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

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erformanc. Qualité de l'eau — Exigences pour l'établissement des caractéristiqes



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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 <u>Annexes D</u> and <u>E</u> (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 e v. Never, o determ. 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]