BUSINESS PLAN

CEN/TC 444
Environmental characterization of solid matrices

EXECUTIVE SUMMARY

Scope
Standardization of methods for the environmental characterization of soil, solid and liquid waste, biowaste and sludge.

This covers:
- Sampling, assessment methods and vocabulary;
- Digestion / extraction, chemical analysis, physical methods, quality assurance and quality control (laboratories);
- Where appropriate and decided by matrix specific environmental Technical Committees: leaching tests, screening methods, sample pretreatment, biological and microbiological analysis, reporting.

Excluded are:
- Sampling, assessment methods and vocabulary related to sludge, which are covered by CEN/TC 308 'Characterization and management of sludges'.

CEN/TC 444 test methods could also be applicable for environmental testing of other matrices and products. CEN/TC 444 operates in close cooperation with matrix specific environmental Technical Committees as described in Annex A 'Code of Practice' of this Business Plan, notably by inviting these TCs to investigate the possibility of developing multi-matrix standards.

NOTE 1 The list of concerned matrices will be amended when additional matrix specific Technical Committees closely cooperate with CEN/TC 444.

NOTE 2 CEN/TC 444 is a multi-matrix environmental TC. The structure is aimed to be open in such a way that when additional TCs start to cooperate, it can easily be adapted.

Business Environment
Reliable data is used for decision making at various levels. Uniform and (European) standardized methods are the basis for obtaining reliable data. Environmental testing is a business which is more and more driven by European legislation. European standards establish close cooperation between public authorities and market operators by providing the technical instruments.
The development and maintenance of European testing standards is essential to create a level playing field for the stakeholders involved and to ensure protection of the environment. If possible multi-matrix standards will be developed to meet the client needs, facilitate efficient testing and obtain comparable data.

Benefits
a. Multi-matrix characterization methods
The users in the various environmental fields use - to a large extent - similar procedures for environmental characterization. The potential combination of available (test)methods across different environmental fields into standards that are applicable to a variety of matrices can therefore be beneficial; both in view of the standard development and maintenance (cost reduction), as - more important - from the point of view of application of the standards.

Consequently, CEN/TC 444 aims to provide common testing standards to be used on multiple solid matrices.

By bringing the analytical experts for the different matrices together in CEN/TC 444, the capacity of experts is used more efficiently. Multi-matrix methods fit with a growing tendency for harmonization of legislation, it creates a level playing field, enhances comparability of results and increases the transparency and uniformity in testing.
A large number of multi-matrix standardized methods is already available.

b. Single matrix characterization methods

With the establishment of CEN/TC 444 and the subsequent disbandment of CEN/TC 292 - Characterization of waste, CEN/TC 345 - Characterization of soils and CEN/TC 400 PC - Horizontal standards in the fields of sludge, biowaste and soil, experts from these TCs have continued their standardization efforts under CEN/TC 444. It is however acknowledged that there will always remain matrix-specific characterization methods. These single matrix methods can also be taken care of within CEN/TC 444 as to centralize all standardization activities for the environmental characterization for the matrices and methods as covered by the scope of CEN/TC 444.

Priorities

Prioritization of work within CEN/TC 444 is done by its members, wherein a certain level of autonomy is given to the Working Groups.

Furthermore the development and revision of standardized methods for the implementation of relevant (EU) legislation has a priority. An additional priority is the harmonization of methods that are inherited from former CEN/TC 292, CEN/TC 345 and CEN/TC 400 PC.

1 BUSINESS ENVIRONMENT OF THE CEN/TC

1.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal, societal and/or international dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this CEN/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards.

1.1.1 Scope of CEN/TC 444

The general scope is to develop and maintain test methods for environmental characterization of soil, solid and liquid waste, biowaste and sludge. CEN/TC 444 develops and maintains both single matrix and multi-matrix standardized methods for the environmental characterization of these matrices. Solid matrices also included in the scope are (excavated) sediment, sludge, soil, biowaste and waste, but the scope can be expanded to other matrices on request of the CEN/TC that is responsible for that matrix.

Cooperation with CEN/TC 308 is sought when relevant.

CEN/TC 444 covers methodologies in all stages of environmental characterization from sampling to reporting:

- sampling,
- sample pretreatment,
- sample handling and preservation
- screening methods (on-site)
- digestion/extraction,
- chemical analysis,
- physical methods,
- QA/QC (laboratory),
- leaching,
- screening methods (laboratory),
- (micro)biological analysis
- Assessment methods
- vocabulary
- reporting

1.1.2 Organization and parties involved

CEN/TC 444 is chaired by Mr F.P.J. Lamé (The Netherlands). The secretariat is held by the Netherlands Standardization Institute (NEN) and secretary is Mr P. Folten (paul.folten@nen.nl). The technical work and development of standards in CEN/TC 444 is carried out in Working Groups (WGs) covering different themes. Eight Working Groups have been established under CEN/TC 444. These are:

– WG 1 'Leaching tests'	convenor: Mr. A. Wijdeveld (NL), secretariat by NEN
– WG 2 'Organic analysis'	convenor: Mrs. L. Amalric (FR), secretariat by AFNOR
– WG 3 'Inorganic analysis'	convenor: Mr V. Linnemann (DE), secretariat by DIN
– WG 4 'Biological characterization'	convenor: Mr P. Pandard (FR), secretariat by AFNOR
– WG 5 'Physical tests'	convenor: Mrs S. Stadler (DE), secretariat by DIN
– WG 6 'Cross cutting issues'	convenor: Mr J.W. Hutter (NL), secretariat by NEN
– WG 7 'Sampling'	convenor: vacancy, secretariat: vacancy
– WG 8 'Assessment'	convenor: Mr. B. Klein Lankhorst (NL), secretariat by NEN

In its activities, CEN/TC 444 aims to include representation of all stakeholder groups to participate in the standardization process:

- European and national governments;
- Industry;
- Public authorities;
- Commercial and public laboratories;
- Universities and research facilities;
- NGOs representing societal interests, including environmental and consumer organizations
- Consultancy.

Furthermore, it seeks to have active contribution from all CEN Member States.

1.1.3 Political and legal factors

European standardization enables the harmonization of methodology in Europe. A number of European standards that fall under the responsibility of CEN/TC 444 are listed in European and/or national legislation. These standards contribute to consistent implementation and enforcement of legislation.

The European Commission has acknowledged the important role of (environmental) standardization by asking CEN to develop a number of standards mandated by the European Commission. Relevant EC mandates within the field of work of CEN/TC 444 can be found in Annex E.

Furthermore, CEN/TC 444 can initiate the development of a standard in anticipation of a future standardization request, in order to support national and European policy makers by providing standards which can be referred to in legislation.

1.1.4 Technological developments

A key question for CEN/TC 444 is to identify and understand the stakeholders needs in terms of developments that lead to a request for new (or revision of existing) European standards. Besides standardization of methods for the different steps of the characterization process, technological developments in the field provide a basis for standardization initiatives.

1.1.5 Financial factors

Standardization is financed by the participating parties. Insufficient support to provide resources is considered as an indication of a lack of stakeholders needs for the development of standards on a particular topic. However, it should be noted that standardization in the environmental field is strongly driven by (European) legislation and is, to a significant level, dependent on funding from the Member Bodies on state level.

A specific and generally expensive part of the development of standards is validation. This is an important part of the standardization process and is an integrated part of standards development within CEN/TC 444. For that purpose, CEN/TC 444 has adopted the CEN Guide 13 as a basis for its approach towards validation. In addition to that CEN/TC 444 also adopted the outcome of a workshop on validation which was organized by ISO/TC 190 ‘Soil quality’ in October 2014. Based on subsequent discussions in some of its WGs and at TC level, CEN/TC 444 also organized a Workshop on Validation on 22 September 2022, which resulted in seven decisions in which more details on the approach to the validation of CEN/TC 444 standards are laid down. The resulting approach of CEN/TC 444 to validation is summarized in Annex C.

Activities that may lead to a more accurate, faster and easier way to validate draft methods, are highly supported. CEN/TC 444 supports validation activities in conjunction with any need for pre-normative research to aid future improvement of test procedures.

1.1.6 Coordination with other committees / stakeholders

CEN/TCs, ISO/TCs and European organizations are invited to establish a liaison with CEN/TC 444 and to appoint a liaison officer.

