CABPUB/67/CDV

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2012-07-10

INTERNATIONAL ELECTROTECHNICAL COMMISSION

DRAFT ISO/IEC CONFORMITY ASSESSMENT PUBLICATIONS THROUGH THE IEC CONFORMITY ASSESSMENT BOARD (CAB)

SUBJECT

ISO/IEC DIS 17067, Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes

BACKGROUND

Following its meeting held in April 2012, CASCO WG 32*, Fundamentals of product certification, Revision of ISO/IEC Guide 67*, agreed to process the Committee Draft (CD) 17067 to DIS ballot.

The Draft International Standard (DIS) ISO/IEC 17067 and voting report on the CD are enclosed.

IEC's weekly closing date being on Friday, the deadline for voting on ISO/IEC DIS 17067 has been determined so as to be as close as possible to the one set for ISO NBs, i.e. 2012-12-07.

Note to IEC NCs*:* should you have any comments, please use the attached IEC commenting template and please clearly state whether your comments are identical to the ones sent to ISO/CASCO.

ACTION

National Committees are invited to vote on CABPUB/67/CDV using the IEC voting system by **2012-12-07**.

National Committees are strongly encouraged to consult the IECEE, IECQ and IECEx communities in their country when developing their national position on this draft.

DRAFT INTERNATIONAL STANDARD ISO/IEC 17067

CASCO Secretariat: **ISO/CS**

Voting begins on **2012-07-05** Voting terminates on **2012-12-05**

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

Évaluation de la conformité — Éléments fondamentaux de la certification de produits et lignes directrices pour les schémas de certification de produits

(Revision of ISO/IEC Guide 23:1982, ISO Guide 27: 1983, ISO/IEC Guide 28: 2004, ISO/IEC Guide 53:2005 and ISO/IEC Guide 67:2004)

ICS 03.120.20

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

This draft is submitted to a parallel enquiry in ISO and a CDV vote in the IEC.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC 17067 was prepared by Technical Committee ISO/TC , *CASCO*, Subcommittee SC , .

This second/third/... edition cancels and replaces the first/second/... edition (), [clause(s) / subclause(s) / table(s) / figure(s) / annex(es)] of which [has / have] been technically revised.

Introduction

This International Standard describes the fundamentals of product certification and provides guidelines for product certification schemes. In this International Standard references to 'product' can also be read to mean 'services' or 'processes'.

As products are designed, produced, distributed, used and ultimately disposed of, they may give rise to concerns with purchasers, users and society in general. Such concerns could relate to safety, health or environmental impacts, durability, compatibility, suitability for intended purposes or for stated conditions.

Generally these concerns are addressed by specifying the required product attributes in a normative document such as a standard.

The supplier of the product then has the task of demonstrating that the product conforms to the requirements of the standard.

It might be sufficient for the supplier to assess and self-declare their product's conformity, but in other cases the user or a regulatory authority may require that conformity be assessed by an impartial third party.

Impartial third party assessment and attestation of the product is referred to as product certification.

This International Standard outlines how schemes for product certification can be structured and managed. It identifies common assessment techniques that are used as a basis for product certification, such as product testing, inspection and auditing.

This International Standard is for those involved with product certification, particularly those who are, or are considering becoming, product certification scheme owners. Product certification scheme owners can include:

product certification bodies;

government and regulators;

purchasing agencies;

non-government organisations;

industry and retail associations; and

consumer organisations.

ISO/IEC 17067 is guidance only and does not contain requirements. It is compatible with ISO/IEC 17065 that specifies requirements for product certification bodies.

In this International Standard, the following verbal forms are used:

"should" indicates a recommendation;

"may" indicates a permission;

"can" indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

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

1 Scope

This International Standard describes the fundamentals of product certification and provides guidelines for understanding, developing, operating or maintaining certification schemes for products, processes and services.

It is intended for use by all with an interest in product certification and especially by certification scheme owners.

NOTE 1 In this International Standard the term "product" can be read as “product", "process" or "service", except in those instances where separate provisions are stated for "processes" or "services". Definitions of product, process and service are given in ISO/IEC 17065.

NOTE 2 The certification of products, processes and services is a third-party conformity assessment activity (see ISO/IEC 17000) carried out by product certification bodies. The requirements for product certification bodies are specified in ISO/IEC 17065

2 References

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles.*

ISO/IEC 17065:201x, *Conformity assessment — Requirements for bodies certifying products, processes and services*

3 Terms and definitions

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

3.1
certification system
rules, procedures and management for carrying out certification

NOTE Adapted from ISO/IEC 17000:2004 clause 2.7

3.2
certification scheme
certification system (3.1) related to specified products, to which the same specified requirements, specific rules and procedures apply

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

[ISO/IEC 17065 3.9]

3.3
scheme owner
person or organization responsible for developing and maintaining a specific certification scheme (3.2)

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

[ISO/IEC 17065 3.11].

4 Product certification

4.1 Concept of product certification

4.1.1 Product certification is the provision of impartial third-party attestation that fulfilment of specified requirements has been demonstrated. Product certification is carried out by product certification bodies which should conform to ISO/IEC 17065. Specified requirements for products are generally contained in standards or other normative documents.

4.1.2 Product certification is an established conformity assessment activity that provides assurance to consumers, regulators, industry and other interested parties that products conform to specified requirements, including for example product performance, safety, interoperability and sustainability.

4.1.3 Product certification can facilitate trade, market access, fair competition and consumer acceptance of products on a national, regional and international level.

4.2 Objectives of product certification

4.2.1 The fundamental objectives of product certification are to:

a) address the needs of consumers, users and, more generally, all interested parties by giving confidence regarding fulfilment of specified requirements;

b) allow suppliers to demonstrate to the market that their product has been attested to fulfil specified requirements by an impartial third party body.

4.2.2 Product certification should provide confidence for those with an interest in fulfilment of requirements and product certification should provide sufficient value so that suppliers can effectively market products. Product certification is most successful when it delivers the required confidence while utilizing the fewest possible resources thereby maximizing value.

5 Product certification schemes

5.1 Basics

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

- **selection** which includes planning and preparation activities in order to collect or produce all the information and input needed for the subsequent determination function;
- **determination** which may include assessment activities such as testing, measuring, inspection, design appraisal, assessment of services, and auditing to provide information regarding the product requirements as input to the review and attestation functions;
- **review** which means verification of the suitability, adequacy and effectiveness of selection and determination activities, and the results of these activities, with regard to fulfilment of specified requirements (clause 5.1 of ISO/IEC 17000);
- **decision** on certification;
- **attestation** which means issue of a statement of conformity, based on a decision following review, that fulfilment of specified requirements has been demonstrated (clause 5.2 of ISO/IEC 17000);
- **surveillance** (where needed) which means systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity (clause 6.1 of ISO/IEC 17000).

NOTE 1 Further information about the functions can be found in ISO/IEC 17000.

NOTE 2 In ISO/IEC 17065, the functions selection and determination have been combined and are named evaluation.

NOTE 3 In ISO/IEC 17065, the function of "attestation" is related to the subclause on "certification documentation".

5.1.2 Whenever product certification is performed a certification scheme (3.2) is in place.

5.2 Functions and activities in product certification schemes

5.2.1 Product certification schemes are developed by defining specific activities for each of the applicable functions described in subclause 5.1.1 The following Table 1 specifies 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 in table 1 are further described in 5.3.

5.2.2 Clause 6 describes the process for deciding on which activities to use for a given situation and the factors to be taken into account in making the decision.

Table 1 — Building a product certification scheme

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

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

[b] A product certification scheme includes at least the activities 1), 2), 3) 4) and 5a).

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

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

5.3 Types of product certification schemes

5.3.1 General

The following examples do not represent all possible types of product certification schemes. They may be used with many types of requirements and may utilize a wide variety of statements of conformity (Note 1 to ISO/IEC 17000 clause 5.2). All types of product certification scheme involve selection, determination, review, decision and attestation. One or more determination activities should be selected from among those in Table 1 considering the product and the specified requirements. The types of schemes referred to in Table 1 differ

according to which surveillance activities (if applicable) are carried out. For scheme types 1a and 1b, no surveillance is required since the attestation relates only to the product items which have been subjected to the determination activities. For the other scheme types, the clauses 5.3.4 to 5.3.8 outline the way in which the different surveillance activities can be used and the circumstances to which they could be applicable.

5.3.2 Scheme Type 1a

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

5.3.3 Scheme Type 1b

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

5.3.4 Scheme Type 2

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

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

5.3.5 Scheme Type 3

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

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

5.3.6 Scheme Type 4

The surveillance part of this scheme allows for the choice between periodically taking samples of the product from the point of production or from the market or both and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements. The surveillance includes periodic assessment of the production process.

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

5.3.7 Scheme Type 5

The surveillance part of this scheme allows for the choice between periodically taking samples of the product either from the point of production or from the market, or both, and subjecting them to determination activities

to check that items produced subsequent to the initial attestation fulfil the specified requirements. The surveillance includes periodic assessment of the production process or audit of the management system or both. The extent to which the four surveillance activities are conducted may be varied for a given situation as defined in the scheme. In the case where the surveillance includes audit of the management system, an initial audit of the management system will be needed.

5.3.8 Scheme Type 6

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

Although services are considered as being generally intangible, the determination activities are not limited to the evaluation of intangible elements (for instance effectiveness of an organization's procedures, delays and responsiveness of the management). In some situations the tangible elements of a service can support the evidence of conformity indicated by the assessment of processes, resources and controls involved. For example inspection of the cleanliness of vehicles for the quality of public transportation.

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

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

6 Development and operation of a product certification scheme

6.1 General

This clause provides guidelines on how to develop and operate a product certification scheme. It is particularly relevant to those persons and organisation that are contemplating the establishment of a scheme or acting as a stakeholder (e.g. manufacturer, service provider, certification body, customer or public authorities).

6.2 Relationship between product certification scheme and product certification system

The product certification scheme will use defined rules, procedures and management which could be unique to the scheme or could be defined in a product certification system applicable to a number of schemes. It is always necessary to have a product certification scheme but only necessary to separately define a product certification system if the same rules, procedures and management are to be used for more than one scheme.

Fig.1a Unique product certification scheme

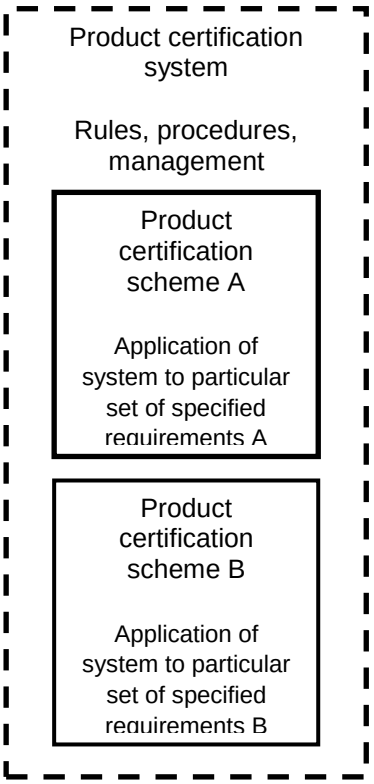

Fig.1b Product certification system relating to several schemes

Fig.1 Relationship between product certification scheme and product certification system

6.3 Scheme owner

6.3.1 The following main types of scheme owners can be identified:

a) Certification bodies which develop a product certification scheme for sole use of their clients;

b) Organizations such as a regulatory body or a trade association not being a certification body which develop a product certification scheme in which one or more certification bodies participate.

NOTE A group of certification bodies, perhaps in different countries, might together set up a certification scheme. In that case it would be necessary for the certification bodies, as joint owners of the scheme, to create a management structure so that the scheme could be operated effectively by all participating certification bodies.

6.3.2 If it was found necessary to operate several schemes which used the same rules, procedures and management, the scheme owner could set up a product certification system under which the different schemes could operate without the need for replicating the management structure for each scheme. In that case the scheme owner would become the system owner and be responsible for the management of the system and the schemes operating within it.

6.3.3 The scheme owner should be a legal entity.

NOTE A governmental scheme owner is deemed to be a legal entity on the basis of its governmental status.

6.3.4 The scheme owner should be able to take on full responsibility for the objectives, the content and the integrity of the scheme.

