



**National Accreditation Board for  
Certification Bodies (NABCB)**



# **Overview of ISO/IEC 17065: 2012**

**Conformity assessment-  
*Requirements for bodies certifying  
products, processes and services*  
&  
ISO/IEC 17067:2013**

## Basic drivers for product, process and service certification:

- ✓ Provide consumers (users) of products with sufficient information to allow them to make informed decisions on products and services;
- ✓ Assist the suppliers of certified products to achieve market acceptance. If the product has a recognizable mark on it, consumers may be more willing to make the purchase;
- ✓ Product certification plays a role in regulated products (subject to technical regulations);
- ✓ Assists manufactures in selecting the components for their own products;
- ✓ Retailers have confidence in the products they are selling

- ❖ The overall aim of certifying products, processes or services is to give confidence to all interested parties that a product, process or service fulfils specified requirements.
- ❖ The value of certification is the degree of confidence and trust that is established by an impartial and competent demonstration of fulfilment of specified requirements by a third party.
- ❖ **Interested Parties but not limited to:**
  - ✓ the clients of the certification bodies;
  - ✓ the customers of the organizations whose products, processes or services are certified;
  - ✓ governmental authorities;
  - ✓ non-governmental organizations; and
  - ✓ consumers and other members of the public

**Interested parties can expect or require the certification body to meet all the requirements of this International Standard as well as when relevant, those of the certification scheme**

# Introduction.....continued

- ✓ This International Standard specifies requirements, the observance of which is intended to ensure that **certification bodies operate certification schemes in a competent, consistent and impartial manner, thereby facilitating the recognition of such bodies** and the acceptance of certified products, processes and services on a national and international basis and so **furthering international trade**.
- ✓ This International Standard **does not set requirements for schemes and how they are developed and is not intended to restrict the role or choice of scheme owners, however scheme requirements should not contradict or exclude any of the requirements of this International Standard**.
- ✓ Statements of conformity to the applicable standards or other normative documents can be in the form of certificates and/or marks of conformity. Schemes for certifying particular products or product groups, processes and services to specified standards or other normative documents will, in many cases, require their own explanatory documentation.

- ✓ 1. Scope
- ✓ 2. Normative references
- ✓ 3. Terms and Definitions
- ✓ 4. General Requirements
- ✓ 5. Structural Requirements
- ✓ 6. Resource Requirements
- ✓ 7. Process Requirements
- ✓ 8. Management system requirements
- ✓ Annex A (informative) Principles for product certification bodies and their certification activities
- ✓ Annex B (informative) Application of this International Standard for processes and services

## Scope of ISO 17065:

- ISO 17065 contains requirements for the
  - ✓ Competence,
  - ✓ Consistent operation, and
  - ✓ Impartialityof product certification bodies.

***Product” can be read as  
“process” or “service”  
-Refer Annex B for details***

- Certification of products is a third-party conformity assessment activity.

# **Annex B (Informative)**-Application of ISO 17065 for processes & services

## **When applying this Standard to the certification of processes:**

- replace “product(s)” with “process(es)”;
- replace “production” with “operation”;
- replace “produced” with “operated”;
- replace “producing” with “operating”.

## **When applying this Standard to the certification of services:**

- replace “product(s)” with “service(s)”;
- replace “production” with “provision”;
- replace “produced” with “provided”;
- replace “producing” with “providing”.



- ❖ ISO 17065 is generally concerned with third parties providing product, process or service certification.
- ❖ However, many of its provisions can also be used for first- and second-party product conformity assessment procedures.
- ❖ ISO 17065 uses following verbal forms:
  - “shall” indicates a requirement;
  - “should” indicates a recommendation;
  - “may” indicates a permission;
  - “can” indicates a possibility or a capability.



The following referenced documents are indispensable for the application of ISO 17065:

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

# Clause 3.0 Terms & definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and those given in ISO 17065 apply

❖ **3.1 Client** - organization or person responsible to a certification body for ensuring that **certification requirements** (3.7), including **product requirements** (3.8), are fulfilled

*(Note- Whenever the term “client” is used in this International Standard, it applies to both the “applicant” and the “client”, unless otherwise specified)*

❖ **3.2 Consultancy** - Participation in

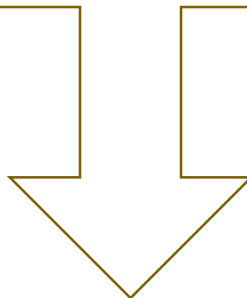
- ✓ the designing, manufacturing, installing, maintaining or distributing of a certified product or a product to be certified, or
- ✓ the designing, implementing, operating or maintaining of a certified process or a process to be certified, or
- ✓ the designing, implementing, providing or maintaining of a certified service or a service to be certified

# Clause 3.0 Terms & definitions

**NOTE** In this standard, the term “consultancy” is used in relation to activities of certification bodies, personnel of CBs & organizations related or linked to CBs.

**3.3 Evaluation** - Combination of the **selection** and **determination** functions of conformity assessment activities.

***Note** - The selection and determination functions are specified in  
**ISO/IEC 17000:2004, Clauses A.2 and A.3***



## **Clause A.2 of ISO/IEC 17000:2004 – Selection**

Selection involves planning & preparation activities in order to collect or produce all the information and input needed for the subsequent determination function.

- ❖ Selection activities vary widely in number and complexity. In some instances, very little selection activity may be needed.
- ❖ It also covers selection of the object of conformity assessment, including sampling – selection of samples from ongoing production; a continuous process or a system; from numerous location.
- ❖ A standard, pre-existing selection criteria (sampling) may be used if appropriate.
- ❖ It should generally provide answers for questions - what types product to be sampled, what frequency, what to be inspected, where.
- ❖ Selection may also include choice of the most appropriate procedures to be used for determination activities, i.e. testing methods or inspection methods.
- ❖ Also, a determination activity may be a review of information alone, and that information must be identified and collected.
- ❖ Can be generic or for particular evaluation activity

## Clause A.3, ISO 17000:2004 – Determination

- ❖ Determination activities are undertaken to develop complete information regarding fulfilment of the specified requirements by the **object of conformity assessment** or its sample. Some types of determination activities are defined in Clause 4.
- ❖ All outputs from the determination function are represented as “**information on fulfilment of specified requirements**”.
- ❖ The **main determination activities associated with Product Certification are - *Testing, Inspection and Audit, alone or in combination.*** There could be some others also like examination or analysis of a design.
- ❖ The output is a combination of all the information created through determination activity, as well as all input to the determination function. Output is usually structured **to facilitate review & attestation activities**

## Review (5.1 of ISO 17000) :

Verification of the suitability, adequacy & effectiveness of selection & determination activities, & the results of these activities, with regard to fulfilment of **specified requirements by an object** of conformity assessment.

**-It constitutes the final stage of checking before taking the decision as to whether or not the object of conformity assessment has been reliably demonstrated to fulfil the specified requirements.**

**Attestation (5.2 of ISO 17000)** - issue of a statement, based on a decision following review (5.1), that fulfilment of specified requirements has been demonstrated.

- ✓ **Attestation** results in a “statement of conformity” in a form that most readily reaches all of the potential users.
- ✓ If fulfilment of specified requirements has not been demonstrated, the finding of nonconformity may be reported.
- ✓ Thus, a “Product certification system” is a conformity assessment system that includes selection, determination, review and finally certification as the attestation activity.



## 3.4 Product - Result of a process

**Note 1** - *Four generic product categories in ISO 9000:2005*

- *services (e.g. transport) (see definition in 3.6);*
- *software (e.g. computer program, dictionary);*
- *hardware (e.g. engine, mechanical part);*
- *processed materials (e.g. lubricant).*

*Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element.*

**NOTE 2** - *Products include results of natural processes, such as growth of plants and formation of other natural resources.*

**NOTE 3** - *Adapted from ISO/IEC 17000:2004, definition 3.3.*

### 3.5 Process - Set of interrelated or interacting activities which transforms inputs into outputs

**Examples**-Welding engineering processes; heat treatment processes; manufacturing processes requiring confirmation of process capability (e.g. operating or producing product within specified tolerances); food production processes; plant growth processes.

**Note** - Adapted from ISO 9000:2005, definition 3.4.1.

### 3.6 Service - Result of at least one activity necessarily performed at the interface between the supplier and the customer, which is generally intangible

**NOTE 1** - Provision of a service can involve, for example:

- an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);
- an activity performed on a customer-supplied intangible product (income statement needed to prepare a tax return);

- *the delivery of an intangible product (the delivery of information in the context of knowledge transmission);*
- *the creation of ambience for the customer (e.g. in hotels and restaurants).*

**NOTE 2** - Adapted from ISO 9000:2005, definition 3.4.2.

**3.7 Certification requirement** - Specified requirement, including **product requirements**, that is fulfilled by the **client** as a condition of establishing or maintaining certification

**NOTE** Certification requirements include requirements imposed on the client by the CB [usually via the certification agreement (see 4.1.2)] to meet this Standard, & can also include requirements imposed on the client by the certification scheme. “Certification requirements”, as used in this Standard, do not include requirements imposed on the CB by the certification scheme.

## 3.7 Contd.

**EXAMPLE** - The following are certification requirements that are not product requirements:

- completing the certification agreement;
- paying fees;
- providing information about changes to certified product;
- providing access to certified products for surveillance activities.

**3.8 Product requirement** - Requirement that relates directly to a product, specified in standards or in other normative documents identified by the certification scheme.

**NOTE** *Product requirements can be specified in normative documents such as regulations, standards and technical specifications.*

❖ **3.9 Certification scheme** - certification system related to specified products, to which the same specified requirements, specific rules and procedures apply.

**NOTE 1** Adapted from ISO/IEC 17000:2004, definition 2.8.

**NOTE 2** A “certification system” is a “conformity assessment system”, which is defined in ISO/IEC 17000:2004, definition 2.7.

**NOTE 3** The rules, procedures and management for implementing product, process and service certification are stipulated by the certification scheme.

**NOTE 4** General guidance for the development of schemes is given in ISO/IEC 17067, in combination with ISO/IEC Guide 28 & ISO/IEC Guide 53.

**Conformity assessment system** (Cl 2.7 of ISO 17000) - rules, **procedures** (3.2) and management for carrying out **conformity assessment** (2.1).

**NOTE:** *Conformity assessment systems may be operated at international, regional, national or sub-national level.*

“Certification system” is a conformity assessment system that includes selection, determination, review and finally certification as the attestation activity.

# Clause 3.0 Terms & definitions

## ❖ 3.10 Scope of certification - Identification of:

- the product(s), process(es) or service(s) for which the certification is granted,
- the applicable certification scheme, and
- the standard(s) and other normative document(s), including their date of publication, to which it is judged that the product(s), process(es) or service(s) comply.

