## VA guidelines 7th edition, 2016



# Agreement Guidelines

Guidelines for the implementation of the agreement on technical cooperation between ISO and CEN



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#### **Preamble**

The Agreement on technical cooperation between ISO and CEN (Vienna Agreement) was formally approved on 27 June 1991 in Vienna by the CEN Administrative Board following its approval by the ISO Executive Board at its meeting on 16 and 17 May 1991 in Geneva. In order to facilitate its implementation, this agreement was accompanied by common ISO/CEN guidelines for Technical Committee or Subcommitee (TC/SC) Chairmen and secretariats, which were revised successively in 1996 and 1998 to incorporate a number of improvements which had been found necessary on the basis of experience, together with changes required following some modifications of rules in ISO and CEN.

After a decade of experience, the need for the Agreement was confirmed by both ISO and CEN and a simplified version, setting out the principles of the original version, was confirmed by ISO Council Resolution 35/2001 and CEN Administrative Board Resolution 2/2001.

The past few decades have seen a significant increase in the global membership of ISO as an organization. Many new countries have joined the organization and have the opportunity to contribute to the development of the best possible and globally relevant ISO standards. Given these changing global dynamics, it is important to take this opportunity to review the ISO/CEN Vienna Agreement (VA) and ensure that the rights of all ISO members are supported in the development of globally relevant International Standards.

There have been many very positive and successful cases of VA implementation in various committees and sectors. But there have also been other committees and sectors for which this has not been a positive experience. While the good intention and text of the VA

itself continues to provide value, difficulties have arisen in the implementation of the VA and in the training and education of National Standards Bodies (NSBs), committee leaders, delegates, experts and Technical Programme Managers (TPMs) on the proper implementation of the VA. With its Resolution 107/2011, the ISO Technical Management Board (ISO/TMB) had established a Task Force (VATF) which was requested to review the VA Guidelines and to come forward with proposals for improvements. The final report of the VATF and the recommendations were approved by ISO/TMB and by the CEN Technical Board (CEN/BT).

All relevant and updated operational and process specifications are grouped in this new edition of the Guidelines for the implementation of the Agreement on technical cooperation between ISO and CEN (Vienna Agreement). ISO, CEN and NSBs must make even greater efforts to train and educate TPMs, PMs, committee leaders and delegates/experts properly on the VA and its implementation. Clearly, the data and information on VA implementation and CEN lead from 2001 to the present shows that many parties within the system do not understand the intentions of the 2001 VA revision and have not been implementing the VA appropriately. This is particularly critical in committees whose work impacts on regulated sectors where standards work advanced under the VA can have public policy implications. For further information or clarification on the implementation of the Vienna Agreement, please contact va@iso.org.

#### 1. Introduction

As with any other business, standardization has to be carried out as efficiently as possible. This implies that duplication of work should be avoided and synergies should be developed. Within this context, the Agreement on technical cooperation between ISO and CEN has been developed with the aim of optimizing the use of available resources and expertise for the benefit of the stakeholders of both organizations. Indeed, essential provisions in the Agreement cover the development and adoption of identical ISO and CEN Standards, with the characteristics and usefulness resulting from both statuses, whereas the drafting work is carried out only once, in one organization.

There are some principles to be respected for the Agreement to produce these intended useful results, notably:

- that all participants in the process adhere to the basic values to which both ISO and CEN are committed, notably transparency and openness
- that the operations are carried out in accordance with the rules, policies and procedures of either ISO or CEN, as relevant for their respective activities
- that standards have to take into account relevant regulatory needs
- that when expected results are not attained, the party which is not satisfied can decide to proceed separately
- that the standard shall be globally relevant in accordance with the principles of ISO

- that ISO lead is the preferred option whenever the acceptance criteria for new work item proposals (NWIPs) are fulfilled (see clause 2.3.5 of the ISO/IEC Directives, Part 1)
- that CEN lead is only possible if this is supported by a simple majority of the P-members of the respective ISO committee that are not CEN national members
- that exemptions are only possible where there are legitimate reasons which are acceptable to the non-CEN national members (e.g. EC Standardization Requests)
- that, as a matter of principle,
   ISO meetings should be held
   in different regions around the world
- that, when taking decisions on places for meetings, committees have to take into account different criteria, such as participation, reduction of cost for experts, visibility in different regions, etc.

The Agreement itself includes the main principles and essential provisions. These Guidelines develop them and translate them into operational terms.



## 2. Cooperation by correspondence

Provisions for exchange of information between an ISO and a CEN committee are established, where necessary, by common agreement between the secretariats of these committees. Each committee may decide on the detailed provisions for making available to its members the documents received from the other organization: for example, all documents, reports of meetings only, drafts of standards only. Formal comments sent by the secretariat of one committee to its counterpart shall reflect the views of the committee.

In addition to comments from an ISO committee, CEN agrees to accept comments on any prEN at CEN enquiry stage from ISO member bodies outside CEN. These comments should be sent directly to the CEN-CENELEC Management Centre (CCMC) with copy to the ISO Central Secretariat (ISO/CS). CCMC shall forward such comments to the appropriate CEN technical body. This body shall report back to CCMC. CCMC shall in turn inform the ISO member body of the action taken, with copy to ISO/CS.

# ... 3. Cooperation through mutual representation at meetings of committees and working groups

**Questions of common interest** to both an ISO and a CEN technical body may call for mutual representation at meetings. Arrangements for such representation should be made as early in the process as possible. It is to be noted that, whilst the Vienna Agreement provides for mutual representation at meetings (ISO representatives at CEN meetings and CEN representatives at ISO meetings), this may not always be essential and will need to be decided. by committees on a case by case basis.