6.3.5 The scheme owner should maintain the scheme and provide guidance when required.

6.3.6 The scheme owner should set up a structure for the operation and management of the scheme.

6.3.7 The scheme owner should document the content of the scheme.

6.3.8 The scheme owner should ensure that the scheme is developed by persons competent in both technical and conformity assessment aspects.

6.3.9 The scheme owner should make arrangements to protect the confidentiality of information provided by the parties involved in the scheme.

6.3.10 The scheme owner should evaluate and manage the risks/liabilities arising from its activities.

NOTE Evaluating risks does not imply risk assessments to ISO 31000.

6.3.11 The scheme owner should have adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its activities.

NOTE Arrangements should be appropriate for the range of activities and schemes undertaken and in the geographic regions in which the scheme operates.

6.3.12 The scheme owner should have the financial stability and resources required for it to fulfil its role in the operation of the scheme.

6.4 Development of product certification schemes

6.4.1 Product certification schemes can be developed for different purposes. Such purposes may include schemes established by regulators to achieve health, safety or environmental outcomes. Other schemes may have the purpose of assisting clients and consumers to differentiate products in the market place and make informed purchasing decisions.

6.4.2 Irrespective of the purpose, scheme owners should understand the assumptions, influences and consequences involved in establishing, operating and maintaining a scheme on an ongoing basis.

6.4.3 In developing a scheme, the scheme owner should have a clear understanding of the objectives of the scheme and the assumptions that underlie the need for, and the acceptance of, the scheme. To assist in this the scheme owner should be able to identify stakeholders and seek their opinions and participation in scheme development.

6.4.4 Before developing the specific content of the scheme (see clause 6.5), fundamental scheme principles should be agreed among the stakeholders. Such principles may include confirmation of the ownership structure, confirmation of the governance and decision making mechanisms that may or may not provide for direct involvement of stakeholders, confirmation of the underlying business and funding model, and providing an outline for monitoring and periodic review of the scheme.

6.4.5 Once developed, the scheme owner should ensure that information about the scheme is made publicly available to ensure transparency, understanding and acceptance. To ensure that the scheme remains relevant, the scheme owner should ensure that the scheme is regularly reviewed following a process that includes stakeholders.

6.5 Content of a scheme

6.5.1 General

A product certification scheme should specify the following elements:

a) the scope of the scheme, including e.g. the type of products covered.

b) the requirements against which the products are evaluated, by reference to standards or other normative documents. Where it is necessary to elaborate upon the requirements to remove ambiguity, the explanations should be formulated by competent people and should be made available to all interested parties;

NOTE Further guidance on how to formulate specified requirements is provided in ISO/IEC 17007.

c) the selection of the activities (see Table 1) appropriate to the purpose and the scope of the scheme. As a minimum, a certification scheme should include the functions and activities 1, 2, 3, 4 and 5a);

d) other requirements to be met by the client, for example the operation of a management system or process control activities to assure the demonstration of fulfilment of specified requirements is valid for the ongoing production of certified products;

e) the requirements for certification bodies and other conformity assessment bodies involved in the certification process. These requirements should not be in contradiction to the requirements of the applicable standards for conformity assessment bodies;

f) whether conformity assessment bodies involved in the scheme (e.g. testing laboratories, inspection bodies, product certification bodies, bodies auditing manufacturers' management systems) are to be accredited, participate in peer assessment or qualified in another manner. If the scheme is to require that conformity assessment bodies are accredited, the appropriate references should be specified, e.g. that the accreditation body is a member of a recognized multilateral recognition arrangement;

g) the content of the statement of conformity (e.g. certificate) which unambiguously identifies the product to which it applies;

h) the conditions under which the client may use the statement of conformity or marks of conformity;

i) where marks of conformity may be used, the ownership, use and control of the marks. The requirements of ISO/IEC 17030 should be applied;

j) the methods and procedures to be used by the conformity assessment bodies and other organizations involved in the certification process, so as to assure the integrity and consistency of the outcome of the conformity assessment process;

k) the resources required for the operation of the scheme including impartiality and competence of the personnel (internal and external), evaluation resources, and the use of subcontractors;

l) the information to be supplied to the certification body by an applicant for certification;

m) how the results of the determination (evaluation) and surveillance stages are to be reported and used by the certification body and the scheme owner;

n) the question of how non-conformities with the certification requirements, which include product requirements, are to be dealt with;

o) surveillance procedures, where surveillance is part of the scheme;

p) the criteria for access of conformity assessment bodies to the scheme and for the access of clients to the scheme;

q) content, conditions and responsibility for publication of the directory of certified products by the certification body or the scheme owner;

r) the need for, and content of contracts for example between scheme owner and certification body, scheme owner and clients, certification body and clients. The rights, responsibilities and liabilities of the various parties should be defined in contracts;

NOTE example contract between a certification body and its clients can be found in ISO/IEC Guide 28:2004 Annex B.

s) general conditions for granting, maintaining, continuing, extending the scope of, reducing the scope of, suspending, withdrawing, certification. This includes requirements for discontinuation of advertising and return of certification documents and any other action if the certification is suspended, withdrawn or terminated;

t) the way in which the clients' complaints records are to be verified if such verification is part of the scheme;

u) the way in which the clients make reference to the scheme in their publicity material;

v) retention of records by scheme owner and certification bodies.

6.5.2 Sampling

Where applicable, the scheme should define the extent to which sampling of the product to be certified is required, and on what basis such sampling should be undertaken both at the selection and surveillance stages. The scheme should define when sampling is required and who is permitted to undertake it.

NOTE Useful information on this topic can be found for example in ISO 10576-1 Statistical methods -- Guidelines for the evaluation of conformity with specified requirements -- Part 1: General principles, ISO 2859 Sampling procedures for inspection by attributes, ISO 3951 Sampling procedures for inspection by variables and ISO 22514, Statistical methods in process management -- Capability and performance.

6.5.3 Acceptance of conformity assessment results

In some cases, clients might have obtained the results of determination activities such as testing, inspection or auditing, prior to making an application for certification. In such a situation, the conformity assessment result may be from a source not within the contractual control of the certification body. The scheme should define whether and under what conditions such conformity assessment results can be considered in the certification process.

6.5.4 Outsourcing of the conformity assessment activities

If the scheme permits outsourcing (subcontracting) of conformity assessment activities such as testing, inspection or auditing, then the scheme should confirm the minimum requirements for such activities, and the degree to which prior agreement must be gained from the scheme owner or the client whose products are being certified under the scheme.

NOTE Requirements for testing can be found in ISO/IEC 17025, inspection in ISO/IEC 17020 and management system auditing in ISO/IEC 17021.

6.5.5 Complaints and appeals to the scheme owner

The scheme should define the complaints and appeals process within its organization and who is responsible for undertaking this process.

Appeals against the decision of the certification body and complaints about the certification body should be addressed to the certification body in the first instance.

Appeals and complaints that have not been, or cannot be, resolved by the certification body can be addressed to the scheme owner.

6.5.6 Licensing and control of the mark

Where the scheme provides for the use of certificates, marks or other statements of conformity there should be a license or other form of enforceable agreement to control such use. Such licenses may be between the scheme owner and product certification body(ies) or the certified client(s). Licenses can include provisions related to use of the certificate, mark or other statement of conformity in communications about the certified product, and requirements to be fulfilled when certification is no longer valid.

6.5.7 Surveillance

If surveillance is included, the scheme should define the set of activities (function 6 in Table 1) that make up the surveillance functions. In deciding upon the appropriate surveillance activities, the scheme owner should consider the nature of the product, the consequences and probability of non-conforming products and the frequency of the activities.

6.5.8 Non-conforming products

The scheme should define requirements that apply when a product no longer fulfils certification requirements such as product recall or providing information to the market.

NOTE see also ISO Guide 27

6.5.9 Reporting to the scheme owner

When reporting to the scheme owner is required, the content and frequency of reporting should be defined. Such reporting may be for the purpose of scheme improvement, for control purposes and for monitoring the extent of conformity by clients.

6.5.10 Subcontracting of the operation of the scheme

If the scheme owner subcontracts all or part of the operation of the scheme to another party, it should have a legally binding contract defining the duties and responsibilities of both parties.

6.5.11 Marketing

The scheme should define the policies and procedures related to marketing including the extent to which certification bodies and clients can make reference to the scheme.

6.5.12 Fraudulent claim of certification

Actions and responsibilities for situations where certification under the scheme is being claimed fraudulently should be described.

6.6 Maintenance and improvement of a scheme

6.6.1 Review of scheme operation

The scheme owner should define a process for reviewing the operation of the scheme on a periodic basis in order to confirm its validity and to identify aspects requiring improvement, taking into account feedback from stakeholders.

6.6.2 Changes in specified requirements

The scheme owner should monitor the development of the standards and other normative documents which define the specified requirements used in the scheme. Where changes in these documents occur, the scheme

owner should have a process for making the necessary changes in the scheme, and for managing the implementation of the changes (e.g. transition period) by the certification bodies, clients and where necessary, other stakeholders.

6.6.3 Other changes to the scheme

The scheme owner should define a process for managing the implementation of other changes to the rules, procedures and management of the scheme.

6.7 Scheme documentation

The scheme owner should create, control and maintain adequate documentation for the operation, maintenance and improvement of the scheme. The documentation should specify the rules and the operating procedures of the scheme and in particular the responsibilities for governance of the scheme.

Bibliography

[1] ISO 2859-10:2006 — *Sampling procedures for inspection by attributes -- Part 10: Introduction to the ISO 2859 series of standards for sampling for inspection by attributes*

[2] ISO 10576-1:2003 — *Statistical methods -- Guidelines for the evaluation of conformity with specified requirements -- Part 1: General principles*

[3] ISO/IEC 17007:2009 — *Conformity assessment -- Guidance for drafting normative documents suitable for use for conformity assessment*

[4] ISO/IEC 17020:1998 — *General criteria for the operation of various types of bodies performing inspection*

[5] ISO/IEC 17021:2011 — *Conformity assessment -- Requirements for bodies providing audit and certification of* management systems

[6] ISO/IEC 17025:2005 — *General requirements for the competence of testing and calibration laboratories*

[7] ISO/IEC 17030:2003 — *Conformity assessment -- General requirements for third-party marks of conformity*

[8] ISO/IEC Guide 68:2002 — *Arrangements for the recognition and acceptance of conformity assessment results*

[9] ISO Guide 27:1983 — *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*

ISO/IEC Guide 28:2004 - Conformity assessment -- Guidance on a third-party certification system for products
[10] ISO/IEC Guide 53:2005 — *Conformity assessment -- Guidance on the use of an organization's quality management system in product certification*

[11] ISO 22514-1:2009 — Statistical methods in process management — Capability and performance

[12] ISO 3951-1:2005 — Sampling procedures for inspection by variables

EXPLANATORY REPORT RAPPORT EXPLICATIF	ISO/DIS 17067
ISO/TC CASCO / SC	Secretariat **CASCO**

This form should be sent to the ISO Central Secretariat, together with the English and French versions of the committee draft, by the secretariat of the technical committee or subcommittee concerned.

Ce formulaire doit être envoyé au Secrétariat central de l'ISO en même temps que les versions anglaise et française du projet de comité, par le secrétariat du comité technique ou du sous-comité concerné.

The accompanying document is submitted for circulation to member body vote as a DIS, following consensus obtained from the P-members of the committee.

Le document ci-joint est soumis, pour diffusion comme DIS, au vote comité membre, suite au consensus des membres (P) du comité obtenu.

on **25-27 April 2012**

☒ at the meeting of / à la réunion du **TC CASCO / SC WG32** — see resolution / voir résolution No. / nº — in / dans le document

☐ by postal ballot initiated on / par un vote par correspondance démarré le

	Number	Countries
P-members in favour: Membres (P) approuvant le projet:	**51**	**see CASCO WG32 N71**
P-members voting against: Membres (P) désapprouvant:	**0**	
P-members abstaining: Membres (P) s'abstenant:	**7**	
P-members who did not vote: Membres (P) n'ayant pas voté:	**13**	

Remarks/Remarques

I hereby confirm that this draft meets the requirements of part 2 of the ISO/IEC Directives
Je confirme que ce projet satisfait aux prescriptions de la partie 2 des Directives ISO/CEI

Date	Name and signature of the secretary Nom et signature du secrétaire
2012.05.04	**Sean MacCurtain**

Result of voting

Ballot Information

Ballot reference	ISO/IEC CD 17067
Ballot type	CD
Ballot title	Conformity assessment -- Fundamentals of product certification
Opening date	2011-11-15
Closing date	2012-03-15
Note	
Vienna agreement	ISO lead

Member responses:

Votes cast (58)

Argentina (IRAM)
Armenia (SARM)
Australia (SA)
Austria (ASI)
Barbados (BNSI)
Belarus (BELST)
Belgium (NBN)
Brazil (ABNT)
Bulgaria (BDS)
Canada (SCC)
Colombia (ICONTEC)
Costa Rica (INTECO)
Côte d'Ivoire (CODINORM)
Cuba (NC)
Czech Republic (UNMZ)
Denmark (DS)
Ecuador (INEN)
Egypt (EOS)
Finland (SFS)
France (AFNOR)
Germany (DIN)
Hungary (MSZT)
India (BIS)
Indonesia (BSN)
Ireland (NSAI)
Israel (SII)

	Italy (UNI) Jamaica (BSJ) Japan (JISC) Jordan (JSMO) Korea, Republic of (KATS) Malaysia (DSM) Malta (MCCAA) Mexico (DGN) Morocco (IMANOR) Netherlands (NEN) New Zealand (SNZ) Norway (SN) Oman (DGSM) Peru (INDECOPI) Philippines (BPS) Poland (PKN) Portugal (IPQ) Romania (ASRO) Serbia (ISS) Singapore (SPRING SG) South Africa (SABS) Spain (AENOR) Sweden (SIS) Switzerland (SNV) Thailand (TISI) Trinidad and Tobago (TTBS) Turkey (TSE) Ukraine (DSSU) United Kingdom (BSI) Uruguay (UNIT) USA (ANSI) Viet Nam (STAMEQ)
Comments submitted (2)	CEOC Libya (LNCSM)
Votes not cast (13)	Botswana (BOBS) Chile (INN) China (SAC) Kenya (KEBS) Luxembourg (ILNAS) Mauritius (MSB) Nigeria (SON) Pakistan (PSQCA) Russian Federation (GOST R) Saudi Arabia (SASO) Slovakia (SUTN) Tunisia (INNORPI) Zimbabwe (SAZ)

Questions:	
Q.1	"Do you agree to the circulation of the draft as a DIS?"

Votes by members	Q.1
Argentina (IRAM)	Yes with comments

Armenia (SARM)	Yes
Australia (SA)	Yes with comments
Austria (ASI)	Yes with comments
Barbados (BNSI)	We abstain
Belarus (BELST)	Yes
Belgium (NBN)	Yes with comments
Brazil (ABNT)	Yes with comments
Bulgaria (BDS)	Yes
Canada (SCC)	Yes
Colombia (ICONTEC)	Yes with comments
Costa Rica (INTECO)	Yes
Côte d'Ivoire (CODINORM)	We abstain
Cuba (NC)	Yes
Czech Republic (UNMZ)	Yes with comments
Denmark (DS)	Yes
Ecuador (INEN)	Yes
Egypt (EOS)	Yes
Finland (SFS)	Yes
France (AFNOR)	Yes with comments
Germany (DIN)	Yes with comments
Hungary (MSZT)	Yes
India (BIS)	Yes with comments
Indonesia (BSN)	Yes with comments
Ireland (NSAI)	Yes with comments
Israel (SII)	Yes
Italy (UNI)	Yes
Jamaica (BSJ)	Yes
Japan (JISC)	Yes with comments
Jordan (JSMO)	Yes
Korea, Republic of (KATS)	Yes with comments
Malaysia (DSM)	Yes
Malta (MCCAA)	Yes
Mexico (DGN)	Yes
Morocco (IMANOR)	Yes

Netherlands (NEN)	Yes
New Zealand (SNZ)	We abstain
Norway (SN)	We abstain
Oman (DGSM)	Yes
Peru (INDECOPI)	Yes with comments
Philippines (BPS)	Yes
Poland (PKN)	Yes with comments
Portugal (IPQ)	We abstain
Romania (ASRO)	Yes with comments
Serbia (ISS)	Yes
Singapore (SPRING SG)	Yes with comments
South Africa (SABS)	Yes with comments
Spain (AENOR)	We abstain
Sweden (SIS)	Yes
Switzerland (SNV)	Yes
Thailand (TISI)	Yes with comments
Trinidad and Tobago (TTBS)	Yes
Turkey (TSE)	Yes
Ukraine (DSSU)	Yes
United Kingdom (BSI)	Yes with comments
Uruguay (UNIT)	We abstain
USA (ANSI)	Yes with comments
Viet Nam (STAMEQ)	Yes with comments

Answers to Q.1: "Do you agree to the circulation of the draft as a DIS?"		
28 x	**Yes**	**Armenia (SARM)** **Belarus (BELST)** **Bulgaria (BDS)** **Canada (SCC)** **Costa Rica (INTECO)** **Cuba (NC)** **Denmark (DS)** **Ecuador (INEN)** **Egypt (EOS)** **Finland (SFS)** **Hungary (MSZT)** **Israel (SII)** **Italy (UNI)** **Jamaica (BSJ)** **Jordan (JSMO)** **Malaysia (DSM)**

		Malta (MCCAA) **Mexico (DGN)** **Morocco (IMANOR)** **Netherlands (NEN)** **Oman (DGSM)** **Philippines (BPS)** **Serbia (ISS)** **Sweden (SIS)** **Switzerland (SNV)** **Trinidad and Tobago (TTBS)** **Turkey (TSE)** **Ukraine (DSSU)**
23 x	**Yes with comments**	**Argentina (IRAM)** **Australia (SA)** **Austria (ASI)** **Belgium (NBN)** **Brazil (ABNT)** **Colombia (ICONTEC)** **Czech Republic (UNMZ)** **France (AFNOR)** **Germany (DIN)** **India (BIS)** **Indonesia (BSN)** **Ireland (NSAI)** **Japan (JISC)** **Korea, Republic of (KATS)** **Peru (INDECOPI)** **Poland (PKN)** **Romania (ASRO)** **Singapore (SPRING SG)** **South Africa (SABS)** **Thailand (TISI)** **United Kingdom (BSI)** **USA (ANSI)** **Viet Nam (STAMEQ)**
0 x	**No**	
7 x	**We abstain**	**Barbados (BNSI)** **Côte d'Ivoire (CODINORM)** **New Zealand (SNZ)** **Norway (SN)** **Portugal (IPQ)** **Spain (AENOR)** **Uruguay (UNIT)**

Comments from Voters

Member:	Comment:	Date:
Argentina (IRAM)	***Comment File***	2012-03-14 21:29:25
CommentFiles/ISO_IEC_CD_17067_IRAM.doc		
Australia (SA)	***Comment File***	2012-03-09 00:42:38
CommentFiles/ISO_IEC_CD_17067_SA.doc		

Austria (ASI)	***Comment File***	2012-03-14 17:28:27
CommentFiles/ISO_IEC_CD_17067_ASI.doc		
Belgium (NBN)	***Comment File***	2012-03-05 13:15:12
CommentFiles/ISO_IEC_CD_17067_NBN.doc		
Brazil (ABNT)	***Comment File***	2012-03-15 19:25:50
CommentFiles/ISO_IEC_CD_17067_ABNT.doc		
Colombia (ICONTEC)	***Comment File***	2012-03-13 05:54:22
CommentFiles/ISO_IEC_CD_17067_ICONTEC.doc		
Czech Republic (UNMZ)	***Comment File***	2012-02-22 08:04:37
CommentFiles/ISO_IEC_CD_17067_UNMZ.doc		
France (AFNOR)	***Comment File***	2012-03-07 09:44:33
CommentFiles/ISO_IEC_CD_17067_AFNOR.doc		
Germany (DIN)	***Comment File***	2012-03-09 08:56:09
CommentFiles/ISO_IEC_CD_17067_DIN.doc		
India (BIS)	***Comment File***	2012-03-12 05:57:27
CommentFiles/ISO_IEC_CD_17067_BIS.doc		
Indonesia (BSN)	***Comment File***	2012-03-14 04:49:48
CommentFiles/ISO_IEC_CD_17067_BSN.doc		
Ireland (NSAI)	***Comment File***	2012-01-24 13:22:11
CommentFiles/ISO_IEC_CD_17067_NSAI.doc		
Japan (JISC)	***Comment File***	2012-02-20 01:50:55
CommentFiles/ISO_IEC_CD_17067_JISC.doc		
Korea, Republic of (KATS)	***Comment File***	2012-03-15 06:11:47
CommentFiles/ISO_IEC_CD_17067_KATS.doc		
Peru (INDECOPI)	***Comment File***	2012-03-15 22:29:18
CommentFiles/ISO_IEC_CD_17067_INDECOPI.doc		
Poland (PKN)	***Comment File***	2012-03-02 12:00:36
CommentFiles/ISO_IEC_CD_17067_PKN.doc		

Romania (ASRO)	***Comment File***	2012-03-02 09:47:31
CommentFiles/ISO_IEC_CD_17067_ASRO.doc		
Singapore (SPRING SG)	***Comment File***	2012-03-15 04:13:37
CommentFiles/ISO_IEC_CD_17067_SPRING SG.doc		
South Africa (SABS)	***Comment File***	2012-02-27 11:05:05
CommentFiles/ISO_IEC_CD_17067_SABS.doc		
Thailand (TISI)	***Comment File***	2012-03-15 08:56:33
CommentFiles/ISO_IEC_CD_17067_TISI.doc		
United Kingdom (BSI)	***Comment File***	2012-03-08 13:08:56
CommentFiles/ISO_IEC_CD_17067_BSI.doc		
USA (ANSI)	***Comment File***	2012-03-09 20:33:32
CommentFiles/ISO_IEC_CD_17067_ANSI.doc		
Viet Nam (STAMEQ)	***Comment File***	2012-03-13 03:51:02
CommentFiles/ISO_IEC_CD_17067_STAMEQ.doc		

Comments from Commenters		
Member:	Comment:	Date:
CEOC	***Comment File***	2012-03-15 11:58:25
CommentFiles/ISO_IEC_CD_17067_CEOC.doc		
Libya (LNCSM)	***Comment***	2012-02-29 17:29:05
no comment		

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
JP 01	All		Ed	When this standard refers to any sub-clauses, it is written "clause 5.1" in most cases. However, in 5.2.1 and 6.4.4, it is written just "5.1", and in 5.2.2, it is written "Section 6". The means of description should be standardized.	Clarify and modify.	1. Agreed
GB 1	General		te/ed	The draft appears to work well for conventional 'product' but less so for 'process' and/or 'service' – see additional comments re Table 1 in clause 5.2	Check & redraft as necessary – see suggestion in GB 3 comment below	2. Noted
GB 2	General		ed	The 'health warning' appearing in 6.3.7 should have greater prominence at the beginning of the standard	Include health warning at beginning of standard	3. Not agreed. Covered in 4.1.1
MX	General			Is better if certification options 1a and 1b are numbered separately as 1 and 2 and renumber all the others.	Change 1a by 1 Change 1b by 2 Renumber 2 to 6 (+1)	4. Not agreed. Users of Guide 67, which this Standard replaces, make reference to the Scheme Types, e.g. Type 5. Changing the numbering would cause unnecessary confusion.
ID	Forward	Par 1-6	ed	Repetition of the paragraph 1-6	Should be omitted one paragraph	5. Agreed
AU	Introduction		ed	The introduction is dense and wordy. The main points could be communicated in a more succinct way.	Replace the current introduction with the following: "This International Standard describes the fundamentals of product certification and provides guidelines for product certification schemes. In this International Standard references to 'product' can also be read to mean 'services' or 'processes'. As products are designed, produced, distributed, used and ultimately disposed of, they may give rise to concerns with purchasers, users and society in general. Such concerns could relate to safety, health or environmental impacts, durability, compatibility, suitability for intended purposes or for stated conditions. Generally these concerns are addressed by specifying the required product attributes in a	6. Agreed, with addition of final paragraph from CD