## ❖ 3.11 Scheme owner - person or organization responsible for developing and maintaining a specific **certification scheme** (3.9)

❖ **NOTE** *The scheme owner can be the certification body itself, a governmental authority, a trade association, a group of certification bodies or others.*

## ❖ 3.12 Certification body - third-party conformity assessment body operating certification schemes.

❖ **NOTE** *A certification body can be non-governmental or governmental (with or without regulatory authority)*



## 3.13 Impartiality - Presence of objectivity.

**NOTE 1** - *Objectivity is understood to mean that conflicts of interest do not exist, or are resolved so as not to adversely influence the activities of the body.*

**NOTE 2** - *Other terms that are useful in conveying the element of impartiality are independence, freedom from conflicts of interest, freedom from bias, freedom from prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment & balance.*

❖ **Conformity Assessment (CA)** - demonstration that specified requirements relating to a product, process, system, person or body are fulfilled (cl 2.1 of ISO/IEC 17000:2004)

**NOTE 1** - The CA activities testing, inspection and certification, as well as the accreditation of conformity assessment bodies.

**NOTE 2** - “Object of conformity assessment” or “object” cover any particular material, product, installation, process, service, system, person or body to which CA is applied.

❖ **Conformity Assessment Body** - body that performs conformity assessment services.

**NOTE** - An accreditation body (2.6) is not a conformity assessment body

# Continued....

❖ **Accreditation body** - authoritative body that performs **accreditation**.

**NOTE** The authority of an accreditation body is generally derived from government.

❖ **Accreditation** - third-party **attestation** (issue of a statement, based on review and decision that the **fulfilment of specified requirements** (3.1) has been demonstrated) **related to a conformity assessment body conveying formal demonstration** of its competence to carry out specific conformity assessment tasks

# Clause 4 General requirements

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- ❖ **4.1 Legal and Contractual Matters**
- ❖ **4.2 Management of Impartiality**
- ❖ **4.3 Liability and financing**
- ❖ **4.4 Non-discriminatory Conditions**
- ❖ **4.5 Confidentiality**
- ❖ **4.6 Publically Available Information**

## ❖ 4.1 Legal and contractual matters

**4.1.1 Legal responsibility** - The certification body (CB) shall be a legal entity, or a defined part of a legal entity, such that the legal entity can be held legally responsible for all its certification activities.

***Note** A governmental CB is deemed to be a legal entity on the basis of its governmental status*

## 4.1.2 Certification agreement

**4.1.2.1** Legally enforceable agreement for the provision of certification activities to its clients. Responsibilities of CB & its clients to be taken in to account.

# Clause 4 General requirements

## 4.1.2.2 Agreement shall ensure client to comply with:

- a) the client always fulfils the 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 CB into disrepute or make misleading statements
- f) Client discontinues the any reference to certification when certification suspended, withdrawn or terminated
- g) Certification documents shall be reproduced in full
- h) Client complies with CB's & scheme requirements in communication media
- i) Client to comply with the scheme requirements for use of mark. (*Refer ISO 17030, ISO Guide 23 & 27*)
- j) Client keeps records of complaints relating to certification; takes appropriate action & documents actions taken
- k) Client informs CB of changes

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

**4.1.3.1** CB to exercise control (as per certification scheme, where relevant) over use & display of licenses, certificates, marks of conformity, etc, indicating a product is certified. (also refer ISO Guide 23 and ISO 17007)

**4.1.3.2** Suitable action shall be taken to address misleading information, misuse of licences, certificates, marks & other means for indicating product is certified (refer ISO Guide 27).



## 4.2 Management of impartiality

4.2.1 Certification activities to be undertaken impartially.

4.2.2 CB shall be responsible for impartiality & not allow commercial, financial/other pressures to compromise.

4.2.3 CB shall identify risks to its impartiality on an **ongoing basis**. This shall include the risks from

- its activities,
- from its relationships,
- the relationships of its personnel (see 4.2.12).

**NOTE 1** Relationship can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing/branding & payment of a sales commission/other inducement for referral of new clients, etc

# Extracts from Annex A (Informative)

**Risks to impartiality include bias** that may arise from the following:

- ❖ **Self-interest** (e.g. overdependence on a contract for service or the fees, or fear of losing the client);
- ❖ **Self-review** (e.g. performing a conformity assessment activity in which the CB);
- ❖ **Advocacy** (e.g. a CB or its personnel acting in support of, or in opposition to);
- ❖ **Over-familiarity**, i.e. risks that arise from a CB or its personnel being overly familiar or too trusting, instead of seeking evidence of conformity;
- ❖ **Intimidation** (e.g. the CB or its personnel can be deterred from acting impartially from fear);
- ❖ **Competition** (e.g. between client & a contracted person)

**4.2.4** Where risk identified, CB shall be able to demonstrate how it eliminates/minimises the risk.

**4.2.5** Shall have top management commitment to impartiality.

**4.2.6** CB or any part of same legal entity shall not

- Be involved in the design, manufacture, installation, distribution, or maintenance of the certified product/process/services.
- Provide consultancy to its clients
- Provide MS consultancy or internal auditing, where certifications scheme covers management system auditing.

**4.2.7 CB (or the legal entity)** shall ensure that the activities of entities with which it has a relationship do not compromise impartiality.

**4.2.8** Independence of personnel involved in the management of CB and review and certification decision making process, from the activities of the separate legal entity involved in consultancy and vice-a-versa.

# Clause 4 General requirements

**4.2.9** CB's activities not to be marketed/offered as linked with an organisation providing consultancy. CB not to state or imply any advantages if specified consultancy used

**4.2.10** CB to specify period during which personnel that were involved in consultancy of a product cannot review or make the certification decision. *A period of two years is often used.*

**4.2.11** CB shall respond and take actions when it becomes aware of risks to impartiality due to actions of others.

**4.2.12** All CB personnel (internal & external) or committees who could influence the certification activities shall act impartially.

## ❖ **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.

# Clause 4 General requirements

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

## **4.4 Non-discriminatory conditions**

**4.4.1** CB's policies & procedures shall be non-discriminatory. Procedures not to be used to impede or inhibit access by applicants, except those specified in ISO 17065.

