TECHNICAL SPECIFICATION

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CEN/TS 14793

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English version

Stationary source emission - Intralaboratory validation procedure for an alternative method compared to a reference method

Emissions de sources fixes - Méthode de validation intralaboratoire d'une méthode 'alternative' comparée à une méthode de référence

Emissionen aus stationären Quellen - Intralaborvalidierverfahren für ein Alternativverfahren verglichen mit einem Referenzverfahren

This Technical Specification (CEN/TS) was approved by CEN on 1 March 2004 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

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page

Foreword

This document CEN/TS 14793:2005 has been prepared by Technical Committee CEN/TC 264 “Air quality”, the secretariat of which is held by DIN.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Annexes A and B are informative.

Introduction

Much has been published in the literature concerning method validation by collaborative study. CEN TC264 working groups try to follow these method validations when a new standard is prepared and the collaborative study is probably the preferred way of carrying out the validation. However, it is not always a suitable option for accredited laboratories. The application for which the method is required may be esoteric to the extent that no other laboratories would be interested in collaboration. Those that might be interested can be competitors.

The present Technical Specification provides one of the possible methods of testing the equivalence of an alternative method with a reference method.

1 Scope

The purpose of this Technical Specification is to specify a validation procedure to show if an Alternative Method (AM) can be used as an alternative to the Standard Reference Method (SRM), both implemented to determine the same measurand. This document has been drawn up for laboratories working in air pollution measurements (and consequently examples taken from this sector are included in the appendices).

In particular, this Technical Specification provides the statistical tools and different criteria to evaluate the alternative method; this does not release the person responsible for this validation from bearing technical and analytical judgement on the evaluation of the different criteria.

Three steps are described in the validation procedure:

— description of the AM and setting of the field of equivalence (range and type of gas matrix);

— determination of the performance characteristics of the AM and calculation of the overall uncertainty where appropriate and check of compliance of the maximum overall uncertainty allowed for the SRM;

— check of repeatability and lack of systematic deviation of the AM in the field in comparison with the SRM for the type of matrix defined in the field of equivalence.

NOTE Some parts of the second step of the validation of the alternative method should be performed by a recognised test-house.

If the AM fulfils the requirement of the procedure, then the laboratory that carried out the whole validation process is allowed to use it as a SRM in the field application where the equivalence has been demonstrated.

However, if the validation process involves at least 4 different accredited laboratories performing simultaneously parallel measurements in the field, and if the AM passes with success all the tests of the procedure, then this method could be proposed to CEN, who can decide to consider this AM as a new reference method (ARM).

The use of this procedure implies that a reference method has been defined by the regulator or in a contract and has been validated.

This Technical Specification only considers the case of linear quantitative methods.

2 Normative references

The following referenced documents are indispensable for the application 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.

ENV 13005, *Guide to the expression of uncertainly in measurement.*

EN ISO 14956, *Air quality – Evaluation of suitability of a measurement procedure by comparison with a required measurement uncertainty (ISO 14956:2002).*

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.*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.