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**INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC) SYSTEM FOR
CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR USE IN
EXPLOSIVE ATMOSPHERES (IECEx SYSTEM)**

Title: Presentation prepared by ISO concerning ISO/IEC 17067 *Conformity assessment – fundamentals of product certification and guidelines for product certification schemes*

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INTRODUCTION

This document concerning **ISO/IEC 17067 *Conformity assessment – fundamentals of product certification and guidelines for product certification schemes*** has been prepared by ISO and is issued for information.

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Introducing ISO/IEC 17067:2013

Conformity assessment –
fundamentals of product certification and guidelines for product
certification schemes

August 2013

The aim of this presentation is to support all parties with an interest in product certification, e.g. scheme owners, conformity assessment bodies, suppliers and users of certified products and those with regulatory responsibilities for the supply and use of products.

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We welcome any proposals for improvement of this presentation or translation in national languages.

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ISO/IEC 17067:2013 - History

1980 *Certification – principles and practice* - ISO/ITC

1982 ISO/IEC Guide 28 *General rules for a model third-party certification system for products*

1983 ISO/IEC Guide 40 *General requirements for the acceptance of certification bodies*

1992 *Certification and related activities* - ISO/IEC

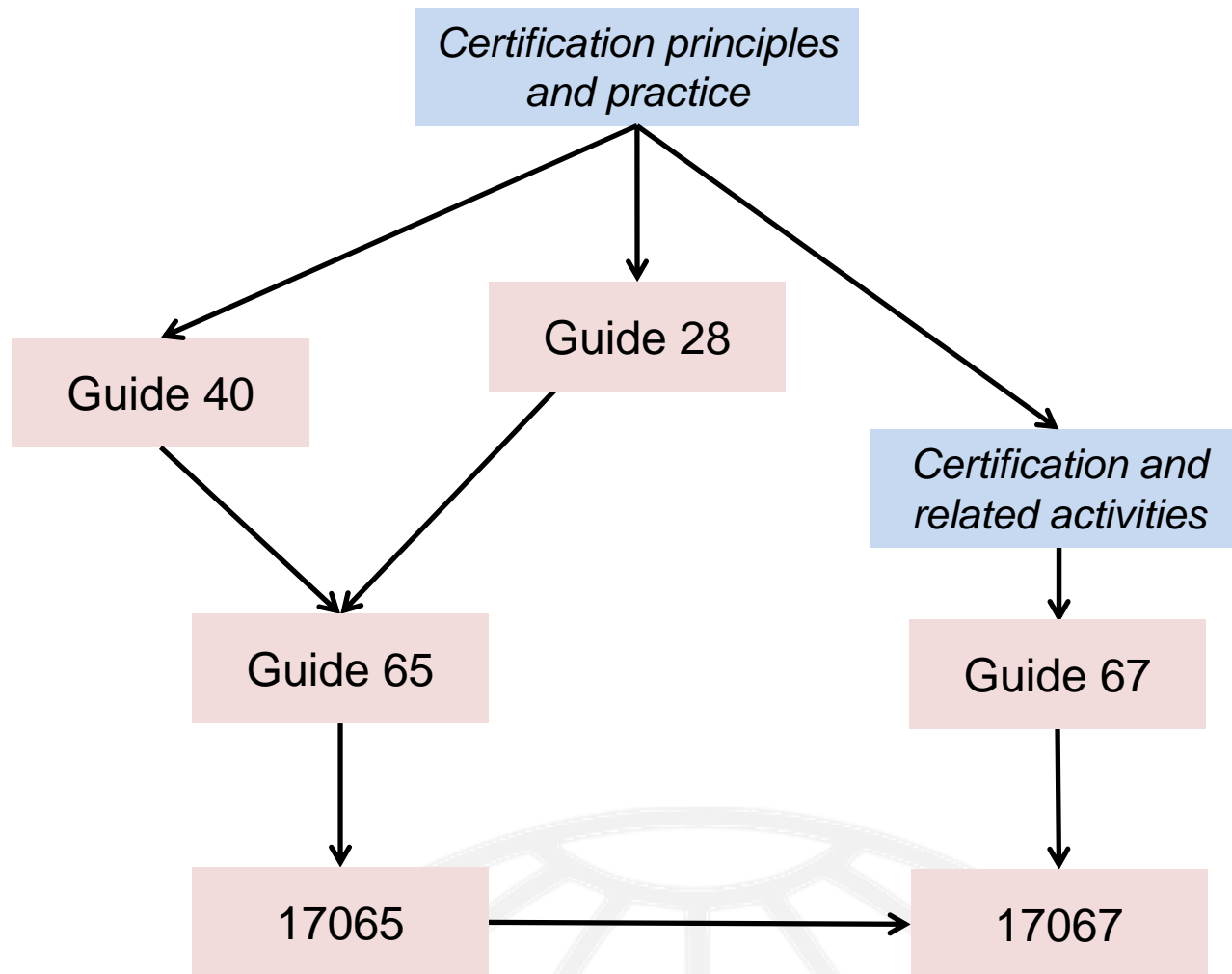
1996 ISO/IEC Guide 65 *General requirements for bodies operating product certification systems*

