# NSAI
Standards

Irish Standard
S.R CEN/TR 10345:2008

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

S.R CEN/TR 10345:2008

*Incorporating amendments/corrigenda issued since publication:*

| *This standard replaces:* | *This standard is based on:* CEN/TR 10345:2008 | *Published:* |
|---|---|---|

| This Irish Standard was published under the authority of the NSAI and comes into effect on: 13 August, 2008 | ICS number: 03.120.30 17.020 |
|---|---|

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Price Code:
N

Údarás um Chaighdeáin Náisiúnta na hÉireann

**S.R.  CEN/TR 10345:2008**

TECHNICAL REPORT

RAPPORT TECHNIQUE

TECHNISCHER BERICHT

# CEN/TR 10345

June 2008

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**

Ref. No. CEN/TR 10345:2008: E

# Contents

# 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.

# 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*

# 3   Principle

An inter laboratory test for method validation is organised at each stage of the development of a standard draft. Changing economical conditions have lead to the optimisation of the work of the participating laboratories. The principle retained by the ECISS/TC 20 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 5725:1994 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 to wrongly eliminating one result in one hundred. Nevertheless, it is essential to investigate with the laboratory that produced the involved results the reasons for this elimination and to pay particular attention to all of the values produced by this laboratory.

Also, 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 a 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: