SLOVENSKI STANDARD
SIST EN 16101:2013

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Kakovost vode - Navodilo za načrtovanje in analizo medlaboratorijskih primerjalnih študij za ekološko oceno

Water quality - Guidance standard on the design and analysis of interlaboratory comparison studies for ecological assessment

Wasserbeschaffenheit - Anleitung zur Planung und Auswertung von Laborvergleichuntersuchungen für ökologische Untersuchungen

Qualité de l'eau - Guide pour la conception et l'analyse des études comparatives interlaboratoires ayant pour objet l'évaluation écologique

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Water quality - Guidance standard on interlaboratory comparison studies for ecological assessment

Qualité de l'eau - Guide pour les études comparatives interlaboratoires ayant pour objet l'évaluation écologique

Wasserbeschaffenheit - Anleitung für Vergleichsprüfungen zwischen Laboratorien für ökologische Untersuchungen

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Foreword

This document (EN 16101:2012) has been prepared by 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of an identical text or by endorsement, at the latest by April 2013, and conflicting national standards shall be withdrawn at the latest by April 2013.

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

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

SAFETY PRECAUTIONS — Safety issues are paramount when surveying surface waters. Surveyors should conform to EU and national Health and Safety legislation and any additional guidelines appropriate for working in or near water.

The importance of data quality in ecological results is explicit in highlighted in several EU Directives. For example the EC Water Framework Directive (WFD 2000/60/EC), Annex V, Clause 1.3.4. "Estimates of the confidence and precision attained by the monitoring system used shall be stated in the river basin monitoring plan." This means that ecological data from aquatic environments should be of a known and verifiable quality. This European dimension drives regulatory agencies, research bodies, universities and contractors working across Europe to become increasingly involved in ensuring that the data produced from laboratory and field analyses is comparable and fit for purpose.

Ecological assessment techniques involve both a field and a laboratory component; each of these needs to be scientifically robust.

Implementation of interlaboratory comparison studies falls into two broad categories; interlaboratory tests designed to demonstrate comparability of data produced by laboratories which are working independently or in separate geographical regions [1] and routine procedures implemented by the laboratories as part of their operational methods.

Existing systems of interlaboratory comparison are generally not well developed for ecological assessments. By their nature the techniques used should be specific to the organism group and may not be readily transferable to other applications. This standard provides general guidance on the design of such systems.

1 Scope

This European Standard provides guidance on interlaboratory comparison with a special focus on biological methods. Guidance on the methods and procedures given in this standard should ensure that field survey results and laboratory analyses are comparable within specified limits. This guidance enables participants in interlaboratory comparison to demonstrate their level of performance. In addition it provides a mechanism for quality improvement. This standard describes a general course of the procedure. Detailed elements can be found in EN 14996, EN ISO/IEC 17000, EN ISO/IEC 17025, and EN ISO/IEC 17043.

2 Terms and definitions

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

2.1
assigned value
value attributed to a particular property of a proficiency test item

Note 1 to entry: ISO 13528:2005, 3.3, refers to this term as 'Value attributed to a particular quantity and accepted, sometimes by convention, as having an uncertainty appropriate for a given purpose'.

[SOURCE: EN ISO/IEC 17043:2010, 3.1, modified – Note 1 to entry has been added]

2.2
interlaboratory comparison
organisation, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

Note 1 to entry: ISO 13528:2005, 3.1, refers to this term as 'organisation, performance and evaluation of tests on the same or similar test items by two or more laboratories in accordance with predetermined conditions'.

Note 2 to entry: The data under test may be qualitative, quantitative, continuous or discrete, and derived from laboratory analysis or field survey.

[SOURCE: EN ISO/IEC 17043:2010, 3.4, modified – Note 1 and 2 to entry have been added]

2.3
participant
laboratory, organisation or individual that receives proficiency test items and submits results for review by the proficiency testing provider

Note 1 to entry: In case of testing field survey methods, e.g. assessing hydro-morphological characteristics of water bodies, test items can by river stretches or lake shore length selected for survey by the participant.

[SOURCE: EN ISO/IEC 17043:2010, 3.6, modified – Note 1 to entry has been added]

2.4
proficiency testing
evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

Note 1 to entry: For the purposes of this International Standard, the term "proficiency testing" is taken in its widest sense and includes, but is not limited to:

a) quantitative scheme — where the objective is to quantify one or more measurands of the proficiency test item;

b) qualitative scheme — where the objective is to identify or describe one or more characteristics of the proficiency test item;

c) sequential scheme — where one or more proficiency test items are distributed sequentially for testing or measurement and returned to the proficiency testing provider at intervals;

d) simultaneous scheme — where proficiency test items are distributed for concurrent testing or measurement within a defined time period;

e) single occasion exercise — where proficiency test items are provided on a single occasion;

f) continuous scheme — where proficiency test items are provided at regular intervals;

g) sampling — where samples are taken for subsequent analysis; and

h) data transformation and interpretation — where sets of data or other information are furnished and the information is processed to provide an interpretation (or other outcome).