2004 ISO/IEC Guide 67 *Conformity assessment - Fundamentals of product certification*

2012 ISO/IEC 17065 *Conformity assessment - Requirements for bodies certifying products, processes and services*

2013 ISO/IEC 17067 *Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes*

ISO/IEC 17067:2013 – History (cont.)



Motivation for revising ISO/IEC Guide 67

In drafting ISO/IEC 17065, it was realised that a major impact on what a certification body does arises from the requirements of the product certification scheme(s) they are operating

Rather than trying to elaborate on these, it was decided simply to make reference to “the requirements of the scheme”

There are 31 such references in ISO/IEC 17065

ISO/IEC Guide 67 provided some basic information about product certification systems and it was decided that the Guide could be revised to include more information on product certification schemes

ISO/IEC Guide 67 to ISO/IEC 17067 – principle changes

Title – extended to include product certification schemes

Introduction – extended to include some of Guide 67, Clause 4

Change from “system” to “scheme” as the focus

Clarification of type and batch certification

New section on product certification schemes providing information relating to “scheme” references in ISO/IEC 17065

System → Scheme

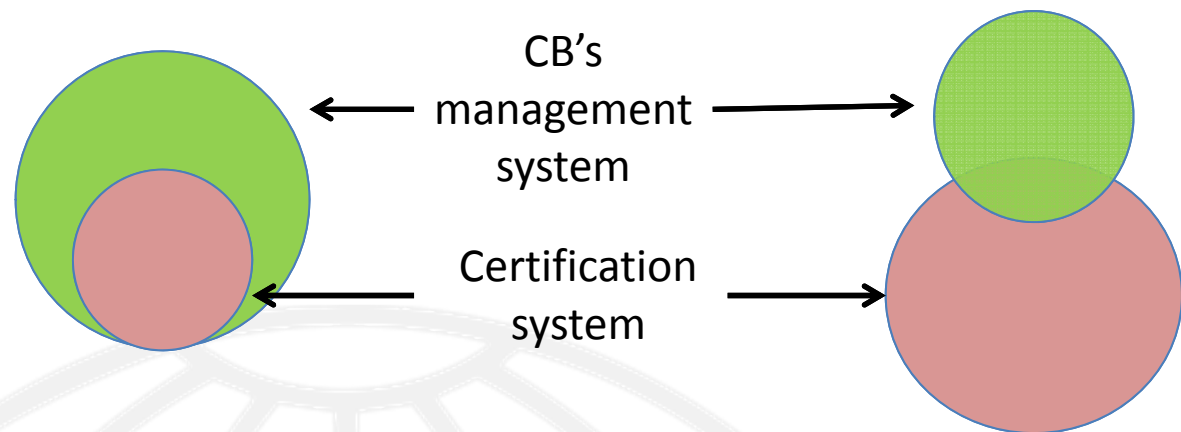
Confusion between certification system and management system

- For certification body's own scheme, certification system is part of management system
- For other schemes in which CB participates, certification system is external to CB's system

Certification scheme is the basic building block

Own scheme

Other scheme



Type and batch certification

“Certification and related activities” was clear on the distinction

- System 1 = type test
- System 7 = batch test
- System 8 = 100% test

Guide 67 merged Systems 7 & 8 into System 1 which was split into System 1a and System 1b

- Wording of 6.3.2 and 6.3.3 was not explicit

Now clarified that:

- Scheme type 1a = type test (5.3.2)
- Scheme type 1b = batch test (including 100%) (5.3.3)

ISO/IEC 17067 – what type of standard?

Shall = normative?

Should = informative?



ISO/IEC 17067 – what type of standard?

Should = informative



ISO/IEC 17067 – what type of standard?

Should = informative

Provides **guidelines** for those involved in developing and operating product certification schemes - particularly scheme owners



ISO/IEC17067: contents

Introduction

1. Scope

2. Normative references

3. Definitions

4. Product certification

5. Product certification schemes

6. Development and operation of a product certification scheme

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.



2. Normative references

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

ISO/IEC 17065:2012, *Conformity assessment — Requirements for bodies certifying products, processes and services*



3. Definitions

3.1 certification system

- rules, procedures and management for carrying out certification

3.2 certification scheme

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

3.3 scheme owner

- person or organization responsible for developing and maintaining a specific **certification scheme** (3.2)

4. Product certification

4.1 Concept of product certification

- assessment and impartial, third party attestation that fulfilment of specified requirements has been demonstrated
- provides confidence to consumers, regulators, industry and other interested parties that products conform to specified requirements
- facilitates trade, market access, fair competition and consumer acceptance of products on a national, regional and international level

4. Product certification (cont.)

4.2 Objectives of product certification

- to address the needs of consumers, users and, more generally, all interested parties by giving confidence regarding fulfilment of specified requirements
- to allow suppliers to demonstrate to the market that their product has been attested to fulfil specified requirements by an impartial third party body
- provide confidence for those with an interest in fulfilment of requirements, and sufficient value so that suppliers can effectively market products

5. Product certification schemes

5.1 Basics – the functional approach

- Selection
- Determination
- Review
- Decision
- Attestation
- Surveillance (where required)

5. Product certification schemes

5.2 Functions and activities

- Each function is performed by carrying out certain conformity assessment activities, e.g. testing
- The activities will depend on the nature of the product and the production process
- Different types of scheme depending on type of surveillance
- Table 1: matrix of functions and activities for different types of scheme

Table 1 Building a product certification scheme

Conformity assessment functions

Conformity assessment activities

Scheme types

Table 1 — Building a product certification scheme

Conformity assessment functions and activities ^a within product certification schemes	Types of product certification schemes ^b							
	1a	1b	2	3	4	5	6	7 ^c
I Definition, including planning and preparation activities, specification of requirements, e.g. normal documents, and sampling, as applicable	x	x	x	x	x	x	x	x
II Determination of characteristics, as applicable, by: a) testing b) inspection c) design approach d) assessment of services or processes e) other determination activities, e.g. verification	x	x	x	x	x	x	x	x
III Review Examining the evidence of conformity obtained during the determine this stage to establish whether the specified requirements have been met	x	x	x	x	x	x	x	x
IV Decision on certification Granting, maintaining, extending, reducing, suspending, withdrawing certification	x	x	x	x	x	x	x	x
V Attestation, licensing a) issuing a certificate of conformity or other statement of conformity (attestation) b) granting the right to use certificates or other statements of conformity c) issuing a certificate of conformity for a batch of products d) granting the right to use marks of conformity (licensing) (based on surveillance [VI] or certification of a batch)	x	x	x	x	x	x	x	x
VI Surveillance, as applicable (see 3.3.4 to 3.3.6) by: a) testing or inspection of samples from the open market b) testing or inspection of samples from the factory c) assessment of the production, the delivery of the service or the operation of the process d) management system audits combined with random tests or inspections				x		x	x	

^a Where applicable, the activities can be coupled with initial audit and surveillance audit of the applicant's management system (as example is given in ISO/IEC Guide 52) 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 An often used and well-titled model for a product certification scheme is described in ISO/IEC Guide 28; it is a product certification scheme corresponding to scheme type 3.

