ICS 75.080 SLOVENSKÁ TECHNICKÁ NORMA Február 2024

STN	**Ropné výrobky a príbuzné výrobky Zhodnosť metód merania a výsledkov merania Časť 4: Použitie štatistických regulačných diagramov na validáciu štatisticky zvládnutého stavu pri používaní normalizovanej skúšobnej metódy v jednom laboratóriu (ISO 4259-4: 2021, opravená verzia 2023-10)**	**STN EN ISO 4259-4** 65 6004

Petroleum and related products - Precision of measurement methods and results - Part 4: Use of statistical control charts to validate `in-statistical-control` status for the execution of a standard test method in a single laboratory (ISO 4259-4:2021, Corrected version 2023-10)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/24

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English Version

Petroleum and related products - Precision of measurement methods and results - Part 4: Use of statistical control charts to validate 'in-statistical-control' status for the execution of a standard test method in a single laboratory (ISO 4259-4:2021, Corrected version 2023-10)

Produits pétroliers et connexes - Fidélité des méthodes de mesure et de leurs résultats - Partie 4: Utilisation de cartes de contrôle statistique pour valider l'état 'sous maîtrise statistique' pour l'exécution d'une méthode d'essai normalisée dans un seul laboratoire (ISO 4259-4:2021, Version corrigée 2023-10)

Mineralölerzeugnisse - Präzision von Messverfahren und Ergebnissen - Teil 4: Verwendung von Kontrollkarten zur Validierung des Status der statistischen Kontrolle bei der Durchführung von genormten Prüfverfahren in einem einzelnen Labor (ISO 4259-4:2021, korrigierte Fassung 2023-10)

This European Standard was approved by CEN on 30 November 2021.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 15 November 2023.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European foreword

This document (EN ISO 4259-4:2022) has been prepared by Technical Committee ISO/TC 28 "Petroleum and related products, fuels and lubricants from natural or synthetic sources" in collaboration with Technical Committee CEN/TC 19 “Gaseous and liquid fuels, lubricants and related products of petroleum, synthetic and biological origin” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2022, and conflicting national standards shall be withdrawn at the latest by December 2022.

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Endorsement notice

The text of ISO 4259-4:2021, Corrected version 2023-10 has been approved by CEN as EN ISO 4259-4:2022 without any modification.

INTERNATIONAL STANDARD

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Petroleum and related products — Precision of measurement methods and results —

Part 4: Use of statistical control charts to validate 'in-statistical-control' status for the execution of a standard test method in a single laboratory

Produits pétroliers et connexes — Fidélité des méthodes de mesure et de leurs résultats —

Partie 4: Utilisation de cartes de contrôle statistique pour valider l'état 'sous maîtrise statistique' pour l'exécution d'une méthode d'essai normalisée dans un seul laboratoire

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 28, *Petroleum and related products, fuels and lubricants from natural or synthetic sources*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 19, *Gaseous and liquid fuels, lubricants and related products of petroleum, synthetic and biological origin*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 4259 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

This corrected version of ISO 4259-4:2021 incorporates the following corrections:

— in 4.3.3.1, the first sentence in 10th bullet has been corrected to read : "If out of statistical control is not confirmed, exclude the initial out of control result and use only the re-analysis result if the initial out of control result exceeds the control limit by an amount > 0,25 s_{chart} or there is MR upper control limit exceedance associate with either the original or the retest result."

Introduction

In the current global business environment, measurement data 'trustworthiness' is a key business driver and an implicit expectation from customers and regulatory entities. Data trustworthiness means the data quality meets expectations and is 'fit-for-use'. Trustworthy data can only be produced by measurement systems that are demonstrated to be stable and are under common cause variation only.

This document describes the applications of specific statistical control charts selected from those that are widely used by the manufacturing sector for the purpose of monitoring and demonstrating the in-statistical-control status of a laboratory in the execution of a standardized test method to produce trustworthy data.

In ISO 4259-2[9], the requirement for assessment of product quality conformance to specification, is to be interpreted that each laboratory's test result is obtained from a test method that is in-statistical-control in terms of precision and bias, to be substantiated by in-house statistical quality control (SQC) charts or other equivalent statistical techniques. While in-house techniques are used by many laboratories for test method quality assurance, standardization on how to establish in-statistical-control is necessary to ensure consistency in application of ISO 4259-2[9]. Addressing the aforementioned necessity is the motivation of this document, which is based on ASTM D6299[1].

INTERNATIONAL STANDARD **ISO 4259-4:2021(E)**

Petroleum and related products — Precision of measurement methods and results —

Part 4: Use of statistical control charts to validate 'in-statistical-control' status for the execution of a standard test method in a single laboratory

1 Scope

This document specifies the process and methodology for the construction, operation, and maintenance of statistical control charts to assess if a laboratory's execution of a standard test method is in-statistical-control and how to establish and validate the 'in-statistical-control' status.

It specifies control charts that are most appropriate for ISO/TC 28 test methods where the dominant common cause variation is associated with the long term, multiple operator conditions. The control charts specified for determination of in-statistical-control are: individual (I), moving range of 2 (MR_2), and either the exponentially weighted moving average (EWMA) or zone-based run rules [similar to Western Electric (WE) run rules[3]] as sensitivity enhancement strategy to support the I-chart.

The procedures in this document have been primarily designed for numerical results obtained from testing of control samples prepared from a homogenous source of petroleum and related products in a manner that preserves the homogeneity of properties of interest between control samples. If the test method permits, a certified reference material (CRM) sample is used as a control sample provided the sample composition is representative of the material being tested and is not a pure compound; if this is done then the laboratory best establishes its own mean for the CRM sample.

This document is applicable to properties of interest that are (known to be) stable over time, and for data sets with sufficient resolution to support validation of the assumption that the data distribution can be approximately represented by the normal (Gaussian) model. Mitigating strategies are suggested for situations where the assumption cannot be validated.

2 Normative references

The following documents are referred to in the text in such a way that some of their content support requirements 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 4259-1:2017, *Petroleum and related products — Precision of measurement methods and results — Part 1: Determination of precision data in relation to methods of test*