The following persons are appointed to represent CEN/TC 444 in other groups:

TC	Name	Since	Liaison officer
CEN/TC 223	Soil improvers and growing media	2021	Baumgarten, Andreas
CEN/TC 230	Water analysis	2022	Vacant
CEN/TC 249	Plastics	2016	Degli Innocenti, Francesco
CEN/TC 260	Fertilizers and liming materials	2021	Baumgarten, Andreas
CEN/TC 264	Air quality	2016	Neuroth, Rudolf
CEN/TC 308	Characterization and management of sludge	2021	Vacant
CEN/TC 351	Construction Products - Assessment of release of dangerous substances	2017	Bartels. Jeroen
ISO/TC 190	Soil quality	2021	Liphard, Klaus
ISO/TC 275	Sludge recovery, recycling, treatment and disposal	2022	Liphard, Klaus

The following Committees have nominated a liaison to follow the work of CEN/TC 444:

Committee	Liaison officer
CEN/TC 223 Soil improvers and growing media	Baumgarten, Andreas
CEN/TC 230 Water analysis	Vacant
CEN/TC 351 Construction products – Assessment of release of dangerous substances	Lamé, Frank

The following organizations are observer to the work of CEN/TC 444:

Organization	Since	Liaison officer
ANEC, European Association for the coordination of Consumer Representation in Standardization	2015	Vuerich, Michela Viala, Franz
ECOS, European Environmental Citizens Organization for Standardization (observer)	2015	Forbicini, Martina Neaves, Michael

Other CEN/TCs, ISO/TCs and groups that may have an interest in the work of CEN/TC 444 have been identified:

- EC/DG Environment (ENV)
- EC/DG Research and Innovation (RTD)
- EC/DG Joint Research Centre (JRC)
- ANEC (European consumer voice in standardization)
- ISO/TC 147 Water quality

If future participation of these or other groups is decided on, this will be formalized.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC

Development of standards within CEN/TC 444 will result in common methodologies for environmental characterization and allows harmonization of methods on a European level. In addition, standardization will create a level playing field for the comparability of data and transparency of environmental assessment.

CEN/TC 444 supports national and European policy makers by developing standards that can be referred to in legislation. Furthermore, standards will be developed in response to a stakeholder's demand within the field of environmental characterization. Where feasible, action is taken to come to standards that cover multiple solid matrices.

3 PARTICIPATION IN THE CEN/TC

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and to appoint experts to Working Groups, ensuring a balance of all interested parties. Participation as observers of recognized European or international organizations is also possible. To participate in the activities of CEN/TC 444, please contact the national standards organization in your country.

4 OBJECTIVES OF THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC

The objective of CEN/TC 444 is to support (European) parties in environmental characterization by providing fit-for-purpose CEN standardized methods.
The objectives identified are:

1. To efficiently and effectively develop multi-matrix standards where possible and matrix specific standards where needed.
2. To coordinate the work program in close liaison with the CEN/TCs active in the environmental field.
3. To coordinate the work program in close liaison with ISO to avoid duplication of efforts and avoid possible conflicts.

4.2 Identified strategies to achieve the CEN/TCs defined objectives

The strategy of CEN/TC 444 is based on three pillars:

1. (Multi-matrix) standard development
2. Quality of standards
3. Implementation and communication on standards

(Multi-matrix) standard development: This concerns both the revision of existing standards to incorporate new insights as well as the development of new standards. Development and maintenance of standards, despite a preference for multi-matrix standards, can also be aimed at single matrix standards.
In order to meet the objectives of CEN/TC 444, standard development needs to be supported by national members and stakeholders. For that, three critical requirements need to be fulfilled in order to proceed with standard development.

1. presence of stakeholder needs
2. presence of relevant matrix specific TC support
3. presence of expertise and financial support

Quality of standards: quality aspects are important on three levels:

1. the level of the organization of documents: The coherence and coordination between the individual standards that form parts of the methodology in the full characterization cycle need to be ensured.
2. the level of performance of methods: a reliable indication of the performance of standardized test methods is an important quality aspect, especially when a method is used to fulfill legal requirements. Performance data need to be an integral part of standards describing measurement methodology.
3. being fit for purpose: there is a balance between costs, speed and accuracy of standardized methods. Depending on the context within which characterization is needed, either costs, speed or accuracy will determine that balance. It implies that e.g. screening methods with a higher level of uncertainty can be standardized next to full laboratory methods for the same parameters. The scope of the standard will state for which type of characterization it serves.

Implementation and communication on standards:

The use of standards developed in CEN/TC 444 should be promoted. The benefits of a broad use of standards are manifold and include increased efficiency and comparability of data. The basis for an extensive use of standards is a broad stakeholder support. Furthermore, the use and implementation of standards can be enhanced by informing the relevant markets about the existence and advantages of European standards, for example through publication of articles, web-alerts and organization of workshops. This is to a large extent the responsibility of the NSB.

4.3 Environmental aspects

CEN/TC 444 is developing European Standards and other documents to investigate, characterize and monitor environmental parameters. A number of standards is being used to support (European or national) legislation and CEN/TC 444 therefore fully supports the idea of promoting environmentally friendly standards taking human health and safety issues into account including considering the effects on the global climate.

CEN/TC 444 supports the banning or replacement of harmful chemicals from test methods that cause negative effects on the environment, including climate change, where possible.
CEN/TC 444 includes environmental aspects into the revision of existing European standards and bases this process on past as well as future applications of the standards.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC WORK PROGRAMME

- Resources and market support for standardization

As indicated in section 1.1.5, standardization should meet the requirement of the presence of sufficient stakeholders needs as well as the requirement that sufficient resources (financial means and expert participation) is available for the development of a standard.

- Funding for validation

Validation of a test method is costly and often dependent on available funding for the necessary co-normative research.
Absence of validation of a particular method shall lead to the publication of a Technical Specification instead of a full standard (see Annex C).

ANNEX A: CODE OF PRACTICE: ON THE INTER-TC COOPERATION IN THE FIELD OF ENVIRONMENTAL STANDARDIZATION

A.1 Introduction

In 2015, CEN/TC 444 has been established (Decision BT C59/2015; CEN/TC 444 Document N01).

In addition to working in accordance with the CEN rules, this Annex covers a Code of Practice to enhance structural inter-TC cooperation in the environmental field. Inter-TC cooperation needs specific attention since CEN/TC 444 is a multi-matrix environmental TC.

A.1.1 Organization

CEN/TC 444 standardization of environmental characterization of solid matrices is strongly related to CEN/TC 351, CEN/TC 230 and CEN/TC 308.
CEN/TC 444 provides service to related TCs, taking care of standardization on matrices and topics as mentioned in the scope (see 1.1.1).
For related TCs (CEN/TC 230, CEN/TC 308 and CEN/TC 351) the transfer of responsibilities is limited to individual standards; decided upon by the related TC on a standard by standard basis.

Based on the establishment of CEN/TC 444, the work program of CEN/TC 292- Characterization of waste, CEN/TC 345 – Characterization of soils and CEN/TC 400 PC - Horizontal standards in the fields of sludge, biowaste and soil has been transferred to CEN/TC 444 and these TCs have been disbanded.

With the disbandment of CEN/TC 292, CEN/TC 345 and CEN/TC 400 PC, and the transfer of the work program of these TCs to CEN/TC 444, all expertise is available in CEN/TC 444. CEN/TC 444 is able and equipped to develop and maintain both multi-matrix and single-matrix standards. The desirability and possibility of multi-matrix standardization will be assessed on a standard by standard basis in close cooperation with the related TCs.

A.1.2 Status of this Code of Practice

From a practical point of view, this Code of Practice (Annex A) is a ‘living’ document under the responsibility of CEN/TC 444, where necessary procedures will be integrated, adapted or removed based on practical experience.

A.2 Work processes

A.2.1 Analysis of the work processes

The following work processes are distinguished:
a. Development of a new standard
b. Maintenance of an existing standard

Communication associated to the multi-matrix standardization process needs careful attention. Development, maintenance and publication of a standard is per definition the responsibility of a single TC. However, that does not exclude the possibility that two TCs work closely together during development and maintenance; see A.2.5 on mutual development.

A.2.2 Transfer of a standard

Transfer of standards will take place whenever CEN/TC 230, CEN/TC 308 or CEN/TC 351 or another TC decides to transfer a specific standard to CEN/TC 444. This could be in order to

develop it into a multi-matrix standard, or, when from the nature of the standard, the standard can best be hosted by CEN/TC 444.
Transferal of a standard, either in the process of standard development or maintenance, implies the transferal of responsibilities. Close cooperation and good two-way communication are therefore essential in that process.

The decision on the transfer of an existing standard to CEN/TC 444 is taken by the matrix-oriented TC that is responsible for that standard. It is a stepwise process, wherein the original TC will take a decision under the condition that CEN/TC 444 will indeed take over the responsibility for that standard. Prior to such a decision CEN/TC 444 will seek advice of its WG that will become responsible for that standard.

In accepting the responsibility of a standard or active work item, CEN/TC 444 will respect the decisions taken on that standard or active work item of the CEN/TC from which the standard originates. CEN/TC 444 will ensure that the time schedule for an active work item as set by the CEN/TC that started the active work item, will be kept.

A.2.3 Communication

The standardization needs of the matrix-oriented TCs in will be an essential determining factor for the work of CEN/TC 444 with respect to both standard development and maintenance. Consequently, well-organized two-way communication will be a major factor for the success of CEN/TC 444 in its task to develop fit-for-purpose standards for all involved matrices.

Whenever a multi-matrix standard is developed or maintained, there will be open and detailed communication between CEN/TC 444 and the related TC in order to ensure that the standard is fit-for-purpose, fits within the set of standard of the matrix TC(s) and to ensure that when it comes to voting, the NSBs are sufficiently aware of its multi-matrix character.

More in general, communication with SABE and NSBs will also be an important issue.
Apart from communication on the transfer, development and maintenance of specific standards, a Chairman's meeting will be organized in conjunction with the meeting of CEN/TC 444 and is open to all participating TCs and on request as well for non-participating TCs.

A.2.4 Validation

Validation is an essential step in the development of standards and needs specific attention with respect to multi-matrix standards.

The CEN Guide 13 'Validation of environmental test methods' and CEN/TS 16800:2020 'Guideline for the validation of physic-chemical analytical methods' (the scope of which is water, but its principle can be used broader), provide a backbone for validation trials. In addition to that, CEN/TC 444 also adopted the outcome of a workshop which was organized by ISO/TC 190 'Soil quality' in October 2014. Further discussion within CEN/TC 444 on the validation of standards took place in its 'Workshop on Validation' organized on 22 September 2022.

In addition to the normal needs for representativeness of samples in the validation of a single matrix standard, the validation of a multi-matrix standard also needs to cover the different matrices. Based on the results it will be decided for what matrices the validation is accepted. For more information on validation see Annex C.

A.2.5 Mutual development

When two TCs want to develop the same standard, there are different possibilities for cooperation. As the development, maintenance and publication of a standard is per definition the responsibility of a single TC, in all situations TC 'A' requests TC 'B' to develop that standard, enlarging the scope of the standard to the joint scope of both TCs.
For the practical cooperation between the TCs different options are possible:

1. TC 'A' fully relies on TC 'B' and is only informed on the developments
2. TC 'A' and TC 'B' organize one or more meetings for their expert to jointly develop the standard
3. TC 'A' and TC 'B' establish a formal Joint Working Group.

In situation 1 there is no real cooperation, while the principles of cooperation between situations 2 and 3 are comparable.

Specifically in situation 2 and 3, a few points in the mutual development process are important and will be helpful to the development process:

- Synchronization of the timeline in both TCs, to ensure that the experts in both TCs follow the same development process
- Clear and frequent communication between the TCs and the involved WGs
- In the interlaboratory tests, the samples need to represent the matrices of both TCs
- Final acceptance of the jointly developed standard prior to the formal vote is the responsibility of both TCs; the standard needs to fulfil the requirements for both TCs and if this is not or insufficiently guaranteed, both TCs can decide to publish their own standard
- Voting will be organized by the TC that is in the lead; to ensure good feedback from the NSBs participating in both TCs, the lead TC will inform the other TC on the voting.

A.3 Relationship to ISO work

A.3.1 General

The work in CEN is closely related to the ISO work. By the Vienna Agreement, CEN and ISO can decide to work together, drafting EN ISO standards. Collaboration between CEN and ISO reduces standardization costs (no double work) and enlarges the field of application of the standards (worldwide recognition instead of only European recognition). Consequently the co-operation with associated ISO/TCs is also essential in the new structure. See also Annex B: Practical guidance for the cooperation between CEN/TC 444 and ISO in the development and maintenance of standards**.**

A.3.2 Practical

Soil

ISO/TC 190 and CEN/TC 444 are closely related. ISO/TC 190 is allowed by ISO/CS to widen the scope of individual standards beyond soil and soil material (including excavated sediments), in order to allow the development of multi-matrix EN ISO standards in the environmental field.

There is a long-term active co-operation between CEN/TC 444 and ISO/TC 190. In general ISO standards for soil (developed by ISO/TC 190), which have been taken over as EN ISO standards and are within the responsibility of CEN/TC 444, will be maintained by ISO/TC 190. Co-operation during any revision of these standards will be based on the Vienna Agreement with ISO lead. However - due to for example broadening of the scope to other matrices – CEN/TC 444 can request to ISO/TC 190 to take over the responsibility for the revision of an EN ISO standard. Such a decision shall always be taken on an individual basis and has to be decided by both CEN/TC 444 and ISO/TC 190.

Sludge
In any case where sludge is part of the scope of an EN ISO standard, ISO/TC 275 will be involved.

Waste
As there is currently no ISO/TC on waste, EN ISO standards for soil and waste can be developed and maintained by co-operation between CEN/TC 444 and ISO/TC 190.

Other
When more CEN/TCs decide to join, the implications on ISO-level need to be reviewed.

In case an ISO standard within the scope of CEN/TC 444 is proposed to be accepted as an EN ISO standard, and there is not yet an EN standard available, this will lead to a single matrix EN ISO standard under the responsibility of the concerned ISO/TC in co-operation with CEN/TC 444.

When an EN multi-matrix standard is proposed for transposition to ISO, communication with relevant ISO/TCs is undertaken in order to maintain the multi-matrix character of the standard.

A.4 Miscellaneous

A.4.2 CEN/TCs interested in participation

Participation by other related CEN/TCs is stimulated and will be possible at any given time. The inclusion of other TCs will be discussed and decided upon in a TC meeting and discussed in the Chairmen's meeting (A.4.5).

A.4.3 Chairmen's meeting

The Chairmen's meeting will have an important role in the steering and monitoring of the process of the inter-TC communication and cooperation. The Chairmen's meeting will deal with the practical and procedural aspects of the inter-TC cooperation and is used as an advisory board for the chairman and secretary of CEN/TC 444.
The participants to the chairman meeting are convenors and secretaries of CEN/TC 444/WGs and Chairmen and/or Secretaries of other interested TCs.
It is envisaged that the Chairmen's meeting will play an essential role in the communication between the TCs. Related TCs and CEN/TC 444/WGs are invited to participate, share information and give advice.

ANNEX B: PRACTICAL GUIDANCE FOR THE COOPERATION BETWEEN CEN/TC 444 AND ISO IN THE DEVELOPMENT AND MAINTENANCE OF STANDARDS

B.1 SUMMARY

This annex provides a guideline for CEN/TC 444 on how cooperation with ISO committees will be organized in case of new Standard development and revision of existing Standards.

This document describes in detail various situations that can occur in the development and maintenance of Standards. However in day-to-day practice, good cooperation between CEN/TC 444, ISO/TC 190 and ISO/TC 275 (and possibly other ISO/TCs) depends on communication and the willingness to actively inform each other and work together.

With this Annex B CEN/TC 444, with the contribution of ISO/TC 190 and ISO/TC 275, has setup a guideline for efficient and consistent standardization for environmental characterization between CEN and ISO. The general points for cooperation as described in the rest of the Annex B are:

- The preference to the development of EN ISO Standards where possible (beyond pure ISO or EN Standards).
- For this purpose, always consult well in time with each other when there is a need within either CEN or ISO for the development or revision of a Standard so that the other party (CEN or ISO) can decide in time on cooperation for the establishment of an EN ISO.
- From the moment cooperation starts the involved TCs agree which TC is in the lead, and how participation and communication is arranged.
- That in all situations where an EN ISO Standard is developed experts from both CEN and ISO can participate in the WG whether the lead is in ISO or CEN.
- That the lead, once established, will not change during the development of the document.
- One CEN/TC and one ISO/TC are formally registering the Work item. If more than one CEN/TC or ISO/TC is involved, the CEN/TC and ISO/TCs that have registered the Work item have to arrange the cooperation between the TCs within their own organization (CEN respectively ISO).
- In case of systematic review of an EN ISO standard (within ISO) the EN ISO Standard under systematic review will be made available in CEN/TC 444 in order to inform the members of CEN/TC 444 and obtain feedback on the future of these Standards.

The following points are highlighted for a successful cooperation:

- The (informal) exchange of information between the concerned Chairs and Secretaries of both CEN and ISO/TCs and/or WGs and SCs.
- Respect and trust each other also when the other organization (CEN or ISO) is in the lead.

B.2 Introduction

B.2.1 Objective

This Annex provides a guideline for CEN/TC 444 on how cooperation with ISO committees will be organized in case of new Standard development and revision of existing Standards. The cooperation between CEN/TC 444 with ISO/TCs is essential in order to make standardization more effective and efficient. With this in mind this procedure will also be shared and communicated with the concerned ISO/TCs.

For inter CEN/TC Standard development and cooperation see Annex A: Code of practice: on the inter-TC cooperation in the field of environmental standardization.

B.2.2 Introduction

CEN/TC 444 strives for a standardization process that is as efficient as possible. This implies the optimal use of available resources and expertise for the benefit of the stakeholders of both CEN and ISO. Duplication of work should be avoided and synergies should be developed. Within this context, CEN/TC 444 aims to make optimal use of the agreement on technical cooperation between ISO and CEN (Vienna Agreement). The Agreement helps ISO and CEN to exchange information and increases the transparency of CEN work to ISO members and vice versa. General practical guidance on how to cooperate are listed in the VA guidelines (7th edition, 2016). In this annex the cooperation between CEN/TC 444 and ISO/TCs (e.g. ISO/TC 190 and ISO/TC 275) is detailed for the specific situation were single-matrix or multi-matrix standardization is foreseen.

B.2.3 Communication

In order to organize and facilitate cooperation between CEN and ISO, communication between CEN/TC 444 and ISO/TCs is essential. Depending on the situation (see Clause B.2.3.1) this annex gives guidance to the cooperation process.

B.2.3.1 Situations for cooperation between CEN and ISO

In the development and maintenance of Standards, Technical Reports and Technical Specifications (all referred to as 'standard' in this annex) different situations can occur. The various foreseen situations for cooperation between CEN/TC 444 and ISO are:

1. Initiative for the development of a new standard by CEN/TC 444
2. Initiative for the development of a new standard by an associated ISO/TC
3. Development of an EN ISO standard under CEN lead
4. Development of an EN ISO standard under ISO lead
5. Revision of a European Standard in case there is also a comparable ISO Standard
6. Revision of an ISO Standard in case there is also a comparable European Standard
7. Revision of an EN ISO standard
8. Existing ISO Standard to be adopted by CEN/TC 444
9. Existing EN Standard to be adopted by ISO/TC(s)

General points of attention for cooperation between CEN/TC 444 and ISO are:

- In case two or more ISO/TCs are willing to cooperate with CEN/TC 444 on Standard development, a decision is needed by the ISO/TCs to determine the ISO/TC that will register the Work item in its work program (only one ISO/TC can be the formal counter TC).
- In case waste is in the scope of the Standard, CEN lead is the preferred option (there is no ISO/TC on waste). Alternatively, ISO/TC 190 can take the lead if soil and waste are concerned. If more matrices are involved, the multi-matrix standards are necessarily developed and maintained under CEN/TC 444.
- Cooperation between CEN and ISO on new work items or revisions of existing items results in an EN ISO standard with identical Standard number in both CEN and ISO.
- a new Standard development project shall contain all matrices concerned in both title and scope (alphabetical order).
- In case of validation a table is added to the Annex of the standard listing per matrix the validation data available in the standard. A sentence can be added in the scope to clarify that the standardized method is potentially applicable for other matrices, when validity is demonstrated by the user.
- Formal reference to either EN standards or ISO standards should be avoided as much as possible, as this would imply that a referred EN standard implicitly becomes mandatory in ISO or vise versa. Reference to either EN or ISO standards are to be made in the bibliography

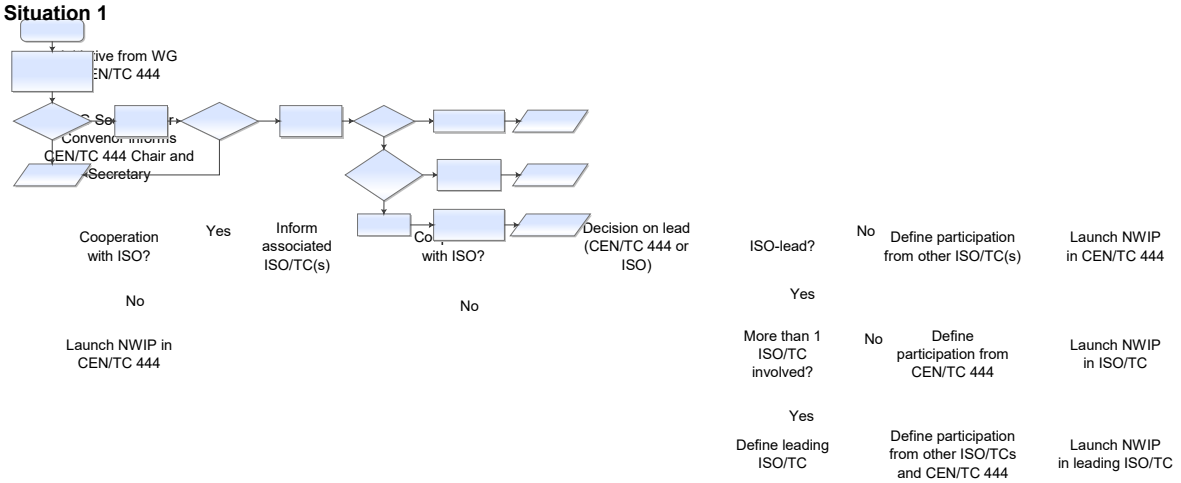
unless that referred EN or ISO standard is essential to the results of the standard in which the reference is made.

– In the case that multiple standards are merged into one and this results in the superseding of certain standards, this information should be added to the WI form when it is created or, at the latest, during development. Consequently, this will get registered in the ISO system and added to the Foreword of the standard. If this information has to be added after the publication of a standard, a BT decision is required.

Situation 1: Initiative for the development of a new standard by CEN/TC 444

The initiative for a NWIP in CEN/TC 444 is shared with the CEN/TC 444 Secretary as soon as possible and preferably before the NWIP is formally submitted to the CEN/TC 444 secretariat. In the involved WG, the experts will also discuss if there might be an interest to publish the standard as EN ISO standard. If so, this information will be forwarded to the CEN/TC 444-secretariat.
If ISO cooperation is not an option CEN/TC 444 launches the NWIP as a CEN Work item see Annex A.

If ISO cooperation is supported by CEN/TC 444, the CEN/TC 444 Secretary contacts the ISO counter TC(s) Secretary with the request for cooperation (resulting in an EN ISO) and proposal for CEN or ISO lead. After having received the response from the ISO/TC(s) the NWIP will be launched (preferably within 4 weeks after the first contact with the CEN/TC 444 Secretary).