Representatives shall be formally appointed by the ISO or CEN committee nominating them. The secretariat of this ISO or CEN committee shall advise

the secretariat of the committee of the other organization of any relevant committee resolution as well as of the necessary information about the representatives (name, address and function in the committee which is nominating them).

Up to four representatives may be appointed to attend meetings of technical bodies of the other organization. In relation to representatives of an ISO committee to attend a CEN technical body meeting, preference will be given to delegates from ISO members that are not CEN national members.

Representatives of an ISO or CEN *committee* attending a meeting of a *committee* of the other organization shall represent the consolidated view of the committee nominating them. The notification appointing them (see above) shall include the nomination of a head of delegation.

Representatives of an ISO or CEN *committee* attending a meeting of a working group of the other organization shall have the status of observers. Nonetheless, they are expected to make contributions on identified items of their concern. Like all other participants, they are expected to display a positive and constructive attitude. An invitation from the parent committee of the working group is not required.

**Note:** It may be useful on occasions to hold consecutive meetings of ISO and CEN technical bodies in the same location and within the same timeframes. However, common meetings shall be avoided. Additionally, ISO/CS and CCMC are willing to organize on a case by case basis, in mutual consultation, joint coordination meetings of appropriate representatives of ISO and CEN technical hodies in order to solve specific problems such as overlaps of programmes of work or parallel voting resulting in diverging results of votes in ISO and CEN.

## ... 4. Adoption by one organization of available publications from the other organization

The organization which wants to adopt an available publication from the other organization submits it to its own adoption procedures. Ideally, this publication should be adopted without change. If this is not possible, the secretary of the committee responsible for the project in the organization which wants to adopt the available publication shall contact the secretary of the committee which has developed the publication in the other organization in order to examine the possible solutions.

Both ISO/CS and CCMC must be informed of such consultations and are available for help. The revision of the publication using the parallel ISO/CEN approval procedure is in principle the best way forward. If this is not possible, the adoption of a modified version of the available publication should be envisaged. This modified version shall include information on the nature and reasons for the changes to the original publication.

# 5. Cooperation by mutually agreed allocation of work with parallel approval of standards in ISO and CEN

#### 5.1 General

This clause 5 describes the main procedures for the parallel approval of standards in ISO and CEN, irrespective of which organization is responsible for developing the standard (the lead organization). More detailed guidance for the development and parallel approval of European and International Standards is given in Annex A.

It is to be noted that other types of publications (Technical Specifications, Technical Reports and Guides) may also be processed in parallel between ISO and CEN. Guidance may be found in the "Frequently asked questions" or is available from CCMC or ISO/CS.

#### 5.2 Decision on ISO lead or CEN lead

ISO lead is the preferred option whenever the acceptance criteria for NWIP are fulfilled (see clause 2.3.5 of the **ISO/IEC Directives**, Part 1). Exceptional CEN lead is only possible if the P-members of the respective ISO committee that are not CEN national members agree by simple majority to allow the CEN committee to lead. This recognizes and provides an opportunity for CEN lead where there may be legitimate reasons which are acceptable to the non-CEN national members. CEN national members are never at any disadvantage in a

question regarding lead as they have the right to participate actively in both ISO and CEN. Therefore, there is no need for all P-members of the ISO committee to decide on CEN lead. The CEN committee should only decide on whether it wishes to accept CEN lead when the non-CEN national members of the ISO committee have agreed by simple majority to that arrangement.

EC funding should not be a factor in taking decisions on lead assignment. In cases of standards linked to EC Standardization Requests, if an ISO committee agrees that the project should advance under CEN lead based on clear documentation that the ISO committee cannot meet the EC Standardization Request, then the decision is delegated to the respective ISO committee. Only cases of dispute shall be presented to both ISO/TMB and CEN/BT.

### 5.3 Decision to carry out a parallel approval of a standard in ISO and CEN

Standardization is a voluntary activity in which the stakeholders themselves determine which standards are needed at the international and European levels. Similarly, it is the stakeholders participating in a technical body of one of the organizations who decide that work being carried out in the other organization should be prepared as a 'common ISO/CEN standard' and consequently needs to be submitted to parallel approval procedures in both organizations.

Such a decision must be taken as early as possible in the process. Obviously, a pre-requisite is that there is a demonstrated need for an International Standard and a European Standard on that particular topic, this being achieved through the relevant procedures in each organization for the approval of new work and ensuring its market relevance. Indeed, one of the major difficulties in implementation

of the Vienna Agreement has been to synchronize the work in ISO and CEN. For example, requests have been received to submit texts for parallel processing without there being approved relevant work items in both ISO and CEN. In such circumstances, either the work must be delayed while the other organization fulfills its procedural requirements for approval of the new work item, or the work will be continued independently in the lead organization.

Although the procedures may be synchronized at a later stage (see below), it is by far preferable that the whole parallel approval process be synchronized. For this purpose, the ISO and CEN committee secretariats shall ensure that the required steps (approval of the work item and formal committee decision concerning allocation of the work) have been taken in both organizations well in advance of the submission of the text of a standard for the enquiry stage. Furthermore, it is essential that both ISO/CS and CCMC are kept fully informed of the relevant decisions of the CEN and ISO committees.

