CEN GUIDE 13

Validation of environmental test methods

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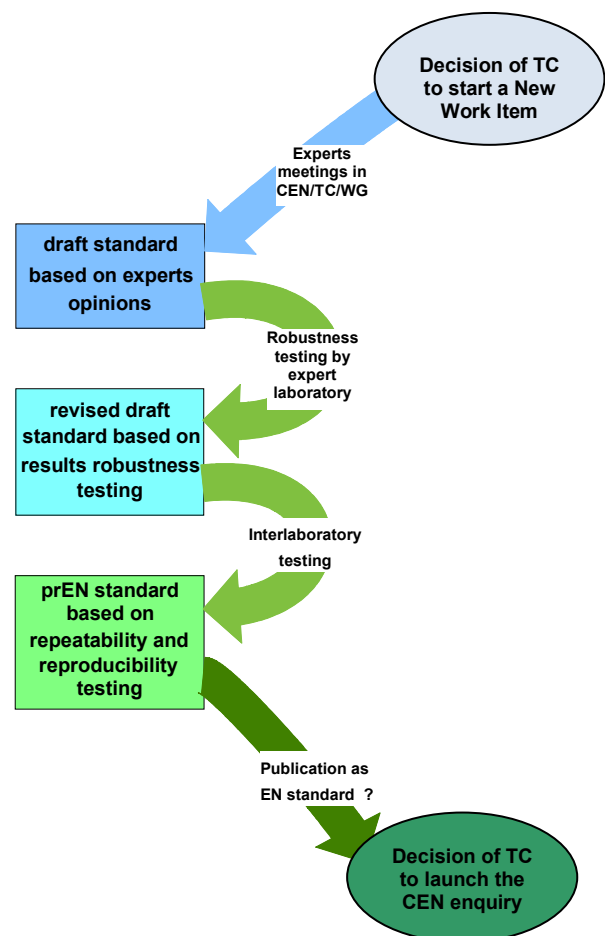# <u>Contents</u>

Foreword

This document has been produced by the CEN-SABE Environmental TCs Cooperation Team (ENV TCs) as a **policy document on validation tasks in the standardisation process of environmental test methods**.

The environmental TCs recognise that these **validation tasks are complex.** They consist of two main steps, the robustness testing and the inter-laboratory testing (determining repeatability and reproducibility), both interacting with the elaboration of the draft standards as shown in the flow chart. Furthermore, they apply to the different inter-related phases of encountered in environmental testing, typically sampling and production of laboratory sample, storage and transportation, extraction, analysis and reporting. Consequently, this document focuses on the 'why' and 'what' of validation tasks in direct relation to the different steps of the standardi-sation process. Given the policy aim of this document, it does not contain detailed procedures for performing the validation (such as number of laboratories, number of samples, etc.).

The environmental TCs recognise that the environmental test methods published as standards are very often used as reference methods in regulations and/or in contracts between several parties. Therefore, a **known quality** is considered as **vital prior to publishing** an environmental test method as a standard. Hence a general need for

validation tasks interacts with the elaboration of the draft standards, and so there is also a general need to document the performed validation tasks and their results in the standard.

This document focuses on the validation tasks in the standardisation process of reference methods, being either the whole measurement process or one of its constituent parts.

Flow chart of the validation tasks in the standardisation process

Introduction

View of the Environmental TCs on validation

This paper is intended by the CEN-SABE Environmental TCs Cooperation Team to be a **policy document on validation**. It defines the view of the Environmental TCs on the role of validation in the process of the standardisation of environmental test methods.

Consequently, this document focuses on the 'why' and 'what' of validation in direct relation to the different steps of the standardisation process. Given the **policy aim** of the document, this document does not contain detailed procedures for performing the validation (such as number of laboratories, number of samples, etc.).

Uncertainty

The tests results in the environmental fields are often applied for the enforcement of regulation or for contract execution. In such legal situations it is vital that the associated uncertainties[1] in the tests' results are known.

The relation between the test result (TR) and the uncertainty (U) is generally presented as TR ± U. When the regulatory or contractual limit value is above TR + U or below TR – U, the conclusion is clear, respectively fulfilling or exceeding the limit value. If the limit value lies between these two boundaries, it is not possible to come to a clear conclusion.

