auditor on the requirements of ISO / IEC 17065 standard must be demonstrated by the CB.
8.7 Corrective actions (Option A)	4.5.3.k	More accurate : Presentation of the processing steps of corrective action
8.8 Preventive actions (Option A)	4.5.3.k	More accurate : Presentation of the processing steps of preventive action

# ISO/IEC 17065 – Overview

- ISO/IEC 17065 identifies requirements that enable PCBs to demonstrate that they are competent and reliable.
- Product can mean tangible products, or products resulting from processes or services (Refer ISO/IEC 17065 Annex B).
- ISO/IEC 17065 notes that general guidance for developing schemes is described in ISO/IEC 17067 (ISO/IEC Guide 67).



# Clause 1 Scope

This International Standard contains requirements for the competence, consistent operation and impartiality of product, process and service certification bodies.

Certification bodies operating to this International Standard need not offer all types of products, processes and services certification. Certification of products, processes and services is a third-party conformity assessment activity.

(See ISO/IEC 17000:2004 definition 5.5)

“Product” can be read as “process” or “service”

See Annex B for details



# Clause 2.0 Normative References

**Both ABs and CABs need copies of these standards :**

- **ISO/IEC 17000** : Conformity assessment -- Vocabulary and general principles
- **ISO/IEC 17021** : Conformity assessment -- Requirements for bodies providing audit and certification of management systems
- **ISO/IEC 17020** : Conformity assessment -- Requirements for the operation of various types of bodies performing inspection
- **ISO/IEC 17025** : General requirements for the competence of testing and calibration laboratories

**Abs** = Assessment Bodies

**CABs** = conformity assesment bodies

# Other Useful References

**Both ABs and CABs can use other references for scheme development :**

- **ISO/IEC Guide 23** :Methods of indicating conformity with standards for third-party certification systems
- **Guide 27** : Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
- **ISO/IEC Guide 28** :Conformity assessment -- Guidance on a third-party certification system for products
- **ISO/IEC 53** : Conformity assessment -- Guidance on the use of an organization's quality management system in product certification
- **ISO/IEC 17007** : Conformity assessment -- Guidance for drafting normative documents suitable for use for conformity assessment

# Other Useful References

**Both ABs and CABs can use other references for scheme development :**

- **ISO/IEC 17030** : Conformity assessment -- General requirements for third-party marks of conformity
- **ISO/IEC 17067** : Conformity assessment -- Fundamentals of product certification and guidelines for product certification schemes
- **ISO/IEC 19011** : Information technology -- Security techniques -- Guidelines for information security management systems auditing
- **ISO 9001** : Quality management systems -- Requirements
- **ISO 9000** : Quality management systems -- Fundamentals and vocabulary

# Clause 3.0 Terms and definitions

- Client
- Consultancy
- Evaluation
- Product
- Process
- Service
- Certification requirement
- Product requirement
- Certification scheme
- Scope of certification
- Scheme owner
- Certification body
- Impartiality

These terms are explained according to ISO 17000 and ISO 9000

# Clause 4 General requirements

# § 4.1 Legal and contractual matters :



## 4.1.1 Legal responsibility :

The certification body shall be a legal entity



# § 4.1 Legal and contractual matters :



## 4.1.2 Certification agreement :

- Legally enforceable agreement for the provision of certification activities
- Agreement shall ensure client to comply with :
  - a) Client always fulfils certification requirements
  - b) Certified product continues to fulfil product requirements
  - c) The client make the necessary arrangements for conducting the evaluation, investigating complaints, and the participation of observers.
  - d) Client only make claims consistent with scope of certification
  - e) Client does not bring the certification body into disrepute or make misleading statements
  - f) Client discontinues the any reference to certification when certification suspended, withdrawn or terminated



# § 4.1 Legal and contractual matters :



## 4.1.2 Certification agreement (cont'd):

- g) Certification documents shall be reproduced full
- h) Client complies with certification body and scheme requirements in communication media
- i) Client to comply with the scheme requirements for use of mark
- j) Client keeps records of complaints relating to certification; takes appropriate action and documents actions taken
- k) Client informs certification body of changes



# § 4.1 Legal and contractual matters :

## 4.1.3 Use of license, certificates and marks of conformity:

- Certification body to exercise control over the use of the mark and other mechanisms to indicate a product is certified.
- Suitable action shall be taken to address misleading information, the misuse of licences, certificates, marks and other mechanisms for indicating the product is certified.

# § 4.2 Management of impartiality:



## 4.2.1 :

Certification shall be impartial

## 4.2.2 :

Certification body responsible for impartiality and not allow financial, commercial or other pressures compromise impartiality.

## 4.2.3 :

Certification body to identify risks to impartiality on an ongoing basis.



## 4.2.4:

Where risk identified, certification body must demonstrate how it eliminates or minimises the risk.

## 4.2.5:

Top management commitment to impartiality.



### 4.2.6 :

Certification body or any part of the same legal entity shall not be involved in the design, manufacture, installation, distribution, or maintenance of the certified product, (Same for processes and services). It cannot offer consultancy or internal auditing.

# § 4.2 Management of impartiality:



## 4.2.7 :

Certification body shall ensure activities of entities with which it has a relationship do not compromise impartiality.

## 4.2.8:

Independence of personnel involved in the review and certification decision making process.



### 4.2.9 :

Certification body's activities not to be linked with an organisation providing consultancy.

Certification body not to state or imply any advantages if specified consultancy used.





### 4.2.10 :

Certification body to specify period during which personnel that were involved in consultancy of a product cannot review or make the certification decision.

### 4.2.11 :

Certification body to respond to any risks to impartiality it becomes aware of.

### 4.2.12 :

All personnel to act impartially.



### 4.3.1:

Certification body shall have adequate arrangements to cover liabilities.

### 4.3.2 :

Certification body shall be financially stable and have the required resources.

# § 4.4 Non-discriminatory conditions



## 4.4.1 :

Policies and procedures shall be non-discriminatory.

## 4.4.2 :

Services to be accessible to all applicants that are in scope of operations.

## 4.4.3 :

Access to certification shall not be conditional.

## 4.4.4 :

Certification body shall confine its certification activities to the scope of certification.

## 4.5.1:

Certification body responsible through legally enforceable commitments.

Information not in public domain considered proprietary.

Certification body to inform client in advance of information intended for the public domain.



## 4.5.2 :

When required by law to release confidential information the client shall be notified.

## 4.5.3 :

Information obtained about the client from other sources shall be treated as confidential.

# § 4.6 Publicly available information



Certification body shall maintain and make available upon request:

- a) Information about certification procedures
- b) a description of how it finances its operations
- c) a description of the rights and duties of  
c) a applicants and clients
- d) Information on complaints and appeals procedures





# Clause 5 Structural requirements

# § 5.1 Organisational structure and top management



## 5.1.1 :

Structure to safeguard impartiality.

## 5.1.2 :

Documented organisational structure.

## 5.1.3 :

Management to identify responsibility for :

- a) development of policies;
- b) supervision of implementation of policies and procedures;
- c) supervision of the finances;
- d) development of certification activities;
- e) development of certification requirements;
- f) evaluation;
- g) review;

## 5.1.1 :

Certification activities shall be structured and managed so as to safeguard impartiality.

## 5.1.2 :

The certification body shall document its organizational structure (duties, responsibilities and authorities).

The structure shall include the line of authority and the relationship to other parts within the same legal entity.



## 5.1.3 :

Management to identify responsibility for :

Related to Management :

- development of policies;
- supervision of implementation of policies and procedures;
- supervision of the finances;
- development of certification activities;
- development of certification requirements;

## 5.1.3

Management to identify responsibility for (Cont'd):

Related to certification process:

- evaluation;
- review;
- decisions on certification;
- delegation of authority to committees or personnel,

## 5.1.3

Management to identify responsibility for (Cont'd): :

Related to resources and competence Management:

- contractual arrangements;
- provision of adequate resources;
- personnel competence requirements;



## 5.1.3

Management to identify responsibility for (Cont'd): :

Related to quality management :

- Responsiveness to complaints and appeals;
- Management system.