However, in exceptional cases, work may be well advanced in one of the organizations, before the other determines the need for a standard on a particular topic. If the second organization approves such a work item before the lead organization has initiated its approval process, then the whole approval process may be carried out in parallel. If the lead organization has already initiated its approval process, the secretariat of the responsible committee in the second organization shall contact its central secretariat (ISO/CS or CCMC) in order to start a consultation on a way forward that meets the need of all interested parties (the secretariats of both ISO and CEN committees, ISO/CS and CCMC).

In the case of preparation of an EN and ISO Standard, it is sometimes possible for the second organization to carry out its own enquiry independently, following which the ISO and CEN procedures can

be synchronized by carrying out a parallel Formal Vote – ISO/FDIS (see Annex A). Otherwise, the second organization will have to await the finalization of the publication in the lead organization and submit this finalized publication to its own approval procedures (see clause 4).

## 5.4 Drafting stage (CEN)/Preparatory and committee stages (ISO)

The document is drafted by the responsible committee in the lead organization in accordance with the policies, rules and procedures of that organization, while keeping the other organization informed. All parallel procedure documents are to be drafted using the "ISO template" and normative references shall not be made to EN ISO standards but to the corresponding ISO International Standards.

All drafts should be shared at an early stage as soon as the text is sufficiently mature (including WD and CD). The secretary of the responsible committee in the lead organization sends a copy of the committee documents relevant to the publication in preparation to his/her counterpart in the second organization (**see clause 2**). The responsible committee in the other organization may comment on these documents and appoint representatives to participate in the meetings of the responsible committee and working group of the lead organization under the conditions stipulated **in clause 3**.

#### 5.5 Enquiry stage

The decision to submit a draft to enquiry (ISO/DIS – CEN Enquiry) is taken by the responsible body of the lead organization in accordance with the rules and procedures of that organization.

The synchronization of the ISO/DIS and CEN Enquiry procedures is ensured by ISO/CS and CCMC. ISO member bodies shall return

their votes and comments to ISO/CS and CEN national members additionally to CCMC.

At the close of the enquiry, the responsible body in the lead organization examines the results of both the ISO/DIS and CEN Enquiry procedures. All the replies and comments (including the comments of the New Approach Consultant (NAC) in cases of standards linked to EC Standardization Requests, **see Annex C**) to the ISO/DIS and CEN Enquiry shall be considered in depth, taken into account and responded to in the table of decisions (CEN)/report of voting (ISO). ISO/CS is authorized to refuse drafts for ISO/FDIS – CEN Formal vote in the case of an incomplete table of decisions/report of voting. In case of CEN lead, comment resolution following voting should be conducted jointly by both committees, preferably by a comments resolution panel comprising experts from both committees. Replies are to be given to comments received both at European and International level.

Should the draft standard be approved in both ISO and CEN at the enquiry stage it should proceed to publication by skipping the ISO/FDIS – CEN Formal Vote procedure.

**Note:** Should the CEN Enquiry results fulfil the approval criteria, the responsible CEN technical body takes a decision whether to skip the Formal Vote or not. The corresponding ISO technical body shall be informed of the CEN technical body decision.

Should the enquiry results fulfil the approval criteria but it is agreed by the lead organization to include an ISO/FDIS – CEN Formal Vote stage, the responsible technical body of the lead organization prepares a revised draft for submission to parallel ISO/FDIS – CEN Formal Vote.

**Note:** An FDIS vote is required when technical changes are made to enquiry drafts under the Vienna Agreement.

#### 5.6 Formal approval stage

The decision to submit a draft to formal approval (e.g. for an EN ISO Standard: ISO/FDIS – CEN Formal Vote) is taken by the responsible body of the lead organization in accordance with the rules and procedures of that lead organization.

The synchronization of the formal approval procedures is ensured by ISO/CS and CCMC.

ISO member bodies shall return their votes to ISO/CS and CEN members shall return their votes to CCMC as well.

ISO/CS and CCMC establish the results of votes in their respective organizations in accordance with their own rules, and decide on the follow-up actions on the basis of the following principles:

Result of vote in ISO	Positive	Positive	Negative	Negative
Result of vote in CEN	Positive	Negative	Positive	Negative
Decision	Identical publications in ISO and CEN (see 5.7.1)	Consultation between ISO and CEN (see 5.7.2)	Consultation between ISO and CEN (see 5.7.2)	Consultation between ISO and CEN. Return of draft to responsible committee

#### 5.7 Publication

#### 5.7.1

After a positive result of vote in both ISO and CEN, ISO/CS finalizes and publishes the adopted International Standard. In cases of CEN lead, there is a proofing stage carried out by the TC secretariat before publication.

CCMC circulates the corresponding European Standard for implementation by the CEN Members. The French and English versions consist only of a title page and European foreword, introduction and European annexes, if any. The German version (if available) includes in addition the German translation of the ISO publication.

#### 5.7.2

After a positive result of vote in one organization and a negative result in the other one, a consultation between ISO/CS and CCMC takes place involving committee officers. When taking decisions on how to proceed based on voting results and comments, committee leaders and secretariats have to take into account the decisions of the respective committees. If it seems likely that the negative votes which resulted in the text being disapproved can be resolved, a second parallel vote may be carried out. If the consultation shows that there is no immediate possibility for reconciling the comments that resulted in disapproval of the document, each organization proceeds in accordance with its own rules.

## ... 6. Maintenance of identical ISO and CEN standards

#### 6.1 General

Standards may be subsequently modified by a number of mechanisms. The mechanisms used to modify in parallel identical ISO and CEN standards are described below.

The acceptance criteria for NWIP have to be fulfilled (see clause 2.3.5 of the **ISO/IEC Directives**, Part 1). As a matter of principle, all ISO standards that are VA projects shall have their revisions take place under ISO lead. Exemptions are only possible where there are legitimate reasons which are acceptable to the non-CEN national members, demonstrated by simple majority vote.

Any past ISO committee resolutions specifying that all standards or groups of standards in a specific field or committee should be developed automatically under CEN lead are void.

## 6.2 Technical corrigenda (ISO) – Corrigenda (CEN)

When errors have been detected in a standard and the committee secretariat and ISO/CS have agreed that a corrigendum should be prepared, CCMC shall be informed. Appropriate steps will be agreed between ISO/CS and CCMC for announcement/issue of the corrigendum in parallel.

#### 6.3 Minor revisions

When a committee has agreed that a standard requires that factual information be updated, it shall draw this to the attention of ISO/CS or CCMC, as appropriate. If this is approved, the other organization shall be informed so that the relevant procedures can be carried out in parallel: Formal vote (12 weeks) in ISO and Enquiry (12 weeks) in CEN.

### 6.4 Revision of, and amendment to, identical ISO and CEN standards

#### 6.4.1 ISO initiative

As soon as CCMC is informed that ISO has decided to revise or to amend an ISO standard for which there is an identical CEN standard in existence, it will create a corresponding work item in CEN in order to carry out a parallel approval procedure on the draft revision or amendment under ISO leadership.

CCMC shall inform ISO/CS and the secretary of the responsible CEN/TC (if any) thereof. The provisions **in clause 5** shall apply.

#### 6.4.2 CEN initiative

As soon as a CEN/TC has determined that there is a need to revise or to amend an EN for which there is an identical ISO standard in existence, the CEN/TC secretary shall provide a justification to CCMC who will propose to ISO/CS that this revision or amendment be carried out in parallel under ISO leadership. This provision also applies when the original publication was developed under CEN leadership

#### . Annex A to the Guidelines

Detailed processes for parallel development and approval of common ISO/CEN standards.

## A.1 Transfer of work from CEN to ISO – ISO leadership

#### A.1.1 Decision to apply the parallel approval procedure

The CEN/TC secretary should ensure beforehand that a corresponding item already exists in the ISO work programme and that the project is still at an early stage (no DIS vote launched). The ISO reference shall be communicated to CCMC.

The CEN/TC shall notify CCMC of their decision to transfer a work item to ISO.

#### Two cases may occur:

- ► The item does not exist in the CEN programme of work. In this case, the CEN/TC takes a delegated decision for the creation of a new work item, specifying its direct transfer to ISO under the Vienna Agreement (see **BOSS** Formatted decisions...)
- The item already exists in the CEN programme of work. In that case, the CEN/TC takes a delegated decision for the transfer of an existing work item to ISO under the Vienna Agreement (see BOSS – Formatted decisions...)

If all the necessary information is available, a new work item is created or an existing one amended through the usual procedure of CCMC and registered under the Vienna Agreement for processing to a parallel vote under ISO lead.

CCMC informs ISO/CS of their decision to apply the Vienna Agreement. ISO/CS confirms that the work item is approved in ISO. The respective databases are aligned by exchanging the CEN work item number and the ISO identification number.

With this transfer, the CEN/TC stops all drafting work on this subject and instead follows the progress of work at ISO level. It should however be understood that CEN can decide to take the work item back into the CEN/TC if the work in ISO does not meet CEN requirements, e.g. in terms of timing or content.

#### A.1.2 Drafting

The ISO committee secretary sends a copy of the documents relevant to the standard in preparation to the CEN/TC secretary. The CEN/TC is allowed to comment on these documents and to appoint representatives to participate in the meetings of the responsible committee and working group in the lead organization under the conditions stipulated **in clause 3**.

#### A.1.3 ISO/DIS - CEN enquiry

- When consensus has been reached in the ISO committee, the committee secretariat sends copies of the committee draft in English and possibly in French to ISO/CS for distribution as a draft International Standard (DIS)
- ISO/CS will notify DIN for the German translation required for the CEN Enquiry at the same time that AFNOR is notified for the French translation (8 weeks)
- During the translation, CCMC submits the draft to the New Approach Consultant (NAC) for assessment if the CEN work item has been identified as one requiring assessment

- ► If the NAC provides a negative assessment, CCMC, the Consultant as well as the CEN/TC and CEN/WG leadership examine which follow-up actions are required. The CEN/TC Secretary shall at all moments inform the ISO/TC of the progress
- ISO/CS notifies CCMC (with a copy to DIN), with at least 1 weeks' notice, of the dates of the DIS vote for synchronization purposes
- ► ISO/CS circulates the English and French versions to the ISO and CEN Members, indicating on the cover page that the DIS covers a subject of interest to European standardization and that consultation of ISO/CEN member bodies on the DIS has the same effect as the CEN Enquiry on the draft European Standard
- At the same time, CCMC prepares the CEN Dispatch Notice and releases the German version and NAC's assessment, if available
- ▶ 12 weeks are allowed for voting and commenting on this text
- The ISO member bodies cast their vote and submit comments to ISO/CS. The CEN member bodies return their reply and comments to CCMC as well. Should the position returned by an ISO/CEN member to CCMC differ from that returned to ISO/CS, that ISO/CEN member shall provide a detailed technical justification with both replies. At the end of the voting period, CCMC establishes the "Report on the parallel enquiry of CEN members" and makes it available to the ISO committee secretariat for consideration and to ISO/CS for information. ISO/CS makes available to the ISO committee secretariat and chairman all the votes, replies and comments received for consideration

