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



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National foreword

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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of an identical text or by endorsement, at the latest by April 2013, and conflicting national standards shall be withdrawn at the latest by April 2013.

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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]

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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:

- 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
- 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

tested and related statistical properties of data produced by this method. Training files and records of competence should be maintained.

NOTE Further details are given in Annexes A to C:

- Annex A: Approaches in interlaboratory comparison;
- Annex B: Statistical analysis;
- Annex C: Characteristics associated with measurement procedure in biological methods.

4.2 Field survey

Field survey comparison starts with defining the methodology specific to the selected organism group. Then the objectives of the subsequent data use should be set and the educational level of the operators should be selected as suited to purpose. Identify the optimum season for survey along with sampling frequency and, whenever possible, take replicates, and define the sample size (e.g. the number of samples, or the volume taken, or the area from which samples are taken). For each biotic element the concrete methodological approach will be different. Identify methods for how the sample sites are selected to best meet the objectives of the survey place. Apply quality assurance (QA) mechanisms like repeat survey, etc. If not regulated according to other standards (e.g. Multi-Habitat sampling for macro invertebrate investigation; site selection procedures for macrophyte investigation) samples should be randomised and duplicates should be taken where appropriate. The sampling procedure shall include details on fixing, transport and storage of samples, where sample stability may be an issue. Validate and optimise the performance characteristics of the techniques used and report precision (see C.2) and detection limits of methods.

The implementation of expert panels providing a "consensus" on complex or ambiguous results is an appropriate procedure to deal with special aspects of methods or groups of organisms. Where a step-by-step approach on methodological errors is impractical a global estimate of sampling error may fit the need for a standardised procedure. For example, a global estimate may be used, if results are based on methods where qualitative scales ("estimator scales") instead of numerical investigation are used.

4.3 Laboratory aspects

Intra-laboratory investigations of operator performance are essential components of interlaboratory comparisons. It is essential that all operators that are regarded as competent in a field are subject to interlaboratory comparison. Any equipment used should be suited to purpose. Laboratories should, where possible, apply quality management systems in agreement with EN ISO/IEC 17025 and EN 14996. Laboratory methods should comply with EU reference methods where they exist. Where alternative methods are applied these should be validated (C.1) against reference methods described by the European Standards. If new laboratory methods are being validated interlaboratory comparisons are essential requirements.

Documented procedures for sample preparation, including stability and homogeneity tests, should be applied and laboratories may construct quality control charts. Acceptability criteria should be defined prior to interlaboratory comparisons through e. g. z-scores, coefficient of variance and/or specific values derived from robust methods, in relation to data type (e.g. not normally distributed or non-continuous data sets).

4.4 Aspects of statistical methodology and approaches

Statistical outputs shall be agreed prior to the comparison study. There should be agreement on the type and contents of the report file template. Variability of analysis and variability of the (natural) system should be assessed separately. If the variability of methods turns out to be higher than the variability of natural system the method shall be improved.

The improvements of inter- and intra-laboratory reproducibility are fundamental aims of this guidance standard. Therefore an appropriate sample size, or number of replicates, respectively, should be ascertained. The pre-defined composition of test samples is also to be considered for comparison procedures when natural variability is very high.

Available options for comparing results are:

- a) Multiple participants carry out sampling at a single location and independent examiners compare these results (in case of application of non-destructive sampling, e.g. investigation of macrophyte abundance or classification of morphological river features in a river stretch selected by independent examiners or expert panel). Non-destructive sampling covers methods which do not inflict on the composition of habitat conditions and/or populations of organisms.
- b) Multiple participants carry out sampling at multiple, but similar locations (in case of application of destructive methods, e.g. Multi-Habitat sampling of macro invertebrates, fish sampling methods). Destructive sampling covers methods which inflict on the composition of habitat conditions and/or populations of organisms. Proof of similarity of sampling locations by independent examiners or expert panels is essential.
- c) Independent examiners or expert panels prepare multiple artificial samples to be analysed by multiple participants (for destructive sampling methods where suitable).

In all cases involving multiple participants, independent examiners or expert panels shall carry out the evaluation of results and the necessary statistical procedures for interlaboratory comparison. As for lab-internal quality assurance procedures the same methodological approaches apply, but results shall be recorded and archived internally.

If results fail to meet quality limits, this outcome can have several reasons, as there are e.g. too low accuracy of measurement, too low number of samples, too low quality of samples, etc. In case of failing quality limits (see Annex B) the whole methodological approach shall be investigated meticulously.

Annex A (normative)

Approaches in interlaboratory comparison

A.1 Stepwise approach in interlaboratory comparison

A.1.1 Identification skills

- A.1.1.1 Depending on the type of organism group the identification of species is done
- a) in the laboratory (e.g. phytoplankton, phytobenthos, macro zoobenthos, work on fish scales, macrophytes with taxonomical properties that cannot be seen without microscope, like mosses), or
- b) in the field at the sampling site without the assistance of optical methods (e.g. fish species or macrophyte species identification).
- **A.1.1.2** For laboratory identification tests a set of organisms of known taxonomical composition shall be prepared by an independent qualified expert or an expert panel.
- **A.1.1.3** The identification of species should be based on defined taxonomic publications, relevant for the geographic region from which the sample organisms originate.
- **A.1.1.4** Participants should then identify the taxa and report to the examiner (or examining expert panel) within a defined time period. This procedure shall guarantee the independence of the identification process.
- **A.1.1.5** The examiner (or expert panel) shall provide the participants with the result of positive identification (e.g. in a percent scale) and about passing a pre-determined threshold of correct identification over all trailed organisms.
- **A.1.1.6** In case of identification at the sampling site (e.g. a river stretch or shore length with macrophyte vegetation, or fish sampling by electro fishing) participants shall determine the taxa present at the site and report in written form to the examiner (or expert panel). In case of identification needing further elaboration in the laboratory, follow A.1.1.2. The evaluation of the identification is given as in A.1.1.5.

A.1.2 Field survey

A.1.2.1 Sampling strategy

- a) Participants shall probe sampling sites (e.g. a river stretch or shore length), which were pre-selected and fully determined by examiners (or expert panel) for species composition and/or abundance or other relevant parameters, according to existing CEN standards or other standardised methods. Results of sampling these pre-determined sites shall be basis for on-site data acquisition, or the sampling of organisms for laboratory identification.
- b) Proper sampling site selection shall be taught by in-service training courses and repeat this training in reasonable intervals.

A.1.2.2 Presentation of data

Where ecological features are performed in the field (e.g. macrophytes, phytobenthos, some hydromorphological parameters) participants shall present their data to the examiner (or expert panel) for evaluation. The result of examination shall be given as in A.1.1.3.

A.1.2.3 Proper use of sampling equipment

Participants shall be taught by in-service training courses and shall show their competence in repeated courses in reasonable intervals.

A.1.3 Laboratory aspects

- **A.1.3.1** Wherever laboratory equipment is used (e.g. inverted microscopes) the proper use of the instrument shall be examined.
- **A.1.3.2** Test material of known taxonomic composition and/or abundance of organisms prepared by examiners (or expert panel) shall be analysed by the participants. The results shall be evaluated by the examiners (or expert panel) and given as in A.1.1.3.

A.2 Single occasion exercise in interlaboratory comparison

- **A.2.1** In cases where a step-by-step sampling procedure and/or identification skills shall be replaced by an "at-the-end"-comparison of laboratories or participants dealing with the sampling and identification of organisms or other relevant parameters of surface waters the following procedure is applicable as an alternative approach.
- NOTE For the definition of 'single occasion exercise', see 2.5.
- **A.2.2** The examiner (or expert panel) samples pre-selected sites and determines taxonomic composition and/or abundance or other relevant test parameters to the best applicable level of accuracy (application of standardised methods).
- **A.2.3** Participants sample these pre-selected sites following standardised methods (preferably according to European Standards). Following this procedure participants determine taxonomic composition and/or abundance of organisms or other parameters from the sampled site in the field (when appropriate for a specific group of organisms or type of investigation) and/or in the laboratory.
- **A.2.4** The final result on composition and/or abundance or data on other parameters is presented to the examiner (or expert panel), who evaluates the results according to the procedure described in A.1.1.3.
- NOTE This "single occasion" method will not reveal the possible deviation of results provided by participants with respect to individual steps in the sampling and identification process of assessing taxa and abundance or other relevant parameters on organisms in surface waters.