^c A product certification scheme includes at least the activities I, II, III, IV and V a).

^d The symbol (N) has been added to show an undefined number of possible other schemes, which can be based on different activities.

Table 1

Conformity assessment functions and activities ^a within product certification schemes		Types of product certification schemes ^b							
		1a	1b	2	3	4	5	6	N ^{c,d}
I	Selection, including planning and preparation activities, specification of requirements, e.g. normative documents, and sampling, as applicable	X	X	X	X	X	X	X	X
II	Determination of characteristics, as applicable, by:								
	a) testing	X	X	X	X	X	X	X	X
	b) inspection	X	X	X	X	X	X	X	X
	c) design appraisal	X	X	X	X	X	X	X	X
	d) assessment of services or processes	X	X	X	X	X	X	X	X
e) other determination activities, e.g. verification	X	X	X	X	X	X	X	X	
III	Review								
	Examining the evidence of conformity obtained during the determination stage to establish whether the specified requirements have been met	X	X	X	X	X	X	X	X
		X	X	X	X	X	X	X	X
IV	Decision on certification								
	Granting, maintaining, extending, reducing, suspending, withdrawing certification	X	X	X	X	X	X	X	X
V	Attestation, licensing								
	a) issuing a certificate of conformity or other statement of conformity (attestation)	X	X	X	X	X	X	X	X
	b) granting the right to use certificates or other statements of conformity	X	X	X	X	X	X	X	X
	c) issuing a certificate of conformity for a batch of products	X	X	X	X	X	X	X	X
d) granting the right to use marks of conformity (licensing) is based on surveillance (VI) or certification of a batch.	X	X	X	X	X	X	X	X	

5. Product certification schemes

5.3 Types of product certification schemes

- Brief descriptions of the features of each scheme type.
- Not a definitive list – it is for the Scheme Owner in consultation with interested parties to define the activities
- All scheme types involve testing (or similar) to determine that a sample fulfills specified requirements
- In most cases the different scheme types involve different surveillance activities

5.3 Types of scheme

Scheme type 1a: type test. Attestation of conformity applies only to samples tested.

Scheme type 1b: batch test, including 100% testing. Attestation of conformity applies to all items in the batch

Scheme type 2: type test plus periodic testing of products from the market

5.3 Types of scheme (cont.)

Scheme type 3: type test plus periodic testing of products from the point of production plus periodic assessment of the production process

Scheme type 4: type test plus periodic testing of products from the point of production and/or the market plus periodic assessment of the production process

Scheme type 5: type test plus periodic assessment of production process and/or audit of management system plus periodic testing of products from point of production and/or the market

NB: Scheme types 3, 4 and 5 require initial assessment of production process and/or management system

5.3 Types of scheme (cont.)

Scheme type 6: applicable to certification of services and processes. Initial and periodic assessment of service or process plus initial assessment and periodic auditing of management system

NB: Insufficient attention yet at ISO level to service and process certification

Scheme type n: included in Table 1 but no separate clause in 5.3 Indicates that scheme owner can select activities that suit the purpose of the scheme, in consultation with stakeholders



New!