#### Results of the parallel CEN Enquiry/DIS

After evaluation of the results of the parallel enquiry, the following decisions may be taken by the ISO committee (skipping the FDIS does not require a decision from the ISO Technical Body):

- to continue further and to prepare the parallel Formal Vote/FDIS (see below)
- ► to launch a 2<sup>nd</sup> enquiry (generally of 8 weeks). In this case, CCMC follows the ISO decision and the drafts are submitted to a 2<sup>nd</sup> parallel CEN Enquiry/DIS, following the procedure described above
- to finalize the draft as TS or TR
- to stop the work and to delete the subject. In this particular case, the CEN/TC may decide to continue the work on its own (no longer under VA) or to delete the work item

**Note:** Draft standards having passed the CEN Enquiry with more than 71% approval but having received a negative NAC assessment should, in principle, not skip the Formal Vote.

#### A.1.4 ISO/FDIS - CEN formal vote

- Once a final text has been agreed upon, the ISO/TC secretariat sends it in English and possibly in French to ISO/CS for issue as a FDIS, together with a full report of voting including all comments from both ISO and CEN members received at the DIS /CEN Enquiry stage as well as adequate responses and decisions related to these comments
- ISO/CS will notify DIN for the German translation as well as transmit copies of the edited text and subsequently the

- proof-read text to DIN. At the same time, ISO/CS notifies AFNOR for the French translation (8 weeks)
- ► ISO/CS circulates the English and French versions to the ISO and CEN Members, indicating on the cover page that the FDIS covers a subject of interest to European standardization and that consultation of ISO/CEN member bodies on the FDIS has the same effect as the CEN Formal Vote on the draft European Standard
- At the same time, CCMC prepares the CEN Dispatch Notice and releases the German version
- ▶ 12 weeks are allowed for voting on this text
- The ISO member bodies cast their vote to ISO/CS. The CEN member bodies cast their vote to CCMC as well. Should the vote returned by an ISO/CEN member to CCMC differ from that returned to ISO/CS, the ISO/CEN member shall provide a detailed technical justification together with both votes
- During the vote, CCMC submits the draft to the New Approach Consultant for assessment (4 weeks) if the CEN work item has been identified as one requiring such review.
- ► If the Consultant provides a negative assessment, the Consultant as well as the CEN/TC and CEN/WG leadership examine which follow-up actions are required (possibly BT involvement). The CEN/TC Secretary shall at all moments inform the ISO/TC of the progress
- ► ISO/CS makes available to the ISO committee secretariat and chairman all the results of vote from its member bodies for information

#### Results of the parallel CEN Formal Vote/FDIS

After evaluation of the results of the votes at ISO/CS and CCMC, the following decisions may be taken:

The results of the vote are positive at ISO and CEN.

In this case, ISO/CS notifies CCMC (with a copy to DIN) of the date of publication and the standard is published by ISO and in parallel is made available by CEN with an EN ISO number.

The results of the vote are positive at ISO and negative at CEN.

A consultation between ISO and CEN takes place (see 5.7.2). In the absence of a more constructive solution, the likely outcome is for the document to be published as ISO xxx only.

*The results of the vote are negative at ISO and positive at CEN.* 

A consultation between ISO and CEN takes place (see 5.7.2). In the absence of a more constructive solution, the likely outcome is for the document to be published as EN yyy only.

The results of the vote are negative at ISO and CEN.

- A consultation between ISO and CEN takes place. The following decisions may be taken:
  - to reconsider the text at the committee level with a view to either issuing a further draft for parallel enquiry or to submit the draft to a 2<sup>nd</sup> parallel formal vote following the procedure described above
  - to finalize the draft as TS or TR
  - to stop the work and delete the item

#### A.1.5 Particular cases (re-synchronization)

Although this should be avoided as far as possible (**see clause 5.3**), the transfer of an ISO work item to CEN may be requested – or made necessary – after the DIS vote has been launched in ISO. In this case, the possibility to re-synchronize by one of the following methods in order to proceed to a parallel CEN Formal Vote/FDIS may be considered.

- ▶ One possibility is to carry out a parallel enquiry although ISO has already carried out a first DIS vote. This means that a 2<sup>nd</sup> DIS vote is launched at ISO level and a first CEN Enquiry is launched in parallel in CEN. **A.1.3** is applied. In this case, the ISO committee shall agree to apply this approach as delay may occur.
- The re-synchronization may also occur by launching a CEN Enquiry of 12 weeks on the ISO/DIS.
   For this purpose the following criteria shall be respected:
  - the work item shall already exist in the CEN programme of work
  - the transfer to ISO for parallel processing shall already be approved
  - the DIS vote shall have started no longer than 12 weeks previously
  - the German version shall be available

If the above criteria are not met (e.g. the DIS vote has already terminated), the CEN/TC will have to wait for the publication of the ISO Standard and then submit the published ISO Standard to the Enquiry + Formal Vote process for adoption.

If the above criteria are met, the CCMC, on request of the CEN/TC, informs ISO/CS of the CEN/TC proposal for consideration by the ISO/TC. The ISO committee may be prepared to delay its work in order to take into consideration the comments made during the CEN Enquiry. Furthermore, if the document is linked to a New Approach Directive/Regulation it may be assessed by a New Approach Consultant (see Annex C).