This is an even bigger problem when the associated uncertainty is unknown, as, despite the test result itself, it is impossible to ascertain that the test result is really above or below the limit value.

Validation of an environmental test method is aimed at providing sound information on the uncertainty of the tests' results, and by that means, providing the possibility to come to sound conclusions based on the standardised measurements (see in bibliography the IPPC-REF document on monitoring).

Request from CEN/SABE

Resolution 26/2004 of SABE taken on 19 October 2004 invites all environmental TCs to establish their own policy regarding the publication of validated or non-validated standards. The environmental TCs agreed that a commonly developed policy on validation would be preferable, therefore giving the lead for the development of this policy statement to the Environmental TC Cooperation Team.

In relation to its request, SABE wished to highlight two issues:

- there may be a financial liability if action is taken on the basis of a CEN document, and as such the uncertainty of the test result should be known;

- the subject of uncertainty influences the credibility of CEN.

Indeed, these two points are fully recognised by the environmental TCs.

Views within CEN

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[1]   Uncertainty: 'A parameter, associated with the result of a measurement that characterises the dispersion of the values that could reasonably be attributed to the measurand' (VIM and GUM).

When developing a policy view on validation, benefit should be taken of already established policies on validation within other CEN-sectors.

In general, the common view is that a test method can only be published as an EN when fully validated (first and second validation steps have been performed). It may happen that the results are considered by the WG expert as very poor and that they recommend to the TC to publish a TS instead. When no or only partial (e.g. first step) validation results are available at the time of completion of the CEN enquiry, the test method is to be published as a Technical Specification (TS).

When (partial) validation has been performed, the resulting performance characteristics are to be included in a separate section of the test method (specific clause or annex performance characteristics).

Consideration should be given to ENV 13005 Guide on Uncertainty in Measurement (GUM). It is to be noted in EN-ISO 17025 that 'General requirements for the competence of testing and calibration laboratories' requires that laboratories provide results with the associated uncertainties.

Major impact

There are different interpretations of the term 'validation', even within the environmental fields. However, there is a consensus that 'validation' is a key step in the standardisation process of environmental tests' methods.

Consequently, the definition of the term 'validation' has a major impact on the quality of the standards that describe a test method.

Defining a common policy on validation within the environmental sector of CEN also has, in turn, an impact on the work of the environmental TCs.

General principle within the environmental sector

The previously mentioned common view within CEN is embraced by the environmental TCs. This implies that only validated test methods can be published as EN standards. Test methods that are not or only partly validated are to be published as TSs. At the same time, the environmental TCs recognise the fact that not all standards are indeed test methods and, therefore, there might be a necessity to differentiate this general principle to some extent.

This policy document aims to clarify in which situations validation is to be considered as essential, and in which cases it is of less or of no importance. In addition, the validation activities during the different steps of the standardisation process are clarified.

Whenever there is a deviation from the general principle to publish validated standards, this should be a conscious decision of the involved TC.

Validation of the whole measurement[2] process

For the user / the customer of a standard or a series of standards, the reliability of the final overall result of a test is of major importance. That is the reliability that is obtained through all steps of the measurement process. Consequently, validation should not be just aimed at a single step of that procedure (like the analysis), but indeed should be aimed at quantifying the uncertainty that is associated with the full test procedure.

Depending on the matrix and the components that are to be assessed, this whole measurement process can be relatively simple or very complex. At least for part of the measurements in the environmental field, the whole

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[2]   i.e. sampling plan, taking of sample, sample pre-treatment in the field, packaging, storage and transportation, storage and conservation, sample pre-treatment, extraction, destruction, leaching, clean-up, analysis / quantification, data management, report

measurement process involving the appliance of a series of standards and full validation of the whole measurement process is not that simple. Therefore, this document starts with the validation of the individual steps of the whole measurement process, like the analytical determination of the content, and only after that will look at the validation of the whole measurement process.

1 <u>Scope</u>

This document provides guidance **on the validation tasks in the standardisation process of environmental test methods**.

It deals with the two main steps of such validation tasks, the robustness testing and the interlaboratory testing (determining the repeatability and reproducibility), both interacting with the elaboration of the draft standards as shown in the flow chart given in clause 2.1. It applies to the different inter-related phases of the environmental test methods, typically sampling and the production of a laboratory sample, storage and transportation of the laboratory sample, extraction, analysis or quantification of a test portion and finally reporting. Consequently, this document focuses on the 'why' and 'what' of validation tasks in direct relation to the different steps of the standardisation process. This document is focussed on the validation tasks in the standardisation process of reference methods either for the whole measurement process or for one of its constituent parts.

Given the guidance aim of this document, it does not contain detailed procedures for performing the validation tasks (such as number of laboratories, number of samples, etc.).

2 Validation of reference methods

2.1 General

In this document reference methods are test methods that have been validated and of which the quality of the test method is, given a specific field of application, accepted by experts and users. It might be the experts that state that the method is a reference method, but in general, the claim that it is a reference method is not made within the standardisation process. In order to have knowledge on the quality of the method and accepting that, information on the quality is essential in order to be defined as a reference method. Validation is therefore an essential step in the standardisation process from which this method originates.

Reference methods can be used as a legal reference in legislation/regulation and/or in contracts between two or more parties. They need, therefore, to be self supportive. Reference methods are not necessarily of the highest metrological quality, however, experts define a reference method as 'reliable' and a good basis for decisions. In general, reference methods are 'fit for purpose'.

Standardised reference methods are developed for 'common and repeated use'. They are not of the same nature as the utmost metrological quality that is required for Certified Reference Material developed in National Reference Laboratories (BAM, LNE, NPL….etc).

Validation of standardised reference methods is generally performed in two steps including performance characteristics relevant for the considered method:

* robustness testing;
* interlaboratory testing (repeatability and reproducibility)

As the first step is based on a first draft of the standard and each of the validation steps will result in a revised draft standard, the implementation of validation in the standardisation process normally relates to three different draft standards, the last one of which will be published as an EN-standard. These steps are depicted in Figure 1.

It is to be noted that the actual state of the art may not be sufficient for the efficient further development of the envisaged standard. In such a case, a so-called pre-normative research may be needed prior to any standardisation with validation.
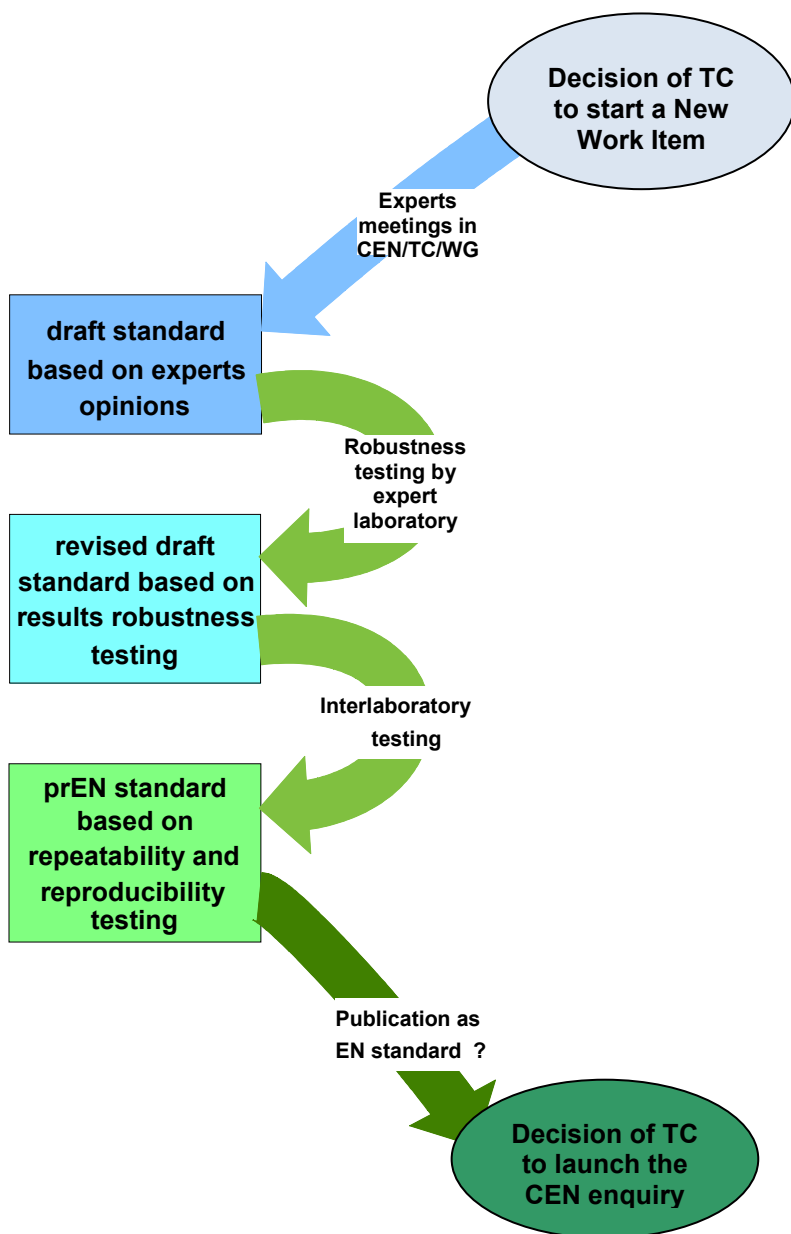
Figure 1: Flow chart of the validation tasks in the standardisation process

The robustness testing is generally performed in one highly competent laboratory which ideally already has experience with the new test method. The repeatability and reproducibility are determined through inter-laboratory experiments. Both steps are needed and contribute to the evaluation of the uncertainty of the test results.

In order to secure comparable data, the associated uncertainty of the test methods will often be based on traceability to SI units[3]. However, this is not, per definition, possible in all cases. Alternatively, the quantification of the uncertainty can also be based on the analysis of certified reference materials. Indeed, in the environmental

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[3]   e.g. weighing traceable to kg SI unit

field certified reference materials are, in most cases, more logical (and applicable) than SI units. Unfortunately, there is also a clear disadvantage with certified reference materials as these are only available for a limited number of components and matrices and are, in general, so expensive that it is not financially possible to use certified reference materials for validation or routine checks to determine if the analyses are still within the predefined bandwidth. A third option, therefore, is also important in the environmental field using (informal) reference materials that are not certified.

Certainly in the environmental field, more often the uncertainty is to be quantified by means of a relative comparison to (informal) reference materials. Therefore, the standardised method shall specify the minimum requirements to be fulfilled in the analysis by:

- a quantification using a set of measurement traceable to SI units; or

- a quantification using certified reference materials; or

- a quantification using reference material specified in the standard

In specific cases the introduction of a new reference method will result in the withdrawal of a previous reference method. For example, due to the general application of new analytical instruments, as a consequence of which the old reference method is in practice no longer applicable. Validation of the new reference method and cross comparison of the results of both the old and the new reference methods allows the continuous use of data collected in the past (the 'historical' data).

When a CEN TC starts a work item, this is generally given to a dedicated WG. The aim of the work is to harmonise as far as possible the European practices on a specific topic. Through a series of steps, consensus among the experts is achieved resulting in a first draft standard that, to the opinion of the experts, reflects the state of the art (in terms of standardisation) and is assumed to be fit for purpose.

This first draft standard will be used as a starting point for the validation work, or, if funds or means for validation are not sufficiently available, may be adopted by the CEN-members and published as a TS. When published as a TS, the document should state that it has not been validated.

2.2 Validation of the whole measurement[4] process

The following clauses deal with the validation of the whole measurement process or of individual steps of the whole measurement process. The standardisation work should ultimately apply to the whole measurement process that consists of different steps and might be described as:

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[4]   The whole measurement process includes not only the quantification / analysis step but also all the other steps needed to obtain a measurement result

Definition of sampling plan → taking of sample → sample pre-treatment in the field → packaging, storage and transportation → storage and conservation → sample pre-treatment → extraction, destruction, leaching → clean-up → analysis → data management → report[5]

One standard or a coherent set of standards might comprise all steps of the measurement process and, consequently, validation of that standard or of that coherent set of standards would imply the validation of all activities that are part of that measurement process.

Technical characteristics of the measurement process may impose such validation cover in the same experiment most of the measurement steps e.g. measurement at stack, physical properties of sludge, etc.

As mentioned in relation to the validation of sampling steps in clause 2.3, it is questionable if full validation of a measurement process is possible. This will, of course, depend on the number of steps in the measurement process, the complexity of these steps and the variety of situations in which the method can be applied. But this will mainly depend on the extent to which it is possible to validate the sampling steps as discussed in clause 2.3.

Consequently, the publication of a method describing the whole measurement process as a standard might be discussed, specifically if no or only partial validation is achievable. At the same time, it might be desirable to publish such a method as a standard, despite the lack of validation results.

The TC concerned should make a conscious decision on the publication of such a method as a standard.

It should be noted that in the application of a coherent set of steps, all such steps of a measurement process have a part in the overall uncertainty of the measurand. Therefore, validation of only part of the whole measurement process is likely to be found insufficient later on when applying the whole measurement process.

It might be noted that validation might be possible when a method is applied for a certain period, and the results are fit for validation as well as for the assessment for which the results were produced originally. In order to be applicable for validation purposes, it is essential that the test method provides duplicate results.

2.3   <u>Validation of the sampling steps</u>

However, relevant for the full measurement process (see also clause 2.2), sampling standards describe only a portion of the full measurement process and they do not deliver a result on their own. Validation of the sampling standard is, therefore, impossible without mutual validation of the test methods (or the application of already validated test methods). Such overall testing is per definition expensive due to the overall testing and the necessity of assessing the variability of the materials to be sampled. Even partial validation, applying a specific sampling protocol on a specific material under predefined conditions, might still ask for major resources or might result in such a limited 'degree of validation' that this cannot be seen as a full validation.

Consequently, it might be argued that due to a lack of validation results the sampling method cannot be published as a standard. However, this might result in a largely negative image of the whole measurement process and is, therefore, undesirable. So sampling methods too may, when there is agreement amongst experts, be published as standards. In this specific situation, the standard should contain a paragraph on validation, obviously in this case mentioning and motivating the achieved degree of validation. Depending on the

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[5]   Depending on the measurement process one should keep in mind that there might be differences in the mentioned steps. Steps might be combined in a standard or are irrelevant for a specific measurement process. However, in all situations the measurement process consists of different activities that are to be performed, indifferent of the question if these activities are incorporated into one standard, or that a series of standards needs to be applied.

characteristics of the sampling scenario being considered, including the properties of the material to be sampled, paired and repeated measurements by several laboratories may provide a significant degree of validation.

In addition, sampling might be carried out on the basis of a predefined procedure that was accepted by all parties involved, without the need for prior validation (acceptance might be based on the experts' opinion and might, for example, be formalised in a contract or in legislation). When the associated uncertainty is to be quantified, it will in such a situation be based on the variability between laboratory samples obtained with the same procedure from the same quantity of material. It should be kept in mind that the quantified uncertainty might originate both from the heterogeneity of the sampled material, the sampling activity itself and the subsequent analytical steps. When all these sources of variability are to be quantified, these different sources of variability are to be taken into account when designing the validation scheme.

2.4   <u>First step of validation (robustness testing)</u>

Robustness testing is performed by means of comparison tests. These tests are designed to assure that there is an appropriate control of the test method, in doing so, establishing the 'robustness' of the test method.

Depending on the test method that is assessed, the robustness testing might aim at an individual step within the test method, or aim at the totality of the test method (see clause 6 on the validation of the whole measurement process). Which approach is chosen will depend on the complexity of the test method.

When a standard incorporates different procedures, possibly as part of the whole measurement method, it is vital to establish that the different procedures produce comparable results. This is to be done at the latest during the robustness testing.

The robustness testing of a reference method requires tests with parallel measurements, measuring the same measurand in the same medium[6].

In addition, when relevant for the considered steps of the measurement process, the robustness testing in the first validation stage should also determine the correctness (based on reference materials applied in the analytical / quantification step itself as specified in the standard) of the test method, as well as the limitations of the test method (lowest and highest concentrations that can be measured, interferences, detection limit, etc.).

The results of those tests are taken on board in a second draft of the test method which is the basis for the second step of the validation. Again, when no further validation is performed, this second draft may be adopted and published as a TS. If so, the TS shall contain the results of the robustness testing.

Test methods may be defined for two or more specific matrices, while, in other situations, an overall definition of a matrix (like 'soil' or 'waste') might actually incorporate a large number of different 'sub'-matrices (for soil this

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[6]   An alternative route is to use Certified Reference Material (CRM). But one should keep in mind that in the environmental fields a CRM is seldom available. Furthermore, when available these CRM are expensive and not easily applicable for the whole measurement process or for a significant part of it.

might be sand, clay, peat, etc.). Prior to robustness testing, (and the subsequent second validation phase) it is essential to define for which ('sub'-)matrices the test method will be validated. Obviously, full validation of a method that incorporates a large variety of ('sub'-)matrices is practically impossible. However, it might well be unnecessary to perform such a wide validation when a limited number of ('sub'-)matrices can be, to the experts' opinion, representative for the whole field of application.

In choosing the matrices for the validation, there is no need to seek the limits of the method by choosing a matrix for which the applicability of the method is, before hand, questionable. Validation in general is aimed at 'proving that the method performs as it should', and not at 'proving that the method does not perform as it should'.

When the test method is assumed valid for a variety of different matrices, at least three matrices should be tested during the validation phase.

2.5 Second step of validation (interlaboratory testing – repeatability – reproducibility)

The second step of the validation process is performed on the revised draft standard that resulted from the first step of the validation. This second step of the validation is performed by means of tests designed to evaluate the intralaboratory and interlaboratory variability of the results obtained by applying the draft standard. This is done by parallel measurements[7], covering the full test method and measuring the same measurand in the same medium.

It is, in general, possible to obtain a 'field' sample out of which laboratory samples can be prepared and distributed to laboratories (two laboratory samples per laboratory). Such parallel measurements are repeated in order to allow for a statistical evaluation of the results.

In performing the interlaboratory testing, it is essential that all laboratories fulfil the minimum requirements of the standard. If not, the results of the interlaboratory trials will not show the repeatability and reproducibility of the test method. Although this seems obvious, providing detailed instructions prior to the actual work, as well as a detailed evaluation of the performed work, is essential in order to assess the results of the interlaboratory trial.

The second step of validation should result in:

- the quantification of the **repeatability** of the test method; i.e. the maximum difference to be expected with a 95% confidence between the results of one laboratory, measuring the same measurand in the same medium and using the same facilities while fulfilling all requirements of the test method (intralaboratory testing);
- the quantification of the **reproducibility** of the test method; i.e. the maximum difference to be expected with a 95% confidence between the results of different laboratories, measuring the same measurand in the same medium, each using their own facilities while fulfilling all requirements of the test method (interlaboratory testing);
- the variability resulting from the inherent differences between laboratory samples (on the basis of sufficient repetitions of the above parallel measurements)

Guidance on the actual performance of the second step of the validation might be obtained from ISO 5725-2 and –5. It is to be noted that repeatability and reproducibility may vary over time (e.g. short term, long term).

2.6 Final draft standard

The results of the second step of the validation are implemented in the third draft of the standard, thus adding detailed information on the validation results to the draft standard. In principle, when the results of the second validation phase are acceptable for the experts, the resulting third draft is in fact a draft prEN which, to the opinion of the experts, is ready for publication. Subject to the TC decision this prEN will be processed within the CEN-system for final publication as an EN-standard.

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[7]   An alternative route is to use Certified Reference Material (CRM). But one should keep in mind that in the environmental fields a CRM is seldom available. Furthermore, when available these CRM are expensive and not easily applicable for the whole measurement process or for a significant part of it.

