SLOVENSKI STANDARD
SIST EN ISO 13843:2017

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Nadomešča:
SIST-TS ENV ISO 13843:2004

Kakovost vode - Zahteve za določitev delovnih karakteristik kvantitativnih mikrobioloških metod (ISO 13843:2017)

Water quality - Requirements for establishing performance characteristics of quantitative microbiological methods (ISO 13843:2017)

Wasserbeschaffenheit - Anforderungen zur Bestimmung von Leistungsmerkmalen von quantitativen mikrobiologischen Verfahren (ISO 13843:2017)

Qualité de l'eau - Exigences pour l'établissement des caractéristiques de performance des méthodes microbiologiques quantitatives (ISO 13843:2017)

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ICS:

07.100.20	Mikrobiologija vode	Microbiology of water

SIST EN ISO 13843:2017 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13843

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ICS 07.100.20

Supersedes ENV ISO 13843:2001

English Version

Water quality - Requirements for establishing performance characteristics of quantitative microbiological methods (ISO 13843:2017)

Qualité de l'eau - Exigences pour l'établissement des caractéristiqes de performance des méthodes microbiologiques quantitatives (ISO 13843:2017)

Wasserbeschaffenheit - Anforderungen zur Bestimmung von Leistungsmerkmalen von quantitativen mikrobiologischen Verfahren (ISO 13843:2017)

This European Standard was approved by CEN on 5 June 2017.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN ISO 13843:2017) has been prepared by Technical Committee ISO/TC 147 "Water quality" in collaboration with Technical Committee CEN/TC 230 “Water analysis” the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by January 2018 and conflicting national standards shall be withdrawn at the latest by January 2018.

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

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Endorsement notice

The text of ISO 13843:2017 has been approved by CEN as EN ISO 13843:2017 without any modification.

INTERNATIONAL STANDARD

ISO 13843

First edition
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Water quality — Requirements for establishing performance characteristics of quantitative microbiological methods

Qualité de l'eau — Exigences pour l'établissement des caractéristiqes de performance des méthodes microbiologiques quantitatives

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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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

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

This first edition of ISO 13843 cancels and replaces ISO/TR 13843:2000, which has been technically revised.

Introduction

Methods are considered microbiological when the quantitative estimate is based on counting of microbial particles either directly with the aid of a microscope or indirectly on the basis of growth (multiplication) into colonies, turbidity, a colour change or fluorescence. The principles and procedures within the scope of this document are commonly known as microscopic count, most probable number (MPN) and colony count. Most of the procedures for the determination of performance characteristics described in this document are applicable to all three types of method. However, where the procedures are not applicable, alternative suggestions are made within the body of the document or in Annexes D and E (for repeatability, reproducibility and uncertainty of counting).

Plaque counts of bacteriophages are in most respects similar to bacterial colony counts.

Some of the "newer" microbiological methods such as those utilizing fluorescent *in situ* hybridization (FISH) or polymerase chain reaction (PCR) can also be covered by this document. However, they may require special consideration, depending upon how they are used. The issues of importance in these situations include the mechanism of determining the numbers of microbes present (e.g. standard curve for qPCR or microscopic count for FISH) and the viability of the organisms detected. If such techniques are used for confirmation as part of a method then all sections of this document are relevant.

While not essential, during the characterization of microbiological methods it may be beneficial to generate data using stressed organisms. Various methods can be used to stress organisms, but the two that are most useful for water are disinfectant stress (usually chlorine injury) and nutrient depletion caused by organisms being in a low nutrient environment (i.e. drinking water and other oligotrophic waters) for a period prior to testing. The effect on some of the performance characteristics of "stressing" organisms is almost totally dependent on the type and degree of stress applied and it is inappropriate to include such detail in this document. However, there are descriptions in the literature that laboratories can follow in case they should wish to determine performance characteristics of a method with stressed cells.

Water quality — Requirements for establishing performance characteristics of quantitative microbiological methods

1 Scope

This document deals with characterization of microbiological methods. In terms of this document, characterization means the study of parameters that can be measured to describe how the method is likely to perform in a given set of conditions, which can be described as performance characteristics. The document describes procedures for the determination of performance characteristics which can be used for subsequent validation or verification of methods.

