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STN	**Kvalita vody Variabilita výsledkov skúšky a neistota merania mikrobiologických metód stanovenia počtu**	**STN ISO 29201** 75 7805

Water quality. The variability of test results and the uncertainty of measurement of microbiological enumeration methods

Qualité de l'eau. Variabilité des résultats d'essais et incertitude de mesure des méthodes d'énumération microbienne

Wasserbeschaffenheit. Variabilität von Untersuchungsergebnissen und Messunsicherheit von mikrobiologischen Zählverfahren

Táto norma obsahuje anglickú verziu ISO 29201: 2012.

This standard includes the English version of ISO 29201: 2012.

125609

Anotácia

Táto medzinárodná norma poskytuje usmernenie na vyhodnotenie neistoty kvantitativnych mikrobiologických analýz založených na počítaní mikrobiálnych častíc po kultivácii. Zahŕňa všetky varianty metód počítania kolónií a metód odhadu najpravdepodobnejšieho počtu.

V norme sú zahrnuté dva prístupy: čiastkový (známy tiež ako „bottom-up“ alebo „step-by-step“, čo znamená zdola nahor alebo krok za krokom) a modifikovaný celkový prístup („top-down“ čo je zhora nadol).

Cieľom normy je špecifikovať ako sa môžu získať hodnoty vnútrolaboratórnej pracovnej variability a kombinovaná neistota pre konečné výsledky skúšok.

Uvedené postupy nie sú aplikovateľné pri metódach iných ako sú metódy počítania kolónií.

Národný predhovor

Normatívne referenčné dokumenty

Nie sú žiadne.

Vypracovanie normy

Spracovateľ: Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, Bratislava

Technická komisia: TK 27 Kvalita vody

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 29201 was prepared by Technical Committee ISO/TC 147, *Water quality*, Subcommittee SC 4, *Microbiological methods*.

Introduction

Testing laboratories are required to apply procedures for estimating uncertainty of measurement (see ISO/IEC 17025[5]). Without such an indication, measurement results cannot be compared, either among themselves or with reference values (see ISO/IEC Guide 98-3:2008[7]).

General guidelines for the evaluation and expression of uncertainty in measurement have been elaborated by experts in physical and chemical metrology, and published by ISO and IEC in ISO/IEC Guide 98-3:2008.[7] However, ISO/IEC Guide 98-3:2008[7] does not address measurements in which the observed values are counts.

The emphasis in ISO/IEC Guide 98-3:2008[7] is on the “law of propagation of uncertainty” principle, whereby combined estimates of the uncertainty of the final result are built up from separate components evaluated by whatever means are practical. This principle is referred to as the “component approach” in this International Standard. It is also known as the “bottom-up” or “step-by-step” approach.

It has been suggested that the factors that influence the uncertainty of microbiological enumerations are not well enough understood for the application of the component approach (see ISO/TS 19036:2006[6]). It is possible that this approach underestimates the uncertainty because some significant uncertainty contributions are missed. Reference [19] shows, however, that the concepts of ISO/IEC Guide 98-3:2008[7] are adaptable and applicable to count data as well.

Another principle, a “black-box” approach known as the “top-down” or “global” approach, is based on statistical analysis of series of repeated observations of the final result (see ISO/TS 19036:2006[6]). In the global approach it is not necessary to quantify or even know exactly what the causes of uncertainty in the black box are.

According to the global philosophy, once evaluated for a given method applied in a particular laboratory, the uncertainty estimate may be reliably applied to subsequent results obtained by the method in the same laboratory, provided that this is justified by the relevant quality control data (EURACHEM/CITAC CG 4[10]). Every analytical result produced by a given method thus should have the same predictable uncertainty. This statement is understandable against its background of chemical analysis. In chemical analyses the uncertainty of the analytical procedure and the uncertainty of the final result of analysis are usually the same. The global principle dismisses the possibility that there might be something unique about the uncertainty of a particular analysis.

The uncontrollable “variation without a cause” that always accompanies counts alters the situation for microbiological enumerations. The full uncertainty of a test result can be estimated only after the final result has been secured. This applies to both the global and the component approaches.

The unpredictable variation that accompanies counts increases rapidly when counts get low. The original global design is therefore not suitable for low counts, and therefore also not applicable to most probable number (MPN) methods and other low-count applications, such as confirmed counts.

It is often necessary, and always useful, to distinguish between two precision parameters: the uncertainty of the technical measuring procedure (operational variability), which is more or less predictable, and the unpredictable variation that is due to the distribution of particles. A modification of the global principle that takes into account these two sources of uncertainty is free from the low-count restriction. This is the global model detailed in this International Standard.

In theory, the two quantitative approaches to uncertainty should give the same result. A choice of two approaches is presented in this International Standard. Offering two approaches is appropriate not only because some parties might prefer one approach to the other. Depending on circumstances one approach may be more efficient or more practical than the other.

Neither of the main strategies is, however, able to produce unequivocal estimates of uncertainty. Something always has to be taken for granted without the possibility of checking its validity in a given situation. The estimate of uncertainty is based on prior empirical results (experimental standard uncertainties) and/or reasonable general assumptions.

INTERNATIONAL STANDARD ISO 29201:2012(E)

Water quality — The variability of test results and the uncertainty of measurement of microbiological enumeration methods

1 Scope

This International Standard gives guidelines for the evaluation of uncertainty in quantitative microbiological analyses based on enumeration of microbial particles by culture. It covers all variants of colony count methods and most probable number estimates.

Two approaches, the component (also known as bottom-up or step-by-step) and a modified global (top-down) approach are included.

The aim is to specify how values of intralaboratory operational variability and combined uncertainty for final test results can be obtained.

The procedures are not applicable to methods other than enumeration methods.

NOTE 1 Most annexes are normative. However, only the annexes relevant to each case are to be applied. If the choice is the global approach, then all normative annexes that belong to the component approach can be skipped and vice versa.

NOTE 2 Pre-analytical sampling variance at the source is outside the scope of this International Standard, but needs to be addressed in sampling designs and monitoring programmes.

NOTE 3 The doubt or uncertainty of decisions based on the use of analytical results whose uncertainty has been estimated is outside the scope of this International Standard.

NOTE 4 The extra-analytical variations observed in proficiency tests and intercalibration schemes are also not detailed in this International Standard, but it is necessary to take them into consideration in analytical control. The use of intercalibration data in uncertainty estimation offers the possibility for the bias between laboratories to be included (Nordtest Report TR 537[12]).