**4.4.2** Services of CB shall be accessible to all applicants within CB's scope of operations.

**4.4.3** Access to the certification process shall not be conditional – size of client, membership of association; no undue financial/other conditions.

**4.4.4** CB shall confine its certification activities & requirements to the scope of certification.

# Clause 4 General requirements

## 4.5 Confidentiality

**4.5.1** Certification body responsible through legally enforceable commitments. Information not in public domain considered proprietary.

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

**4.5.2** When required by law/authorized by contract to release confidential information the client shall be notified of information provided.

**4.5.3** Information about client obtained from other sources (complainant/regulator) to be treated as confidential.

## 4.6 Publicly available information

CB shall maintain & make available upon request:

- a. Information on certification scheme & evaluation process, for certification, granting, maintaining, extending, suspension, withdrawal, etc.
- b. A description of how it finances its operations and general information about fees charged
- c. description of the rights & duties of applicants & clients, including requirements of use of CB's name, certification mark & certificate
- d. Information on procedures for handling of complaints & appeals

# Clause 5 Structural requirements

## 5.1 Organization Structure and Top Management

## 5.2 Mechanism for safeguarding

### 5.1 Organizational structure and top management

5.1.1 Certification activities shall be structured & managed to safeguard impartiality.

5.1.2 CB shall document:

- ✓ its organizational structure,
- ✓ duties, responsibilities & authorities of management & other certification personnel & any committees.
- ✓ a structure that shall include the line of authority and the relationship to other parts within the same legal entity, when the CB is a defined part of a legal entity



# Clause 5 Structural requirements

## 5.1.3 CB management to identify a board, group of persons, or person with overall authority & responsibility for the following:

- a) development of policies relating to operation of CB;
- b) supervision of implementation of policies & procedures;
- c) supervision of the finances of the CB;
- d) development of certification activities;
- e) development of certification requirements;
- f) evaluation (see 7.4);
- g) review (see 7.5);
- h) decisions on certification (see 7.6);
- i) delegation of authority to committees or personnel;
- j) contractual arrangements;
- k) provision of adequate resources for certification activities;
- l) responsiveness to complaints & appeals;
- m) personnel competence requirements;
- n) management system of the CB (see Clause 8).

# Clause 5 Structural requirements

**5.1.4** The CB shall have formal rules for appointment, terms of reference & operation of any committees that are involved in the certification process.

- Such committees shall be free from any commercial, financial & other pressures that might influence decisions. The CB shall retain authority to appoint and withdraw members of such committees.

## **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:

# Clause 5 Structural requirements

## 5.2.1 Contd.....

- a) the policies and principles relating to the impartiality;
- b) any tendency of CB to allow commercial or other considerations to prevent impartiality in certification activities;
- c) matters affecting impartiality & 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 CBs, 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.*

# Clause 5 Structural requirements

**Note 4** *If the CB also provides management systems certification, a committee that fulfils ISO/IEC 17021:2011, can also fulfill this sub-clause providing that all the requirements of 5.2 are met.*

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

a) a balanced representation of interests.

**No single interest to predominate (internal or external personnel of the CB are considered to be a single interest);**

b) access to all the information necessary to enable it to fulfill all its functions.

**5.2.3** Mechanism shall have right to take independent action (informing authorities, stakeholders, ABs) if top management does not follow inputs.

- Confidentiality to be respected.

Inputs, in conflict with operating procedures of CB or other mandatory requirements may not be followed,

# Clause 5 Structural requirements

❖ Management to document reasons for above.

**5.2.4 CB** shall have identified and invited significantly interested parties.

**Note** - *Interested parties - clients of CB, customers of clients, manufacturers, suppliers, users, CA experts, industry/trade associations, governmental regulatory bodies/services, NGO's consumer organizations.*

## ❖6.1 Certification Body Personnel

## ❖6.2 Resource for Evaluation

### 6.1 Certification body personnel

#### 6.1.1 General

**6.1.1.1** The CB shall employ, or have access to, a sufficient number of personnel to cover its scope of operations and certification schemes.

**Note:** The personnel include *those normally working for the CB*, as well as *persons working under an individual contract or a formal agreement that places them within the management control and systems/procedures of the CB (see 6.1.3).*

❖**6.1.1.2** The personnel shall be competent for the functions they perform, including making required technical judgments, defining policies and implementing them.

# Clause 6 Resource Requirements

❖ **6.1.1.3 Personnel**, including any committee members, personnel of external bodies, or personnel acting on the CB's behalf, shall keep confidential all information, except as required by law or by the certification scheme.

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

**6.1.2.1** CB shall establish, implement and maintain a procedure for management of competencies of personnel involved in certification process, which shall require CB to:

- a) determine the criteria for the competence of personnel for each function in the certification process, taking into account the requirements of the schemes;
- b) identify training needs and provide the same. Include training programs on certification processes, requirements, methodologies & relevant certification scheme requirements;

## Clause 6.1.2.1 Contd.

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- c) demonstrate that the personnel have the required competencies as per duties undertake;
- d) formally authorize personnel for functions in the certification process;
- e) monitor the performance of the personnel.



## 6.1.2.2 **Personnel records** to be maintained:

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

**6.1.3 Contract with the personnel** - Personnel involved in certification process to sign contract or other document committing them to:

- Comply with rules defined by CB for confidentiality & independence from commercial or other interests;
- declare prior/present associations which are considered to be conflict of interests (consultancy -supplier/designer of products);
- reveal any situation known that may present a conflict of interest

CB shall use this information as input to identifying risks to impartiality, individual as well as due to organizations employing them.

## 6.2 Resources for evaluation

**6.2.1 Internal resources** - When performing evaluation activities (with internal resources or resources under its direct control), CB shall meet the applicable requirements of relevant standards & the scheme;

- For testing - applicable requirements of ISO 17025;
- For inspection - applicable requirements of ISO 17020;
- For MS auditing - the applicable requirements of ISO 17021.

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

## 6.2.2 External resources (outsourcing)

**6.2.2.1** The CB shall **outsource evaluation activities** only to bodies that meet the applicable requirements of the relevant International Standards & other documents specified by the certification scheme.

- For testing - applicable requirements of ISO 17025;
- For inspection - applicable requirements of ISO 17020;
- For MS auditing - applicable requirements of ISO 17021.

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

**Note 1** *Examples of reasons as to why some requirements are not applicable include the following:*

- *expertise is available within the CB when using the results of the evaluation activity;*
- *the extent of control the CB has over testing (including witnessing the testing), inspection (e.g. specifying inspection methods or parameters) or management system assessment (e.g. requiring specific details of a management system);*
- *a particular requirement is covered in an equivalent way by this International Standard, or is not needed to give confidence in the certification decision.*

**Note 2** *This can include outsourcing to other CBs. Use of external personnel under contract is not outsourcing.*

**Note 3** *For the purposes of this Standard, the terms “outsourcing” & “subcontracting” are synonyms.*

# Continued....

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

**6.2.2.3** 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).

**6.2.2.4 The certification body shall:**

- a) take responsibility for all outsourced activities;
- b) ensure that the body that provides outsourced services, and the personnel that it uses, are not involved, either directly or through any other employer, in such a way that the credibility of the results could be compromised;
- c) have documented policies, procedures and records for the qualification, assessing and monitoring of all outsourced activities and bodies providing it;

## Clause 6.2.2.4 continued:

- d) maintain a list of approved providers of outsourced services;
- e) implement corrective actions for any breaches of the contract or other requirements;
- f) inform the client in advance of outsourcing activities, in order to provide the client with an opportunity to object.

**Note** *If the qualification, assessing and monitoring of the bodies that provide outsourced services are performed by other organizations (e.g. by ABs, peer assessment bodies or governmental authorities), the CB can take this qualification and monitoring into account provided that:*

- *it is provided for within the scheme requirements;*
- *the scope is applicable to the work being undertaken;*
- *the validity of the qualification, assessing and monitoring arrangements is verified at a periodicity determined by the CB.*

# Clause 7 Process Requirements

- ❖ 7.1 General
- ❖ 7.2 Application
- ❖ 7.3 Application review
- ❖ 7.4 Evaluation
- ❖ 7.5 Review
- ❖ 7.6 Certification decision
- ❖ 7.7 Certification documents
- ❖ 7.8 Directory of certified products
- ❖ 7.9 Surveillance
- ❖ 7.10 Changes Affecting Certification
- ❖ 7.11 Termination, reduction, suspension or withdrawal of certification
- ❖ 7.12 Records,      7.13 Complaints and appeals



# Clause 7 Process Requirements

## 7.1 General

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

**Note** - Refer ISO 17067 and ISO Guide 28 & 53 for guidance on development of schemes.

**7.1.2** Products shall be evaluated against requirements specified in standards and other normative documents. (Refer ISO 17007)

**7.1.3** Explanations on application of documents, if required shall be formulated by relevant and impartial persons or committees with the necessary technical competence and shall be made available to client.

**7.2 Application-** CB shall obtain all the necessary information to complete the certification process in accordance with the relevant certification scheme.

**Note 1** Examples of necessary information:

- ✓ the product(s) to be certified;
- ✓ the standards for which the client is seeking certification (see 7.1.2);
- ✓ client's general features, name and address(es) of physical location(s), its process & operations & relevant legal obligations;
- ✓ information relevant to the field of certification - client's activities, its human & technical resources, laboratories and/or inspection facilities, its functions & relationship in a larger corporation, if any;
- ✓ **information of outsourced processes**, contractual arrangements and controls exercised by client;
- ✓ all other information needed in accordance with the relevant certification/scheme requirements

**Note 2** A variety of media and mechanisms can be used to collect this information at various times, including an application form. Such information gathering can be in conjunction with, or separate from, the completion of the legally binding agreement (the certification agreement) specified in 4.1.2.

**Note 3** Application for an extension of the certification scope could involve similar products, different locations, etc.

### 7.3 Application review

**7.3.1 CB to** review of application information to ensure:

- a) Sufficiency of information for conduct of certification process;
- b) any known difference in understanding are resolved;
- c) the scope of certification sought is defined;
- d) **means are available to perform all evaluation activities;**
- e) the CB has the competence and capability to perform the certification activity

## 7.3 Application review

- 7.3.2** CB shall have process to identify when client's request includes product, normative document or certification scheme for which CB has no prior experience.

**Note** Products can be considered to be of the same type when the knowledge of requirements, characteristics and technology related to one product is sufficient to understand requirements, characteristics & technology of another product.

- 7.3.3** In such cases, CB shall ensure it has the competence & capability for certification activities it will be required to undertake and maintain record of justification for decision to continue.

- 7.3.4** **CB shall decline if not competent & capable.**

- 7.3.5** If the CB relies on certifications it has already granted to the client, or has already granted to other clients, to omit any activities, then the CB shall reference the existing certification(s) in its records. If requested by the client, the CB shall provide justification for omission of activities.

## 7.4 Evaluation

**7.4.1** The CB shall have a plan for the evaluation activities to allow for the necessary arrangements to be managed.

**Note** Depending on the characteristics of the certification scheme and the product requirements, the plan can be either a generic plan applicable to all activities, including evaluation of the quality management system, when applicable, or a specific one for a particular activity, or a combination of both.

**7.4.2** The CB shall assign personnel to perform each evaluation task that it undertakes with its internal resources (see 6.2.1).

