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Item 8 (a) of the provisional agenda

CONFORMITY ASSESSMENT

Principles of conformity assessment New definitions based on a functional approach

This paper has been submitted by Mr. Lucien Tronel, Rapporteur on Conformity Assessment. It contains proposals for action by the Working Party.

This document is presented for information, discussion and decision (see page 5). It is reproduced in the form in which it was received by the secretariat.

Principles of conformity assessment

New definitions based on a functional approach

History of the UNECE's involvement in the terms and definitions related to standardization and related activities.

1. The first set of general terms and their definitions concerning standardization and certification was prepared by UNECE primarily to facilitate the work of the Economic Commission for Europe aimed at the removal of barriers to international trade arising from lack of harmonization of standards or inadequate international application of standards. At that time, UNECE was active through its Group of Government Officials Responsible for Standardization created in 1970. UNECE recognized that it was of considerable importance that harmonization of definitions be achieved at the international level and therefore expressed the hope that the relevant international organizations – in their activities regarding definitions – would take the definitions into account.

2. After approval in both UNECE and ISO, the first series was published as ISO/UNECE Guide 2-1976. ISO considered that publication of the definitions would assist in the creation of a common language between ISO and intergovernmental organizations as well as between ISO members and government officials, even though some of the definitions might not completely meet the requirements of standardization technology.

3. In this regard, WP.6 has a service to provide to and a function to perform vis-à-vis WTO for the implementation of the TBT Agreement. This function of UNECE was acknowledged by the GATT TBT Agreement, and defined now in Article 1, paragraph 1.1, of the WTO TBT agreement, stating that “*general terms for standardization and procedures for conformity assessment shall normally have the meaning given to them by definitions adopted within the United Nations system by international standardizing...*”

From ISO/IEC Guide 2 to ISO/IEC 17000

4. When in April 1996 the UNECE decided to transform the Group of Government Officials Responsible for Standardization into a Working party on Standardization Policies, ISO/IEC Guide 2 was at its 6th edition (1991) which incorporated amendments in response to requests from GATT and UNECE. Its implementation put in evidence the growing importance of conformity assessment, far beyond the initial certification activities, and led to the 7th edition (1996) of ISO/IEC Guide 2 endorsed by WP.6 (i.e. “Recommendation J” in the publication of UNECE Recommendations on Standardization Policies).

5. Although the 1996 edition of Guide 2 incorporated important changes, not all users were fully satisfied. Users want simple clear and consistent language, understandable by people with limited experience in conformity assessment methodologies, free from cultural or linguistic bias and readily translatable. Users need also a central place for easy access to all the concepts, terms and definitions used in the field of conformity assessment.

6. Having also in mind the extension of conformity assessment activities covered by new ISO/IEC standards prepared by ISO/CASCO and the need of their coordination, ISO and IEC decided to transfer the revision of clauses 12 to 17 of Guide 2 related to conformity assessment into the preparation of a separate specific new standard, the future ISO/IEC 1700.

7. The drafting is at the level of a 2nd Committee Draft, CD 2 1700, on which the comments of WP.6 would be welcome.

CD2 17000 Conformity assessment - General vocabulary and functional description

8. In July 2002 a second Committee Draft of ISO/IEC 17000 was issued for consultation under the title 'Conformity assessment – General vocabulary and functional description'. This International Standard will specify general terms and definitions relating to conformity assessment, including the accreditation of conformity assessment bodies, and the use of conformity assessment to facilitate trade. A functional description of conformity assessment is included as an informative annex, as a further aid to mutual understanding, in both voluntary and regulatory environments, among users of conformity assessment, conformity assessment bodies and their accreditation bodies.

9. As a common basis for the preparation and maintenance of any standards and guides relating to conformity assessment activities, ISO/IEC 17000 is intended to offer a consistent framework within which more specific concepts may be defined appropriately and denoted by the most appropriate terms. It does not set out to provide a vocabulary for all of the concepts that may need to be used in describing particular conformity assessment activities. Terms and definitions are given only where the concept defined would not be understandable from the general language use of the term or where an existing standard definition is not applicable.

10. Conformity assessment is defined as 'activity that provides demonstration that specified requirements relating to a product, process, system, person or body are fulfilled'. It covers such activities as calibration, testing, inspection and certification, as well as the accreditation of conformity assessment bodies.

11. The expression ‘object of conformity assessment’ is used in ISO/IEC CD2 17000 to encompass the product, process, system, person or body to which the specified requirements apply, in place of ‘product, process or service’. the wording adopted in Guide 2 to cover the subject of standardization in a broad sense. Supporting terms with definitions borrowed or adapted from ISO 9000:2000, Quality management systems – Fundamentals and vocabulary include ‘product’, indicating services as one of four generic product categories.

Implementation of a “functional approach”

12. ISO/CASCO WG 5 was reconvened to begin work on ISO/IEC 17000 when work on a “functional approach” was nearing completion, as a main output of the report of the Joint ISO/CASCO and CEN/CENELEC TC 1 Working Group established in 1997 to investigate a possible improvement of the EN 45000 standards and relevant ISO/IEC Guides (now also including the relevant ISO International Standards), taking into account proposals to reflect the functions of the conformity assessment process rather than the structure of the bodies involved.

13. The functional approach advocated in that report has since been adopted by ISO/CASCO and developed by WG 5 in describing conformity assessment and structuring its vocabulary. Conformity assessment is explained as a series of three functions: selection, determination, and review and attestation - focused sets of activities that satisfy a need, or demand, for demonstration that specified requirements are fulfilled. It may involve surveillance, defined as a systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement resulting from attestation.(see diagram in annex).

