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Tasks and responsibilities of the New Approach consultants

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The present guide provides guidance on the tasks and responsibilities of the New Approach consultants working with CEN and CENELEC. It was approved by CENELEC BT decision D134/C056 and by CEN Resolution BT C072/2008.



**European Committee for
Standardization**



**European Committee for
Electrotechnical
Standardization**

iTeh STANDARD PREVIEW
Avenue Marnixlaan 17
(standards.iteh.ai)
B – 1000 Brussels

Tel: +32 2 550 08 11

Fax: +32 2 550 08 19

www.cen.eu

[SIST-V CEN/CLC Guide 15:2009](http://standards.iteh.ai/catalog/standards/sist/3c7c311c-831c-4624-b191-13ae738304c6/sist-v-cen-clc-guide-15-2009)

Tel: +32 2 519 68 71

Fax: +32 2 519 69 19

www.cenelec.eu

Tasks and responsibilities of the New Approach consultants

1 Scope

This document is the CEN/CENELEC guide on the tasks and responsibilities of the New Approach consultants working with CEN and CENELEC.

It deals with the:

- Role and profile of the consultant
- Main tasks and responsibilities of the consultant
- Consultant's involvement in the development of standards
 - Involvement from the time of the creation of the NWI
 - Comments at enquiry stage
 - Advice and comments following the enquiry stage
 - Formal assessment prior to formal vote/UAP
 - Resolution of disputes
- Selection of a new consultant
- Induction and introduction of a new consultant
- Handover from previous consultant
- Reporting and evaluation of consultant's work
- Treatment of complaints

2 Background

European Directives (hereinafter called directives) contain *essential requirements*. These essential requirements shall be fulfilled by the product before it may be placed on the market.

Standardisation work related to directives is described in Mandates to the ESO's.

European Standards provide a means for manufacturers to demonstrate conformity to the essential requirements of directives. Such European Standards are referenced as *harmonised standards*.

The relevant technical body of CEN or CENELEC is responsible for deciding which technical requirements will be included in a European Standard.

The references and titles of harmonised European Standards are published by the European Commission in the Official Journal of the European Union (OJEU).

The European Commission and EFTA request that CEN and CENELEC assess the conformity of all candidate harmonised standards to the relevant essential requirements of relevant directives.

CEN, CENELEC and the European Commission/EFTA appoint independent consultants to carry out this assessment and to provide assistance and guidance to the technical bodies developing these European Standards in relation to the relevant directives and their respective essential requirements. Mandates can influence this work in particular ways. Consultants may also explain some elements of the relevant Mandates.

Many harmonised European Standards are based on international standardization according to the Vienna or Dresden Agreements. In such cases the consultant shall also be consulted with the development of such standards.

3 Role and profile of the consultant

3.1 Role of the consultant

The consultant is responsible for assisting experts to prepare harmonised standards and provides the necessary recommendations, explanation and support in relation to the relevant directive(s) and the respective essential requirements.

The consultant shall be involved with the technical bodies from the earliest possible stage in the development of a European Standard at the latest when a working draft is available in order that his/her comments may be taken into account from the beginning.

When requested by a technical body, the consultant shall obtain clarification on the scope of the directive or mandate from the Commission.

The consultant shall examine if the work programme of the relevant technical bodies covers all aspects indicated in the related directives and mandates (i.e. essential requirements, product families...) and identify any gaps which may be bridged by standards.

The consultant is **not** responsible for deciding or choosing which technical requirements will be included in a European Standard. This is the responsibility of the technical bodies.

The consultant informs the technical body on the compliance of a draft standard with the provisions of the relevant directive¹⁾; during development of the draft from the creation of the work item, through the preparation of the draft standard, during the public enquiry and before the Formal Vote or UAP.

¹⁾ Directive has to be understood in its broad sense (e.g. TSI's in case of Railway Interoperability, RID/ADR/AND agreements in the case of dangerous goods, ...).

3.2 Competence of the consultant

A consultant is required to be impartial and independent.

In order to fulfil his/her tasks, the consultant shall have:

- a deep technical understanding of the field of work of the relevant technical bodies and a recent state of the art experience of the subject;
- extensive knowledge and experience of relevant directives;
- experience of developing and implementing standards;
- knowledge of the main rules (e.g. CEN/CLC Internal Regulations, ISO/IEC Directives, different timeframes within the drafting process);
- knowledge of the Vienna Agreement, Dresden Agreement;
- social competence/interpersonal skills.

