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# Water quality — ~~Guidance~~Requirements and ~~requirements for designing~~recommendations for designing an interlaboratory trial for validation of analytical methods

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## Foreword

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This document was prepared by Technical Committee ISO/TC 147, *Water quality*, Subcommittee SC 2, *Physical, chemical and biochemical methods*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

## Introduction

The final validation step during standardization of an analytical method is the evaluation of performance through an interlaboratory trial to demonstrate that a new method is fit for purpose.

This document is intended to assist ~~project leaders or organizers of~~ persons organizing interlaboratory trials ~~within ISO/TC 147/SC 2 in designing~~to design and ~~organizing~~organize international interlaboratory comparisons for the validation of ~~standard analytical~~new standardized physical, chemical and biochemical methods for water analysis.

# Water quality ~~— Guidance document on~~ — Requirements and recommendations for designing an interlaboratory trial for validation of analytical methods

## 1 Scope

This document specifies ~~some details~~requirements and recommendations for the ~~special case~~design and execution of ~~designing and performing~~ an interlaboratory comparison for validation of new standardized analytical methods in the field of water analysis, e.g. the number of participating laboratories~~,~~ and time schedules. ~~It~~This document is based on ISO 5725-1 and ISO 5725-2.

NOTE The scope of other standards in the field of interlaboratory comparison, such as ISO/IEC 17043[~~2~~3] and ISO 13528[1], is proficiency testing of analytical laboratories and not interlaboratory comparison for the validation of analytical methods.

## 2 Normative references



The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.



ISO 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

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*

~~ISO/TS 13530:2009, *Water quality — Guidance on analytical quality control for chemical and physicochemical water analysis*~~

## ~~4~~3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 5725-1 apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

## ~~5~~4 Principle

A representative number of laboratories analyse within the sample stability period the same sample material prepared and distributed by the organizer of the interlaboratory trial. The results are used to calculate the performance data of the standardized method (see ~~Annex~~ Clause A.3).

# ~~6~~5 Preconditions

## ~~6.1~~5.1 General

The prerequisite for the performance of the interlaboratory trial is that the method development and the validation of the individual steps of the whole measurement process according to ISO/TS 13530 have been completed. ~~Generally, this is the case when a DIS proposal has been developed based on an approved CD.~~

NOTE 1~~:~~ Validation of analytical methods is also described in References ~~[3~~ [4] and [~~4~~5].

As the aim of this kind of interlaboratory comparison is the evaluation of the performance data of an analytical method, no technical alterations of the given protocol of the ~~draft standard~~standardized analytical method are allowed to the participants of the interlaboratory trial.

NOTE 2 This is in contrast to proficiency testing interlaboratory comparisons, where the participating laboratories use different analytical methods for the determination of the same parameter.

All registered participants of an interlaboratory trial should get all samples. Only in exceptional cases they could be entitled to select samples in advance, because it is important to receive as many test results as possible. It is highly recommended that all samples are tested by the participants and results of all parameters be submitted to the organizer of the interlaboratory trial to ensure a maximum number of individual test results after outlier rejection within the evaluation.

If there are several options within the ~~draft standard, e.g.~~standardized analytical method, for example, for extraction or detection, separate performance data are evaluated for each option and for the undifferentiated data set. The decision to merge data sets is taken by experts of the ~~working group in charge of the development of the standard~~interlaboratory trial after examination of the influence of the chosen option on the final measurement result. It is the result of the evaluation of the fitness for purpose of the tested standard.



## ~~6.2~~5.2 Special preconditions for validation of non-crucial method ~~modifications~~options in analytical methods for organic analytes

This subclause is not applicable to operationally defined analytical methods.

Non-crucial method ~~modifications~~options mean, only ~~modifications~~alternatives or variants of single analytical steps, as extraction options or the change to direct injection using a highly developed apparatus instead of a specified enrichment technique are considered non-crucial. But, changing the analytical principle like switching from GC-MS to LC-MS is considered crucial and not the scope of this subclause. The alternatives or ~~modifications~~options in this sense are not independent methods.

The ~~working group~~experts in charge of the ~~standard~~ of the development of the standardized analytical method defines whether ~~a modification~~an option is crucial or non-crucial, based on experiments and/or experience.

In general, a method ~~modification~~option has to be as well described as a normative method. All necessary references to the method in the main part of the standard and vice versa shall be given. Pre-normative validation work has to be performed as well as for the main method. Results according to the ~~alternative~~alternatives or ~~modification~~options shall be equivalent.

All authorized ~~modifications~~options of one single analytical step ~~have to~~shall be mentioned in the main document. If ~~so, it~~required, they can be described in detail in an ~~informative or normative~~ annex. It has to be clear that all the ~~modifications~~options are equivalent and ~~may~~can be used.

A documented evaluation of any ~~non-crucial modified~~alternative step of a method is needed. This has to be provided by the experts of the responsible working group before carrying out the interlaboratory trial.