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
					normative document such as a standard. The supplier of the product then has the task of demonstrating that the product conforms to the requirements of the standard. It might be sufficient for the supplier to assess and self-declare their product's conformity, but in other cases the user or a regulatory authority may require that conformity be assessed by an impartial third party. Impartial third party assessment and attestation of the product is referred to as product certification. This International Standard outlines how schemes for product certification can be structured and managed. It identifies common assessment techniques that are used as a basis for product certification, such as product testing, inspection and auditing. This International Standard is for those involved with product certification, particularly those who are, or are considering becoming, product certification scheme owners. Product certification scheme owners can include: (a) product certification bodies; (b) government and regulators; (c) purchasing agencies; (d) non-government organisations; (e) industry and retail associations; and (f) consumer organisations. ISO/IEC 17067 is guidance only and does not contain requirements. It is compatible with ISO/IEC 17065 that specifies requirements for product certification bodies. "	
SG	Introduction	Paragraph 2	TE	A more detailed definition is needed to describe the term "independent and expert assessment". Who would constitute as an expert for independent assessment. This		7. Noted, see 6

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
				is required to provide for two situations: low and high stakes dispute resolution.		
SG	Introduction	para 2 4.2.1b	TE	The term "suppliers" shouldn't it be consistent with most changes of other international standard that have already revised & redefined to as "organization" and "subcontractors" to avoid misinterpretation & confusion for those moving towards integrated systems?	To standardise the term "supplier" to be consistent with other international standards.	8. Not agreed. In the field of product certification the supplier and user of a product are key players.
US	Introduction	7th para	te	7th Para, first sentence; the phrase "and those with responsibility for evaluating such schemes". We disagree with the premise that schemes would be evaluated.	Remove the concept that schemes will be evaluated.	9. Agreed, see 6
TH	Introduction	Last paragraph	ed		"the world "may"" should read "the word "may"".	10. Agreed, see 6
US	Introduction	Last paragraph	ed	Typographical error on the first line.	Change "world" to "word"	11. Agreed, see 6
SG	NOTES	NOTES	ED	Why do some reference "Notes" make reference to international standard with the Year of publication whereby most of the other references do not include the "Year" of publication, shouldn't it be consistence? Case-in-point; Clause 5.1.2-NOTE1 versus NOTE 2 & NOTE 3 and also Clause 6.5.1 (g) NOTE,	To standardise when making reference to international standard; either to indicate or remove the Year of publication.	12. Agreed, delete reference to year
ZA	Request to add new clause for "recourse"		ge	An important part of the responsibility of a body operating a mark is that, if a member of the public or a regulator complains about a mark bearing product, the CB should take action with the supplier. The matter is somewhat worse when the product is regulated and the mark is mandatory or is used in a "deemed to satisfy" demonstration of conformity. It becomes essential that the CB acts on non-conforming (illegal) product even being responsible for recalling or for verifying the effectiveness of measures used by the supplier to effect a recall of non-conforming products.		13. Partially agreed, insertion of word "integrity" among the scheme owner responsibility under 6.3.4

1	2	(3)	4	5	(6)	(7)
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				With many countries now enacting consumer protection and product liability legislation and, the advent of many schemes where the "Scheme Owner" contracts the conformity assessment to a third party, the question of recourse is one certainly worthy of further discussion in the drafting of 17067. There is also the question of requirements for indemnification that some scheme owners place on third parties which could be interpreted as an attempt to avoid responsibility for recourse.		
US	Scope		ge	Fundamentals of product certification are addressed within 17065 and other standards.	Remove any language that addresses product certification concepts addressed in 17065 or other standards.	14. Not agreed. 17065 is about product certification bodies with Guide 67 currently providing the overview of the context within which the bodies work. 17067 will continue to fulfil that role.
GB 3	Scope and Note 1	P1 L2 whole note	te	ISO/DIS 17065 defines product in alignment with ISO 9000, ISO 17067 makes normative reference to ISO/IEC 17065 vocabulary. The result is that the term and its definition of "product" are normative. The use of the language related to product is nonsensical where "service" is normatively recognised to be a category of product. To repeat Jurgen Jacob's example for the nth time – product AND service, product OR service is precisely the same as fruit AND lemon , fruit OR lemon. The part in the scope and the whole of the note needs to eradicate this nonsense that seems to remain, strangely sensible mainly or only to people whose background is steeped entirely in manufactured hardware product, engineering or conformity assessment of relevant standards.	Scope ……certification schemes for products including services, and processes Or certification schemes for products . NOTE 1 In this International Standard the term "product" can be read as —product (including service) and process, except in those instances where separate provisions are stated for "processes" or "services". Definitions of product as including service , service and process are given in ISO/IEC 17065. This clarification of concept reference should then be made wherever appropriate in the draft	15. Not agreed. The product certification community working in CASCO WG 29, has decided for the sake of continuity to refer to products, processes and services. WG 32 should follow suit.

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
				From another tack - The generic concept of 'product' is conveniently applicable within CASCO in addressing requirements appertaining to the certification of things that are supplied, as opposed to the certification of suppliers' capability. Both processes and services become the object of certification in the former context only when they are the kind of thing that is being supplied. So it is nonsense to include them in this context as if they were any other kind of thing.		
US	Scope Notes 2 & 3		te	The use of 'bodies' in the two notes are inconsistent.	Use a consistent term and concept for notes 2 & 3.	16. Agreed. See new wording
GB 4	2		te/ed	Should ISO/IEC 17007 be referenced here?	Reference 17007	17. Not agreed. It is referred to in a Note and is included in the bibliography
AR	3		Te	In some cases is difficult identify when issue a licence or a certificate for the different certification schemes. Which is the difference between licensing and attestation?	Define "licensing" Identify (in table 1) when the type of product certification schemes use a licensing and when use an attestation	18. Agreed in principle but better dealt with in the body of the Standard rather developing a definition. See 91
DE	3		ge	Align terms and definitions of ISO/IEC 17067 with ISO/IEC 17065.		19. Agreed
AT	3.1		ed		Delete the comma after the word "procedures"	20. Agreed
FR	3.2		te	Indicate that we are considering only "product" certification schemes and not management system certification schemes	Proposal : Add the term "product" to the defined term 3.2: "**product certification scheme**"	21. Not agreed, see 17065
GB 5	3.2	Note	ed	….for implementing product, process and service certification are stipulated by the certification scheme.	…stipulated by the certification scheme for certification of product are often different when general categories of product, service (product) particularly and process standards are concerned	22. Not agreed. This is an important point but not appropriate to cover it in a note to a definition
FR	3.3		te	A scheme owner cannot be a physical person (see 6.3.3)	Delete the term "person" in this sentence "~~person or~~ organization that is responsible for developing and maintaining a specific certification scheme"	23. Not agreed. A person can be a legal entity.

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
GB 6	3.3	def	ed	The addition of "specific" is confusing the otherwise straightforward definition. Does the concept "scheme owner" only apply to specific schemes? Bearing in mind a certification scheme is defined as applying to specific product… the term should then be "specific certification scheme owner" and the nature of the specificity either added as a characteristic of the concept or at least in a note. If as expected this is related to the specificities that apply to the concept of "certification scheme" then it is redundant, confusing by introducing ambiguity and should be deleted.	Delete "specific" from the definition. Each and every certification scheme is a specific certification scheme. Otherwise re-term the entry "specific certification scheme" and alter the text accordingly – terms and their definitions are normative to their use in the text.	24. Not agreed. This is the 17065 definition.
RO	3.3	Note	ge	Unclear explanation for certification scheme owner: "... group certification bodies or other"	"... group certification bodies."	25. Not agreed 17065 uses "others"
US	3.3		ed	Suggest to remove the reference to "person" on the definition of "Certification Scheme Owner" as it contradicts clause 6.3.3 where it specifies that the scheme owner should be a legal entity.	**3.3** **certification scheme owner** ~~person or~~ organization that is responsible for developing and maintaining a specific certification scheme (3.2)	26. Not agreed, see 23
US	3.3.		te	The term 'certification scheme owner' is not consistent with 17065.	17065 uses 'scheme owner' (3.11). Use the 17065 definition.	27. Agreed
ID	4	-	ed	Title of sub clause 4.1 should not in question statement	**4.1 What is product certification?** replace with **4.1 General**	28. Partially agreed, see new wording
US	4		te	Section 4 is a poor reflection of the concepts in 17065.	Include the concepts by document reference to 17065 without restatement or interpretation.	29. Not agreed. To fulfil its role as an introduction to product certification, 17067 needs to describe the fundamental aspects. Improvements based on the FDIS 17065 should be considered
	4.1	Title		Shouldn't use the question for the title	"Concept of product certification" or "General"	30. Agreed, 1st suggestion

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
PL	4.1		te	As clarification and description of the purpose it should be passed to the Introduction rather than text of the standard body.	Transfer the whole clause to the Introduction part.	31. see 29
TH	4.1	Title	ge		The title of this clause should be "4.1 General".	32. See 30
US	4.1		te	The title is inappropriate.	Change to 'product certification'.	33. see 30
US	4.1 & 4.2		ed	With the removal of subclauses 4.1.1 through 4.1.3 the current 4.1 is no longer needed	Renumber current 4.2 as 4.1 and 4.2.1 and 4.2.2 to 4.1.1. and 4.1.2.	34. Not agreed, present wording is good introduction to product certification
AU	4.1.1		Ed	The first sentence current has no subject.	Replace the first sentence as follows: Product certification is the provision of an impartial third-party attestation that a product's fulfilment of specified requirements has been demonstrated.	35. Not agreed, existing wording fulfils the intent
GB 7	4.1.1	P1L2	ed	"Product certification is carried out by product certification bodies which should conform to ISO/IEC 17065" leaves the object of conformity slightly ambiguous – product certification or bodies?	Product certification, which should conform to ISO/IEC 17065, is carried out by product certification bodies	36. Not agreed. 17065 relates to the bodies
US	4.1.1		te	2nd sentence: The word 'should' implies that this standard does not support the use of 17065.	Remove the sentence.	37. Not agreed. In a guidance document "should" is as strong as it gets.
US	4.1.1		ed	This subclause, as written appears to be a definition.	Move to section 3, Terms and definitions under the heading "product certification" and reword as "the provision of impartial third-party attestation that fulfilment of specified requirements has been demonstrated and is carried out by bodies, which should conform to ISO/IEC 17065. Specified requirements for products are generally contained in standards and other normative documents."	38. Not agreed. This is where we engage the reader in the fundamentals of product certification
AU	4.1.2		Ed	Conformity assessment 'technique' is too narrow a term to describe product certification. 'Techniques' could refer to testing, inspection or auditing. It would be more	Replace the word 'technique in the first sentence with 'activity'.	39. Agreed

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
				appropriate to say 'activity' instead of technique.		
US	4.1.2		ed	This subclause is better suited under current section 4.2.	Move to section 4.2 as a new 4.2.1a, replacing the current wording and delete the first three words of the sentence.	40. See 34
US	4.1.2		ed	Suggest to add the underlined statement. This is to prevent any potential future misunderstanding of the intent of product certification. For example, not all product standards specify safety aspect or sustainability aspect. By including statement, this would clarify any future misconception that because a product is certified to a standard, the product is guaranteed to be safe.	**4.1.2** Product certification is an established conformity assessment technique that provides assurance to consumers, regulators, industry and others that products conform to specified requirements, including for example product performance, safety, interoperability and sustainability (if specified in the requirements).	41. Not agreed, already specified product requirement
TH	4.1.3		ge	Clause 4.1.3 should be moved to under clause 4.2 since it describes benefit of product certification the same way as clause 4.2.2.	The clause should read : "4.2.3 Product certification can facilitate trade, market access, fair competition and consumer acceptance of products on a national, regional and international level."	42. See 34
US	4.1.3		ed	This subclause is better suited under current section 4.2.	Move to section 4.2 as a new 4.2.1c and delete the first three words of the sentence.	43. See 34
CA	4.1.3		General	The line does not define what product certification is, but what it can be used for. It does not align with title of 4.1, which is meant to define product certification, or fit with other two points, 4.1.2 and 4.1.3.	Remove 4.1.3, place it in Introduction, page 5	44. See 34
IN	4.2.1	a) First paragraphfirst line	Te	'Fulfilment of requirement' is a generic term. In cl. 4.1.1 & 4.1.2, specified requirements have been mentioned. In order to make the objectives of product certification more precise, specified requirements are to be fulfilled.	The words "specified" may be inserted before requirement.	45. Agreed
AU	4.2.1	b)	Ed	Includes "specified product requirements", remainder of the document uses "specified requirements"	Delete product	46. Agreed
AU	4.2.1	b)	Te	'independent' is a relational term (i.e. independent from what?) and may be difficult to confirm if a supplier is paying for product certification services. It is best not to focus on the concept of independence; rather it is more appropriate to focus on impartiality. For further explanation see the	Replace the word 'independent' with 'impartial'.	47. Agreed, with addition of "third party" to be consistent with 4.1.1 wording