## 5.1.4 :

The certification body shall have formal rules for the appointment, terms of reference and operation of any committees that are involved in the certification process (commercial, financial pressures)

### 5.2.1 :

Certification body shall have a mechanism to safeguard impartiality. The mechanism shall provide input on:

- a) policies and procedures relating to impartiality;
- b) Tendencies to allow commercial or other interests to prevent impartiality;
- c) Matters affecting impartiality and confidence in certification;



### 5.2.2 :

The mechanism shall be formally documented :

- a) balanced representation of interests
- b) access to information to fulfil its functions

## § 5.2 Mechanism for safeguarding impartiality



### 5.2.3 :

- Mechanism has right to take independent action if top management does not follow their input.
- Confidentiality to be respected.
- If input not followed management to document reasons.

### 5.2.4 :

Certification body shall have identify and invite significantly interested parties.

# Clause 6 Resource requirements



# § 6.1 Certification body personnel



## 6.1.1 General General :

- Certification body shall employ or have access to a sufficient number of personnel.
- Personnel shall be competent.
- Personnel (Interne et externe) shall ensure confidentiality of all information related of the certification activities.

## 6.1.2 Management of competence for personnel involved in the certification process :

- Procedure for management of competencies required.
- Requires certification body to:
  - a) determining the criteria for competence
  - b) identify training needs and provide training to ensure competence demonstrate personnel have the required competencies
  - c) formally authorise personnel for functions
  - d) monitor performance of personnel

# § 6.1 Certification body personnel

## 6.1.2 Management of competence for personnel involved in the certification process (Cont'd) :

Personnel records to be maintained :

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

### 6.2.1 Internal resources :

When performing evaluation activities certification body shall meet the applicable requirements of the relevant International Standards and other documents as specified by the certification scheme:

- for testing - ISO/IEC 17025;
- for inspection - ISO/IEC 17020; and
- for management system auditing - ISO/IEC 17021.

Impartiality requirements of evaluation personnel stipulated in the relevant standard shall always be applicable.

### 6.2.2 External resources (outsourcing) :

Certification body shall outsource evaluation activities only to bodies that meet the applicable requirements of the relevant International Standards and other documents as specified by the certification scheme:

- for testing - ISO/IEC 17025;
- for inspection - ISO/IEC 17020; and
- for management system auditing - ISO/IEC 17021.

Impartiality requirements of evaluation personnel stipulated in the relevant standard shall always be applicable.

Use of external personnel under contract is not outsourcing.

### 6.2.2 External resources (outsourcing) (cont'd) :

- The certification body shall ensure that the evaluation activities outsourced to non-independent bodies (e.g. client laboratories), are managed in a manner which provides confidence in the results, and records are available to justify the confidence.
- Certification body shall have a legally binding contract with the body that provides the outsourced contract with the body that provides the outsourced service, including provisions for confidentiality and conflict of interest.



### 6.2.2 External resources (outsourcing) (cont'd) :

Certification body shall:

- a) take responsibility for all outsourced activities;
- b) ensure credibility of results of outsourced services are not compromised;
- c) have documented policies, procedures and records for the qualification, assessing and monitoring of all outsourcing bodies;
- d) maintain a list of approved providers of outsourced services;
- e) implement corrective actions for breaches of the contract or other requirements;
- f) inform the client in advance of outsourced activities.

# Clause 7 Process requirements



### 7.1.1:

Certification body shall operate certification schemes.

### 7.1.2 :

Products to be evaluated against requirements specified in standards and other normative documents.

### 7.1.3:

Explanations on application of documents to be formulated by relevant and impartial persons or committees with the necessary technical competence.

## § 7.2 Application



Certification body shall obtain necessary information as required by the certification scheme.

### 7.3.1 :

Certification body to review information to ensure :

- a) sufficient for certification
- b) any known differences are resolved
- c) scope of certification sought is defined
- d) the means to evaluate are available
- e) certification body is both competent and capable

### 7.3.2 :

Certification body to have process to identify when client's request includes product, normative document or certification scheme for which certification body has no prior experience.

### 7.3.3 :

Where 7.3.2 applies, certification body will ensure it has the competence and capability for the certification activities.  
If certification continues records of justification to be maintained;

### 7.3.4 :

Certification body shall decline if not competent and capable.



### 7.3.5 :

If the certification body relies on certifications it has already granted to the client, or has already granted to other clients, to omit any activities, then the certification body shall reference the existing certification(s) in its records.

If requested by the client, the certification body shall provide justification for omission of activities.

## § 7.4 Evaluation

### 7.4.1 :

Certification body shall have a plan for the evaluation activities to allow for the necessary arrangements to be managed.

### 7.4.2 :

Certification body shall assign personnel to perform each evaluation task that it undertakes with its internal resources internal resources.

### 7.4.3 :

Certification body shall ensure all necessary information and/or documentation is made available for performing the evaluation tasks.

### 7.4.4 :

Certification body shall carry out evaluation activities with its internal and outsourced resources in with its internal and outsourced resources in accordance with the evaluation plan.

Products shall be evaluated against requirements covered by the scope of certification and other requirements specified in the certification scheme.

### 7.4.5:

Certification body shall only rely on evaluation results completed prior to the application for certification completed prior to the application for certification.

It takes responsibility for the results and satisfies itself that the body performing the evaluation fulfils the requirements contained in 6.2.2 and those specified by the certification scheme.

### 7.4.6 :

Certification body shall inform the client of all nonconformities.

### 7.4.7 :

If nonconformities have arisen, and client wishes to continue the certification process, certification body shall provide information regarding the additional evaluation tasks needed to verify that nonconformities have been corrected.

### 7.4.8 :

If the client agrees to completion of the additional evaluation tasks, the process specified in 7.4 shall be repeated to complete the additional evaluation tasks.

### 7.4.9:

The results of all evaluation activities shall be documented prior to review.

### 7.5.1 :

Certification body shall assign at least one person to review all information and results related to the evaluation.

Review shall be carried out by person(s) who have not been involved in the evaluation process 7.4.1.





### 7.5.2 :

Recommendations for a certification decision based on the review shall be documented, unless the review and the certification decision are completed concurrently by the same person.

## § 7.6 Certification decision

### 7.6.1 :

Certification body shall be responsible for, and shall retain authority for, its certification decisions.

### 7.6.2 :

One person to be assigned to make the certification decision based on all information related to the evaluation, its review, and any other relevant information.

The certification decision shall be carried out by a person or group of persons that has not been involved in the process for evaluation.

## 7.6.3 :

The person(s) [excluding members of committees] assigned to make a certification decision shall be employed by, or shall be under contract with:

- the certification body; or
- an entity under the organisational control of the certification body.

## 7.6.4 :

Certification body's organizational control shall be:

- whole or majority ownership of another entity;
- majority participation on the board of directors of another entity;
- a documented authority over another entity in a network of legal entities (in which the certification body resides), linked by ownership or board of director control.

### 7.6.5 :

Persons employed by, or under contract with, entities under organizational control shall fulfil the same requirements of this International Standard as persons employed by, or under contract with, the certification body.



### 7.6.6:

Certification body shall notify the client of a decision not to grant certification and shall identify the not to grant certification, and shall identify the reasons for the decision.

# § 7.7 Certification documentation

## 7.7.1 :

Certification body shall provide the client with formal certification documentation that clearly conveys, or permits identification of the following:

- a) the name and address of the certification body;
- b) the date certification is granted;
- c) the name and address of the client;
- d) the scope of certification (see 3 10);
- e) the term or expiry date of certification, if certification expires after an established period;
- f) any other information required by the certification scheme.





### 7.7.2:

Certification documentation shall include the signature or other defined authorization of the signature or other defined authorization of the person(s) of the certification body assigned such responsibility.



## 7.7.3 :

Formal certification documentation shall only be issued after, or concurrent with, the following:

- a) the decision to grant or extend the scope of certification has been made;
- b) certification requirements have been fulfilled;
- c) the certification agreement has been completed/ signed.