**NOTE** Outsourced tasks are completed by personnel usually assigned by the organization to which the task is outsourced. Such personnel are not normally assigned by the CB.

## 7.4 Evaluation

**7.4.3** The CB shall ensure all necessary information and/or documentation is made available for performing the evaluation tasks.

**NOTE** *The evaluation tasks can include activities such as design and documentation review, sampling, testing, inspection and audit.*

**7.4.4** CB shall carry out the evaluation activities that it undertakes with its internal resources (6.2.1) & manage outsourced resources (6.2.2) as per the evaluation plan.

✓ The products shall be evaluated against requirements covered by scope of certification & certification scheme requirements.

**7.4.5** CB shall only rely on evaluation results of certification completed prior to application, where it can take responsibility for the results & satisfies itself that the body that performed the evaluation fulfils requirements contained in 6.2.2 & those specified by the certification scheme.

**NOTE** This can include work carried out under recognition agreements between CBs.

**7.4.6** CB shall inform client of all nonconformities.

**7.4.7** If nonconformities have arisen, and if the client wishes to continue the certification process, CB 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.

**Note 1** This documentation can provide an opinion as to whether product requirements (including requirements such as those for the quality management system under which the product is produced, if required by the certification scheme) have been fulfilled.

**Note 2** The certification scheme can indicate whether the evaluation is performed by the CB, under its responsibility, or is performed prior to the application (see 7.2) for the certification process. In the latter case, the requirements of 7.4 are not applicable.

## 7.5 Review

**7.5.1** The CB shall assign at least one person to review all information and results related to the evaluation.

✓ The review shall be carried out by person(s) who have not been involved in the evaluation process.

**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** The CB shall be responsible for, and shall retain authority for, certification decision.

**7.6.2** At least one person to be assigned to make 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 (a committee 5.1.4) that has not been involved in the process for evaluation.*

**Note** The review and the certification decision can be completed concurrently by the same person or group of persons.

**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 CB (see 6.1);
- Or an entity under the organizational control of the CB.

**7.6.4** A CB's organizational control shall be one of following:

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

**NOTE** - For governmental CB, other parts of the same government can be considered to be “linked by ownership” to the CB.

**7.6.5** The persons employed by, or under contract with, entities under organizational control shall fulfill the same requirements of this Standard as persons employed by, or under contract with the CB.

**7.6.6** The CB shall notify the client of a decision not to grant certification, and shall identify the reasons for the decision.

**Note-** If the client expresses interest in continuing the certification process, the CB can resume the process for evaluation from step at clause 7.4.

## **7.7 Certification documentation**

**7.7.1** The CB shall provide the client with formal certification documentation that clearly conveys, or permits identification of the following:

- a) the name and address of the CB;
- b) the date certification is granted (which shall not precede date of completion of certification decision);

- c) the name and address of the client;
- d) the scope of certification (see 3.10);

*Note- Where the standard(s) or other normative documents to which conformity is being certified include reference to other standards, these do not need to be included in the formal certification documentation.*

- 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 person(s) of the CB 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 CB shall maintain information on certified products including:

- 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.

These requirements are also generally stipulated in the relevant certification schemes, including the means of making the information public. As a minimum, 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.

## 7.9 Surveillance

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

**Note 1** Refer ISO 17067 for types of surveillance activities.

**Note 2** The criteria & process for surveillance activities are generally defined by each certification scheme.

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

**7.9.3** When continuing use of a certification mark on a certified product is authorized, surveillance shall be established & shall include periodic surveillance of marked products to ensure ongoing validity of the demonstration of fulfillment 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 fulfillment of process or service requirements.

## **7.10 Changes affecting certification**

**7.10.1** When the certification scheme introduces new or revised requirements that affect the client, CB shall ensure these communication of changes all clients. e Implementation of changes to be verified by the CB actions taken as required by the scheme.

**Note** *Contractual arrangements with clients to ensure implementation of these requirements.*

**7.10.2** Other changes affecting certification to be considered, including changes initiated by the client. Appropriate actions to be decided by CB.

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

**7.10.3** The 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).

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. No evaluation, review & decision activities necessary, when a certification requirement that is not a product requirement changes

## 7.11 Termination, reduction, suspension or withdrawal of certification

**7.11.1** When a nonconformity with certification requirements is substantiated, (in surveillance or otherwise), the CB shall consider and decide upon the appropriate action.

**Note** Appropriate action can include:

- a) continuation of certification under conditions of increased surveillance;
- b) reduction in the scope of certification to remove NC product type;
- c) suspension of the certification pending remedial action by the client;
- d) withdrawal of the certification.

**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 (by request of the client), suspended or withdrawn, the CB shall take actions 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.
- ✓ If a scope of certification is reduced, CB to take actions as above , in order to ensure the reduced scope of certification is clearly communicated to the client & clearly specified in certification documentation & public information.

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

- actions needed to end suspension & restore certification for the product(s) in accordance with 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 certification scheme, shall be completed in accordance with the applicable parts of 7.4, 7.5, 7.6, 7.7.3, 7.9 and 7.11.3.

**7.11.6** If certification is reinstated after suspension, the CB shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order 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 CB shall take all above 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.

## 7.12 Records

- 7.12.1 CB shall retain records to demonstrate that all certification process requirements have been effectively fulfilled (also see 8.4).
- 7.12.2 CB shall keep records confidential, including during the process of transportation/transmission.
- 7.12.3 If the certification scheme involves complete re-evaluation of the product(s) within a determined cycle, records shall be retained for the current and the previous cycle. Otherwise, records shall be retained for a period defined by the CB.

## 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.

CB shall record & track complaints & appeals, as well as actions undertaken to resolve them.