#### After consideration of the situation:

- if the ISO committee accepts the re-synchronization at FV (Formal Vote)/FDIS, CCMC launches the Enquiry without delay and the databases of ISO and CEN are updated accordingly
- if the ISO committee is not prepared to wait for re-synchronization, CCMC contacts the CEN/TC to decide on an alternative solution (e.g. by launching of an Enquiry upon publication of the ISO Standard).

## A.2 Transfer of work from ISO to CEN – CEN leadership

#### A.2.1 Decision to apply the parallel approval procedure

The following items are separate decisions which both the concerned ISO and CEN committees must take in order to implement the Vienna Agreement:

- decision to process a project under the VA
- decision on assignment of the lead for the project to either the ISO or the CEN committee

A simple majority of the P-members of the committee is necessary to take the decision to process the project under the VA. If the ISO or CEN committee vote, either at a meeting or by electronic balloting, that the VA will be implemented, the next decision to be taken is to decide which organization shall take the lead.

#### The second decision may result such that:

► ISO takes the lead to develop the project, with parallel consultations in CEN at the enquiry and formal approval stages, with all comments received from the CEN enquiry being addressed, adequately responded to and reported back to the CEN committee by the ISO committee; or CEN takes the lead to develop the project, with parallel voting in ISO at the DIS and FDIS stages, with all comments received from DIS voting being addressed, adequately responded to and reported back to the ISO committee by the CEN committee

ISO lead is the preferred option. Exemptions are only possible where there are legitimate reasons which are acceptable to non-CEN national members (e. g. EC Standardization Requests). A simple majority of the P-members of the respective ISO committee that are not CEN national members is necessary to take the decision on assignment of the lead for the project to either the ISO or the CEN committee.

Assignment of lead may generally be granted to the CEN committee in cases of standards related to EC Directives/Regulations, but an EC Standardization Request does not mean it is mandatory for CEN to take the lead or do the standards development work.

The decisions on approval of new work items and on VA implementation are two votes with no requirements in the VA or these guidelines that they be linked. No conditions regarding implementation of the Vienna Agreement are acceptable during the new work item proposal

ballot (e.g. no ISO or CEN member should submit a conditional vote on a new work item stating that they will approve the new work item only on condition that the Vienna Agreement be implemented and ISO or CEN be assigned the lead, or that the technical content must meet the EC's expectations).

Once lead is assigned to either the CEN or ISO committee, its counterpart committee should decide whether:

- it wishes to review and comment on all relevant drafts, documents and information from the lead committee regarding the project throughout its development
- it wishes to wait until voting at the ISO/DIS stage or CEN enquiry stage to become further engaged

If the committee not assigned lead decides on the first option, this should be communicated to the secretariat of the lead committee. The secretariat of the second committee shall circulate all such materials and establish mechanisms for developing the committee's consensus positions/comments in a timely manner.

An ISO committee may agree to assign lead to the corresponding CEN committee contingent on there being a committee draft (CD) vote of the document within the ISO committee. An ISO committee may wish to conduct such a CD vote in order that the substantial technical comments of its members may be considered prior to the DIS stage.

Upon receipt of information on ISO committee resolution, ISO/CS informs CCMC of ISO's decision to apply the Vienna Agreement. CCMC confirms that the work item has been approved in CEN.

The respective databases are aligned by exchanging the document reference number, the CEN work item number and the ISO identification number.

With this transfer, the ISO committee stops all drafting work on this subject and instead follows the progress of work at CEN level. It should however be understood that ISO can decide to take the work item back into the ISO committee if the work in CEN does not meet ISO requirements, e.g. in terms of timing or content.

#### A.2.2 Drafting

The CEN/TC secretary sends a copy of the documents relevant to the standard in preparation to the ISO/TC secretary. The ISO committee may comment on these documents and appoint representatives to participate in the meetings of the responsible committee and working group in CEN under the conditions stipulated **in clause 3**. All parallel procedure documents are to be drafted using the "ISO template" and that normative references are to ISO International Standards and not to EN ISO standards.

#### A.2.3 CEN enquiry – ISO/DIS

- Once a decision has been reached in the CEN committee to proceed with the enquiry, the text shall be supplied by the CEN/TC secretariat to ISO/CS in the reference language version. The CEN/TC secretary posts documents in the Submission interface, help can be directly requested from projects@iso.org
- ► ISO/CS will notify DIN for the German translation required for the CEN Enquiry at the same time that AFNOR is notified for the French translation (8 weeks)
- During the translation, CCMC submits the draft to the New Approach Consultant for assessment, if the CEN work item has been identified as one requiring assessment

- ► If the Consultant provides a negative assessment, CCMC, the consultant as well as the CEN/TC and CEN/WG leadership examine which follow-up actions are required. The CEN/TC Secretary shall at all moments inform the ISO/TC of the progress
- ► ISO/CS notifies CCMC (with a copy to DIN), with at least one week's notice, of the dates of the DIS vote for synchronization purposes
- ► ISO/CS circulates the English and French version to the ISO and CEN Members, indicating on the cover page that the DIS covers a subject of interest to European standardization and that consultation of ISO/CEN member bodies on the DIS has the same effect as the CEN Enquiry on the draft European Standard
- ► At the same time, CCMC prepares the CEN Dispatch Notice for CEN Enquiry, and makes available the German version and New Approach Consultant's assessment, if available
- ▶ 12 weeks are allowed for voting and commenting on this text
- ► The CEN member bodies shall return their reply and comments to CCMC. The ISO member bodies cast their vote and submit comments to ISO/CS. Should the position returned by an ISO/CEN member to ISO/CS differ from that returned to CCMC, the ISO/CEN member shall provide a detailed technical justification together with both replies
- ISO/CS makes available the ISO table of replies and comments to the CEN/TC with copy to the ISO committee secretariat and chairman for information
- CCMC makes available to ISO/CS the replies and the comments of its member bodies. CCMC also sends a copy to the CEN/TC secretary and to the ISO committee secretariat for information