The emphasis is on selective quantitative methods and this document applies to all types of water. For methods that are not based upon direct microscopic count, colony count or most probable number, the applicability of the procedures described in this document should be considered carefully.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes 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 17994:2014, *Water quality — Requirements for the comparison of the relative recovery of microorganisms by two quantitative methods*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org./obp

3.1
accuracy
measurement accuracy
closeness of agreement between a measured quantity value and an assigned quantity value of a measurand

Note 1 to entry: The concept ‘measurement accuracy’ is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.

Note 2 to entry: ‘Measurement accuracy’ is sometimes understood as closeness of agreement between measured quantity values that are being attributed to the measurand.

[SOURCE: ISO/IEC Guide 99:2007, 2.13[16], modified — “...a true quantity value” replaced by “... an assigned quantity value; Notes 1 and 2 to entry added]

3.2
analyte
component represented in the name of a measurable quantity

Note 1 to entry: In water microbiology, the analyte is ideally defined as a list of taxonomically defined species. In most cases, in practice the analyte can only be defined by group designations less accurate than taxonomic definitions.

[SOURCE: ISO 17511:2003, 3.2[14]]

3.3
analytical portion
test portion
volume of particle suspension (sample) inoculated into a detector unit (agar plate, membrane filter, test tube, microscopic grid square)

3.4
bias
measurement bias
estimate of a systematic measurement error, or the systematic difference between the quantitative assigned value and the average of measurement replicate results

3.5
categorical characteristics
method performance characteristic numerically expressed as a relative frequency based on P/A or +/- classification

3.6
colony-forming unit
CFU
colony-forming particle
CFP

organism (or cluster of organisms) with the ability to form a colony under certain specified conditions

Note 1 to entry: The term was originally introduced to convey the idea that a colony may originate not only from a single cell but from a solid chain or aggregate of cells, a cluster of spores, a piece of mycelium, etc. It mistakenly equates the number of colonies observed to the number of living entities seeded on the medium. Growth unit, viable particle, propagule and germ are terms with the same meaning but convey the original idea better and apply not only to colony count methods but also to the most probable number (MPN).

3.7
collaborative method performance
method or laboratory performance test where several laboratories join in an experiment planned and co-ordinated by a leader laboratory

Note 1 to entry: Collaborative tests are mainly of two types. Intercalibration exercises are made to allow laboratories to compare their analytical results with those of other participating laboratories.

Note 2 to entry: Method performance tests produce precision estimates (repeatability, reproducibility) out of data accumulated when several participating laboratories study identical samples with a strictly standardized method.

3.8
confirmed colony count
verified colony count
presumptive colony count corrected for false positives

Note 1 to entry: Mathematically:

$$pc = \frac{k}{n} c$$

where

c is the presumptive count;

p is the true positive rate;

n is the number of presumptive positives isolated for confirmation;

k is the number confirmed.

3.9
corroborated count
count obtained when using a secondary confirmation procedure

3.10
detection level
minimum concentration of organisms that produce evidence of growth with a probability of $P = 0{,}95$ when inoculated into a specified culture medium and incubated under defined conditions

Note 1 to entry: The theoretical level that conforms to this definition is an average of three viable cells in an inoculum volume.

3.11
detection set
combination of plates or tubes on which quantitative estimation of sample microbial concentration is based

Note 1 to entry: The detection set is the set of plates or tubes utilized for numerical estimation of a single value.

EXAMPLE Parallel plates of a suspension, plates from consecutive dilutions, 3 × 5 tube MPN system, microtitre plate.

3.12
detector
particle detector
plate of solid matrix or a tube of liquid containing a nutrient medium for counting or detecting biologically active particles

3.13
efficiency
E
fraction of colonies that are correctly assigned as positives and negatives

Note 1 to entry: Mathematically:

$$E = \frac{a+d}{n}$$

where

a is the number of typical colonies confirmed as being the target organism (true positives);

d is the number of atypical colonies confirmed as not being the target organism (true negatives);

n is the total number of colonies tested for confirmation.

3.14
false negative
result indicated by the test method to be negative which has subsequently been shown to contain the target organism