**7.13.2** Upon receipt of a complaint or appeal, CB shall confirm whether it relates to certification activities it is responsible for & 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 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) independent of the relevant certification activities.

- ❖ **7.13.6** Personnel who provided consultancy for a client, or been employed by a client, shall not be used to review or approve the resolution of a complaint or appeal within two years following the end of 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.

# Clause 8 Management System

## 8.1 Options

**8.1.1 General** - Establish and maintain a management system capable of achieving consistent fulfillment of requirements of ISO 17065 as per Option A or Option B.

**8.1.2 Option A** - The management system of the CB shall address following:

- general management system documentation (e.g. 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 - A CB that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfillment of the requirements of ISO 17065, fulfils the management system clause requirements (see 8.2 to 8.8).

**Note-** *Option B is included to enable a CB which operates a management system in accordance with ISO 9001 to use that system to demonstrate fulfilment of the management system requirements in 8.2 to 8.8 of this International Standard. Option B does not require that the CB's management system is certified to ISO 9001.*

## 8.2 General management system documentation (Option A)

**8.2.1** CB's top management shall establish, document, & maintain policies & objectives for fulfillment of ISO 17065 & the certification scheme.

Shall ensure the policies & objectives are implemented at all levels of the CB's organization.

**8.2.2 Top management** shall provide evidence of its commitment to the development & implementation of the management system and its effectiveness in achieving consistent fulfillment of ISO 17065.

**8.2.3** The CB's 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, related to the fulfillment of the requirements of ISO 17065, 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, as applicable to their responsibilities.

### **8.3 Control of documents (Option A)**

**8.3.1** Procedures to control the documents, internally generated & external origin, shall be established.

**8.3.2** Procedures shall define the controls needed to:

- a) approve documents for adequacy prior to issue;
- b) review and update & re-approve documents;
- c) ensure identification of changes & current revision status;
- d) ensure availability of relevant versions at points of use;
- e) ensure that documents remain legible & readily identifiable;
- f) ensure identification & distribution control of external documents;

g) prevent the unintended use of obsolete documents, & to apply suitable identification if retained for any purpose.

**NOTE** Documentation can be in any form or type of medium.

## **8.4 Control of records (Option A)**

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

**8.4.2** Procedures for retaining records (see 7.12) for a period, consistent with its contractual and legal obligations shall be established.

Access to records shall be consistent with the confidentiality arrangements.

## 8.5 Management review (Option A)

### 8.5.1 General

#### 8.5.1.1 CB's top management shall establish procedures

to review management system at planned intervals,

to ensure its continuing suitability, adequacy and effectiveness and the stated policies and objectives related to the fulfillment of this standard.

#### 8.5.1.2 Reviews to be conducted at least once a year. Or 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** - Input to the management review shall include information related to following:

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

**8.5.3 Review outputs** - 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 CB related to the fulfillment of this International Standard;
- c) resource needs.

## **8.6 Internal audits (Option A)**

**8.6.1** Procedures for internal audits to be established:

to verify that it fulfils the requirements of this International Standard and that the management system is effectively implemented and maintained

**NOTE** - Refer ISO 19011 for guidance.

**8.6.2** Audit program to be planned, taking into consideration importance of processes & areas to be audited, as well as the results of previous audits.

## 8.6 Internal audits (Option A)

### 8.6.1 Procedures for internal audits to be established:

to verify that it fulfils the requirements of this International Standard and that the management system is effectively implemented and maintained.

**NOTE** - Refer ISO 19011 for guidance.

### 8.6.2 Audit program to be planned, taking into consideration importance of processes & 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.

### 8.6.4 The CB shall ensure that:

- a) internal audits are conducted by personnel knowledgeable in certification, auditing and the requirements of ISO 17065;
- b) auditors do not audit their own work;

#### ❖ 8.6.4 Contd.

- 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.

### **8.7 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 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.

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

- a) identifying nonconformities;
- b) determining the causes of nonconformity;
- d) correcting nonconformities;
- e) evaluating the need for corrective actions for preventing recurrence;
- f) determining and implementing the actions needed in a timely manner;
- g) recording the results of actions taken;
- h) reviewing the effectiveness of corrective actions.



## 8.8 Preventive actions (Option A)

**8.8.1** The CB shall establish procedures for taking preventive actions (PAs) to eliminate 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 PAs shall describe:

- a) identifying potential nonconformities and their causes;
- b) evaluating the need for action to prevent the reoccurrence of nonconformities;
- c) determining and implementing the action needed;
- d) recording the results of actions taken;
- e) reviewing the effectiveness of the PAs taken.

NOTE Procedures for CAs and PAs can be same

# **Annex A (Informative) Principles for product CBs & their certification activities**

**A.1.1** 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 & trust that is established by an impartial & competent demonstration of fulfillment of specified requirements by a third party. Parties that have an interest in certification include, but are not limited to the following:

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

## A.1.2 The principles for inspiring confidence are:

- A.2 Impartiality
- A.3 Competence
- A.4 Confidentiality and openness (including Access to information)
- A.5 Responsiveness to complaints and appeals
- A.6 Responsibility

**Responsibility of the AB** – Ensuring that only competent and impartial CB's are accredited and that the schemes have the capability of fulfillment of the principle stated in A.6.2

# ISO/IEC 17067:2013

Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes

## 4. Objectives of Product certification

**The fundamental objectives of product certification are:**

- a) to address the needs of consumers, users and all interested parties by giving confidence regarding fulfilment of specified requirements;
- b) to allow suppliers to demonstrate to the market that their product has been attested to fulfil specified requirements by an impartial third party body.