However, if the results of the second validation phase are, to the opinion of the experts, not satisfactory, the test method can be published as a TS subject to the TC's decision. The results of the first and second validation phases are to be incorporated in the TS as it would if it was a standard, but the table of results should be accompanied with a discussion of the experts why these results are not of such a quality that the method can be published as a standard.

The results of both validation stages shall provide the information and experimental data needed to apply the GUM (=ENV 13005) for the determination of uncertainties. It is to be noted that EN-ISO 17025 calls for measurement reports to include uncertainties statements. It is also to be noted that EN ISO 20988 illustrates how the GUM can be applied in an environmental field such as 'Air Quality'.

The results of both validation stages are to be included in the prEN in the form of a summarising table, containing details on:

- Robustness;
- Correctness (based on reference materials applied in the analytical / quantification step itself as specified in the standard);
- Lowest and (when relevant) highest concentrations for which the method is valid
- Repeatability;
- Reproducibility

In addition to the results of the validation itself, the prEN should also contain a table of demands for the laboratory that applies the test method, and which has to prove that it fulfils the specifications of the standard. This implies that, based on the results of the validation, criteria ('performance characteristics') have to be set for:

- Recovery requirements;
- Detection limit;
- Correctness (based on reference materials applied in the analytical / quantification step itself as specified in the standard);
- Repeatability;
- Estimated reproducibility based on the repeatability results;
- Results from field blanks

3 Validation of alternative methods

In addition to the validation of reference methods as discussed in clause 2, the proposed test method might be a secondary, simplified or indirect method; in this document referred to as a 'alternative method'.[8]

An alternative method will differ from the reference method. Consequently, it might have an enlarged chance of finding biased results and/or results with a larger degree of variability. Thus the uncertainty of the method might be larger than that of the reference method. An alternative method may also be more focused on a narrower field of application than a reference method covering wider applications and, therefore, exhibiting a lower uncertainty.

For the validation of alternative methods, two approaches are available:

• Full validation as applies to reference methods;

• Relative validation in which a comparison is made to the reference method

As validation has to take place prior to the practical application of the method, the method of validation will determine if the alternative method can be used on a stand-alone basis (after full validation), or only in conjunction with the reference method (relative validation).

In the first situation there is, from the perspective of validation, no difference with the reference method. Therefore, this clause focuses on the concept of relative validation, also known as 'cross comparison testing'.

For the practical application of alternative methods, it will often prove necessary, in addition to relative validation, to do an in-situ calibration with the reference method. This means checking if the results of the alternative method are indeed representative in comparison with the reference method when applied to the same samples coming from a specific site. Cross comparison can be made on the resulting paired samples.

After a relative validation the application of an alternative method may normally be insufficient for legal purposes.

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[8]   Note that there are numerous definitions of the term 'alternative' method. The essential point in this document is that an alternative method generally has a narrower field of application and should be used in close connection with the reference method to which it relates. As a consequence of this definition, alternative methods are often used for field measurements or to make a pre-selection of samples to be analysed with the reference method. They may also be used in routine measurement in a narrow field of application for which they have been specifically developed.

4   <u>Validation of guidelines</u>

Methods defined within the standardisation process can also be (far) less prescriptive than test methods, but provide valuable guidance on specific aspects of the measurement process (see also clause 2.2).

Given the fact that there is an apparent lack of concrete instructions due to the nature of these guidance documents, validation is principally impossible.

It might be argued that this type of document cannot be published as a standard as validation results are not available. There is, however, a high degree of comparison with the standard on terminology as discussed in clause 5 as, in both cases, we are dealing with a fundamental reason why validation is not possible. At the same time, there may be obvious reasons why publication as a standard is to be preferred. For example, this may occur when a general guidance document is the basis of a series of standards that provide more detailed instructions (and can be potentially validated).

The TC concerned should make a conscious decision on the publication of such a guidance document as a standard.

5   <u>Validation of non-experimental methods</u>

In the previous clauses the main focus was on the validation of experimental methods. In addition to the standardisation of test methods, other types of standards are also possible. An apparent example is a standard on terminology.

Validation of a terminology standard is obviously impossible in the experimental way. However, the lack of validation for these types of standards cannot be an argument against publication as an EN standard. This implies that in line with the process as described in clause 2, the agreement of involved experts already results in a draft standard which, after normal consultation within the CEN-system, will be published as EN-standard.