## § 7.8 Directory of certified products



The certification body shall maintain information on certified products including:

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

The parts of this information that need to be published or made available upon request in a directory are stipulated by the relevant scheme(s). Certification body shall provide information upon request about the validity of a certification.



### 7.9.1:

If surveillance is required by the certification scheme, or as specified in 7.9.3 or 7.9.4, the certification body shall initiate surveillance of the product(s) covered by the certification decision in accordance with the certification scheme.

### 7.9.2:

When surveillance utilizes evaluation, review or a certification decision, the requirements in 7.4, 7.5 or 7.6, respectively, shall be fulfilled.



### 7.9.3:

When continuing use of a certification mark is authorized surveillance shall be established and shall include periodic surveillance of marked products to ensure ongoing validity of the demonstration of fulfilment of product requirements.



### 7.9.4 :

When continuing use of a certification mark is authorized for a process or service, surveillance shall be established and shall include periodic surveillance activities to ensure ongoing validity of the demonstration of fulfilment of process or service requirements.

# § 7.10 Changes affecting certification



## 7.10.1 :

Certification scheme changes that affect the client, shall be communicated to all clients.

Implementation of the changes to be verified and actions taken as required by the scheme.

## 7.10.2:

Other changes affecting certification to be considered, including changes initiated by the client.

Appropriate action shall be decided.





## 7.10.3

Actions to implement changes affecting certification shall include, if required, the following:

- evaluation (see 7.4);
- review (see 7.5);
- decision (see 7.6);
- issuance of revised formal certification documentation (see 7.7) to extend or reduce the scope of certification;
- issuance of certification documentation of revised surveillance activities (if surveillance is part of the certification scheme).



## 7.10.3 (cont'd)

These actions shall be completed in accordance with applicable parts of 7.4, 7.5, 7.6, 7.7 and 7.8.

Records shall include the rationale for excluding any of the above activities (e.g. when a certification requirement that is not a product requirement changes and no evaluation review or decision activities changes, and no evaluation, review or decision activities are necessary).



### 7.11.1:

When a nonconformity with certification requirements is substantiated the certification body shall consider and decide upon the appropriate action.

### 7.11.2:

When the appropriate action includes evaluation, review or a certification decision, the requirements in 7.4, 7.5 or 7.6, respectively, shall be fulfilled.

### 7.11.3:

If certification is terminated, suspended or withdrawn, the certification body shall take actions y specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure it provides no indication that the product continues to be certified.

### 7.11.3 (cont'd):

If a scope of certification is reduced, the certification, body shall take actions in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

### 7.11.4 :

If certification is suspended, the certification body shall assign one or more persons to formulate and communicate the following to the client:

- actions needed to end suspension and restore certification for the product(s) in accordance with the certification scheme;
- any other actions required by the certification scheme.

These persons shall be competent in their knowledge and understanding of all aspects of the handling of suspended certifications (see 6.1).



### 7.11.5 :

Any evaluations, reviews or decisions needed to resolve the suspension or that are required by the resolve the suspension, or that are required by the certification scheme, shall be completed.



### 7.11.6 :

If certification is reinstated after suspension, the certification body shall make all necessary modifications to ensure all appropriate indications exist that the product continues to be certified. If a decision to reduce the scope of certification is made as a condition of reinstatement, the certification body shall make all necessary modifications... in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified.



### 7.12.1 :

Certification body shall retain records to demonstrate that all certification process requirements have been effectively fulfilled.

### 7.12.2 :

Certification body shall keep records confidential including those being transported, transmitted and transferred.



### 7.12.3:

If the certification scheme involves complete re-evaluation of the product within a determined cycle, records shall be retained for current and previous cycle. Otherwise, records shall be retained for a period defined by the certification body.



### 7.13.1 :

Certification body shall have documented process to receive, evaluate and make decisions on complaints and appeals. Certification body 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 certification body 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:

Certification body shall acknowledge receipt of a formal complaint or appeal.

### 7.13.4:

Certification body shall be responsible for gathering and verifying all necessary information to progress the complaint or appeal to a decision.



