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Irish Standard Recommendation
S.R. CEN/TR 10345:2013

Guideline for statistical data treatment of inter laboratory tests for validation of analytical methods

S.R. CEN/TR 10345:2013

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TECHNICAL REPORT

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English Version

Guideline for statistical data treatment of inter laboratory tests for validation of analytical methods

Guide pour le traitement statistique des données de validation de méthodes d'analyse, issues d'essais interlaboratoires

Richtlinien für die Behandlung von statistischen Daten von verschiedenen Laboren für die Validierung von Analysenverfahren

This Technical Report was approved by CEN on 29 July 2013. It has been drawn up by the Technical Committee ECISS/TC 102.

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Foreword

This document (CEN/TR 10345:2013) has been prepared by Technical Committee ECISS/TC 102 “Methods of chemical analysis of iron and steel”, the secretariat of which is held by SIS.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes CEN/TR 10345:2008.

In comparison with the previous version of CEN/TR 10345, the following significant technical change was made in Annex A: correction of the error in the last sentence of A.2 concerning the appropriate number of significant figures.

1 Scope

This Technical Report is a guideline to carry out the statistical evaluation of data from an inter laboratory test for method validation.

Its purpose is to detail the methodology of ISO 5725-1:1994, ISO 5725-2:1994 and ISO 5725-3:1994 for the treatment of the data collected under the conditions used within the ECISS/TC 102 working groups.

NOTE The present document is not a simplification of the ISO 5725 standard, which is the only reference document.

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 5725-1:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

ISO 5725-2:1994, *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 5725-3:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 3: Intermediate measures of the precision of a standard measurement method*

3 Principle

An inter laboratory test for method validation is organized at each stage of the development of a standard draft. Changing economic conditions have led to the optimization of the work of the participating laboratories. The principle retained by ECISS/TC 102 is to have three values by participant laboratory: two values obtained in repeatability conditions (day 1) and a third obtained in intra laboratory reproducibility conditions (day 2). The data evaluation requires a complex statistical analysis, which may be very confusing for a non-specialist, even if it is widely detailed in the ISO 5725 standard. Consequently, it seems useful to clarify the methodology of this standard for the above purpose and to underline that difficulties found should be discussed and solved with statisticians.

Values that are identified as statistically abnormal at 99 % (outliers) using numerical Cochran's and Grubbs' tests lead to the elimination of the laboratory that produced them, at the stage at which they are detected: this principle is adopted even though we risk wrongly eliminating one result in one hundred. Nevertheless, it is essential to advise the laboratory concerned about the reasons for these eliminations and to pay particularly attention to this laboratory's results.

Furthermore, in the case of a laboratory which produces values that are determined as statistically significant at 95 % (stragglers) by numerical Cochran's and Grubbs' tests, particular attention should be paid to all the other values produced by this laboratory.

4 Preliminary rules

4.1 First rule ('to be clear')

The inter laboratory test should be adapted in order to meet the following requirements: