TECHNICAL REPORT

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Water quality — Guidance on validation of microbiological methods

Qualité de l'eau — Lignes directrices pour la validation des méthodes microbiologiques

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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 3.

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.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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

ISO/TR 13843 was prepared by Technical Committee ISO/TC 147, *Water quality*, Subcommittee SC 4, *Microbiological methods*.

Water quality — Guidance on validation of microbiological methods

1 Scope

This Technical Report deals with validation of microbiological methods, with particular emphasis on selective quantitative methods in which the quantitative estimate is based on counting of particles either directly, with the aid of a microscope, or indirectly, on the basis of growth (multiplication) into colonies or turbidity.

The principles and procedures within this scope are commonly known as the presence/absence (P/A), most probable number (MPN), colony count and direct (microscopic) count.

This Technical Report does not apply to the validation of the so-called rapid or modern methods which mostly depend on measuring products or changes due to microbial activity but do not address the detection of individual particles.

2 Terms and definitions

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

2.1
accuracy of measurement
closeness of the agreement between a test result and the accepted reference value

NOTE The term “accuracy”, when applied to a set of test results, involves a combination of random components and a common systematic error or bias component.

[ISO 3534-1:1993, 3.11]

2.2
analyte
measurand
particular quantity subjected to measurement

NOTE 1 See reference [5].

NOTE 2 In microbiology the analyte is ideally defined as a list of taxonomically defined species. In many cases, in practice the analyte can only be defined by group designations less accurate than taxonomic definitions.

2.3
analytical portion
test portion
volume of particle suspension inoculated into a detector unit

NOTE Examples of a detector unit are agar plate, membrane filter, test tube, microscopic grid square.

2.4
application range
range of particle concentrations routinely subjected to measurement by a method