Annex B (informative)

Statistical analysis

B.1 Statistical analysis aspects to be considered in interlaboratory comparison activities

B.1.1 General annotations

B.1.1.1 While the previous guidelines aimed at optimising the data quality, this annex provides instructions for maximising the quality of the statistical data analysis. Any statistical analysis relies on the quality of the input data, but it also depends on the number of samples that were taken, on the number of features that have been measured, and on the type of input data (e.g. ratio, differential, categorical or continuous data).

B.1.2 Normal distribution

- **B.1.2.1** Many statistical methods and tests require normally distributed data. For example, the assumption of normal distribution is typically used for constructing confidence intervals, for testing for the equality of the means of two or more groups, or for analysing the relations among variables with the classical correlation measure.
- **B.1.2.2** The use of such "classical" methods with data that severely deviate from normal distribution (e.g. categorical data recorded when applying ecological investigation methods based on estimator scales, e.g. some morphological criteria of river reaches), can lead to completely biased results, even if the data quality *per* se is excellent. It is thus strongly recommended to test for normal distribution before such methods are applied.
- **B.1.2.3** Deviation from normal distribution may be tested by various statistical tests (e.g. Kolmogorov-Smirnov, Shapiro-Wilks) as well as graphical methods (QQ-plot) for testing normal distribution. If the data significantly deviate from normal distribution, one can transform the data (e. g. log-transformation, Box-Cox transformation) and test again for normal distribution of the transformed data values. Another possibility is to use other methods (typically non-parametric methods) that do not rely on normal distribution.

B.1.3 Small sample size

- **B.1.3.1** If only a few observations are available (say, less than 10 to 15), statistical comparisons become more difficult. Confidence intervals become larger, and hypotheses of statistical tests are typically rejected only in case of very severe differences or deviations.
- **B.1.3.2** In this situation, graphical comparisons are in general preferable over statistical tests. For example, when comparing means of several groups, a graphical comparison with parallel boxplots of the groups, not only shows the different group medians, but also the spread of the groups, information on data symmetry and tailedness, as well as information on outliers in the data.
- **B.1.3.3** In contrast, ANOVA yields only one number (the p-value) as a basis for the decision. Note that ANOVA also gives a p-value if data requirements are not fulfilled which, however, are difficult to check in case of small sample size.

B.1.4 Multivariate data

- **B.1.4.1** If several features (variables) have been observed simultaneously on the same objects, a multivariate statistical analysis can result in a much clearer picture of the data structure than separate analyses of the single variables (univariate analysis).
- **B.1.4.2** However, the same general rules concerning data requirements apply as in the univariate case: Skewed distributions or small sample sizes can lead to biased or instable results.
- **B.1.4.3** Many of the multivariate statistical methods are correlation-based (like principal component analysis or discriminant analysis), and the classical procedures (in contrast to robust or non-parametric correlation measures) even require that the data are close to a multivariate normal distribution, an assumption that is usually not met in presence of categorical data. Graphical data comparisons are thus often preferable.

B.1.5 Outliers

- **B.1.5.1** Even in case of high data quality it is possible that due to uncontrollable external factors some of the data values are exceptionally high or low. Such univariate outliers can have a severe effect on the statistical analysis. Even worse, the data can include outliers that are not extreme along the single variables, but which deviate from the multivariate data structure. These outliers are not visible in standard graphical illustrations, but they can spoil the multivariate data analysis.
- **B.1.5.2** It is thus advisable to compare results from classical statistical analyses with those from robust statistical methods, and/or to use appropriate diagnostic tools for multivariate outliers.
- **B.1.5.3** Useful metrics for assessing the limits within which results should be located (confidence limits) are shown below (see Table B.1). Not all listed metrics can be applied to all types of data. Unless e.g. normal distribution of data is verified other methods shall be applied. In case of a great range of variance statistical transformation of data may be required.
- NOTE Both z-score (Z) and the coefficient of variance (C_V) can only be used when data are of continuous type. Not suitable for categorical data sets, which need other appropriate methods of comparison. Such methods are covered by standards which are specific for certain groups of organisms.