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
				background work of ISO/CASCO WG23 in the development of ISO PAS 17001 on impartiality.		
US	4.2.1	b	TE	The phrase "has been attested" is unnecessarily confusing – as is the use of "independent body" instead of the defined term "third party activity" in ISO/IEC 17000	allow suppliers to utilize a third party process to demonstrate to the market (including regulators) that their product ~~has been attested to~~ fulfills specified product requirements ~~by an independent body~~	48. Partially agreed, see 47
PE	4.2.1.	b	te	**4.2.1** The fundamental objectives of product certification are to: a) address the needs of consumers, users and, more generally, all interested parties by giving confidence regarding fulfilment of requirements; ***b) allow suppliers to demonstrate to the market that their product has been attested to fulfil specified product requirements by an independent body.***	Replace the term "suppliers" by "client" because in DIS 17065 the term client is used. In any case we suggest the harmonization of this term between both standards	49. Not agreed. At this point, the focus is on the supplier of a product. "Client" only comes into play when the supplier engages the services of a certification body as in 17065. See 51
AU	4.2.2		Te	What is the meaning of the last sentence in 4.2.2. This is a normal expectation for any economic activity and seems odd to mention it here.	Delete the last sentence.	50. Not agreed. This is an important message to scheme owners.
FR	4.2.2		te	Consistency with DIS 17065 about the term supplier	Add a note : "**the supplier is called "client" in 3.1 of ISO/CEI DIS 17065**"	51. Not Agreed, context in 6.3.1 a) makes the meaning of client clear
JP 02	4.2.2		Ed	The first sentence is more or less duplicated by 4.2.1.	Delete the 1st sentence, and move the 2nd sentence to 4.2.1 NOTE.	52. Not agreed, these are important consideration for the potential user of product certification
ID	5	-	te	Clause 5 has covering System and Schemes	Clause **5 Product certification schemes** change with **5 Product certification system and schemes**	53. Not agreed. The main subject is schemes
AT	5 and 6	Table 1	te	According to the definitions in 3.1 and 3.2 in both clauses 5 and 6 as well as in table 1 put instead of the word "scheme" the word "system". In all literature as well as in the daily practice for the general description of the different types of product certification the reference e.g. "type 5 of product	Use in the clauses 5 and 6 as well as in table 1 the term "product certification system" instead of "product certification scheme".	54. Not agreed. The WG found at an early stage that "system" could be used in different ways, e.g. international certification system

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
				certification system according to ISO Guide 67" is used since decades. The term "scheme" is used up to now in practice as a subterm of "system" for the application of a certification system for the different families of products.		(IECEE) and CB's system for operating certification. "Scheme" has a single meaning and is the basic building block of product certification.
AU	5.1.1		Ed	While 5.1.1 is correct, it appears a very stark statement in a guidance document, especially when ISO/IEC 17067 is meant for those with only an introductory level of knowledge of product certification. As such this statement could be reworded and placed after the explanation of product certification systems and schemes.	Move 5.1.1 to appear after Table 1, and reword as follows: A product certification scheme, however identified, is deemed to be in place whenever product certification is performed.	55. Partially agreed, reworded and moved to 5.1.2
GB 8	5.1.1	P	te	Making the statement in the present tense results in the provision being a requirement. This is not part of a Guidance standard unless some indication is made of hybrid clauses.	Whenever product certification is performed a product certification scheme (3.2) should be in place	56. see 55.
SG	5.1.2		GE	Annex A to ISO/IEC17000: 2004 & ISO/IEC17065 are not provided in Annex and also not addressed in the "Bibliography" page 13? ISO/IEC Guide 28:2004 = not provided in Annex B and also not addressed in the "Bibliography" page 13?	To state ISO/IEC 17000, ISO/ IEC 17065 and ISO.IEC Guide 28 into Bibliography.	57. Partially agreed– Guide 28 should be in the Bibliography. 17000 and 17065 are referenced in Clause 2.
CO	5.1.2		te	Accordingly with ISO/IEC 17000 the Audit is a concept solely apply to management systems. In the context of product certification is possible to apply the audit when the certification scheme had specified, for example schemes number 5 or 6. See too ISO/IEC Guide 53	determination which may include testing, measurements, inspection, design appraisal, assessment of services, and auditing of quality management system as examples of techniques used to provide information regarding the product requirements as input to the review and attestation functions	58. Not agreed. The 17000 definition is not restricted to management systems though the Note does make reference to usage as related to "assessment". In product certification, auditing could be carried out on e.g. a manufacturing process.
?	5.1.2	Para. 1			Annex A **of** ISO/IEC 17000	59. Noted – ISO editors

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
AU	5.1.2		Te	Certification schemes should follow the functional approach however not systems, especially in the way the document portrays the relationship between system and scheme in Figure 1.	Delete "systems and".	60. Agreed
AU	5.1.2		Te	It is agreed that Schemes should implement the functional approach, however as detailed in Clause 6.5, schemes should include more detail than that which relates to the functional approach.	Amend to read "should implement, as a minimum, the functional approach to conformity assessment".	61. Not agreed. Implementing the functional approach does not prevent the scheme from including additional measures.
ID	5.1.2	-	ed	Content in 5.1.2 is about certification system, we propose to delete the word "schemes" in 5.1.2 Product certification systems and schemes should implement the functional approach as described in Annex A to ISO/IEC 17000.	5.1.2 Product certification systems should implement the functional approach as described in Annex A to ISO/IEC 17000.	62. Not agreed. See 60
JP 03	5.1.2		Te	Although the functional approach in ISO/IEC 17000 doesn't include licensing, Table 1 of this standard refers to licensing as the important aspects of conformity assessment activities. It would be better to explain about licensing in the note of this sub-clause in order to help understanding.	Add note explaining about licensing.	63. Partially agreed. New clause 6.5.6
AU	5.1.2	2nd bullet	Ed	Slight editorial change to improve readability.	Reorder the second bullet as follows: Determination, which may include assessment techniques such as testing, measurements, inspection, design appraisal, and auditing, in order to provide information regarding the product's fulfilment of requirements to be used as input into the review and attestation functions;	64. partially agreed, see rewording
GB 14	5.1.2	2nd bullet	ed		Replace 'measurements' with 'measuring' or delete altogether	65. Agreed to use "measuring" as a technique - see 64
GB 15	5.1.2	2nd bullet	te/ed	Why exclude process (certification) when specifically mentioning 'service'? (and to be consistent with Table 1 2) d))	Redraft to include '.. assessment of services and/or processes'	66. See 64
GB 9	5.1.2	5th bullet	te	The phrase "maintaining the validity of the statement of conformity" requires qualification. The validity relates to	After "conformity" add "for products which are produced after the initial attestation"	67. Not agreed, it is the definition from 17000

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
				products produced after the evaluation of the initial product(s). As currently worded, it could be read as applying to the initial product(s) and their ongoing conformity whilst in service. This aspect would normally be the concern of an inspection scheme.		
AU	5.1.2	Note 1	Ed	Unnecessary as mentioned already in opening sentence of 5.1.2.	Delete the note.	68. partially agreed, see rewording
KR	5.1.2	Note 2	ed	Put a comma after "In ISO/IEC 17065"	In ISO/IEC 17065, the functions selection and determination have been combined and are named evaluation.	69. Agreed
KR	5.1.2	Note 3	ed	Put a comma after "In ISO/IEC 17065"	In ISO/IEC 17065, the term "decision" is used in place of "attestation"	70. Agreed
US	5.1.2	NOTE 3	TE	This statement cannot be true based on the definition of "certification" in ISO/IEC 17000. In that definition, the attestation FOLLOWS the decision (which is based on review). As a result, it is not possible for 17065 to use the term "decision" in PLACE OF attestation. In 17065, the issuance of the formal certification documentation is the "attestation" per the ISO/IEC 17000 definitions. This is different than the "decision" described in 17065	Delete	71. Partially agreed, NOTE reworded
IN	5.2.1	Line 2	Ed	Functional approach as described in Annex to ISO/IEC 17067 have been addressed in Cl. 5.1.2 and hence it is more appropriate that reference is to be given to Clause 5.1.2.	Replace "5.1" with "5.1.2".	72. Agreed
TH	5.2.2		ed	"Section 6" does not exist in this standard.	The clause should read : "5.2.2 The process for deciding on which activities to use for a given situation and the factors to be taken into account in making the decision as described in 5.3.".	73. Partially agreed. Change to "Clause 6"
US	5.2.2		te	Redundant with 6.1.	Remove.	74. Not agreed to remove as it prepares the reader for what to expect later in the document

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
GB 16	5.2	Table 1	te/ed	Needs further development to 'fit/align' better with the concept of the certification of services and/or processes (see comment below)	Check & redraft as necessary	75. See 85
MX	5.2.2	Table 1 4 and 5)	Technical	Include all the options of certification decision, see ISO/IEC DIS 17065.	Granting, maintaining, extending, reducing, suspending, restoring, withdrawing ...	76. Partially agreed, "reducing" only included as "restoring" is not is 17065 (6.1.5 r)
MX	5.2.2	Table 1 6)	Editorial	Is unnecessary to specify "as applicable" because each type of certification scheme is marked depending if is needed.	Surveillance~~, as applicable,~~ by:	77. Not agreed, there are options as to which activities applied as explained in 5.3
MX	5.2.2	Table 1 6)	Editorial	Is better if we change the order of c) by d) and vice versa, the order of the "X's" are clearer.	a) testing or inspection of samples from the open market b) testing or inspection of samples from the factory c) ~~quality system audits combined with random tests or inspections~~ assessment of the production process or service d) ~~assessment of the production process or service~~ quality system audits combined with random tests or inspections	78. Agreed
MX	5.2.2	Table 1 note a)	Technical	Change the term QUALITY SYSTEM by QUALITY MANAGEMENT SYSTEM	Where applicable, the activities can be coupled with initial audit and surveillance audit of the applicant's quality management system ...	79. Agreed
DE	5.2.2	Table 1	ge	To avoid confusions with the numbering of other scheme types it should be clear that this scheme types are based on ISO/IEC 17067.	Please combine this scheme types together with ISO/IEC 17065.	80. Not agreed, already addressed in 17065
US	5.2.2	Table 1	TE	This Parenthetical cannot be true based on the definition of "certification" in ISO/IEC 17000. In that definition, the attestation FOLLOWS the decision (which is based on review). As a result, it is not possible for the term "decision	First column – item 4 – ~~(decision on certification)~~	81. Partially agreed, reworded

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
				on certification" to be the same as "Atttestation".		
US	5.2.2	Table 1, number 6 a & b	te/ed	The word "inspection" is used as a surveillance method. However "inspection" is also used as a Determination characteristic in number 2 which must comply with ISO/IEC 17020. This surveillance method may or may not require an inspection in accordance with ISO/IEC 17020. The word "inspection" needs to be change to "factory (product) production control" or both terms should be included. This requirement is contingent on the scheme owner.	Change the word "inspection" to "factory (product) production control" or include both terms in 6a&b.	82. partially agreed, reference to 17020 and 17025 deleted.
FR	5.2.1	Table 1	te	According to ISO/CEI Guide 67 (clause 6.2 table 1) and to clause 5.3.8 in the present standard, the selection is not an activity for the scheme type 6.	Delete the cross "X" in line 1) "selection of normative documents and sampling as applicable" for "type of product certification schemes"6"	83. Not agreed. The X should have been in Guide 67. Effective determination requires planning and that is a key part of "Selection"
AU	Table 1		Te	Footnote "c" appears in the right hand side of the table title row. This footnote refers to conformity assessment activities and should therefore be in the left hand column of the table where footnote "a" appears.	Amend the table.	84. Not agreed. Footnote "c" is about a type of scheme.
GB 10	Table 1	Heading of left hand column	te	5.2 relates to "activities and functions" The "functions" are mentioned in the table at 1), 2) etc. so "functions" should be included in the column heading. Also the activities and functions are carried out within the context of a certification scheme, so the term "scheme" should be added to the heading.	Amend heading to read: "Conformity assessment functions and activities within product certification schemes"	85. Agreed
GB 11	Table 1	Row 1)	te	The repetition of "selection" could be avoided, and the wording could be made more informative if the reference was to the specification of product requirements.	Amend to read : "1) **Selection** including ~~selection~~ specification of product requirements, e.g. in normative documents, and sampling as applicable"	86. Partially agreed, reworded
ID	Table 1	Table 1 no.1	ed	Consistency with clause 5.1.2, we propose to add "planning and preparation activities" in Selection activities	**Selection** including **planning and preparation activities**, selection of normative documents and sampling as applicable	87. See 86
CZ	Table 1, page 4	point 2)	te	missing item: possible quality systems audit	add one item under point 2) a) testing (ISO/IEC 17025	88. Not agreed, "audit" covered by note a)