Note 2 to entry: Some providers of proficiency testing in the medical area use the term “External Quality Assessment (EQA)” for their proficiency testing schemes, or for their broader programs, or both (see Annex A). The requirements of this International Standard cover only those EQA activities that meet the definition of proficiency testing.

Note 3 to entry: ISO 13528:2005, 3.2, refers to this term as ‘determination of laboratory testing performance by means of interlaboratory comparisons’.

[SOURCE: EN ISO/IEC 17043:2010, 3.7, modified – Note 3 to entry has been added]

2.5
single occasion exercise
proficiency test items provided on a single occasion

2.6
standard deviation for proficiency assessment
measure of dispersion used in the evaluation of results of proficiency testing, based on the available information

Note 1 to entry: The standard deviation applies only to ratio and differential scale results.

Note 2 to entry: Not all proficiency testing schemes evaluate proficiency based on the dispersion of results.

Note 3 to entry: ISO 13528:2005, 3.2, refers to this term as ‘standard deviation used in the assessment of proficiency which may be related to the reproducibility standard deviation or to a statement of the fitness for purpose of the measurement method’.

[SOURCE: EN ISO/IEC 17043:2010, 3.13, modified – Note 3 to entry has been added]

2.7
***z*-score**
one of the standardised measures of laboratory bias, calculated using the assigned value and the standard deviation for proficiency assessment (applicable to continuous data only)

[SOURCE: ISO 13528:2005, 3.5]

3 Principle

Results of biological and ecological assessments from laboratories across the European Union are increasingly used to inform decision making and investment programmes. There is a clear need to ensure that these assessments are based upon sound science and validated data, comparable between laboratories within member states and between member states. Effective interlaboratory comparisons are based on the adoption of procedures to quantify and control process errors (Clause 4) within specified limits, and to enable participants to demonstrate that their analyses fulfil requirements for quality, and to maintain their

performance. This guidance standard describes the principles required for effective interlaboratory comparisons, as well as permitting laboratories to apply appropriate corrective action in relation to both analyst performance and analytical results, thereby driving improvement in quality. Interlaboratory comparison does not exist in isolation as it is part of a framework on quality assurance, which must not ignore the human dimension (e. g. significant recent experience of professionals and repeated instruction).

The selection of a suitable method for interlaboratory comparison will depend on several factors including: the required level of comparability between individuals and laboratories; an analysis of the data types generated during ecological assessments (see Note below); an understanding of the statistical distribution of the data; sources of variability in the methods used. A key step in the process of interlaboratory comparison is the determination of the assigned value for a taxon, the count or estimate of abundance, or the value of a particular parameter associated with the taxon (e.g. the mean body weight or length).

NOTE Data types are usually either continuous data, which are obtained by counting of individuals or measuring the size of individuals, or categorical data, which are obtained when estimator scales are applied, e.g. for assessing some morphological aspects of rivers or the abundance or size of organisms in "classes".

This standard provides an overview on interlaboratory comparisons and guidance on method selection for commonly used ecological assessments. Supporting details of quality managing systems relating to documentation, training and instrument calibration are described in EN ISO/IEC 17025. General requirements on proficiency testing are described in EN ISO/IEC 17043. For specific quality issues in ecological assessments additional detail is provided in EN 14996.

4 Procedures

4.1 General concepts

The quantitative and qualitative investigation of information on biological and ecological samples is usually based on biological taxa and their abundance, and in some cases on other data describing properties of individuals (e.g. body length of fish). These investigations are regulated by either European or national standards. Depending on the type of organisms assessed methods differ and therefore the approach of comparing the results shall respect the peculiarities of the applied methods.

In general the comparison of each stage of the sampling and investigation process should occur within the limits of applicability. This starts with sampling strategies, followed by sampling procedures (especially field analyses, see 4.2), sample processing, sample analysis (including lab methods, see 4.2), etc. Knowledge is needed therefore on sources of variability. The fundamental concept of survey design should be defined by the quality of the output and the purpose for what it is to be used such as absolute value or Ecological Quality Ratio (EQR, an output for the European Water Framework Directive) or a classification.

European Standards shall be used where they exist.

Several approaches exist for the comparison of ecological data (see [1]) on which interlaboratory comparison methods for field survey data can be based. The selection of an appropriate design of an interlaboratory comparison shall first relate to the exact methods used and on the level of taxonomic resolution, and the method of investigation of other than taxonomic data. In a next step guidance shall be given on the statistical methods to be applied, and on the skills of the analysts involved.

To ensure good results all individuals involved in field surveys as well as in lab procedures should have training programs on the methods and the taxonomy of the type of organisms assessed.

The comparison of identification skills is the first step, which should be followed by testing the proper use of the sampling equipment.

In the event of perceived quality defects traceability throughout sampling, analysis, data handling and production of final reports is an essential element for identifying sources of error in the process. For interlaboratory comparison the minimum number of participants shall be defined according to the method