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SIST-V CEN/CLC Guide 22:2022

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Vodilo o organizacijski strukturi in postopkih za ocenjevanje kriterijev za članstvo CEN in CENELEC

Guide on the organizational structure and processes for the assessment of the membership criteria of CEN and CENELEC

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Guide on the organizational structure and processes for the assessment of the membership criteria of CEN and CENELEC

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CEN and CENELEC decided to adopt this CEN-CENELEC Guide 22 through CENELEC/AG Decision AG62/05 and CEN/AG Decision 31/2021 on 2021/11/25.



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1 Scope

This Guide complements, and is intended to be read in conjunction with, the membership criteria of CEN and CENELEC included in the CEN-CENELEC Internal Regulations Part 1 (IR1), Part 1D.

This Guide supersedes CEN-CENELEC Guide 22:2015 and Guide 22:2018, in line with the decisions of the CEN and CENELEC General Assemblies taken in June 2021 to review the organizational structure and processes for the assessment of the membership criteria of CEN and CENELEC.

This Guide aims to illustrate the organizational model implementing the management of the exercises of peer assessment, external assessment or self-assessment combined with EN ISO 9001 certification of the membership criteria laid down in IR1, Part 1D, as well as their reports and follow-up of actions.

The agreed organizational model aims at building trust and accountability of the CEN-CENELEC system, while ensuring efficient and effective management. Indeed, the implementation of such an assessment system replies to the ambitious goal of “excellence” embedded in the provisions of the membership criteria.

The assessment exercises are handled under the supervision of a recognized *super partes* body, and independent Chair and by competent assessors, be they independent from the Member assessed (e.g. in case of peer or external assessment) or within the same Member (self-assessment combined with EN ISO 9001 certification).

The blend of competence and independence of judgment of the Chair and assessors and the effective and efficient processes of follow-up actions will ensure the integrity of the CEN-CENELEC assessment system and the recognition of those CEN and CENELEC stakeholders closely linked to, and benefiting from, standardization.

2 Governance process

The three approved assessment models of “Self-assessment exercise integrated with the EN ISO 9001 certification”, “Peer assessment exercise” and “External assessment exercise” are built around the following organizational principles:

- the Presidential Committee leads the process, in full collaboration with the CEN and CENELEC General Assemblies (AGs) and the CEN and CENELEC Board (CAs) in the case of External assessment exercise;
- the Membership Relations and Monitoring Committee (MRMC) manages the process including assessment activities, reporting and follow-up actions with the Members;
- a channel of reporting from the MRMC to the AGs through the Presidential Committee raises awareness of good practices;
- the CEN and CENELEC Boards identify external assessors in case of External assessment;
- a standing team of peer assessors or Members’ internal assessors supports the assessment process.

3 Membership Relations and Monitoring Committee (MRMC)

3.1 Mandate

The MRMC is the core of the system.

The MRMC is mandated by the CEN and CENELEC General Assemblies to:

- a) manage the CEN-CENELEC assessment system and ensure the overall quality, coherence and fairness of the Self-assessment combined with EN ISO 9001 certification, Peer assessment or External assessment reporting;

- b) ensure a smooth and effective management of a coherent self-assessment combined with EN ISO 9001, Peer assessment or External assessment approach through appropriate processes, preparation and maintenance of the necessary documents and templates, as well as selection and training of qualified assessors;
- c) seek continuous improvement on the definitions of the criteria for membership based on the experience acquired;
- d) ensure the effective follow-up of the outcomes of the reports on the assessments made and coordinate and disseminate good practices to the CEN-CENELEC members with a view to facilitating the exchange of information among the Members through appropriate mechanisms;
- e) coordinate the assessment process of those organizations applying for membership in CEN and CENELEC;
- f) coordinate the assessment process in case of change of legal status of a Member of CEN and/or CENELEC.

The MRMC reports to the Presidential Committee and, at least once a year, to the General Assemblies.

The MRMC's main tasks, in accordance with the above mandate, are further detailed in its Terms of Reference (ToR) as approved by the CEN and CENELEC General Assemblies in October 2012 (CEN/AG Resolutions 31 and 32/2012 and CLC/AG53_CCMC_12_211/2012_RV).

3.2 Composition

The composition of MRMC is as follows:

- the Chair;
- two members appointed by CEN;
- two members appointed by CENELEC;
- the CEN-CENELEC Director General.

The Chair, who is an impartial person trusted by the whole community, is appointed by the CEN and CENELEC General Assemblies for a 4-year term and receives some financial compensation for the time they devote to this activity.

The other members of the Committee are appointed by the respective CEN and CENELEC Governing Bodies following a call for nomination. They are appointed for a 3-year term and re-eligible for an additional term of 3 years. They divest themselves from any representation of specific interests of the organization that nominated them.

The Director General attends the Committee meetings as an observer with an advisory role.

3.3 Decisions

The Committee decides by consensus. The Chair, the CEN and the CENELEC nominated members take decisions. The ToR specifies those cases of abstention from voting when, for instance, the MRMC's decisions concern the national organization from which the representative comes from.

3.4 Management

The MRMC works mainly by electronic means, holding online meetings as appropriate, but at least once a year holds a physical meeting.

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The working language of the Committee is English.

The MRMC Chair and members shall abide to specific confidentiality rules in order to ensure that the information in the assessment reports of CEN and CENELEC Members is managed with due care within the MRMC.

3.5 CCMC support

CCMC appoints a member of its staff to be in charge of ensuring the secretariat and the administration of the MRMC's work (meetings and flow of information) and assisting the Chair in specifically identified tasks related to the preparation and follow-up of MRMC meetings.

4 The assessment options

4.1 General

This clause describes the three identified options of assessment approved by the CEN and CENELEC General Assemblies with their distinctions underlined whenever necessary for the different types of CEN and CENELEC Members (Article 7.1 of the CEN Statutes and Article 7.2 of the CENELEC Statutes):

- **Blue-type Members**: NSB/NC from a European Economic Area State
- **Red-Type Members**: NSB/NC from an EFTA state (not Blue-type Members), or from States that are officially identified as candidate countries for accession to the EU
- **Yellow-Type Members**: NSB/NC from a State having an agreement with the EU and demonstrating regulatory convergence or compatibility with the essential regulations that support the Single Market in areas that are relevant to CEN and CENELEC activities.

4.2 Self-assessment exercise combined with EN ISO 9001 certification

4.2.1 General and time cycle of the assessment report

Under this option, CEN and CENELEC Members of Blue and Red types organize and conduct their self-assessment combined with EN ISO 9001 certification and report the findings to the MRMC. The time cycle of the assessment Report is every 3 years.

The following specific elements should be taken into account.

4.2.2 Certification EN ISO 9001

Members having chosen this option shall have a quality management system in place, which is EN ISO 9001 certified at their own cost, in addition, the following applies:

- Membership requirements shall be covered by the QMS system of the Member;
- The Member shall provide information to the external auditor about the scope and membership requirements as outlined in the relevant documents before completing the EN ISO 9001 audit;
- The assessment report and action plan for dealing with non-conformities to the membership criteria shall be agreed between the management and the external auditor before it is sent to MRMC;
- An annual monitoring during the internal audits within the exercise of EN ISO 9001 certification should be carried out by the internal assessor to ensure ongoing compliance.

It is the Member's responsibility to decide the most convenient organizational modalities regarding the involvement of the external auditor in the assessment of the membership criteria.

4.2.3 Internal assessors' team

The Members nominate their own internal team of assessors in line with the practices of the quality management system in place. Please also refer to Annexes B and F.

4.2.4 Membership Relations and Monitoring Committee

The MRMC is called to:

- agree on the yearly calendar of self-assessment combined with EN ISO 9001 certification exercises to be held by the concerned Members;
- monitor the execution of the scheduled self-assessment combined with EN ISO 9001 certification;
- receive, accept and handle the reports produced by the Members;
- benchmark the result of reports with a view to defining some good practices.

4.2.5 Main implementation steps of the self-assessment exercise combined with EN ISO 9001 certification and follow-up

- a) Review and assessment by the CEN or CENELEC Member's internal assessors

The CEN or CENELEC Member's internal assessor(s) are expected to fully understand the relevant documents. If needed, they can request at any time additional information and clarification from the MRMC on matters related to the handling of the self-assessment and on the organization of this exercise.

- b) Final Report and feedback

The Member sends the final report produced by its internal assessors to the MRMC, which will accept it following the review and recommendation of the Chair. The Committee handles the report with due confidentiality.

Where relevant in case of non-conformities, the MRMC provides specific recommendations and feedback to the Member on possible improvements (see Clause 5) and may also indicate good practices from other Members. The MRMC may also facilitate the exchange of information on good practices by inviting the Member to contact other relevant members on specific matters.

- c) Review of the relevant parts of EN ISO 9001 certification by the internal assessors

In order to allow the MRMC to be able to compare the reports received from the Members, the assessors of each Member shall ensure that all relevant information of the EN ISO 9001 auditors' report is properly included in their self-assessment report respecting the given template. It is also important to underline two important aspects:

- not all parts of EN ISO 9001 audit reports are relevant for the membership criteria; and
- the assessment of the membership criteria is not entirely covered by the EN ISO 9001 audit.

In order to make sure that the MRMC only receives the relevant part of the Member's EN ISO 9001 report produced by the auditors, the Members' internal assessors should define:

- what information within their EN ISO 9001 exercise is relevant for the self-assessment reporting on the basis of the membership criteria;
- what are the additional specific assessment activities that are needed to fulfil the self-assessment reporting.

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4.2.6 Working language

The working language in this option will be the language of the country of the Member. However, the report will be drafted in English.

4.3 Peer assessment exercise

4.3.1 General and time cycle of the peer assessment report

Under this option, CEN and CENELEC Members of the Blue, Red and Yellow types organize a peer assessment model based on independent and competent teams of assessors coming from the staff of the Members. For Blue and Red type Members, the time cycle of the peer assessment audit is 3 years. For Yellow-type Members, a peer assessment exercise must be delivered in the first two years after becoming a Member as well as an external assessment while applying for membership and then every following third year.

It should be noted that peer assessment exercises may be requested by the MRMC at any time in case of change of legal status of an existing CEN and/or CENELEC Member and in case of a new application for membership in CEN and CENELEC, as laid down in clause 3.2 of the CEN-CENELEC IR Part 1D.

4.3.2 Membership Relations and Monitoring Committee

In addition to the responsibilities of the MRMC already outlined, in the case of peer assessment the Committee will also be in charge of:

- a) the organization of the peer assessment processes;
- b) the selection, appointment and coordination of the peer assessors.

4.3.3 Chair of the Membership Relations and Monitoring Committee

The Chair is expected to ensure: [SIST-V CEN/CLC Guide 22:2022](https://standards.iteh.ai/catalog/standards/sist/0cb69476-35e2-411b-90d1-116871aa9044/sist-v-cen-clc-guide-22:2022)

- a) the most appropriate composition of the peer assessment teams, taking into account the size and other specificities of each Member, including (if possible) the national language;
- b) the efficient management of the assessment visits held by the peer assessors.

The Chair will not act as a peer assessor in order to avoid a conflict of interests between the two positions.

4.3.4 The peer assessors

The assessments on the membership criteria under this option are made by individual peer assessors or teams of peer assessors, depending on the size of the Member.

The peer assessors are competent persons appointed to handle the assessment exercises and to report accordingly to the Membership Relations and Monitoring Committee. They commit to be independent in their judgment and behaviour.

The names of the peer assessors enabled to run peer assessments are included in a list that is made available to all Members.

4.3.5 Criteria for nomination and selection of peer assessors and remuneration

Each Member may nominate a candidate peer assessor. However, common CEN and CENELEC Members may nominate only one candidate peer assessor.

The call for nomination of the peer assessors is made through an open process based on objective criteria to be laid down in a separate document. Members are expected to nominate their own staff as candidates to become peer assessors. Candidates should demonstrate, at least:

- a good knowledge of English and, possibly, of other national language(s) spoken in the Member's country(ies);
- previous knowledge/work experience with quality audit exercises;
- knowledge on standardization development.

Following the deadline of the call, the MRMC evaluates the proposed curricula according to the agreed criteria and establishes a list of maximum 15 appointed assessors.

The peer assessors are expected to remain available in the shortlist for a period of 4 years.

Calls for peer assessors are normally handled once every 4 years.

Each time a peer assessor is called to handle an assessment exercise, the Member in which this assessor is employed receives a financial compensation for the time its employee spends on the assessment exercise. This is calculated for an amount of € 600 per day/assessor plus travel costs (reimbursed upon real flight expenses) and accommodation costs (reimbursed upon fixed daily allowance based on the EC official rates for European projects).

The same financial compensation and reimbursement of cost is applied to the CEN and/or CENELEC Member that changes its legal status requiring an assessment of compliance with the membership criteria. In case of the assessment following a new application for membership in CEN and CENELEC, the same financial conditions as above will apply, and the related cost will be charged directly to CEN and CENELEC and invoiced to CCMC.

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4.3.6 Establishment of the peer assessors' team for the Member assessment

The Chair of the MRMC appoints the peer assessors to handle the assessment visits.

Confidence in the process is key to the relevance of the peer assessment process. Therefore, the Chair appoints the peer assessors in a dialogue with the Member to be assessed. A contact person in the Member's organization is to be nominated to this end.

Depending on the size of the Member to be assessed, the MRMC can agree to allow just one peer assessor to handle the exercise or to have a team of peer assessors composed of a lead assessor and one assessor.

The Chair appoints the peer assessors who have the qualifications required for the specific assessment, bearing in mind the profile of, and their independency from, the Member to be assessed.

The Member to be assessed has the right to reject a peer assessor, providing reasons for their non-acceptance.

In all cases, the team is appointed in agreement with the Member to be assessed.

4.3.7 Main implementation steps of the peer assessment and follow-up

a) Desk review and preparation of the visit on location

Relevant documents are sent by the Member to the assessors' team in advance. The need for specific translations is discussed on a case-by-case basis.

The assessors' team studies the documents, requests additional information (if needed) and clarifies items as much as possible before the assessment on location.

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In order to ease the assessment visit, a preliminary short report and a proposed assessment schedule (topics, persons, documents, and timetable) are sent to the Member for comments and agreement.

b) Visit by the Assessors to the Member

The visit and assessment are organized on the basis of good audit practices. At the end, a first oral summary of findings, results and recommendations will be given to the Member's management by the assessors' team.

c) Draft report

The draft report is sent to the Member for comments within a given timeframe. If the Member does not agree with the findings in the assessors' report, further clarifications to find consensus are possible.

The Chair of the MRMC may intervene to facilitate the exchange of information between the assessors and the Member.

If consensus is not possible, the Member sends its written comments or clarifications to the MRMC. The diverging positions between the assessors and the Member are quoted in the final Report (see also Clause 5).

d) *Final report and feedback*

The assessors' final report is sent to the Member concerned and to CCMC for processing to the MRMC, which handles it with due confidentiality. The MRMC may also provide specific feedback to the assessed Member on possible remedies and improvements. It also indicates good practices of other Members and facilitates the exchange of information on these by inviting contact to be made with other relevant Members on specific matters.

e) *Non-conformities*

Should non-conformities be revealed, a reasonable timeframe for reaching compliance is agreed with the Member concerned. In case of persistent failure of compliance, MRMC will engage in an escalation process as defined under Clause 5.

4.3.8 Working language

The choice of the assessors will also take into account their language skills, so as to facilitate the reading and use of the Member's documents. However, it may be required that at least the main documents are translated into English. The peer assessment report will be drafted in English.

4.3.9 Other complaints on peer assessors

The Member may put forward formal complaints to the MRMC about the assessors' work and/or behaviour. Any complaint must be accompanied by the relevant evidence.

4.4 External assessment exercise

4.4.1 General and time cycle of the external assessment report

CEN and CENELEC Yellow-type Members shall undergo an external assessment focusing on regulatory compatibility when applying for membership and then every third year after becoming a Member. The external assessment model is based on a team of independent and competent assessors appointed by the CEN and CENELEC Administrative Boards upon recommendation of the Presidential Committee.

