## ISO/IEC 17065:2012

Conformity assessment – Requirements for bodies certifying products, processes and services

Presentation on the new standard



### Introduction

This presentation has been developed by the Drafting Group of ISO CASCO WG 29.

The aim is to support all interested parties concerned by the implementation of this new standard, e.g. conformity assessment bodies, accreditation bodies, industries with general information and contribute to an harmonized transition.

This is an open presentation without any copyrights and can be used by anyone.

We welcome any information about product certification in your region, country, e.g. number of schemes, number of accredited certification bodies, number of certificates under ISO/IEC Guide 65 / ISO/IEC 17065, if you have any please send it to charlet@iso.org

ISO CASCO Secretary
Sean MacCurtain

ISO CASCO Convenor WG 29 Christian Priller



# Examples - Importance and Impact of product certification for global trade

An unknown number of sectors, regulators, schemes and CB's run their operation under this requirements with an unknown number of certificates and products, this shows the great importance.

#### International level

#### **IEC CB Scheme:**

74 National Certification Bodies
382 CB Testing Laboratories
45 Satellite Laboratories
2800 Manufacturer's Testing Laboratories
70'000 CB Test Certificates issues in 2011

#### **Europe:**

New Legilation Framework (NLF) over 20 European Directives, Trade volume 1500 mrd €, about 2000 Notified Bodies 974 accredited certification bodies in Europe (source: European Co-operation Accreditation)

#### Germany:

GS-mark 91 bodies

#### **Brasil**

70 accredited Certification Bodies

#### **Asia**

#### Japan

JIS-mark: 25 certification bodies JAS-mark: 142 certification bodies PSE-mark: 10 certification bodies PSC-mark: 9 certification bodies PAL: 13 certification bodies

#### China:

35 accredited Certification Bodies 10 Certification Bodies response for China Compulsory Certification (CCC) 50,728 companies with 280,000 certificates for CCC

#### New Zealand/Australia

36 certification bodies for product certification 70 product certification schemes delivered by 36 accredited bodies

USA

120 Accredited Certification Bodies



## **Product, Process and Service Certification** (1)

The overall aim of certifying products, processes or services is to give confidence to all interested parties that a product, process or service fulfills specified requirements.

The value of certification is the degree of confidence and trust that is established by an impartial and competent demonstration of fulfillment of specified requirements by a third-party.



# **Product, Process and Service Certification (2)**

consumers and other members of the public.

nongovernmental organizations; and the clients of the certification bodies;

Parties that have an interest in certification include, but are not limited to: the customers
of the
organizations
whose products,
processes or
services are
certified;

governmental authorities;



## Purpose of Revision ISO/IEC Guide 65 to ISO/IEC 17065

#### **ISO IEC Guide 65**



Maintain the proven parts of Guide 65

Improve where necessary

#### **ISO IEC 17065**





## Content of ISO/IEC Guide 65 to ISO/IEC 17065 (1)

➤ The content is aligned with the new structural requirements decided by ISO CASCO (8 chapters instead of 15 in ISO/IEC Guide 65)

1.	Scope
2.	Normative references
3.	Terms and definitions
4.	General requirements
5.	Structural requirements
6.	Resource requirements
7.	Process requirements
8.	Management system requirements



## Content of ISO/IEC Guide 65 to ISO/IEC 17065 (2)

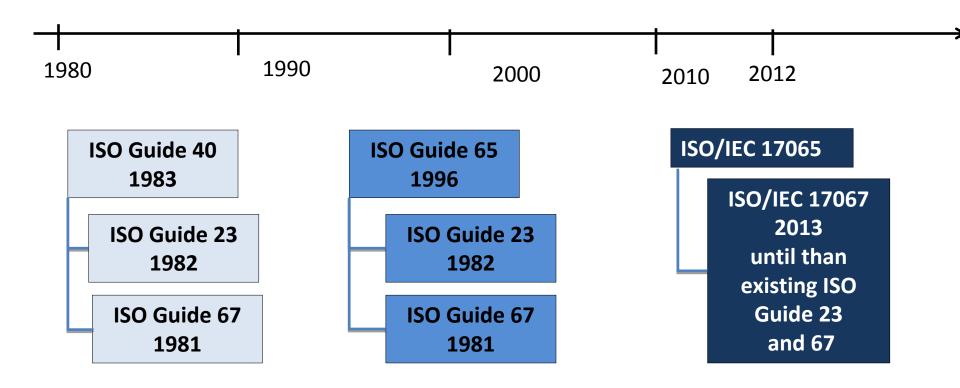
➤ The obligatory requirements of the ISO/PAS are included in ISO/IEC17065

- 1. ISO/PAS 17001 on Impartiality included in clause 4.2
- 2. ISO/PAS 17002 on Confidentiality included in clause 4.5
- 3. ISO/PAS 17003 on Complaints and appeals included in clause 7.13
- 4. ISO/PAS 17004 on Disclosure of information included in clause 4.6
- 5. ISO/PAS 17005 on Use of management systems included in clause 8



<sup>\*</sup> The PAS requirements may also be addressed in other parts of the standards than the ones listed above

### **History and Relationship**





## Relation between certification body and scheme owner

#### Scheme

Scheme owner runs a scheme

#### Stakeholder

#### Scheme owner

Certification Body and Conformity assessment Guidelines for schemes are given in ISO/IEC 17067

Requirements for certification bodies are given in ISO/IEC 17065

manufactorer,
operator,
deliverer of a
product, process or
services

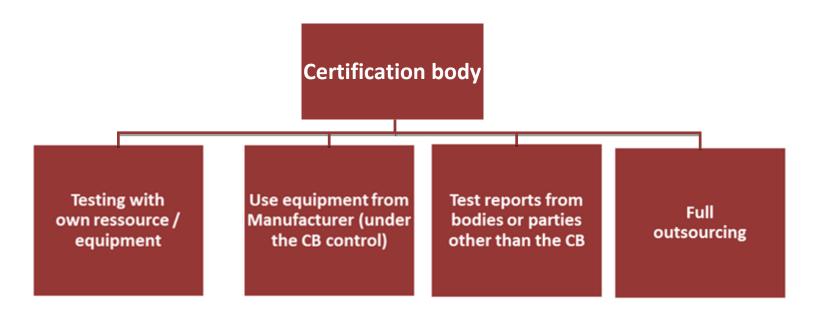
#### Customer

Scheme owner can be the certification body, governmenal authority, trade association, group of CB'S, .....

ISO/IEC 17030 for the labels and their use



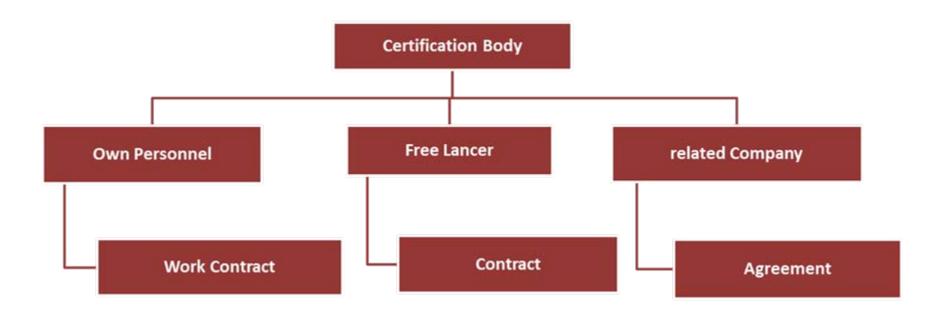
# **Examples of resources used for testing, inspection and auditing**



All those examples are covered in Clauses 6 of ISO/IEC 17065



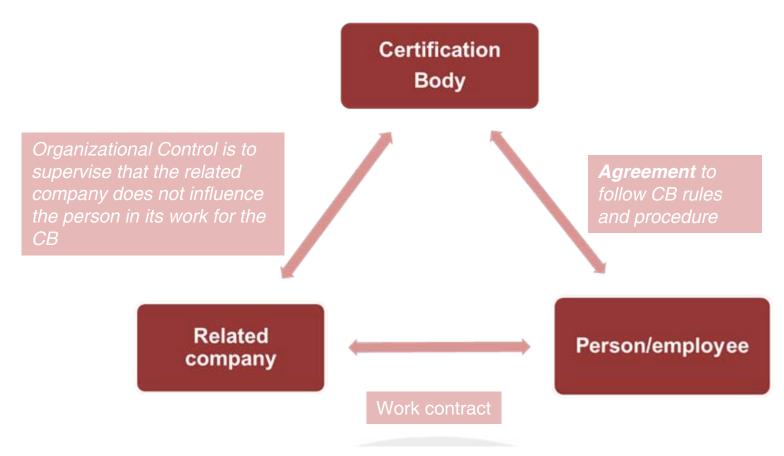
### **Examples of Resources Personnel**



All those examples are covered in Clause 6 of ISO/IEC 17065



# **Example of possible arrangement for Organizational Control**

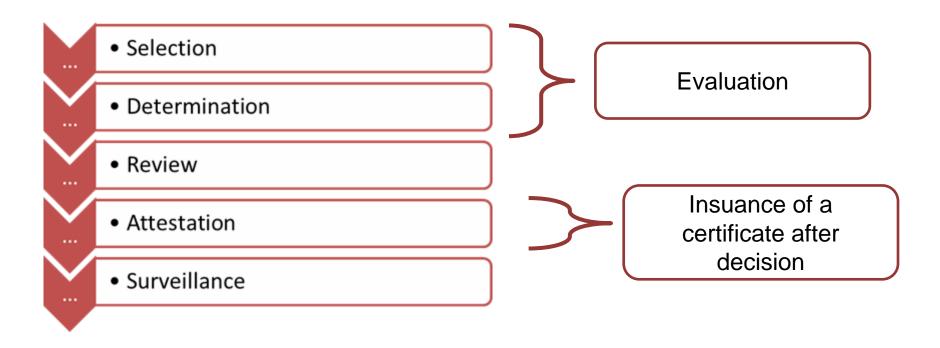


This relates to Clause 7.6.4 of ISO/IEC 17065. This is one possibility for organisational control among many



### **Functional Approach**

The functional approach is described in ISO/IEC 17000 (left part of the chart below)



The right part of the chart (evaluation – Insuance of certificate) is the terminology used in ISO/IEC 17065



### Process steps / requirements

M	• 7.1	General
Y	• 7.2	Application
Y	• 7.3	Application review
$\mathbf{Y}$	• 7.4	Evaluation
$\mathbf{Y}$	• 7.5	Review
$\searrow$	• 7.6	Certification decision
$\searrow$	• 7.7	Certification documentation
$\searrow$	• 7.8	Directory of certified products
$\mathbf{Y}$	• 7.9	Surveillance
Y	• 7.10	Changes affecting certification
$\searrow$	• 7.11	Termination, reduction, suspension or withdrawal of certification
V	• 7.12	Records
V	• 7.13	Complaints and appeals