## 5. Product Certification Scheme

**Product certification schemes to implement the functional approach as described in ISO/IEC 17000:2004, Annex A. The functions are:**

**Selection** - planning & preparation activities in order to collect or produce all the information and input needed for the subsequent determination function;

**Determination** - Conformity assessment (CA) activities such as testing, inspection, design appraisal, auditing, etc, to provide information regarding product requirements as input to review & attestation functions;

NOTE - In ISO/IEC 17065, functions of “selection” and “determination” are combined & referred as “evaluation”.

**Review** - verification of the suitability, adequacy & effectiveness of selection and determination activities, and the results of these activities, with regard to fulfillment of specified requirements.

**Decision** on certification;

## 5. Product Certification Scheme

**Attestation** - Issue of a statement of conformity, based on review & decision, that fulfillment of specified requirements has been demonstrated.

**Surveillance** - systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity.

**Whenever Product Certification is performed a Certification Scheme is in place.**

### 5.2 Functions and activities in product certification schemes

Product certification schemes are developed by defining specific activities for each of the applicable functions.

**Table 1** shows how to build a product certification scheme by using these functions, and outlines some of the combinations of activities in use in the wide range of fields where product certification is employed.

The types of product certification schemes are further described in clause 5.3.



# Types of Scheme

## Scheme Type 1a

- ✓ One or more samples of the product are subjected to determination activities
- ✓ Certification of conformity or statement of conformity issued
- ✓ Subsequent production items are not covered
- ✓ Samples are representatives of subsequent production items

## Scheme Type 1b

- ✓ Involves the certification of a whole batch of products, following selection and determination as specified in the scheme
- ✓ The proportion to be tested, which can include testing of all the units in the batch (100% testing)
- ✓ If the outcome of the determination, review and decision is positive, all items in the batch may be described as certified
- ✓ Mark of conformity to be affixed if scheme defines

## Scheme Type 2

- ✓ Market Surveillance and subjecting them to determination
- ✓ May identify the impact of distribution channel on conformity of the product
- ✓ when significant nonconformities are found, effective corrective measures may be limited since the product has already been distributed to the market

# Types of Scheme.....

## Scheme Type 3

- ✓ Involves periodically taking samples of the product from the point of production and subjecting them to determination activities
- ✓ Surveillance includes periodic assessment of the production process
- ✓ When serious nonconformities are found, the opportunity may exist to resolve them before widespread market distribution occurs

## Scheme Type 4

- ✓ Choice between periodically taking samples from the point of production or Market or from both and subjecting them to determination activities
- ✓ Surveillance includes periodic assessment of the production process
- ✓ Impact of the distribution channel on conformity and provide a premarket mechanism to identify and resolve serious nonconformities

## Scheme Type 5

- ✓ Choice between periodically taking samples from the point of production or from the Market subjecting them to determination activities
- ✓ Surveillance includes periodic assessment of the production process or audit of the management system or both

# Types of Scheme.....

## Scheme Type 6

- ✓ Applicable for **Services** and **Processes**
- ✓ Although services are considered as being generally intangible, the determination activities are not limited to the evaluation of intangible elements (e.g. effectiveness of an organization's procedures, delays and responsiveness of the management).
- ✓ In some situations, the tangible elements of a service can support the evidence of conformity e.g. *inspection of the cleanliness of vehicles for the quality of public transportation*
- ✓ As far as processes are concerned, the situation is very similar e.g. the determination activities for welding processes can include testing and inspection of samples of the resultant welds, if applicable.
- ✓ Surveillance part should include periodic audits of the management system and periodic assessment of the service or process

## Conformity assessment functions and activities<sup>a</sup> within product certification schemes

## Types of product certification schemes

<sup>c</sup>

		1a	1b	2	3	4	5	6	N <sup>d,b</sup>
I)	<b>Selection</b> , including planning and preparation activities, specification of requirements, e.g. normative documents, and sampling, as applicable	x	x	x	x	x	x	x	x
II)	<b>Determination of characteristics</b> , as applicable by:	x	x	x	x	x	x	x	x
	a) Testing								
	b) inspection								
	c) design appraisal								
	d) assessment of services or processes								
	e) other determination activities, e.g. verification								
III)	<b>Review</b> 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	x
IV)	<b>Decision on certification</b> Granting, maintaining, extending, reducing, suspending, withdrawing certification	x	x	x	x	x	x	x	x
V)	<b>Attestation, licensing</b>								
	a) Issuing a certificate of conformity or other statement of conformity (attestation)	x	x	x	x	x	x	x	x
	a) Granting the right to use certificates or other statements of conformity	x	x	x	x	x	x	x	
	c) Issuing a certificate of conformity for a batch of products		x						
	c) granting the right to use marks of conformity (licensing) is based on surveillance (VI) or certification of a batch.		x	x	x	x	x	x	
VI	<b>Surveillance</b> , as applicable (see 5.3.4 to 5.3.8), 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) assessment of the production, the delivery of the source or the operation of the process				x	x	x	x	
	d) Management system audits combined with random tests or inspections						x	x	

# Other useful References for Development of Schemes

## Useful references for scheme development

- ❖ ISO/IEC 17007: 2009 (Guidance for drafting normative documents suitable for use for conformity assessment) – Referred in Note under clause 7.1.2
- ❖ ISO/IEC 17067: 2013 (Fundamentals of product certification and guidelines for product certification schemes) - Referred in Note 1 under clause 7.9.2
- ❖ ISO/IEC TR 17026: 2015 Conformity assessment -- Example of a certification scheme for tangible products (Guide 53)
- ❖ ISO/IEC 17030: 2003 (Requirements for third-party marks of conformity use of marks) - Referred in Note 1 of cls. 4.1.3.1

# Thank You!!

## National Accreditation Board for Certification Bodies (NABCB) Quality Council of India

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