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
					b) inspection (ISO/IEC 17020) c) audits, e.g. audits of quality management systems (ISO/IEC 17021) d~~c~~)design appraisal e~~d~~) assessment of services or processes f~~e~~) other determination activities, e.g. verification, ~~audit~~	
ID	Table 1	Table 1 no.2	ed	Consistency with clause 5.1.2, we propose to add the word "measurement"	Determination, of characteristics, as applicable, by a) testing (ISO/IEC 17025) b) measurement c) inspection (ISO/IEC 17020) d) design appraisal e) assessment, or services, or processes f) other determination activities, e.g. verification, audit	89. partially agreed, removal of measurement in new 5.1.1 2nd bullet
IN	Table 1, Col. 2		Te	Since the product certification Scheme Type 1a does not require maintenance, extending and withdrawing certification except granting. Granting should be shown separately and X mark given.	Point No. 4, a separate paragraph for granting should be given under product certification Type 1 (a). 5) Licensing 1a) Granting X Maintaining, extending, suspending….. requirements	90. not agreed, even for type certificate it could still be withdrawn if found not in conformity
GB 12	Table 1	Row 5)	te	This is the only time in the document when "licensing" is mentioned and it is not referred to at all in 17000. If it is to be included as a distinct function in the table it has at least to be mentioned in 5.1 where the Functional Approach is outlined. Otherwise it could be mentioned as a sub-set of Attestation even if the issuing of certificates and licences might be two separate activities in some schemes. The proposed wording is offered as a starting point for discussion.	Incorporate 5) within 4) as follows: "4) Attestation (decision on certification) a) Granting, maintaining, extending, suspending, withdrawing certification b) Granting, maintaining, extending, suspending, withdrawing the right to use certificates, marks or other statements of conformity on products conforming to the specified requirements e " New note "e Some schemes include the affixing of	91. Partially agreed, reworded see also 63

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
					marks of conformity on conforming products by the manufacturer under the terms of a licence issued by the certification body or the scheme. The issuing of the certification and the licence can be handled as separate activities." 5) Licensing	
GB 13	Table 1	Row 6 d)	te	It is not clear what "or service" refers to in the context of "assessment of the production process or service". If it is intended to relate to surveillance of a certified service then the expression should be "assessment of the service delivery process". However the reference to "assessment of the production process" is relevant for certified (tangible) products.	Amend d) to read: "assessment of the production, or service delivery, process"	92. Partially agreed, see rewording in new c)
CO	Table 1	Note a	te	Consistency with the current concept in ISO 9000 and ISO 9001 standard and ISO/IEC Guide 53	Where applicable, the activities can be coupled with initial audit and surveillance audit of the applicant's quality management system (an example is given in ISO/IEC Guide 53) or initial assessment of the production process. The order in which the assessments are performed may vary and will be defined within the scheme.	93. Agreed, and word "quality" removed to take account of other management systems
AU	5.3		Te	As a general rule, Scheme Types 2, 3, 4 & 5 rely on selection in accordance with Type 1a, yet the document does not make it that clear.	Describe the scheme structure and not just the surveillance approach.	94. Agreed
AU	5.3		Te	Given that Type 1a only certifies the type of product, is Type 1a product certification scheme or merely a component of other schemes?	For committee discussion.	95. Not agreed, type 1a is a type of product certification scheme
AU	5.3		Te	As one considers the various scheme types, it appears that Type 1a and 1b are limited to the specific product or batch being considered. Types 2, 3, 4, 5, 6 increasingly include a focus on the production process in addition to the product, and in the context of services and processes it is almost entirely the 'production process' and not necessarily the product which is the focus of the certification. Does this migration of focus need to be made more explicit?	For committee discussion.	96. Not agreed, the table and text in 5.3 provide explanation

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
US	5.3		te	Table 1 emphasizes the narrowness of scope of the types presented. This section has the appearance of limiting scheme development: • It appears that surveillance is the main differentiator. This is most likely not the intent; • Five of the six scheme types focus on samples of products (apparently manufactured physical items); • Only one scheme type addresses process and services.	Remove this section.	97. Not agreed, explanation of the table is necessary
TH	5.3.1		te	The determination activities in type 1a,1b, 2, 3, 4, 5 should include at least "testing".	The clause should read : "5.3.1 General … One or more determination activities <u>which include at least testing</u> should be selected from among those in Table 1 …."	98. Not agreed, testing is not always appropriate
AU	5.3.1	Last sentence	Ed	This sentence starts "For the other scheme types" that is schemes other than 1a and 1b, yet 5.3.2 and 5.3.3 covers 1a and 1b. It would appear that 5.3.2 and 5.3.3 are not required as there is no surveillance	Delete 5.3.2 and 5.3.3.	99. Partially agreed, see rewording in 5.3.1
FR	5.3.2		te	The description of the types of certification scheme is limited to surveillance activities for type 2 to 5 To complete the definition with relevant sentences from ISO/CEI Guide 67 (§ 6.3.2) *add before § 5.3.2 the § 6.3.2 guide 67*	Add the sentence in the beginning of 5.3.2 "**This system includes testing; samples of the product are assessed for conformity. The sampling may or may not be statistically significant of the entire population of product**."	100. Not agreed the present wording is adequate, include all type of determination
PE	5.3.2		te	**5.3.2 Scheme Type 1a** In this scheme, one or more samples of the product are subjected to the determination activities. The samples are representative of subsequent production items but these items are not covered by the attestation of conformity. A certificate of conformity or other statement (e.g. letter or ***<u>completed data sheets</u>***) is issued for the product type, the characteristics of which are detailed in the certificate or a document referred to in the certificate. Subsequent	We would like to know more in detail please, how can a completed data sheet can be considered a certificate of conformity. How can this kind of document comply with 17065 **<u>in terms of decision-making.?</u>**	101. Partially agreed to delete "data sheets".

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
				production items cannot be described as —certifiedll but could be referred to as being manufactured in accordance with the certified type.		
MX	5.3.2	Unique	Editorial		...Subsequent production items cannot be described as —certifiedll but could be referred to as being manufactured in accordance with the ~~certified~~ certification type	102. Not agreed. It is the product type which is certified, hence "certified type". If there is a translation problem, we could consider an alternative form of words but "certification type" does not work in English.
FR	5.3.3		te	The description of the types of certification scheme is limited to surveillance activities for type 2 to 5 To complete the definition with relevant sentences from ISO/CEI Guide 67 (§ 6.3.3) *add before § 5.3.3 the § 6.3.3 (Guide 67)*	Add the sentence in the beginning of 5.3.3 "**This system includes testing; samples of the product are assessed for conformity. The sampling covers the entire population of product. A certificate of conformity is given to each product represented by the sample."**	103. See 100
MX	5.3.4	Paragraph 2	Technical	Prevention take place when undesirable situation is intended to occur, but in the case mentioned in the document the undesirable situation already happened. The correct actions is apply corrective measures (or corrective actions).	... Also, when significant nonconformities are found, effective ~~preventative~~ corrective measures may be limited since the product has already been distributed to the market.	104. Agreed
FR	5.3.4		te	The description of the types of certification scheme is limited to surveillance activities for type 2 to 5 To complete the definition with relevant sentences from ISO/CEI Guide 67 (§ 6.3.4) *add before § 5.3.4 the § 6.3.4 (Guide 67)*	Add the sentence in the beginning of 5.3.4 **"This system includes testing and market surveillance. Market surveillance is conducted and samples of the product from the market are assessed for ongoing conformity."**	105. Not agreed, covered under 5.3.1
IE	5.3.4		Ed	Regarding the phrase, "…effective preventative measures…" the word 'preventive' is preferable, and more consistent with its use throughout other ISO standards.	"…effective preventive measures…"	106. See 104

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
FR	5.3.5		te	The description of the types of certification scheme is limited to surveillance activities for type 2 to 5 To complete the definition with relevant sentences from ISO/CEI Guide 67 (§ 6.3.5) *add before § 5.3.5 the § 6.3.5 (Guide 67)*	Add this sentence in the beginning of 5.3.5 **"This system includes testing and factory surveillance. Factory surveillance is conducted and samples of the product from the point of production are assessed"**	107. See 105
SG	5.3.5 5.3.6		GE	Scheme Type 3 and Scheme Type 4 = it is necessary to describe identically both clauses on "taking samples of the product from the point of production" whereby Scheme Type 4 & already addresses pre-market control and Scheme Type 5 already addressed samples from the market similar to Scheme Type 4?		108. See 111
FR	5.3.6		te	The description of the types of certification scheme is limited to surveillance activities for type 2 to 5 To complete the definition with relevant sentences from ISO/CEI Guide 67 (§ 6.3.6) *add before § 5.3.6 the § 6.3.6 (Guide 67)*	Add this sentence in the beginning of 5.3.6 **"This system includes testing and surveillance of samples from the factory or the open market, or both."**	109. See 105
GB 17	5.3.6	1st para	te	If the first "or" in Line 2 is operative, then the scheme is either Type 2 (from the market) or Type 3 (from the factory). What distinguishes Type 4 is that both activities are carried out.	In Line 2, replace first "or" by "and" and delete "or both"	110. See 111
JP 04	5.3.6	1st sentence	Te	"… taking samples from the point of production or from the market or both" According to table 1, samples should be taken both from the open market and the factory. If samples are taken only from the factory, there will be no difference between Type 3 and Type 4.	"…taking samples both from the point of production and from the market"	111. partially agreed, see rewording
AU	5.3.7		Te	The last sentence seems to be at odds with Table 1. Table 1 indicates that both quality system audits and assessment of production processes are required. However the final para of 5.3.7 indicates that it could be either QMS audit or process assessment	Amend to read:"The surveillance includes periodic assessment of the production process and an audit of the quality management system."	112. Partially agreed, see rewording

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
CO	5.3.7		te	The scheme type 5 can vary in the parts of quality management system relevant with the risks of the no conformity of the product or regulatory requirements. Accordingly with the guidance of ISO/IEC Guide 53, in the design or the certification scheme there is risk considerations in the specification of whish elements of a QMS should be considered To see the conformity assessment for medical devices in the Directive of the European Union Consistency with the current concept in ISO 9000 and ISO 9001 standard and ISO/IEC Guide 53	**5.3.7 Scheme Type 5** The surveillance part of this scheme involves periodically taking samples of the product either from the point of production or from the market, or both, and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements. The surveillance includes periodic assessment of the production process or audit of the some elements or entire of quality management system or both.	113. Partially agreed, see 112
FR	5.3.7		te	The description of the types of certification scheme is limited to surveillance activities for type 2 to 5 To complete the definition with relevant sentences from ISO/CEI Guide 67 (§ 6.3.7 *add before § 5.3.7 the § 6.3.7 (Guide 67)*	Add this sentence in the beginning of 5.3.7 **"This system includes testing and assessment of the involved quality system. Surveillance of the quality system is conducted and samples of the product may be taken from either the market or the point of production, or both, and are assessed for ongoing conformity."**	114. Partially agreed, see rewording
IN	5.3.7	First paragraph, last line	Te	"Periodic assessment of production process or audit of the quality system as given in the last line in Scheme Type 5" allows scheme Type 4 to come under Scheme Type 5, since audit of quality management system is optional. Further, in Table 1 also, under Scheme Type 5, quality system audit has been shown as mandatory by putting X mark under that clause.	The last line may be changed as "The surveillance includes periodic assessment of the production process **and** audit of the quality system or both".	115. See 114
JP 05	5.3.7		Te	In Table 1, 6) c), it is written "quality system audits combined with random tests or inspection". However, the 1st sentence explains about a) and b) of Table 1, and there is no description about "random tests or inspection" in 5.3.7. It would be better to add explanation about it. According to Table 1, surveillance for Type 5 includes three types of testing or inspections, a) samples from the open market, b) samples from the factory and random	Add the explanation about "random tests or inspection", or modify Table 1 not to duplicate a) and b) with random tests or inspections in c).	116. Noted (as there is no proposal), the random test and inspection are needed for type 6

