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Guideline for the validation of physico-chemical analytical methods

Lignes directrices pour la validation des méthodes d'analyse physico-chimiques

Anleitung zur Validierung physikalisch-chemischer Analysenverfahren

This Technical Specification (CEN/TS) was approved by CEN on 14 March 2015 for provisional application.

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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (CEN/TS 16800:2015) has been prepared by Technical Committee CEN/TC 230 “Water analysis”, the secretariat of which is held by DIN.

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Introduction

Environmental monitoring of chemical substances is increasingly carried out within a European framework, and there is concern about the comparability of data at the European level. In particular methods used for the monitoring of substances with recent interest have often not been properly validated either in-house (i.e. within a single laboratory) or at the international level.

These issues may be addressed by adopting a harmonized approach towards method development and validation. The main objective of this document is to provide a common European approach to the validation of chemical methods for the respective monitoring of chemical substances in a broad range of matrices. Although the development of this approach was triggered by the needs for monitoring of emerging pollutants, it is of general nature and can be applied to the measurement of a wide range of substances in a variety of matrices.

This guidance takes into account the different requirements for the level of method maturity and validation at different stages of the investigation or regulation of chemical substances.

In the case of a specific monitoring task, this protocol will guide the user through the following steps:

— classification of existing methods with respect to their status of validation, and the selection of the appropriate validation approach;

— development of a method so as to extend its application; for example, if a method for determining a required target compound in a particular matrix is available, but is not suitable for the same compound in a different matrix of interest;

— the validation procedures to be carried out in order to effectively demonstrate the validation status of a selected method according to the two approaches adopted.

Many (national and international) standards currently contain in their scope a statement like “this method is applicable from a concentration level of xx µg/l or yy mg/kg dry matter”, without any statement how this concentration level was established. When the limit of quantification (LOQ) is evaluated using the procedure of this Technical Specification, there is a possibility that it does not meet the lower limit of the claimed range.

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1 Scope

This Technical Specification describes an approach for the validation of physico-chemical analytical methods for environmental matrices.

The guidance in this document addresses two different validation approaches, in increasing order of complexity. These are:

a) method development and validation at the level of single laboratories (intra-laboratory validation);

b) method validation at the level of several laboratories (between-laboratory or inter-laboratory validation), with a focus on methods that are sufficiently mature and robust to be applied not only by a few expert laboratories but by laboratories operating at the routine level.

The concept of these two approaches is strictly hierarchical, i.e. a method shall fulfil all criteria of the first level before it can enter the validation protocol of the second level.

This Technical Specification is applicable to the validation of a broad range of quantitative physico-chemical analytical methods for the analysis of water (including surface water, groundwater, waste water, and sediment). Analytical methods for other environmental matrices, like soil, sludge, waste, and biota can be validated in the same way. It is intended either for analytical methods aiming at substances that have recently become of interest or for test methods applying recently developed technologies.

The minimal requirements that are indispensable for the characterization of the fitness for purpose of an analytical method are: selectivity, precision, bias and measurement uncertainty. The aim of validation is to prove that these requirements are met.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 78-2, *Chemistry — Layouts for standards — Part 2: Methods of chemical analysis*

ISO 5725, *Chemistry — Layouts for standards — Part 2: Methods of chemical analysis*

ISO 11352:2012, *Water quality — Estimation of measurement uncertainty based on validation and quality control data*

ISO 21748:2010, *Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation*

ISO/IEC Guide 99:2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99:2007 (VIM) and the following apply.

3.1
accepted reference value
value that serves as an agreed-upon reference for comparison, and which is derived as:

a) a theoretical or established value, based on scientific principles;

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