Situation 2: Initiative for the development of a new standard by an associated ISO/TC

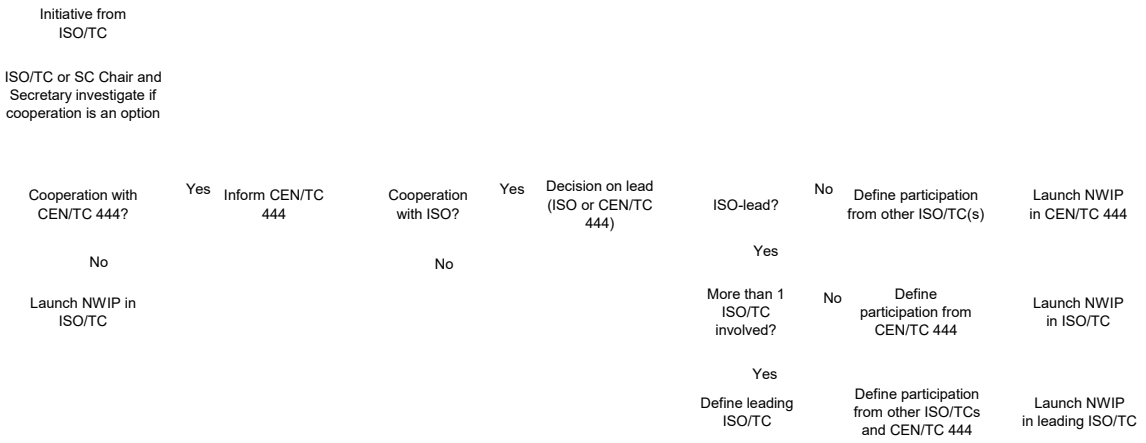
The ISO/TC and/or ISO/SC Secretary investigates whether cooperation with CEN/TC 444 is an option. If so, the ISO-Secretary contacts the CEN/TC 444 Secretary.
The CEN/TC 444 Chair and Secretary will discuss with the relevant Working Group Convenor (convenor may decide to consult WG members) if cooperation with ISO is an option. CEN/TC 444 responds within 2 weeks.
The CEN/TC 444 Secretary will inform the ISO Secretary whether cooperation on the ISO proposal is supported by CEN/TC 444, consequently the NWIP will be launched indicating CEN or ISO lead. CEN or ISO lead will be decided on a case-by-case basis (since it is an ISO initiative ISO lead is most logical).
If CEN ISO cooperation is not an option for CEN/TC 444 the ISO/TC continues with the development of a pure ISO standard and launches the NWIP.

In case an ISO/TC launches a NWIP for voting without prior communication with CEN/TC 444 and the item is of interest for CEN/TC 444, CEN/TC 444 Chair and Secretary will discuss with the CEN/TC 444/WG Convenor if cooperation with ISO should still be considered. If so, the ISO/TC is informed on the wish to cooperate.

Points of attention:

- Considering that the initiative comes from ISO side, the most obvious way forward will be with ISO-lead.
- Cooperation between CEN and ISO and parallel voting results in an EN ISO standard with identical Standard number.

Situation 2



Situation 3: Development of an EN ISO standard under CEN lead

The NWIP is approved by both CEN and ISO members and there is agreement on CEN lead in the Standard development. CEN/TC 444 assigns the work item to one of its Working Groups.

The CEN/TC 444/WG starts drafting the Standard, communicates with the ISO counterpart(s) and requests the ISO/TC(s) to nominate experts. If desired, non-European ISO members are welcome to participate in the CEN/TC 444/WG responsible for the development of the standard.

NOTE 1 It might occur that an ISO/TC is showing interest on a CEN/TC 444 work item after a CEN/NWIP has been approved, but before the CEN enquiry is initiated. In this case the CEN/TC 444 Secretary will verify if cooperation is preferred and contacts CCMC on the wish for cooperation with the ISO/TC. The lead for the Standard development will remain in CEN/TC 444.

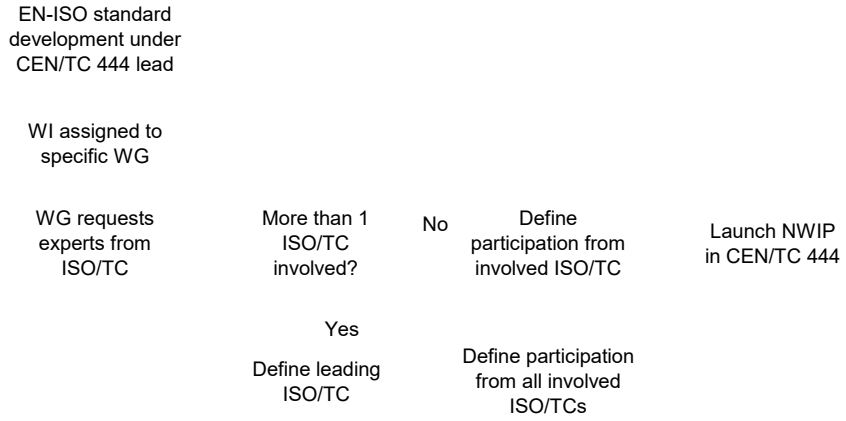
NOTE 2 If an ISO/TC is showing its interest to cooperate with CEN/TC 444 on a work item that already passed the CEN enquiry stage, the ISO/TC is advised to consider situation 9.

It is up to CEN/TC 444 to decide whether or not to skip the Formal Vote. The decision to decide whether or not to skip the FDIS is made by the cooperating ISO/TC.

Points of attention:

- If desired the involved ISO/TC(s) can nominate representatives to attend the CEN/TC 444 meetings.
- The ISO/TC(s) shall be kept informed and given the opportunity to contribute to the drafting of the standard at all stages of the Standard development process. Preferably by the nominated ISO representative.

Situation 3



Situation 4: Development of an EN ISO standard under ISO lead

The NWIP is approved by both CEN and ISO members and ISO takes the lead in the standard development. If desired, CEN/TC 444 nominates representatives to attend the ISO meetings and/or participate to the work.

The ISO/TC Working Group starts drafting the Standard and cooperates and communicates with the CEN/TC 444/WG and shares relevant Working Drafts.

NOTE 1 It might occur that an ISO/TC Working Group is working on the development of a Standard and CEN/TC 444 is interested to cooperate before the ISO/DIS voting starts. In this case the CEN/TC 444 Secretary will contact the ISO/TC in order to apply for cooperation. The lead for the Standard development will remain in ISO.

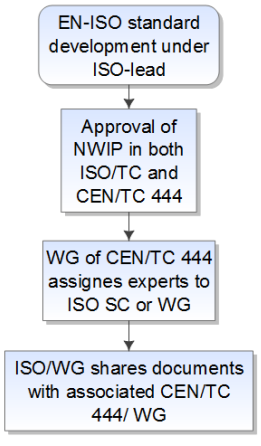
NOTE 2 If CEN/TC 444 is willing to cooperate and the ISO/DIS voting has already passed, situation 8 is applicable.

In case of parallel voting the ISO/TC can decide to skip ISO/CD and / or FV/FDIS voting. The decision to skip a voting and speed up the process is only made after consultation between CEN/TC 444 and the ISO/TC.

Points of attention:

- If desired, CEN/TC 444 can nominate representatives to attend meetings of the ISO committee.
- CEN/TC 444/WG shall be kept informed and given the opportunity to contribute to the drafting of the standard at all stages of the Standard development process. Preferably by the nominated CEN representative.

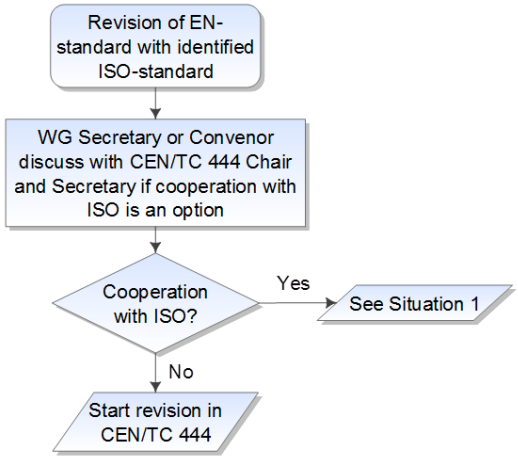
Situation 4



Situation 5: Revision of a European Standard in case there is also a comparable ISO Standard

The proposer of the NWIP to revise a European standard identifies one or more relevant existing ISO Standard(s). Before the NWIP is formally submitted to the CEN/TC 444 Secretary, the CEN/TC 444 Chair and Secretary verify with the relevant CEN/TC 444/WG Convenor if, from the perspective of CEN/TC 444, cooperation with ISO is an option.
In case cooperation with ISO is identified as an option, the ISO/TC(s) Secretary is contacted. Situation 1 applies.
In case a related ISO Standard is identified, the ISO/TC(s) Secretary is consulted to discuss the possibilities to develop a new EN ISO standard that could replace the existing EN Standard and existing ISO standard. Consultations amongst members in both CEN/TC 444 and the respective ISO/TC(s) will be performed to learn about the consequences of replacing the existing European and ISO standard by a new EN ISO standard before a decision is being taken on the way forward. Cooperation between CEN and ISO and parallel voting results in an EN ISO standard with identical Standard number. Before launching the NWIP, the availability of identical numbers in the CEN and ISO databases needs to be checked. Preferably, the EN number should be taken in case of CEN lead. If it is not possible to adopt either the existing EN or the existing ISO number, a new number needs to be found and assigned. In case of the merger/revision of more than two standards, a new number is always assigned.
In case the ISO number is used for the EN ISO standard, a European foreword will state the withdrawal/replacement of the old EN standard.

Situation 5

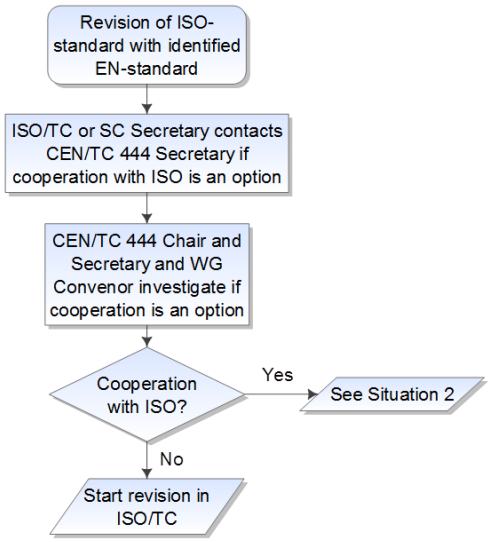


Situation 6: Revision of an ISO Standard in case there is also a comparable European Standard

An associated ISO/TC takes the initiative to revise an existing ISO Standard for which there is a comparable EN Standard in the work program of CEN/TC 444. The ISO/TC Secretary contacts the CEN/TC 444 Secretary to check if cooperation is an option. CEN/TC 444 Chair and Secretary contact the CEN/TC 444 WG Convenor to discuss if cooperation could be an option. The consequences for cooperation with ISO for the existing European and ISO Standard should be investigated since cooperation will lead to an EN ISO standard that supersedes the existing European Standard. If cooperation is decided on, Situation 2 applies.
If cooperation is not supported by CEN/TC 444, the ISO/TC starts with the revision of the ISO Standard without CEN involvement (resulting in an ISO standard).

Cooperation between CEN and ISO and parallel voting results in an EN ISO standard with identical Standard number. Before launching the NWIP, the availability of identical numbers in the CEN and ISO databases needs to be checked. Preferably, the ISO number should be taken in case of ISO lead. If this is not possible and also the CEN number is not feasible for ISO, a new number needs to be found and assigned. In case that more than two standards are merged/revised, a new number is assigned in any case.
In case the EN number is used for the EN ISO standard, the ISO foreword will state the withdrawal/replacement of the old ISO standard.

Situation 6



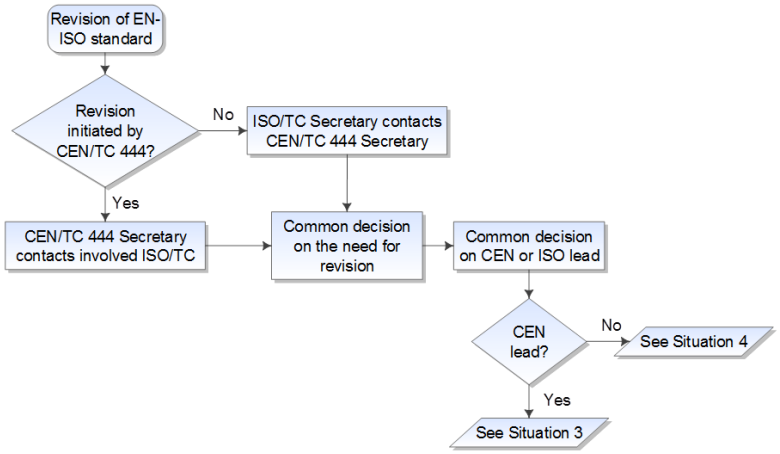
Situation 7: Revision of an EN ISO standard

If CEN/TC 444 wishes to revise an EN ISO standard, the CEN/TC 444 Secretary contacts the ISO/TC. If the need to revise an EN ISO standard is initiated in the ISO/TC, the CEN/TC 444 Secretary would like to be informed by the ISO Secretary. The ISO/TC and CEN/TC decide on their need for a revision. Based on the need, matrices and available experts a decision on CEN or ISO lead for the revision of this Standard is agreed between CEN/TC 444 and the ISO/TC. Depending on the lead, situation 3 (CEN/TC 444 lead) or situation 4 (ISO lead) applies.

Points of attention:

- For EN ISO Standards, CEN does not carry out systematic reviews. ISO carries out the systematic reviews on the corresponding – identical – ISO standards and decides on their future. The EN ISO Standards under systematic review will be made available in CEN/TC 444 by the Secretary in order to inform the members of CEN/TC 444 and obtain feedback on the future of these Standards.

Situation 7



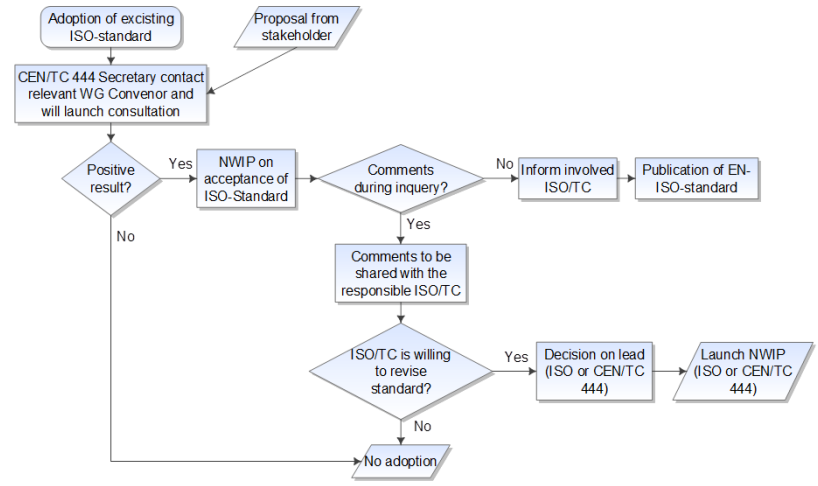
Situation 8: Existing ISO Standard to be adopted by CEN/TC 444

All stakeholders can submit a proposal to the CEN/TC 444 Secretary for European acceptance of an existing ISO Standard. The CEN/TC 444 Chair and Secretary will contact the respective CEN/TC 444/WG Convenor to advise whether existing EN Standards are of concern.
After positive consultation in CEN/TC 444 (Decision by Correspondence with two months consultation), CEN/TC 444 Secretary will inform both the ISO/TC Secretary and CCMC and a NWIP on the European acceptance of the ISO Standard is started in CEN/TC 444.
In case no comments are received on the NWIP and subsequent Enquiry; publication of the EN ISO Standard follows. Eventual existing EN Standards of concern are superseded.

In case comments are raised by the CEN members these shall be communicated with the respective ISO committee in charge of this publication, to see whether a revision of this ISO method is in place.

- If agreed to revise, the CEN/ISO members will accept parallel development and work together on an EN ISO Standard (see situation 1).
- If not, CEN/TC 444 can either:
  a. decide to disregard the comments and continue to publish as EN ISO;
  b. accept the ISO document with modifications as an EN Standard.

Situation 8

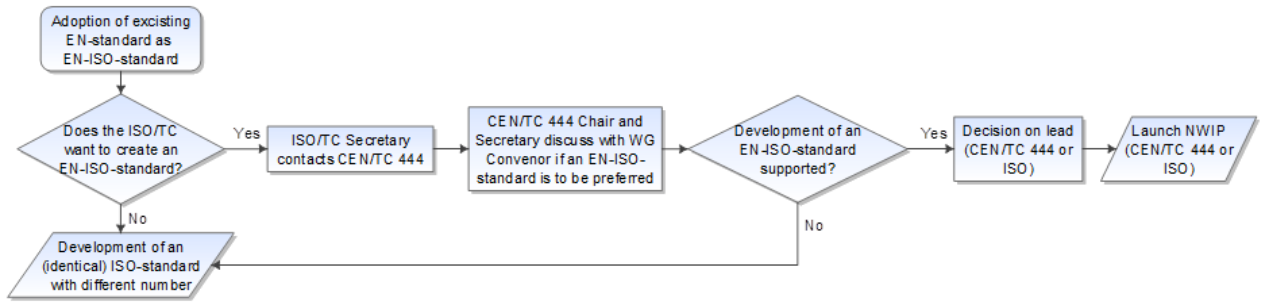


Situation 9: Existing EN Standard to be adopted by ISO/TC(s)
When an ISO/TC decides to adopt a European Standard the Standard will be published as an ISO Standard (which could be technically identical to the EN Standard or contain minor changes). CEN/TC 444 could decide to adopt this ISO Standard as an EN ISO Standard if this is favored. Another and preferred option to publish EN ISO Standards is that the ISO Secretary could contact the CEN/TC 444 Secretary on this planned action. Subsequently, the CEN/TC 444 Chair and Secretary discuss with the CEN/TC 444/WG Convenor (convenor may decide to consult WG members) if the development of a common EN ISO Standard is preferred over an identical, but standalone ISO standard and what will be the consequences of revising the EN standard to become an EN ISO standard. After this consultation the ISO/TC is informed on the CEN/TC 444 position. In case it is agreed to cooperate on the revision of the EN Standard resulting in the development of a new EN ISO standard, then situation 1 or 2 applies. Otherwise the ISO/TC will proceed to adopt the EN Standard as a stand-alone ISO standard (probably with a non-identical ISO number). In case a multi-matrix EN Standard is concerned the ISO/TCs involved need to decide on the lead position for adoption as the EN standard can only be adopted in ISO once.

Points of attention:

- In case a multi-matrix European Standard is involved, CEN/TC 444 will strive to have this Standard adopted as a whole by only one ISO/TC (as an identical multi-matrix Standard). In case more than one ISO/TC is involved, CEN/TC 444 will strive for good communication between all involved TCs.
- It is up to the ISO/TCs to decide on the adoption procedure at ISO level.

Situation 9



ANNEX C: INFORMATION ON THE VALIDATION OF EUROPEAN STANDARDS

C.1 General

This Annex provides further information on the validation of European standards as developed by CEN/TC 444. The backbone for the validation policy of CEN/TC 444 is defined by:

- CEN Guide 13 – Validation of environmental test methods of 29 October 2008
- CEN/TS 16800 'Guideline for the validation of physic-chemical analytical methods'
- The outcome of the Workshop 'Validation' that has been organized during the ISO/TC 190 'Soil quality' meeting in Berlin on 20 October 2014.
- The summary of the CEN/TC 444 'Workshop on Validation' on 22 September 2022 (Doc. N459) and the subsequent decisions of CEN/TC 444 on its validation policy (Decisions 281 – 287).

This annex only provides the main issues with respect to validation; a more comprehensive overview, including previous decisions of CEN/TC 444 with respect to validation, can be found in the discussion document which was prepared for the workshop of 22 September 2022 (Doc. N439) and the summary of the workshop itself (Doc. N459).

C.2 Defining validation

Based on the principles on validation as laid down in CEN Guide 13, which principles were accepted by the Environmental CEN/TCs in 2008, a test method can only be published as a full standard if validated. However, as already identified in CEN Guide 13, not all standards are test methods. Therefore this general principle needs further detailing:

- Even within a single solid matrix, there can often be a wide variety of 'materials' (e.g. soil: peat, clay, sand, etc.) which might have a significant effect on for example the extraction performance. Therefore a conscious decision is necessary when selecting the material used in the validation trial. Nevertheless, the costs of the validation will limit the number of materials that can be tested and therefore the method could already be considered to be validated for e.g. soil when one soil sample was included in the validation trial.
- When the standard covers more than one matrix, each matrix should be included in the validation trial.
- When the standard covers more than one component, the results of the validation might proof to be insufficient for part of those components. Still, the standard as such is considered to be validated and will be published as a full standard for the components that met the validation criterium.

C.3 Validation plan

If the development of a full standard is foreseen, the proposer of a new work item shall present a 'validation plan' which describes the validation process in sufficient detail to allow the involved WG to decide if this will indeed be adequate enough to validate the (draft) standard.
As a new work item first needs to be accepted and the standard is developed in a stepwise process, it is envisaged that the validation plan is developed stepwise:

- at the NWIP stage the validation plan can be limited to its main aspects
- before the intra-laboratory trial the validation plan will focus on the intra-laboratory trial
- before the inter-laboratory trial the validation plan will focus on the inter-laboratory trial.

Prior to these steps the involved WG will discuss and accept the validation plan.

The proposer of a new work item is responsible for the execution of the validation.
If the deliverable is a full standard, based on the validation plan the WG shall recommend and CEN/TC 444 shall decide on the necessity and degree of validation:

- No validation required (reasons shall be given for this decision);

- Adoption of existing validation data from equivalent standards;
- Limited validation (e. g. limited set of samples, matrices, compounds, number of laboratories) required;
- Full validation required.

The validation of a standard will be done in accordance with CEN/TS 16800 – 'Guideline for the validation of physico-chemical analytical methods' and the statistical analysis of the validation results will be done in accordance to ISO 5725-2 – 'Accuracy (trueness and precision) of measurement methods and results - Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method'.

All procedural steps in the standard (can) add to the variability of the results. It is therefore essential that during the inter-laboratory trial:

- it is ensured that the participating laboratories follow the draft standard precisely
- metadata is gathered in order to ensure that potential differences in results can be explained.

If data from accredited laboratories using an already published Technical Specification are available, the WG may recommend and CEN/TC 444 may decide that these data can be used for the validation of the Technical Specification in which way the CEN/TS can be upgraded to a full standard.

C.4 Selection of matrices and materials

All matrices for which the standard is developed are to be included in the validation. When during the validation process the standard appears not to be valid for one or more of these matrices, these matrices will be deleted from the scope prior to publication of the final standard.

For the selection of a material (e.g. peat, clay, sand) that represents a matrix (e.g. soil), the selection criterium is based on trying the standard for the 'most difficult' material. Thus for the determination of e.g. organic components in soil, a soil rich in organic matter (> 10%) should be selected.
It is important to select materials in which the components of interest will be present at a relevant concentration level; see also section C.10.
The organizer of the validation trial has to be specific on the materials used in the validation plan (e.g. characteristics of the soil type or waste code).

C.5 Selection of the components

For the selection of the components that are to be included in the validation trial a differentiated approach might be necessary depending on the nature of the components of interest.
For elements, each individual element needs to be part of the validation trial. If an element is not included in the validation trial, it is not mentioned in the scope of the standard.
When the standard describes the analysis of one or more specific organic components and / or sum-parameters (e.g. sum-PAH) for which the individual components are defined, all these individual components need to be included in the validation trial. The approach is therefor similar to the approach for elements.
When the standard describes the analysis for a group of components that is (very) large (e.g. PFAS, pesticides), the selection of components to be validated should be based on the components mentioned in legislation(s). In addition, emphasis should be given to potential subtypes (e.g. based on mobility) in order to cover all relevant subtypes for that group of components.

C.6 Setting a criterium for the inter-laboratory validation trial

Prior to the inter-laboratory trial, the involved WG will set a limit to the relative standard deviation of the inter-laboratory trial (RSD_R). When deciding on the limit value for the RSD_R, the involved WG will take account of at least the following aspects and the relative weight of these aspects:

- the component(s) to be analyzed (the RSD_R for organic compounds is usually higher than for inorganic compounds and physico-chemical characteristics)
- the (type of) matrix and its complexity for the analysis
- the results of the intra-laboratory trial
- the concentration range in the materials for the inter-laboratory trial
- the level on which the component is to be determined (e.g. related to the legislative value)
- the LOD and LOQ for the component
- the variability between the samples for the inter-laboratory trial as determined by one laboratory

Taking these points into account, it is preferable to set the limit value for the RSD_R below 50%, but this is not be a mandatory limit.

Independent of the set limit value for the RSD_R and whether that criterium will be met in the inter-laboratory trial, the proposal shall be treated as a full standard (i.e. all stages: WD, prEN), but shall be changed to a CEN Technical Specification after prEN voting if the criterium is not met.

C.7 Definition of the samples for the inter-laboratory trial

Depending on the standard, there are two options for the samples that will be sent to the participating laboratories:

- When the standard describes only the analysis, the analytical sample (the test portion) is sent to the laboratories.
- When the standard in addition to the analysis also describes other steps (e.g. sample pretreatment or taking of the analytical sample), the laboratory sample is sent to the laboratories.

When the analytical sample is sent to the laboratories, it should be ensured that indeed the full analytical sample is used for the analysis; subsampling is not allowed in this situation. To ensure that the quantity delivered at the laboratory is indeed the full amount that is used in the inter-laboratory trial, information on the size of the analytical sample is to be obtained from the participating laboratories prior to the preparation of the analytical samples.

Independent of the type of samples used (analytical sample or laboratory sample), the heterogeneity of the samples should be as small as possible. For the samples two criteria are set:

- The homogeneity test for the samples as set in ISO 5725-2 shall be met.
- In addition to that, the variability between the samples should not exceed 10 to 15%.

The first criterium is hard, but not very critical. The second criterium is a guideline and is based on the observation that with a larger variability between the samples, it will not be possible to reach an acceptably low degree of variability in the inter-laboratory trial; the limit to the RSD_R will then probably not be met.

C.8 Different methods

It might be that for the determination of a component different methods can be used. There is a distinction between two situations:

Situation 1: A standard might allow the inclusion of different options for part of the procedure, for as far as these options will not influence the (variability of the) result of the standard.

Situation 2: It is possible to develop separate standards for the determination of a component, for as far as there is a need to allow different determination techniques.

For situation 1 it is mandatory that:
- the different options in the standard are all be tested and compared in the intra-laboratory trial in order to ensure that these options will not result in additional variability and/or bias in the method
- in the inter-laboratory trial the participating laboratories report on the options they have used

For situation 2 it is mandatory that:
- the title and scope of the standard have a clear and specific description
- the purpose of the standard is clearly described

C.9 Participation to the inter-laboratory trial

In order to ensure that the inter-laboratory validation will provide usable results, it is essential that the participating laboratories are experienced in the field wherein the inter-laboratory trial is performed. Accreditation of the laboratory for this type of analysis is preferred and the necessary equipment should be available. Nevertheless, detailed instructions to the laboratories are necessary to guide them in the inter-laboratory validation.
At least 8 laboratories should participate in the inter-laboratory trial, but preferably there will be (a minimum of) 12 participating laboratories.
It is noted that due to the voluntary participation of the laboratories, there often are no ‘hard’ guarantees that indeed the standardized method is followed in detail. The gathered metadata should provide information at this level.

C.10 Blending and spiking

Spiking should be avoided as this will not give a representative result for the analytical test compared to real samples. When real sample material is available, but not all components are present, blending of two materials can be considered. Those two materials will need to have comparable characteristics (e.g. particle size distribution). Spiking is only a last resort.

C.11 Statistical analysis of the inter-laboratory trial

Statistical analysis of the validation results can be done with Excel, but there is also more sophisticated software available. To ensure the quality of the statistical analysis, it is encouraged to use specific software and to let the statistical analysis be performed by an experienced data analyst.

C.12 Judging the results of the inter-laboratory trial

Based on the statistical analysis of the inter-laboratory trial and the limit value set to the RSD_R, the experts in the involved WG will judge the results of the inter-laboratory trial.
If for a component the validation criterium is not met (RSD_R is too large), the component will not be mentioned in the scope, but the results of the inter-laboratory validation for that component will be included in the annex of the standard.

C.13 Providing the results of the inter-laboratory trial

The summarized results of the inter-laboratory trial will be incorporated in an annex to the standard. This will be done for all components that were measured during the inter-laboratory trial, independent if the criterium for the RSD_R for that component has been met.

Full results of the validation trial will not be included in the standard, but will preferably available in an open source document.

Where appropriate, a statement can be included in the scope that other components can also be analyzed with the standard, under the provision that suitability has been proven by the laboratory.

ANNEX D: HISTORY TO THE ESTABLISHMENT OF CEN/TC 444

CEN/TC 444 was established in 2015. The initiative for this CEN/TC 444 came from CEN/TC 292 (Characterization of waste), CEN/TC 345 (Characterization of soils) and CEN/TC 400 PC (Horizontal standards in the field of sludge, biowaste and soil) after discussing their status and future perspectives. These TCs encountered similar issues in terms of reduction of the number of experts available to develop standards, reduced interest from stakeholders in general, as well as reduced financial means to support the secretariat, perform validation studies, and allow people to travel to meetings. All are needed to ensure maintenance of standards that have been developed by these TCs in the past as well as to ensure the development of new standards to cover future needs.

It was observed that a number of TCs in the environmental field are moving from a stage of standards development towards predominantly standards maintenance (reviewing, adaptation, renewing) and transposition of ISO standards into EN ISO standards. At the same time, the future challenges in the environmental sector were no longer matrix oriented, but integrated (e.g. climate change, circular economy). Both underlined the need to discuss whether the current (predominantly singe matrix) organization of environmental standardization in CEN will remain fit-for-purpose in the future.

TCs in the environmental field use similar ways of characterizing their matrix and face similar future needs for standardization. It was also recognized that a new organization could also be relevant to a number of other TCs currently active in the environmental field.

On 5 June 2014, SABE organized a workshop to discuss the ideas raised by CEN/TC 292, CEN/TC 345 and CEN/TC 400 PC with a larger group of TCs and their stakeholders (European Commission, national authorities, EU industries, laboratories, NGOs and regulatory bodies).

Based on the outcome of the SABE workshop, responses of mirror committees and the decisions taken in the plenary meetings of CEN/TC 292, CEN/TC 345 and CEN/TC 400 PC in October 2014, the new structure was proposed to CEN/BT in May 2015. In August 2015 the creation of CEN/TC 444 was approved by the NSBs (Decision BT C59/2015).

CEN/TC 292 and CEN/TC 345 adjusted their scopes with the establishment of CEN/TC 444. CEN/TC 400 PC has been disbanded in 2016 after transferring all of its standards to CEN/TC 444.

In 2020 CEN/TC 292 and CEN/TC 345 have also been disbanded. The remaining work items have been transferred to CEN/TC 444, and the title and scope of CEN/TC 444 was adapted accordingly. Two additional WGs (WG 7 ‘ Sampling’ and WG 8 ‘Assessment’) are installed to account for the placement of those remaining work items.

In 2022 it was decided to start standard development for the sampling, sampling pretreatment and determination of microplastics in solid matrices. For this purpose a Task Group on Microplastics has been established under CEN/TC 444/WG 6.

ANNEX E: OVERVIEW OF EC MANDATES ISSUED TO CEN IN RELATION TO CEN/TC 444

CEN/TC 444 partly developed and maintains standards that have been requested by the EC through a financed mandate. The EC mandates listed have been published by the former CEN/TCs that transferred their standards to this CEN/TC 444.

These EC mandates are:

- M/326, Standardization mandate to CEN for the development of standardized methods for the characterization of waste (originally CEN/TC 292)
- M/330, Mandate given to CEN for the development of horizontal standards in the fields of sludge, biowaste and soil (originally CEN/TC 400 PC)
- M/395, Mandate to CEN for the development of standardized methods relating to the characterization of wastes from the extractive industries (originally CEN/TC 292)

ANNEX F: PROCEDURE FOR MUTUAL CONSULTATION BETWEEN CEN/TC 351 AND CEN/TC 444

This procedure for mutual consultation between CEN/TC 351 and CEN/TC 444 was accepted by Decision 54 (02/2017).

The draft multi-matrix (horizontal) methods on leaching and analysis of CEN/TC 351 '*Construction products: assessment of release of dangerous substances'* are circulated for comments in CEN/TC 444 (through the CEN/TC 444 secretary).

- For CEN/TSs, this is in parallel with the regular consultation of construction product TCs.
- For ENs, this will be in parallel with the CEN enquiry procedure. Comments sent by CEN/TC 444 will be considered in the relevant CEN/TC 351/WG; voting is for CEN members only.
- For new test methods/NWIs by either TC, collaboration will be sought. This could result in experts joining the appropriate WGs or even in a joint WG.

CEN/TC 444 will take relevant standards from CEN/TC 351 (and vice versa) into consideration when updating its existing standards.