In particular, the external assessment shall include all agreements with the EU and documents that certify compliance with regulatory convergence or compatibility with the essential regulations that support the Single market in the areas that are relevant to CEN and/or CENELEC.

4.4.2 Membership Relations and Monitoring Committee

In addition to its above-mentioned responsibilities, in the case of an external assessment the MRMC is in charge of:

- a) the organization of the external assessment process;
- b) advising the Presidential Committee on the identification and composition of the teams of external assessors.

4.4.3 The external assessors

The external assessors are competent persons appointed to handle the assessment exercises and to report accordingly to the Membership Relations and Monitoring Committee. They commit to be independent in their judgment and behaviour.

4.4.4 Establishment of the external assessors' team and remuneration

The composition and the size of the team are decided by the Administrative Boards upon recommendation of the Presidential Committee. The Presidential Committee shall consult the MRMC for the identification of the assessors.

The Administrative Boards appoint external assessors who have the qualifications required for the specific assessment, bearing in mind the profile of, and their independency from, the Member to be assessed.

The Administrative Boards, upon recommendation of the Presidential Committee, appoints a leader among the external assessors responsible for assigning specific roles and tasks, for the coordination of the team and for the final drafting and delivery of the assessment report.

The assessment costs shall be covered by the assessed organization. The overall calculated costs for work and accommodation are the same as those indicated for the peer assessment exercise under clause 4.3.5. The assessed Member does not have the right to reject an assessor appointed by the Boards.

4.4.5 Main implementation steps of the external assessment and follow-up

- a) Desk review and preparation of the visit on location

Relevant documentation, including extensive legal evidence establishing compliance with the membership criteria for Yellow type Members are sent by the Member to the external assessors' team in advance. The need for specific translations is discussed on a case-by-case basis.

The assessors review the documents, request additional information (if needed) and clarify items as much as possible before the assessment on location.

In order to facilitate the assessment visit, a short preliminary report and a proposed assessment schedule (listing topics, persons to meet with, documents to access and timetable) are sent to the Member for comments and agreement. Additional meetings to define the needs and objectives of the assessment exercise may also be proposed.

- b) Visit by the Assessors to the Member

The visit and assessment are organized on the basis of good audit practices. At the end, a first oral summary of findings, results and recommendations will be given to the Member's management by the assessors' team.

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c) Draft report

The draft report is sent to the Member for comments within a given timeframe. If the Member does not agree with the findings in the assessors' report, further clarifications to find consensus are possible. The Member does not have the right to object the findings and recommendations provided in the draft report.

The Chair of the MRMC may intervene to facilitate the exchange of information between the assessors and the Member.

If consensus is not possible, the Member sends its written comments or clarifications to the MRMC. The diverging positions between the assessors and the Member are quoted in the final Report

d) *Final report and feedback*

The external assessors' final report is sent to the Member concerned and to CCMC for processing to the MRMC, which handles it with due confidentiality.

The MRMC may provide specific feedback to the assessed Member on possible remedies and improvements. It also indicates goals and practises of other Members and facilitates the exchange of information on these by inviting contacts to be made with other relevant Members on specific matters.

Based on the final report, the MRMC provides a detailed recommendation to the Presidential Committee, which may contain specific feedback on possible remedies to non-conformities and possible improvements. It also underlines good practices and other supporting evidence and information.

e) *Non-conformities*

Should non-conformities be revealed, the PC asks the MRMC to manage the follow-up process. A reasonable timeframe for reaching compliance is agreed with the Member concerned. In case of persistent failure of compliance MRMC provides the PC with a negative feedback on the Member's Membership status.

f) *Recommendations of the Presidential Committee*

Based on the feedback of the MRMC, the Presidential Committee provides further recommendation to the Administrative Boards.

g) *Recommendations of the Administrative Boards*

The Administrative Boards analyse the recommendations provided by the PC and deliver final recommendations on Membership status to the General Assemblies.

h) *Final Decision of the General Assemblies*

The General Assemblies decide on the Membership status of the assessed Member during their common session.

4.4.6 Working language

The criteria established under clause 4.3.8 applies.