4 Main tasks and responsibilities of the consultant

The consultant's main tasks and responsibilities are:

- to explain to the technical bodies the different elements of the relevant directive(s) and mandate(s), especially the essential requirements, as far as necessary;
- to give recommendations to the technical bodies during the development of a standard with the consistency of the draft standard to the relevant directive(s);
- to identify shortcomings in the technical requirements chosen by the technical body in relation to the essential requirements in the relevant directive(s), and where possible suggest remedies, noting that the responsibility for the choice of technical requirement remains with the technical body;
- to advise whether the work programme of the technical body covers all aspects indicated in the relevant directive(s) (i.e. essential requirements, product families, risks...);
- to provide formal assessments on draft standards prior to formal vote/UAP in relation to the relevant directive(s) as requested and strictly by the deadline requested by the central secretariat²⁾;
- to keep up to date with the latest developments of the directive(s) they are contracted for;
- to identify new standardization needs and check for duplication of work.

²⁾ In this document "central secretariat" refers to CEN Management Centre (CMC) and/or CENELEC Central Secretariat (CLC/CS).

In particular, the consultant **shall**:

- ensure that candidate harmonised standards comply with the relevant essential requirements laid down by the relevant directive(s). This activity is to be maintained for the entire duration of the development of the standard, at the latest starting with the first working draft, during the enquiry (prEN) and before the formal vote/UAP;
- comment on all draft standards under his/her responsibility during the Enquiry Stage;
- give a formal assessment to all final drafts prior to the Formal Vote/UAP under his responsibility;
- check each draft standard, that is under his/her responsibility and that is in support of directive(s), for the existence and the contents of an annex (Annex Z) giving the relation between the standard and the essential requirements in the relevant directive(s);
- by mutual agreement attend meetings of technical bodies;
- be available to the European Commission (usually DG Enterprise and Industry) and the relevant Standing Committee(s) for questions related to the preparation of the standards;
- co-operate and co-ordinate with other consultants who are advising the technical body in relation to other directives or aspects of directives;
- co-operate and co-ordinate with the central secretariat for the setting of work and priorities;
- identify the need for formal assessment of draft standards by consultants responsible for other sectors.

Additionally the consultant may:

- help the technical body to identify new harmonised standards to be prepared;
- give recommendations to technical bodies in the light of what standards are being prepared or are planned in other technical bodies in order to avoid duplication of work and contradictions;
- be asked to support the central secretariat in tasks related to standardization in the field of his/her competence;

5 Consultant's involvement in the development of standards

A flowchart in Annex A is outlining the procedures described in this clause.

Each time a standard is drafted in the framework of the Vienna Agreement, the guidelines for the implementation of the Vienna Agreement apply for the involvement of the consultant.

For standards drafted in the framework of the Dresden Agreement:

- CENELEC/CS asks for the formal assessment from the consultant at CDV and FDIS stage for all projects associated with directives;
- In order to allow possible "corrective" action at IEC level, it is recommended that CENELEC should also ask an informal advice from the consultant on the CD;
- When there is a CENELEC technical body mirroring the IEC activities, it is the responsibility of this body to manage the alignment of their (upcoming) standards to the ERs of the directive. This includes possible requests for informal advice (e.g. on CD) from the consultant;
- When there is no CENELEC technical body mirroring the IEC activities - and as a support to the Reporting Secretariat – CENELEC/CS would in the future also ask for the informal advice from the consultant on the CD³⁾.

5.1 Involvement from the time of the creation of the NWI

The consultant shall be involved with the technical body, e.g. by giving written comments or attending meetings, from the earliest possible stage in the development of a European Standard and at the latest when a working draft is available in order to provide advice to the technical body in relation to the essential requirements of the directive(s).

5.2 Comments at enquiry stage

The central secretariat ensures that all relevant draft standards that are submitted to the enquiry⁴⁾ are given to the respective consultant(s).

The consultant(s) shall provide comments to the relevant technical bodies on **all** draft standards submitted to enquiry under his/her responsibility.

The technical body shall then take into account the consultant's comments along with all comments made as a result of the enquiry in order to further develop and consolidate the technical requirements contained in the draft standard.

5.3 Advice and comments following the enquiry stage

Following the closure of the enquiry the technical body reviews all comments received, including those from the consultant, and revises the draft standard accordingly.

If agreed by the technical body the consultant receives the resulting revised draft standard and further versions as necessary and provides additional comments and guidance to the technical body.

The goal of both the consultant and the technical body should be to achieve a final draft standard that when presented for formal vote or UAP will receive a positive assessment from the consultant.

³⁾ EMC issues are exempted, as these are duly coordinated through installed provisions by CLC/TC 210.

⁴⁾ For standards being developed in parallel by IEC/CENELEC under the Dresden Agreement commenting at the CD stage might be appropriate.