The previously mentioned standards on terminology are an apparent example of 'non-experimental methods' that need a different approach in validation. It might well be that there are other topics for which the same argumentation might apply. The TC concerned should make a conscious decision on the publication of such a method as a standard.

Annex: Explanations of terms used in this document

Since this document is a policy document, the terms used are not sharply defined. At the same time, for the correct understanding of this document, clarity on the used terms is important. This annex intends to provide as clear as possible explanations of terms in order to avoid misunderstanding between the Environmental TCs. This annex is, therefore, helpful to obtain a harmonised approach on validation amongst the Environmental TCs.

The terms **test method, method and measurement method** are used to designate a procedure that is either standardised or under standardisation. This procedure is described mainly by normative minimum requirements and aims to produce quantitative results. Such a procedure generally consists of several **steps**, typically seven: definition of the sampling plan, taking of sample, storage and transport, extraction, preparation, quantification-analysis-enumeration and reporting. A standard addresses one, several or all steps, making vital the proper interfacing between them, especially for validation and accreditation. It shall be self supportive e.g. shall not require another method for calibration.

A method can be used as a **reference method** by the users either in regulations or in contracts. Such 'legal' reference shall have a quality fit for its purpose. Consequently, it does not necessarily comply to the utmost metrological performance. For specific or routine uses standardisation is done for **alternatives methods,** also called secondary, indirect or simplified methods. Validation of such methods requires making them traceable to the relevant reference method, i.e. to correlate them. In all cases, it is necessary to assess the **correctness** of the quantification-analysis-enumeration step. This can be done by traceability to SI units e.g. when weighing a quantity of material using scales traceable to the kg unit of mass. This can also be done by using reference materials. It is to be noted that in the environmental field it is almost impossible to have available and to use reference material for the whole measurement process.

Standardisation of a test method assumes that the basis of the test method is available either as a national standard or as the result of research activities. On the other hand, the validation as a key part of the standardisation process consists of two parts; the robustness validation; and the interlaboratory validation. A **full validation** includes both parts. A **partly validation** would include at least a robustness validation. A partly validation would provide some information for uncertainty calculations but the full validation providing information on repeatability and reproducibility. In this policy paper, the concept of **uncertainty**[9] is used since it is the more meaningful for the user being generally expressed as a range. It is to be noted that the more technical terms of **accuracy, trueness** (see also correctness above) are generally presented in terms of standard deviation (requiring, in practice, the determination of an extension factor) even if they can be presented as range i.e. **repeatability limits** and **reproducibility limits**.

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[9]   Uncertainty: 'A parameter, associated with the result of a measurement, that characterises the dispersion of the values that could reasonably be attributed to the measurand' (VIM and GUM).

It is, finally, to be noted that the validation of the procedure applied by a laboratory under accreditation **EN ISO 17025** is different. It is aiming at demonstrating that the laboratory procedure is in accordance with the normative requirements specified in the standard for which accreditation is claimed.

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- CEN TC 345 N179 – Minimum requirements for the validation of analytical methods for the characterisation of soils

- EN 12580 – Soil improvers and growing media – Determination of a quantity

- EN 15259 – Air quality — Measurement of stationary source emissions — Requirements for measurement sections and sites and for the measurement objective, plan and report

- EN ISO 17025 – General requirements for competence of testing and calibration laboratories

- CEN/TS15675 – Air Quality — Measurements of stationary source emissions — Application of EN ISO/IEC 17025:2005 to periodic measurements

- EN ISO 20988:2007 - Air quality - Guidelines for estimating measurement uncertainty (ISO 20988:2007)

- ENV 13005 – Guide on uncertainty in measurement GUM

- ISO 5725 – Accuracy (trueness and precision) of measurement methods and results – Part 1: General principle and definitions

- ISO 5725 – Accuracy (trueness and precision) of measurement methods and results – Part 5: Alternative methods for the determination of the precision of a standard measurement method

- CEN TF 151 N091 – Guidance document for developing CEN measurement standards prepared for several matrices within project horizontal

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