

ICS 03.120.30; 17.020

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  
interlaboratoire

Richtlinien für statistische Verfahren der Probenahme und  
Analyse von Eisen, Stahl und anderen Eisenmetallen

This Technical Report was approved by CEN on 22 October 2007. It has been drawn up by the Technical Committee ECISS/TC 20.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**Management Centre: rue de Stassart, 36 B-1050 Brussels**

## Contents

Page

Foreword.....	3
1 Scope .....	4
2 Normative references .....	4
3 Principle.....	4
4 Preliminary rules.....	4
4.1 First rule ('to be clear') .....	4
4.2 Second rule ('to be modest') .....	5
4.3 Minimal characteristics of data population.....	5
5 Procedure .....	6
5.1 Bases .....	6
5.2 Raw data examination .....	6
5.3 Intra laboratory repeatability variance (Cochran's test).....	6
5.4 Intra laboratory reproducibility variance (Grubbs' test).....	6
5.5 Inter laboratory reproducibility variance (Grubbs' test).....	7
5.6 Retained data examination .....	8
5.7 Calculation of the variances associated to the tested method.....	8
5.8 Treatment for unexpected calculated variances .....	8
5.9 Estimation of a function linking variance and level.....	8
6 Report .....	9
7 General remarks.....	9
Annex A Steps for the validation of a Draft Standard.....	10
Annex B Synoptic of the operations described in Annex A.....	12
Annex C Examples.....	17
Bibliography .....	46

## Foreword

This document CEN/TR 10345:2008 has been prepared by Technical Committee ECISS/TC 20 "Methods of chemical analysis of ferrous products", the secretariat of which is held by SIS.

This document is a preview generated by EVS

## 1 Scope

This document 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, -2 and -3:1994 standards for the treatment of registered data in the conditions used within the ECISS/TC 20 working groups.

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

## 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.

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*