



## 6th Working Draft of ISO/IEC 17065

3<sup>rd</sup> meeting of WG 29 on June 29-30 - July 1

### Introduction from the Convenor

April 30th, 2009  
Mario O. Wittner

The Drafting Group prepared the WD 6 of ISO/IEC 17065 after many discussions, taking into account the different kinds of certification bodies and certification processes, which are assessed with the ISO/IEC Guide 65.

It was a hard work, trying to conceal different visions: from the purely “performance” one stating that only the principles and main goals should be stated to a strict “requirements” with all necessary explanations, thus focused on avoiding the need of further “guidance” on the requirements.

The WD 6 is the result of this work. It is clear that many drafting issues will have to be improved. However, I kindly ask the WG 29 members to concentrate their comments only on technical aspects.

ISO/IEC 17065 must move to the Committee Draft stage at this meeting if the project is to remain within acceptable time limits. The purpose of this Working Group meeting is to reach consensus on a draft document so that a ballot to CASCO members will be productive (obtain a DIS).

In the following paragraphs are listed some of the main factors taken into account. They were prepared on the basis of the papers provided by two experts of the Drafting Group: Keith Mowry (ANSI) and Ian Cleare (BSI).

## 1. Scope of ISO/IEC 17065

- Requirements for the competence, consistency and impartiality of certification bodies for products (including services) and processes

### Impact on drafting ISO/IEC 17065

- *Fulfillment of each ISO/IEC 17065 requirement needs to make a meaningful contribution to the assurance of competence, consistency and impartiality of the compliant certification body*

- *Each ISO/IEC 17065 requirement needs to be meaningful for the certification of products, including services and processes*

## **2. Maturity of product certification**

- Product certification has been practiced for over 100 years and is used extensively in the global economy at the sub-national, national, regional and global level.
- The use of product certification continues to expand geographically and to new industries/technologies.
- Product certification is being used in a wider variety of fields today than in the 1990s when ISO/IEC Guide 65 was developed, including agri-food products, “green” issues and commercial services. ISO/IEC 17065 has to be able to meet certification needs in these and other emerging applications.

### **Impact on drafting ISO/IEC 17065**

- *A well developed set of general principles for the competence, consistency and impartiality of certification bodies exists and should be reflected in the ISO/IEC 17065 requirements*

## **3. Experience with ISO/IEC Guide 65**

- ISO/IEC Guide 65 has been in use for 13 years and applied to an enormous volume and significant variety of product certification activity.
- Accreditation and peer assessment of product certification has grown substantially since 1996.
- Product certification has been highly successful as a market and regulatory tool for driving fulfillment of specified requirements and the benefits expected from fulfillment of those requirements (e.g., protection of safety, health and the environment; interoperability; reduced energy consumption; etc.).
- ISO/IEC Guide 65 repeated requirements in different places or split different aspects of the same requirement in to different clauses.

### **Impact on drafting ISO/IEC 17065**

- *New ISO/IEC 17065 requirements that exceed ISO/IEC Guide 65 (added cost ultimately for consumers) must be justified by sufficient benefit in the form of needed additional assurance of competence, consistency and impartiality should be considered.*
- *Each requirement in ISO/IEC 17065 must be stated only once in the most logical location possible*

## **4. Developments in product certification since 1996**

- Significant growth of the number of certification schemes especially schemes with owners (regulators and private sector) separate from the product certification bodies that operate the scheme.
- Significant growth of certification of processes on the basis of specific process standards and the use of process based requirements for certification of tangible products.
- Significant growth of certification services, on the basis of specific service standards.

### **Impact on drafting ISO/IEC 17065**

- *ISO/IEC 17065 requirements must not restrict the role or choices of scheme owners*
- *ISO/IEC 17065 must not set requirements for schemes nor how schemes are developed (in many cases, schemes are developed through regulatory or standards development processes)*
- *Each ISO/IEC 17065 requirement needs to be meaningful not only for product but for the certification of services and processes (see Scope)*
- *ISO/IEC 17065 requirements must be applicable to the entire range of product certification body organizations - from the most simple to the most complex*

## **5. Developments in ISO and ISO CASCO since 1996**

- ISO-IAF MOU and the development of IAF Guidance on ISO/IEC Guide 65

- Growing importance of performance requirements in ISO Standards

ISO/IEC 17000:2004 has set out the “functional approach” to conformity assessment: Selection - Determination - Review - Attestation (+ Surveillance, where appropriate)

- ISO/CASCO has adopted a series of PASs (Publicly Available Specification) (17001 to 17005) which set out the mandatory and optional text to be included in standards developed by ISO/CASCO and which contain requirements for:

Impartiality	PAS 17001
Confidentiality	PAS 17002
Complaints and appeals	PAS 17003
Disclosure of information	PAS 17004
Use of management systems	PAS 17005

Those parts of the ISO/IEC Guide 65 text which address the above issues need to be replaced or adapted from the text of the related PAS.

- ISO/CASCO has specified a structure for its standards for bodies (in CASCO document: QS/CAS/PROC/01) which, for the normative technical content, must include the following sections:
  - Terms & definitions
  - Principles
  - (General) requirements
  - Structural requirements
  - Resource requirements
  - Information requirements
  - Process requirements
  - Management system requirements

This structure was used when ISO/IEC Guide 62 was converted to ISO/IEC 17021:2006. In applying this structure to ISO/IEC 17065, it has been necessary to move the text of ISO/IEC Guide 65 into the appropriate sections.

### **Impact on drafting ISO/IEC 17065**

- *ISO/IEC 17065 must be able to be used by product certification bodies by accreditation bodies and peer assessment schemes, by regulators, by scheme owners (governmental or private ones.)*

- *ISO/IEC 17065 content should eliminate or minimize the need for IAF Guidance.*
- *ISO/IEC 17065 requirements should reflect the Functional Approach **the PASs** and be performance requirements to the extent possible.*
- *The general structure and text of certain sections for the initial Committee Draft of ISO/IEC 17065 are mandated by CASCO Plenary Resolution.*

## **6. Other highlights: the process of preparing WD 6**

6.1 The Working Draft (WD) 6 has been developed by the Drafting Group in various meetings since the first one of the WG in April 2007 and the working group has a first opportunity to consider the developments in its meeting of April 2008. This WD 6 was agreed by the DG in its meeting of March 30 and 31, 2009.

6.2 The WD 6 includes existing texts in ISO/IEC Guide 65 organized in the present CASCO approved structure for standards for bodies (see 5).

6.3 The Drafting Group took into account, as much as possible, the alignment with ISO/IEC 17021, for certification of management systems: the reasons being that many certification bodies provide certification for products and for management systems.