### 7.13.5:

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 who have provided consultancy for a client, or been employed by a client, shall not be used by the certification body 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, certification body shall give formal notice of the outcome and the end of the complaint process to the complainant.



### 7.13.8:

Certification body shall give formal notice of the outcome and the end of the appeal process to the appellant.

### 7.13.9 :

Certification body shall take any subsequent action needed to resolve the complaint or appeal. needed to resolve the complaint or appeal.

# Clause 8 Management System requirements

### 8.1.1 General :

A management system capable of achieving the consistent fulfilment of the requirements of this International Standard in accordance with either Option A or Option B shall be established and maintained.



### 8.1.2 Option A :

The management system of the certification body shall address the following:

- general management system documentation (manual, policies, definition of responsibilities, see 8.2);
- control of documents (see 8.3);
- control of records (see 8.4);
- management review (see 8.5);
- internal audit (see 8.6);
- corrective actions (see 8.7);
- preventive actions (see 8.8).

### 8.1.3 Option B : (ISO 9001)

A certification body that has established and maintains a management system, satisfying the requirements of ISO 9001, complies.



### 8.2.1 :

Top management shall establish, document, and maintain policies and objectives for fulfilment of this International Standard and the certification scheme.

They shall ensure policies and objectives are acknowledged and implemented at all levels of the certification body.

### 8.2.2 :

Top management shall provide evidence of its commitment to developing and implementing the management system and its effectiveness in fulfilling this International Standard.

### 8.2.3 :

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that include the following:

- a) ensuring that processes and procedures needed for the management system are established, implemented and maintained;
- b) reporting to top management on the performance of the management system and any need for improvement.

### 8.2.4 :

All documentation, processes, systems, records, etc. shall be included, referenced, or linked to documentation of the management system.

### 8.2.5 :

All personnel involved in certification activities shall have access to the parts of the management system documentation and related information that y are applicable to their responsibilities.

### 8.3.1 :

Procedures to control documents (internal and external) related to the fulfilment of this International Standard shall be established.

### 8.3.2 :

Procedures shall define the controls needed to:

- a) approve documents for adequacy prior to issue;
- b) review, update and re-approve documents;
- c) ensure that changes and the current revision status of documents are identified;
- d) ensure that relevant versions of applicable documents are available at points of use;



### 8.3.2 (cont'd) :

- e) ensure that documents remain legible and readily identifiable;
- f) ensure that documents of external origin are identified and their distribution controlled;
- g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.



### 8.4.1 :

Procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records related to the fulfilment of this International Standard shall be established.

### 8.4.2 :

Procedures for retaining records for a period consistent with contractual and legal obligations shall be established.

Access to these records shall be consistent with confidentiality arrangements.



### 8.5.1 General :

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 fulfilment of this International Standard.



### 8.5.1 General (cont'd):

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 shall be maintained.

### 8.5.2 Review inputs:

Input to management review shall include the following:

- a) results of internal and external audits;
- b) feedback from clients and interested parties;
- 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 fulfilment of objectives;
- g) changes that could affect the management system;
- h) appeals and complaints.

### 8.5.3 Review inputs:

Outputs from 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 certification body related to the fulfilment of this International Standard;
- c) resource needs.

### 8.6.1 :

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 shall be established.



### 8.6.2 :

An audit programme 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 the frequency of internal audits or the time frame in which internal audits shall be completed.



### 8.6.3 (cont'd) :

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 Certification body 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; 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.



### 8.7.1 :

Certification body shall establish procedures for identification and management of nonconformities in its operations.

### 8.7.2 :

Certification body shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence in order to prevent recurrence.

### 8.7.3 :

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



### 8.7.4 :

Procedures for corrective actions shall define requirements for the following: 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.



### 8.8.1:

Certification body 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 probable impact of the potential problems.





### 8.8.3:

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.

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



- Impartiality :
  - CB to be impartial to give confidence
  - Risks to impartiality
- Competence
- Confidentiality and openness
- Responsiveness to complaints and appeals
- Responsibility



- Application to processes
- Application to services

End

Thank you

Any Questions?