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
				tests or inspections combined with quality system audits. (It might be the traces of the table earlier than Guide 67.)		
FR	5.3.7	Last sentence	te	Incomplete distinction of surveillance activities between schemes type 4 and type 5	Replace the sentence "the surveillance includes periodic assessment of the production process or audit of the quality system or both" by :"The surveillance includes periodic assessment of the production process and audit of the quality system"	117. See 112
MX	5.3.8	Paragraph 4	Technical	The management system certification not necessarily is a mandatory requirement	For both services and processes, the surveillance part of this scheme should include ~~periodic audits of the quality system and~~ periodic assessment of the service or process and could include periodic audits of the quality system.	118. Not agreed, Guide 67 does not allow the choice
CO	5.3.8		te	Consistency with the current concept in ISO 9000 and ISO 9001 standard and ISO/IEC Guide 53	For both services and processes, the surveillance part of this scheme should include periodic audits of the quality management system and periodic assessment of the service or process.	119. Partially agreed, quality replaced by management
FR	5.3.8		te	The description of the types of certification scheme is limited to surveillance activities for type 2 to 5 To complete the definition with relevant sentences from ISO/CEI Guide 67 (§ 6.3.8 *add before § 5.3.8 the § 6.3.8 (Guide 67)*	Add this sentence in the beginning of 5.3.8 : 6.3.8 System 6 **"This system addresses especially certification of processes and services."**	120. Not agreed, WG agreed in previous meeting
GB 18	5.3.8	P2L3 P3	te	"Service" qua "service" is not generally but always predominantly intangible when analysed as to what the customer is actually paying for i.e. it is always the background system of processes, appropriate resources (especially human competences) and controls involved in the provision of anything tangible that the customer is actually paying for – not the necessary tangible result where that exists. E.g. the food in a restaurant, s/he is not paying for the individual items on the plate but all that goes to produce and deliver the service of a meal. If they are paying for the items they eat it becomes goods, not service. That which is tangible in the service will never be the object of certification otherwise it is "other product" of some sort, not service and not Group 6.	Reduce the implication of assurance to be gained from the tangible element of a service in these sentences. "In some situations the tangible elements of a service can support the evidence of conformity indicated by the assessment of processes, resources and controls involved. For example inspection of the cleanliness of vehicles for the quality of public transportation". "As far as processes are concerned, the situation is very similar. For example, the determination activities for welding processes can include testing and inspection techniques of samples of the	121. Agreed

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
				The danger of the suggestion in both of these examples is that involved in transferring results in samples taken on one day in the delivery of a service to provide assurance for a year or other periodic time when each journey and each weld can face differing specifications. The assessment of the intangible elements for the robustness of the processes and resources, especially human competences is paramount for the assurance given by the standard and by the determination of conformity activity. Inspection of instances of the results of the process as part of the determination is of minimal value to that assurance in comparison to all that is intangible. If we take a translation service as an example, the only thing that is tangible is the paper upon which it is written – the content on that paper is the result of an intangible intellectual process involving competence and each translation by a single translator has a different result.	resultant welds".	
IE	5.3.8	3	Te	There are several very common forms of process certification in the food production sector, where the object of certification is the food production process, rather than the food itself, which may not be tested or sampled. This section could benefit by having a second example, relating to food production.	"As far as processes are concerned, the situation is very similar. For example, the determination activities for welding processes can include testing and inspection techniques of the resultant welds. In food production, determination activities for the production process could include auditing of the HACCP system."	122. Not agreed, see new wording
FR	6.1	2nd sentence	te	A person cannot be a scheme owner (see 6.3.3)	Delete the term "person" in this sentence"It is particulary relevant to those ~~persons and~~ organization that are contemplating the establishment of a scheme or acting as a stakeholder"	123. Not agreed. The persons would not end up scheme owner at this point
FR	6.1			A stakeholder as defined might also be a regulator	Add "public authorities" to the examples given in the brackets (e;g manufacter, service provider, certification body, customer or **public authorities**)	124. Agreed
US	6.1		te	This section does not reflect the breadth of schemes. Scheme owners do not have to develop a scheme based on consensus. Government regulators are an example.	Reflect the concept that scheme owners can choose whether to develop the scheme using a consensus process.	125. Not agreed, consensus is not mentioned in 6.1.

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
MX	6.1		Technical	The certification scheme owner is the main interested that the scheme works.	This clause provides guidelines on how to develop and operate a product certification scheme. It is particularly relevant to the certification scheme owner and those persons and organisation that are ~~contemplating the establishment of a~~ related to scheme or acting as a stakeholder (e.g. manufacturer, service provider, certification body, or customer).	126. Not agreed, no improvement
FR	6.2	title	te	clarity	Replace « 6.2 Relationship of product certification scheme and system" by "6.2 Relationship of product certification scheme and **product certification** system"	127. Agreed, but see 128
US	6.2	Fig 1.b	te	We do not agree that it is necessary to further 'name' the concept that occurs when a scheme owner operates more than one scheme. This appears to add an additional unnecessary layer.	Remove the concept of a scheme owner operating multiple schemes.	128. Not agreed, useful concept widely applied
CA	6.2	Fig.1	General	Chart on page 7 requires formatting corrections		129. Agreed
BE	6.3		GE	There are no real requirements, which the scheme owner has to meet, for the actions he has to take and/or for the structure he has to provide to organise the consultation of the market and/or the stakeholders in order to substantiate the (market)support of the scheme.		130. Not agreed, see clause 6.4.3
MX	6.3.1	a)	NEW	Appoint a note clarifying that these CB are called MEMBERS according to ISO/IEC 17000 (2.11).	Note These certification bodies are kwon as members of the certification scheme in ISO/IEC 17000	131. Not agreed. a) relates to a CB running its own scheme
MX	6.3.1		Note	Use the ISO/IEC 17000 definition of PARTICIPANT (2.10).	...the scheme could be operated effectively by all ~~participating certification bodies~~ participants in the certification scheme.	132. Not agreed, no improvement
JP 06	6.3.1	1st sentence	Ed	The term "main" in "The following main types…" is not clear.	The term "main" should be deleted.	133. Not agreed, since this is not an exclusive list.
US	6.3.1		te	The types of "scheme owners" discussed is limiting.	Clearly define a scheme and simply say that a scheme owner is one who operates the scheme.	134. Not agreed. It is important to say that a scheme can be owned

1	2	(3)	4	5	(6)	(7)
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						and operated by a CB for its own use or that a CB may operate within a scheme owned by another party.
US	6.3.2		te	Section 6.3.2 implies that a product certification system constitutes a number of schemes.	Remove.	135. Not agreed, it provides useful information, see also 128
US	6.3.4		ed	The term "content" is mis-used.	Replace "content" with "rules".	136. Not agreed. Rules is not sufficient, content is wider
US	6.3.5		ed	The term "advice" is mis-used. "Advice" could be easily confused with consulting.	Replace "advice" with 'interpretation'	137. Partially agreed, replacement of advice with guidance
DE/AT/CEOC	6.3.7 6.5.1 d)		ge	The clauses 6.3.7 and 6.5.1 d) should be combined in one clause.	**Delete 6.3.7 and amend 6.5.1 d) as follows:** d) the requirements for certification bodies and other conformity assessment bodies involved in the certification process. These requirements should not be in contradiction to the requirements of the applicable standards for conformity assessment bodies;	138. Agreed
US	6.3.8		ed	The term "content" is mis-used.	Replace "content" with "rules" wherever this applies.	139. See 136
AT/CEOC/DE	6.3.11		te	The evaluation of risks is another expression for risk assessment and implies risk assessments according to ISO 31000. It is recommended to delete "risks" or to replace it by "consequences" or to add a Note clarifying that evaluation of risks does not mean a risk assessment according to ISO 31000.	**Alternative 1:** The scheme owner should evaluate and manage the ~~risks/~~liabilities arising from its activities. **Alternative 2:** The scheme owner should evaluate and manage the ~~risks~~ consequences/liabilities arising from its activities. **Alternative 3:**	140. Agreed to alternative 3

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
					Add the following Note: NOTE Evaluating risks does not imply risk assessments to ISO 31000	
PE	6.3.11, 6.3.12 and 6.3.13		te	**6.3.11** The scheme owner ***should evaluate and manage the risks/liabilities arising from its activities***. **6.3.12** The scheme owner ***should have adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its activities***. NOTE Arrangements should be appropriate for the range of activities and schemes undertaken and in the geographic regions in which the scheme operates. **6.3.13** The scheme owner ***should have the financial stability and resources required for it to fulfil its role in the operation of the scheme.***	The scheme owner could be a regulatory body or trade association which is not a Certification Body. In this case is not clear for us how these requirements could be applicable it would depend on the policy and procedures of the regulatory body and trade association in each country.	141. Noted.
AU	6.3.12		Te	Is this clause needed given 6.3.11?	Delete	142. Not agreed, This reflects 4.3.1 and 4.3.2 of 17065
US	6.4		te	The clauses in this section make specific assumptions about scheme development that are not always valid.	Replace the clauses of 6.4 with "The scheme owner should periodically review the effectiveness of the rules of the scheme considering input from stakeholders".	143. Not agreed, 6.4 provides useful information to scheme owners
CA	6.4		Technical	One of the 4.2.2 stated objectives is missing from the guidance for development of product certification schemes. Namely 4.2.2 last sentence indicating successful certification schemes delivers the required confidence while "utilizing the fewest possible resources thereby maximizing value". This aspect needs to be paraphrased and elaborated upon in 6.4. Such as 'don't invent unnecessary and unique requirements the majority of other participants don't agree are justified, as these add cost, resource, time delay and used as an excuse to not accept test reports from other participants.		144.Noted, proposal required
TH	6.4.2		ge	The term "appreciate" does not match the intention of this clause, and should be replaced by "consider".	The clause should read : **"**6.4.2 Irrespective of the purpose, scheme owners should consider the assumptions, influences and consequences involved in establishing, operating	145. partially agreedsee alternative wording

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MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
					and maintaining a scheme on an ongoing basis.".	
FR	6.4.3		te	Precision about the conditions of the participation of interested parties to the scheme development	Add a sentence after last sentence : ***(Issu de la NF X50-067, § 5.2)*** "The scheme owner should : — make sure that relevant interested parties are selected, taking specifically account of representativeness, the scope of the certification and the content and objectives of the scheme; — make sure that the representation balance does not lead any interested party to predominate. Note The list of interested parties shall at least include representatives from the following groups: — professionals producing the products (e.g. associations, federations, unions, individual producers); — consumer and/or end user representatives, or end-users themselves; — public authorities involved (either local or national regulatory authorities responsible for setting rules relating to the product and responsible for market surveillance). If the certification body deems it relevant, the	146. Not agreed, useful information but too detailed for this International Standard

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
					shortlist of interested parties may also include the following: — product retailers,, organisations in charge of installation, maintenance, recycling and/or disposal ; — authorities organizing services provided to end-users (e.g. urban community groups, regional councils, transport unions) and/or prescribing organisations; — experts in the technical or industrial field."	
RO	6.4.3		ge	"... the scheme owner should be able to identify affected stakeholders and seek their opinions and participation in scheme development."	"... the scheme owner should be able to identify affected stakeholders and seek their opinions in scheme development."	147. Not agreed, as the level of participation is not defined
FR	6.4.3	Last sentence	te	The interested parties are not always directly affected by the scheme	Replace "affected stakeholders" by "interested parties" in this sentence "To assist in this the scheme owner should be able to identify interested parties and seek their opinions and participation in scheme development.	148. Partially agreed, removal of "affected"
AU	6.4.4		Ed	6.4 in brackets should read 6.5	Amend	149. Agreed
AU	6.4.4		Ed	The para uses both "interested parties" and "stakeholders", are they different? Neither term is defined in ISO/IEC 7000 or ISO/IEC DIS 17065. Need to standardise on terminology here and throughout the document.	Define and Amend	150. See 148
BR	6.4.4		ed	There is an editorial error.	ABNT recommends replacing the term "…(see **6.4** below)…" by "…(see **6.5** below)…"	151. See 149
FR	6.4.4	1st sentence	te	Wrong reference to 6.4	Replace "6.4" by "6.5" in the bracket "(see **6.5** below)	152. See 149