14. Definitions are provided for first-party, second-party and third-party conformity assessment, based on supporting definitions for ‘supplier’ and ‘user’ in this context. A Supplier’s declaration, as a “first-party attestation”, is distinguished from certification, which is defined as a “third-party attestation related to products, processes, systems or persons”. Accreditation (of conformity assessment bodies) is then distinguished as a “third-party attestation related to conformity assessment bodies”, supported by a note indicating the recognition that accreditation conveys.

Consultation of WP.6 on CD 2 17000

15. CASCO WG 5 meets again on 5 November 2002 to review the outcome of the consultation on the second draft, and it is hoped this time, with the help of comments received, to be able to prepare the Draft International Standard.

16. UNECE has always played an important role in the design and promotion of harmonized definitions in the field of conformity assessment. At the present stage of the drafting of a new standard designed to replace clauses 12 to 17 of Guide 2:1996 endorsed by WP.6, comments from WP.6 would be timely and very welcome by the CASCO WG5 in charge of the draft.

Conclusions:

17. Some actions might be useful before the October session of WP.6, and the rapporteur recommends that:

- Delegations having not had the opportunity to study the existing draft, in due time (the formal CASCO enquiry on CD2 17000 is closed on 12 September 2002), could provide their major comments on the present draft to their CASCO members before the next meeting (5 November 2002) of the CASCO related working Group.
- Delegations having major disagreements on the contents of CD2 17000 should also inform, as soon as possible, the secretariat/rapporteur, so that their views could be considered by WP.6 during its October 2002 session and possible common views defined.

Actions proposed by the Rapporteur

WP:6 is invited to:

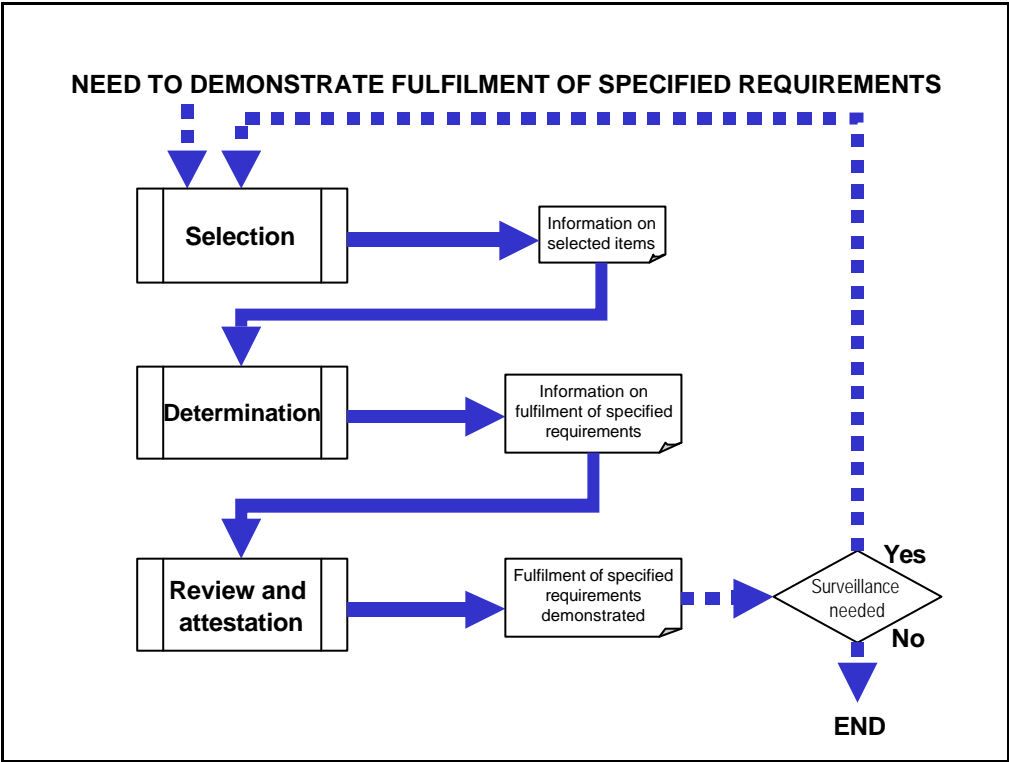
- (a) note this report;
- (b) invite delegations to provide comments on the present and next draft for ISO/IEC 1700 through their Nations Committee's to ISO/CASCO, having in mind that channelling the views of national interested circles, including regulatory authorities, on CASCO work is the responsibility of CASCO members;
- (c) define what the secretariat/rapporteur should do with any comments received (input to ISO/CASCO WG 5 ongoing work etc.);
- (d) ask the secretariat/rapporteur to come back with the final text of the ISO/IEC 1700 standard for endorsement by the WP.6;
- (e) invite delegations to forward any comments they might have on other parts of the definitions in ISO/IEC Guide 2: 1996.

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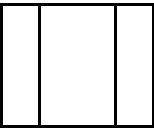
Annex

**DIAGRAM ON
FUNCTIONAL APPROACH TO CONFORMITY ASSESSMENT**

NEED TO DEMONSTRATE FULFILMENT OF SPECIFIED REQUIREMENTS



The following shape in the above diagram



represents a conformity assessment function. The specific activities in each function can vary from one type of conformity assessment to another, based on the needs of users, the nature of the specified requirements and the object of conformity assessment that is involved.

The following shape in the above diagram



represents output from a function and is also the input to the next function. The nature of the output varies, depending on the specific activities that have been undertaken

The solid arrows in the above diagram link the conformity assessment functions and their outputs/inputs.

The broken arrows express the needs/demands for conformity assessment.

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