► The CEN/TC secretary produces a CEN Table of decisions containing all of the comments received from both CEN and ISO members and adequate responses and decisions related to these comments. CEN/TC secretary sends the Table of decision to the CEN/TC members, the ISO committee Chairman, the ISO committee secretary and posts it on the ISO/CS server with the text for the Formal Vote

#### Results of the parallel CEN Enquiry/DIS

After evaluation of the results of the parallel enquiry, the following decisions may be taken by the CEN/TC:

- to continue further and to prepare the parallel Formal Vote/FDIS (see below)
- to skip the Formal Vote/FDIS and proceed to publication. This requires a decision of the CEN/TC but is not possible in case of technical changes made or in case of a negative NAC assessment
- ► to launch a 2<sup>nd</sup> enquiry (generally of 8 weeks). In this case, ISO follows the CEN decision and the drafts are submitted to a 2<sup>nd</sup> parallel CEN Enquiry/DIS vote, following the procedure described above
- to finalize the draft as a TS or TR
- to stop the work and to delete the subject. In this particular case, the ISO committee may decide to continue the work on its own (no longer under VA) or to delete the work item

**Note:** Draft standards having passed the CEN Enquiry with more than 71% approval but having received a negative assessment should, in principle, not skip the Formal Vote.

#### A.2.4 CEN formal vote – ISO/FDIS

- Once a final text has been agreed, the CEN/TC secretariat posts it on the submission interface for the Formal Vote, together with the CEN Table of decisions
- ► ISO/CS will notify DIN for the German translation required for the CEN Formal Vote at the same time that AFNOR is notified for the French translation (8 weeks)
- ISO/CS notifies CCMC (with a copy to DIN), with one week's notice, of the dates of the FDIS vote for synchronization purposes
- When the English and French versions are available, ISO/CS circulates the English and French versions to the ISO and CEN Members, indicating on the cover page that the FDIS covers a subject of interest to European standardization and that consultation of ISO/CEN member bodies on the FDIS has the same effect as the CEN Formal Vote on the draft European Standard. At the same time, CCMC prepares the CEN Dispatch Notice and makes available the German version
- ▶ 8 weeks are allowed for voting on this text
- ► The ISO member bodies cast their votes to ISO/CS and the CEN member bodies cast their votes to CCMC as well. Should the vote returned by an ISO/CEN member to CCMC differ from that returned to ISO/CS, the ISO/CEN member shall provide a detailed technical justification together with both votes
- During the vote, CCMC submits the draft to the New Approach Consultant for assessment (4 weeks) if the CEN work item has been identified as one requiring such review

- ► If the Consultant provides a negative assessment, the Consultant as well as the CEN/TC and CEN/WG leadership examine which follow-up actions are required (possibly BT involvement). The CEN/TC Secretary shall at all moments inform the ISO/TC of the progress
- ISO/CS makes available to the ISO committee secretariat and chairman and to CEN/TC secretariat for information all the results of the FDIS vote from its member bodies

#### Results of the parallel CEN Formal Vote/FDIS

After evaluation of the results of the votes at ISO/CS and CCMC, the following decisions may be taken:

The results of the vote are positive at ISO and CEN.

► In this case, ISO/CS notifies CCMC (with a copy to DIN) of the dates of publication and the standard is published by ISO and in parallel is made available by CEN with an EN ISO number.

The results of the vote are positive at ISO and negative at CEN.

► A consultation between ISO and CEN takes place (**see 5.7.2**). In the absence of a more constructive solution, the likely outcome is for the document to be published as ISO xxx only.

The results of the vote are negative at ISO and positive at CEN.

► A consultation between ISO and CEN takes place (see 5.7.2). In the absence of a more constructive solution, the likely outcome is for the document to be published as EN yyy only.

The results are negative at ISO and CEN.

A consultation between ISO and CEN takes place. The following decisions may be taken:

- to reconsider the text at the committee level with a view either to carrying out a further parallel enquiry or to submit the draft to a 2<sup>nd</sup> parallel formal vote following the procedure described above
- to finalize the drafts as TS or TR
- to stop the work and delete the item

#### A.2.5 Particular cases (re-synchronization)

Although this should be avoided as much as possible (**see clause 5.3**), the transfer of work to CEN may be requested – or made necessary – after the CEN Enquiry has taken place. In this case, the possibility to re-synchronize by one of the following methods in order to proceed to a parallel CEN Formal Vote/FDIS may be considered:

- ► One possibility is to carry out a parallel enquiry although CEN has already carried out a first enquiry. This means that a 2<sup>nd</sup> enquiry is launched at CEN level and a first DIS vote is launched in parallel in ISO. **Annex A.2.3** is applied. In this case, the CEN committee shall agree to apply this approach as delay may occur
- Re-synchronization may also occur by launching an ISO/DIS vote without delay, but the following criteria are to be taken into consideration:
  - The starting time of the CEN enquiry
  - The readiness of the CEN/TC to revise its draft following the ISO/DIS vote (recognizing that delay may occur)

ISO/CS, on request of the ISO committee, informs CCMC of the ISO committee proposal for consideration by the CEN/TC.