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
IN	6.4.4		Ed	There is no clause 6.4 below the clause 6.4.4 and the applicable clause under reference is 6.5.	The word "C-6.4 below" should be replaced with "C-6.5 below".	153. See 149
SG	6.4.4		ED	Clause 6.4.4 stated (see 6.4 below) = shouldn't it be either (see 6.4 above) or (see 6.4.3 above) or (see 6.4.5 below) or (see 6.7.1 below)?	Shouldn't it be either (see 6.4 above) or (see 6.4.3 above) or (see 6.4.5 below) or (see 6.7.1 below)?	154. See 149
TH	6.4.4	Line1	ge	Wrong reference.	"(see 6.4 below)" should read "(see 6.5 below)".	155. See 149
US	6.4.4	First line	Ed	The parenthetical clause reference is incorrect.	Change "6.4" to "6.5" (see 6.5.below)	156. See 149
MX	6.4.4		Ed	To clarify that the opinion of interested parties is considered.	...To ensure that the scheme remains relevant, the scheme owner should ensure that the scheme is regularly reviewed following a process that includes interested parties <u>opinion</u>.	157. Not agreed, existing wording adequate
US	6.5		ed	The term "content" is mis-used.	Replace "content" with "rules" wherever this applies.	158. See 137
MX	6.5.1	c)		Place the correct terms defined in ISO 9000: QUALITY MANAGEMENT SYSTEM (3.2.3) and QUALITY CONTROL (3.2.10) and include the QUALITY ASSURANCE (3.2.11) option	other requirements to be met by the client, for example the operation of a quality <u>management</u> system<u>, quality assurance</u> or ~~process~~ <u>quality</u> control activities to assure the demonstration of fulfilment of specified requirements is valid for the ongoing production of certified products	159. Partially agreed. Add "management". <u>Process</u> controls are intended.
MX	6.5.1	d)		Consider the possible ACCREDITATION requirements. Accreditation is not considered as CONFORMITY ASSESSMENT ACTIVITIES, we have to specify it separately.	the requirements for <u>accreditation bodies,</u> certification bodies and other conformity assessment bodies involved in the certification process	160. Not agreed. Accreditation is covered by e)
MX	6.5.1	New NOTE		We can consider some voluntary elements for schemes, we can insert as a note	<u>Note In addition to elements described in 6.5.1, another voluntary elements could be:</u> a) <u>A period of announcement</u> b) <u>Minimum and maximum conformity assessment</u>	161. Partially agreed, see 6.7.2 with addition of transition period

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
					participants c) Transition period in case of updating the normative document that is going to be certificated or the rules of the scheme Others that the scheme owner consider relevant	
FR	6.5.1		te	Precision about the scope of the certification scheme. Add a new first idem in the beginning.	Add a new first item a): a) the scope, identifying i.a. the products and the use of them relevant to the certification scheme, the eventual geographical specifications ***(Issu de la NF X50-067, § 4.2)*** The scope should identify the product and its intended use. Where relevant, specific reference should be made to any products excluded from the certification scope. Identification may include: — Any related product and information relevant to the use of the product (associated products — instructions leaflet, packaging, etc.); — Associated services, particularly services related to the acquisition or supply of the actual product.	162. Partially agreed, see new a)
US	6.5.1		ge	This clause mixes product certification body concepts and scheme concepts.	Remove the concepts that are redundant with 17065.	163. Not agreed. We need to provide for the scheme references in 17065

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
FR	6.5.1 a)		te	Precision about the certification criteria	Add a sentence : The certification requirements should be : ❑ specific to the product to be certified (eg. technical or physical specifications) ❑ measurable, quantifiable, or verifiable.	164. Not agreed, the reference to 17007 is sufficient
US	6.5.1 b		TE	These sentences are redundant and confusing compared to the clearer 5.2.1. The use of the word "selection" in thi sentence is especially confusing since "selection" has already been used as a function in section 5.1 and a Table 1 item in 5.2. Text aligned with 5.2.1 should be used	Replace with: The elements in Table 1 to be included in the scheme (elements 1,2,3,4 should always be used) and the specific activities that will comprise each of these elements (see 5.2.1).	165. partially agreed, see rewording, change to "functions and activities"
TH	6.5.1 b)		te		The clause should read : "b) the selection of the activities (see Table 1) appropriate to the purpose and the scope of the scheme. As a minimum, a certification scheme should include the functions 1, 2, 3 and 4;".	166. See 165
FR	6.5.1 c)		te	Precision	Add the sentence "The scheme should define: the beneficiaries of the certification (suppliers); (NSA: Or which kind if suppliers can be certified) — pre-requisite requirements for certification, when relevant; — the options for single-site or multi-site certification; when relevant, specific requirements relating to how the certification document is applied in certain geographic areas if there are different rules for different areas"	167. Not agreed. Too detailed for this Standard
CO	6.5.1.c		te	Consistency with the current concept in ISO 9000 and ISO 9001 standard and ISO/IEC Guide 53	c) other requirements to be met by the client, for example the operation of a quality management system or process control activities to assure the	168. Partially agreed, change to management system

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
					demonstration of fulfilment of specified requirements is valid for the ongoing production of certified products	
JP 07	6.5.1 e)	1st sentence	Te	"accreditation" is not only the way to evaluate CAB's competency.	"…are to be accredited or peer assessed."	169. Agreed with additional wording
IN	6.5.1 h)		Ed	The two sentences under this clause does not make the meaning clear. Hence, these two lines should be combined.	The sentence may be changed as follows: "……control of marks, the requirements……"	170. Not agreed. The proposal does not work well with the lead-in phrase of 6.5.1
FR	6.5.1 j)		te		Add a sentence : "**Impartiality is based on objectivity, prevention of conflict of interest and independance**" (cf. 4.3 of ISO/PAS 17001)	171. Not agreed. Covered by 17065.
AU	6.5.1	m)	Ed	"including product requirements" is unnecessary as it is in the definition of certification requirements	Delete	172. Not agreed, useful for new reader, see rewording
TH	6.5.1 p)		ge	Replace "scheme" with "scheme owner".	The clause should read : "p) content, conditions and responsibility for publication of the directory of certified products by the certification body or the scheme owner;".	173. Agreed
AU	6.6		Te	The text of this section of the standard does not provide information about the operation of a scheme but provides an explanation/guidance/elaboration of most of the information contained in Section 6.5 of the document.	Combine Sections 6.5 and 6.6 under the heading of 6.5	174. Not agreed, current structure adequate
TH	6.6		ge	Clause 6.6 Operation of a scheme should describe all functions given in Table 1 to cover every scheme type. Therefore, "Licensing" should be described under 6.6.	Add new clause "Licensing" under 6.6.	175. Agreed, new sub clause 6.6.8
US	6.6.1		te	Description of sampling is not appropriate for a scheme. What is described here is product sampling. This is addressed in 17065.	Address sampling here only if there is a unique aspect to sampling that applies to schemes.	176. Partially agreed, see 177

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
US	6.6.1	Note	te	This note is inappropriately restricted to statistical methods. Statistical methods are not appropriate for all schemes.	Remove Note 6.6.1.	177. Partially agreed, NOTE reworded to be made less prescriptive
GB 19	6.6.2		te	Surveillance will be a major element of many schemes and it is the point at which the scheme owner will be tempted either - to impose a more onerous and intrusive regime than is warranted by the nature and use of the products, or - to apply a lightweight regime in the interests of minimizing costs whilst the consequences of product non-conformity could be severe. While the WG has been concerned not to produce a "Textbook", this is one area where some more help can be given to scheme owners in weighing up the various aspects to be considered when designing a surveillance function.	Amplify the clause along the following lines: "In deciding upon the appropriate surveillance activities and their frequency, the scheme owner should consider: a) the consequences if non-conforming products are placed on the market and put into use; b) the nature of the products and the production process in terms of the possibility that non-conforming products could be produced; c) the conformity assessment activities (testing, inspection, audit, etc.) which could prevent non-conformities from occurring or non-conforming products from being released onto the market; d) the frequency with which the conformity activities would need to be carried out to achieve the desired level of product conformity; e) the resources required for performing the surveillance activities and how the costs are to be borne.	178. Partially agree, the 1st sentence of proposal added to clause and reworded
JP 08	6.6.2		Ed	It would be better to use same description with Table 1.	Sentence should be changed to "…set of activities (activity 6) in Table 1)", instead of "…set of activities (activity 6 in Table 1)"	179. See 180
TH	6.6.2				The clause should read : "If surveillance is included, the scheme should define the frequency and set of activities (function 6 in Table 1) that make up the surveillance action.".	180. Agreed
GB 20	6.6.3		ed	The first sentence does not read well and could be confusing to those new to product certification.	Reword first sentence: "In some cases, clients might have obtained the results of determination activities such as testing, inspection or auditing, prior to making an application for certification."	181. Agreed

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
AU	6.6.5		Te	The last sentence implies that Appeals can be considered by the scheme owner. As a general rule, appeals can only be considered by the CB as an appeal is against a decision of the CB	Delete "Appeals and"	182. Partially agreed, see rewording
ID	6.6.5		ed	Propose complaints is written before appeals because normally client/customers express complaints first and then appeals	6.6.5 complaints and appeals to the scheme owner	183. Agreed
CA	6.6.5		Technical	An additional paragraph or sub-clause is necessary to include as part of the appeals process the ability to appeal to the relevant National Accreditor or ILAC and IAF if necessary where a participant is not adequately following the rules of the scheme.		184. Not agreed, not appropriate to this context
JP 09	6.6.6		Ed	It seems that the term "permission" is not suitable.	"prior permission" should be changed to "prior agreement".	185. Agreed
GB 21	6.6.7	Title	ed	Superfluous "s" on "operations"	Delete "s" from "operations"	186. agreed
IN	6.6.7		Te	For contract to be effective, it is required that contract is legally binding. Further, important points like confidentiality and conflict of interest should be addressed. In clause 6.2.2.3 of ISO/IEC DIS 17065, the same has been addressed.	Instead of contractual agreement, it may be changed to legally binding contractual agreement including confidentiality and conflict of interest.	187. Partially agreed, see rewording
US	6.6.7		ed	Subcontracting is a mis-use. Subcontracting is used in a different way in 17025 and other 170xx standards.	Change title to "Operations of the Scheme Performed by a Contractor".	188. Partially agreed, the reference to sub contracting in 6.6.6 changed to outsourcing to align with 17065
FR	6.6.9		te	To develop the description of possible corrective actions	Add at the end of the sentence : "**or customer information**"	189. Agreed
US	6.6.9	Note	te	17067 Revision Information lists ISO Guide 27. This is	Remove the note	190. not agreed, reference to

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted Convenor's recommendations
				circular.		Guide 27 is correct
FR	6.7.2		te	When changes are operated, in a scheme, provisions of 6.4.5 shall be applied	Add a note : "when changes in specified requirements are made, provisions of 6.4.5 applied"	191. Partially agreed, see new wording
FR	6.7.3		te	When changes are operated, in a scheme, provisions of 6.4.5 shall be applied	Add a note : "when changes to the scheme are made , provisions of 6.4.5 applied"	192. Not agreed, not necessary for context of scheme
MX	6.7.3		Technical	The scheme owner has the responsibility of the whole scheme, it should have the capability of add and retire participants according to the performance of the scheme and the performance of each participant, misbehaviour for instance	The scheme owner should define a process for managing the implementation of other changes to the rules, procedures ~~and~~, management and addition or reduce of participants of the scheme.	193. Not agreed, see 6.5.1 r)
JP 10	6.8	1st sentence	Ed	Clarification	Sentence should be changed to "…for the operation, maintenance and improvement of the scheme.", instead of "…for the operation of the scheme."	194. Agreed
TH	6.8	Line 2	te	"operating rules" should be defined.		195. Partially agreed, reworded
RO	Bibliography	Relevant documents to be considered	ge	There is no reference to European standard EN 45011:1998- General requirements for bodies operating product certification systems (ISO/IEC Guide 65:1996)	**Adding document EN 45011:1998- General requirements for bodies operating product certification systems (ISO/IEC Guide 65:1996) to Bibliography**	196. Not agreed. Not appropriate for inclusion in an International Standard