6. Development and operation of a product certification scheme

In response to many references in ISO/IEC 17065*, new clause to provide guidelines for scheme owners and others

* ISO/IEC 17065:2012, *Conformity assessment – Requirements for bodies certifying products, processes and services*



6. Development and operation of a product certification scheme

6.1 General

6.2 Relationship between product certification scheme and product certification system

6.3 Scheme owner

6.4 Development of product certification schemes

6.5 Content of a scheme

6.6 Maintenance and improvement of a scheme

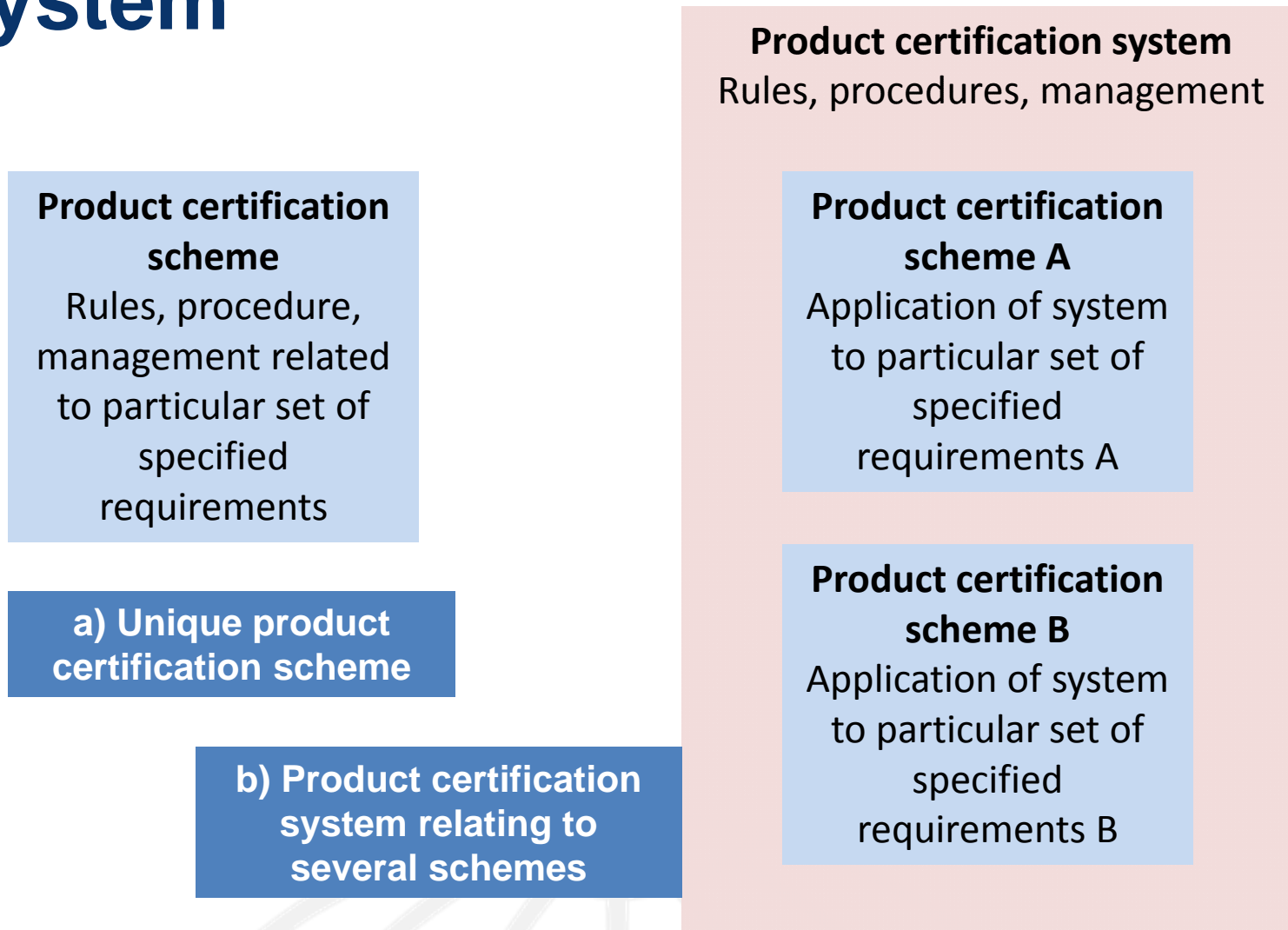
6.7 Scheme documentation

17067: 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 organizations that are considering the establishment of a scheme or acting as a stakeholder (e.g. manufacturer, service provider, certification body, customer or public authority).