#### After consideration of the situation:

- ► if the CEN/TC accepts the re-synchronization at FV/FDIS, CCMC provides ISO/CS with the latest issue of the document at the enquiry stage, ISO carries out a DIS vote on this document without delay and the databases of ISO and CEN are updated accordingly
- ► if the CEN/TC is not prepared to wait for re-synchronization, the ISO/CS contacts the ISO committee to decide an alternative solution (e.g. by launching the Fast Track procedure upon publication of the EN)



#### **Annex B to the Guidelines**

Joint co-ordination group (JCG) of the ISO technical management board (ISO/TMB) and CEN technical board (CEN/BT)

The monitoring of the application of the Vienna Agreement is entrusted to a Joint Co-ordination Group (JCG) of the ISO Technical Management Board (ISO/TMB) and CEN Technical Board (CEN/BT). Monitoring includes reporting to these respective boards on progress or specific issues of concern and, where necessary, the review of existing mechanisms with proposals for improvement.

The chairman and secretary of the JCG are the chairman and secretary of the ISO/TMB or CEN/BT (alternating each year). Meetings are only convened if this is requested by ISO/TMB and/or CEN/BT.

#### **Annex C to the Guidelines**

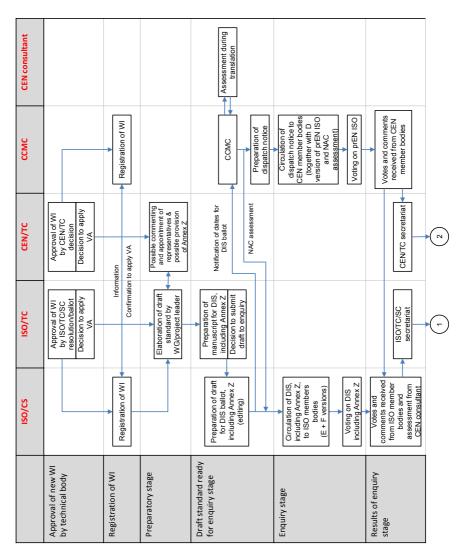
## Particular case of common ISO/CEN publications intended to support European legislation

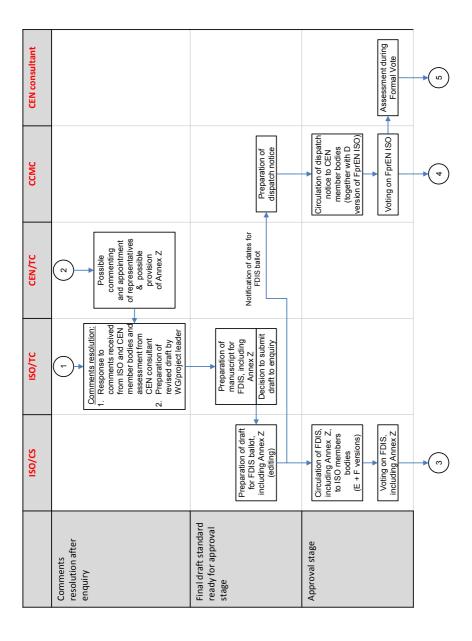
Special provisions apply in the case of European Standards intended to support European legislation. In particular an Annex Z is required in any version of the draft publication and the draft needs to be reviewed by a designated New Approach Consultant to confirm coherence with the relevant European Directive/Regulation. The relevant New Approach Consultant is available for help. At publication stage, Annex Z is maintained in the CEN standard but not in the ISO standard.

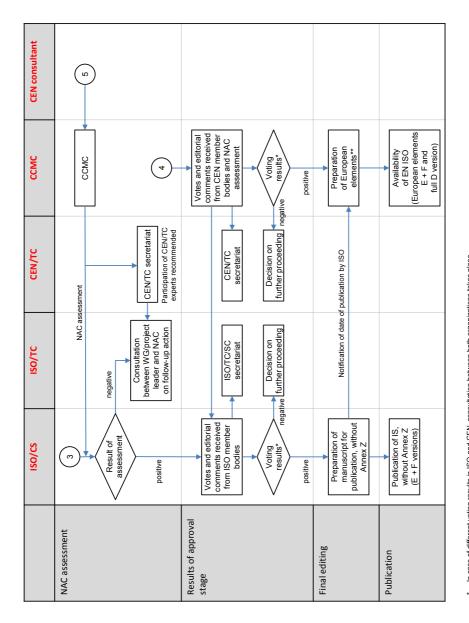
The role of the New Approach Consultant is to assess whether or not a standard linked to an EC Standardization Request covers the legal requirements of New Approach Directives/Regulations (so called "essential/basic requirements"). A negative assessment means that the standard needs further improvement to be suitable for reference in the Official Journal of the European Union, and consequently to claim "presumption of conformity". Without reference in the Official Journal of the European Union it is more difficult for manufacturers to get access to the European market. The legal situation cannot be changed. If an ISO/TC is not in a position to take into account the comments made by the New Approach Consultant, it may be necessary to decouple the work item from the VA.

#### **Annex D to the Guidelines**

Flowchart for parallel development and approval of common ISO/CEN publications intended to support European legislation (ISO lead)







In case of different voting results in ISO and CEN, consultation between both organizations takes place.
 Title page, European foreword, Annex Z

#### European Committee for Standardization

CEN-CENELEC Management Centre Avenue Marnix 17  $4^{\rm th}$  Floor B - 1000 Brussels Belgium

#### cen.eu

#### International Organization for Standardization

ISO Central Secretariat
Ch. de Blandonnet 8
Case Postale 401
CH – 1214 Vernier, Geneva
Switzerland

iso.org

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