Table B.1 — Some methods for assessing limits of confidence

	Abundance	Biomass	Presence/absence ^a
			or Identification
Macro invertebrates	Z / C_V	Z / C_V	Number or % missing or misclassified taxa
Phytoplankton	Z / C_V	ZIC_V	Number or % missing or misclassified taxa
Zooplankton	Z / C_V	ZIC_V	Number or % missing or misclassified taxa
Macrophytes	Z / C_V (only for continuous data) ^b		Number or % missing or misclassified taxa
Fish	Z / C_V (e.g. for fishing effort)	Z / C_V	Number or % missing or misclassified taxa
Phytobenthos (benthic diatoms)	Z / C_V (relative abundance)	Z / C_V	Number or % missing or misclassified taxa
Hydromorphological features	Z / C_V (only for continuous data) ^b	_	Number or % missing or misclassified features

a Includes sorting and identification skills

b Estimator scales, e. g. cover % or occurrence in classes, do not provide continuous data.

Annex C

(informative)

Characteristics associated with measurement procedure in biological investigation methods

C.1 General characteristics

C.1.1 Measurement uncertainty

Measurement uncertainty is a parameter associated with the result of a measurement. It characterises the dispersion of the values that could be reasonably attributed to the measurand. It is additional information on a result, usually a number following a ± symbol. It can also be expressed in graphic form.

It can be used e.g. to decide whether there is a difference between results from different laboratories or from the same laboratory at different occasions.

Values resulting from methods which use estimator scales for quantification need special statistical procedures suitable for this type of data.

C.1.2 Validation

Validation is the process of checking, if the results of application of a biological investigation method or part of a method (e.g. field survey, laboratory taxonomical identification) meet specifications. Independent validation ensures that the validation is performed by an independent examiner (or expert panel).

C.2 Characteristics related to precision

C.2.1 Reproducibility

Closeness of the agreement between the results of measurement of the same measurand carried out under changed conditions of measurement (observer, time, location, instruments, etc.).

NOTE 1 Methodological results produced by a particular surveyor/researcher or group of surveyors/researchers can be evaluated by an independent surveyor/examiner (or expert panel), who is repeating the same method under the same conditions (e.g. same river reach, same seasonal period, same discharge conditions). Upon comparison it shows if the results of the original surveyor/group gives similar results as those of the independent surveyor/examiner (or expert panel).

NOTE 2 Reproducibility always relates to results produced by different surveyors. It can be reported e.g. as a standard deviation (for normally distributed data).

C.2.2 Robustness

Robustness is the quality of a method to withstand changes in circumstance or coping well with – unpredictable – variation (e.g. discharge in a river, turbidity).

C.2.3 Repeatability

Closeness of the agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement.

NOTE This closeness can be expressed as a variation that is smaller than an agreed limit. Repeatability relates to field surveys as well as laboratory investigations and comprises methodology, location, observer and same short period of time.

C.3 Characteristics related to the true value — Representativeness

Representativeness is the degree to which data accurately represent characteristics of a population, variations at a sampling point, or an environmental condition. Representativeness is also the correspondence between a e.g. survey results and the actual condition at a sampling site.

C.4 Procedures related to performance characteristics

C.4.1 General

Performance characteristics can be described for sampling procedures, field survey methods, laboratory based analysis or any other part of methodology. Performance can also be determined for individuals carrying out the same procedure in assessing the type and/or abundance of biota.

C.4.2 Performance

Performance of participants of a test group is compared to the results given by e.g. an independent surveyor/examiner (or expert panel). Results of performance tests can be given as percentage of correct values (e.g. from counting individuals of different aquatic species or from estimator scales when assessing objects in classes), within certain limits (e.g. confidence limits assigned to a specific method).

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