6.2 Relationship between scheme and system



6.3 Scheme owner

6.3.1 Types of scheme owner –

- Certification body,
- Other – regulatory body, trade association, group of certification bodies, etc.

6.3.2 Combine several schemes within product certification system

6.3.3 Legal entity

6.3.4 Full responsibility for objectives, content, integrity of scheme

6.3.5 Maintain scheme and provide guidance



6.3 Scheme owner (cont)

6.3.6 Set up structure for operation and management of scheme

6.3.7 Document content of scheme

6.3.8 Scheme developed by competent persons

6.3.9 Arrangements to protect confidentiality of information

6.3.10 Evaluate and manage risks/liabilities arising from scheme

6.3.11 Arrangements to cover liabilities arising from owner's activities

6.3.12 Financial stability and resources

6.4 Development of product certification schemes

6.4.1 Purpose of scheme

6.4.2 Understand assumptions, influences and consequences

6.4.3 Identify stakeholders and seek input

6.4.4 Agree fundamental scheme principles with stakeholders

6.4.5 Information on scheme publicly available – transparency, understanding, acceptance

6.5 Content of a scheme

6.5.1 General – elements of a scheme

6.5.2 Sampling

6.5.3 Acceptance of conformity assessment results

6.5.4 Outsourcing of conformity assessment activities

6.5.5 Complaints and appeals to scheme owner

6.5.6 Licensing and control of mark

6.5.1 Elements of a scheme

Scope

Product requirements

CA activities

Certification requirements

Requirements for CA bodies : accreditation? peer assessment?

CA methods and procedures

Information supplied by client

6.5.1 Elements of a product certification scheme (cont.)

Statement of conformity

Mark of conformity

Use of certificate and mark

Resources for operating scheme - impartiality, competence, outsourcing

Reporting results of determination and surveillance activities

Dealing with non-conformities: client, product

Surveillance procedures

6.5.1 Elements of a product certification scheme (cont.)

Criteria for access to scheme: CBs, clients

Directory of certified products

Contracts: owner, CB, client

Conditions for certification: granting, withdrawing, etc.

Clients' complaints records, need for verification by CBs

Clients' reference to scheme in publicity material

Records to be retained by scheme owner and CBs

6.5 Content of a scheme (cont)

6.5.7 Surveillance

6.5.8 Non-conforming product

6.5.9 Reporting to scheme owner

6.5.10 Subcontracting of operation of scheme

6.5.11 Marketing

6.5.12 Fraudulent claim of certification

6.6 Maintenance and improvement of a scheme

6.6.1 Review of scheme operation

6.6.2 Changes in specified requirements

6.6.3 Other changes to the scheme



6.7 Scheme documentation

Scheme owner:

- Creates, controls and maintains adequate documentation for operation, maintenance and improvement of scheme

Documentation specifies:

- rules
- operating procedures
- responsibilities for governance of the scheme


ISO/IEC 17067 - Summary

- Revises and updates ISO/IEC Guide 67
- Changes focus from system to scheme
- Provides information on scheme requirements as referenced in ISO/IEC 17065
- Emphasises crucial role of Scheme Owner
- Clarifies difference between type and batch certification schemes

Ongoing issues



Updating of ISO/IEC Guides 28 and 53 → ISO/IEC TR 17026



Further consideration of help with certification of services and processes



Acknowledgements

I would like to thank the following for their role in the production of ISO/IEC 17067:

- The members of ISO/CASCO WG 32 for their co-operation, inspiration and hard work in drafting the International Standard
- The wider CASCO and ISO membership for their helpful comments and their positive votes
- The CASCO Secretariat staff for their dedication and guidance

Ian Cleare

Convenor, WG 32



The background features a large, semi-transparent globe grid pattern. Overlaid on this is the text 'ISO' in a very large, bold, sans-serif font. The 'I' and 'S' are on the left, and the 'O' is on the right. The text is semi-transparent, allowing the globe grid to be seen through it.

Thank you

Confidence has a nickname...

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