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Water quality — Selection and application of ready-to-use test kit methods in water analysis

Qualité de l'eau — Choix et application des méthodes utilisant des kits prêts à l'emploi en analyse de l'eau

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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 2.

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.

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.

ISO 17381 was prepared by Technical Committee ISO/TC 147, *Water quality*.

Introduction

In water and waste-water monitoring, an appropriate, standardized procedure exists for practically every parameter to be investigated. However, in certain circumstances, the employment of a simpler, faster and often more economical method is preferred, provided that this does not entail a breach of legislation.

This International Standard refers to methods for the analysis of water samples which can be undertaken outside the analytical laboratory, either on-site or as a field test, when the purpose of the test is to characterize the water under test for either quality or control purposes. In the case of determinands which are unstable after sampling, and which cannot be stabilized, ready-to-use methods provide the most suitable means of obtaining reliable test results. The test methods are simple procedures for use by a non-chemist after suitable training as well as by the trained chemist.

The methods described in this International Standard are not intended as a substitute for, or alternative to, other standards on the quantitative analysis of waters, which remain the reference methods for use in the laboratory.

The choice of the most suitable method depends upon the type of analysis required, and on the necessary quality of the results. This International Standard is intended to set out boundary conditions for selecting a non-standardized analytical method and to define the requirements with regard to both the application and the production of ready-to-use methods.

When applying the information contained in this International Standard, highly specialized expert knowledge is required when selecting suitable methods, whereas less stringent demands are made upon the subsequent application, in particular of simplified methods.

Water quality — Selection and application of ready-to-use test kit methods in water analysis

WARNING — Persons using this standard should be familiar with normal laboratory practice. This standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user to establish appropriate safety and health practices and to ensure compliance with any national regulatory conditions.

1 Scope

This International Standard gives guidance on the selection, and requirements for the application, of ready-to-use methods in water analysis. The so-called "ready-to-use methods" are of increasing interest because, compared to standard methods, they allow fast and often inexpensive results for analytical problems. Under certain conditions these methods can be applied in routine control of water quality, provided they give reliable results.

This International Standard deals with practical aspects concerning quantitative ready-to-use methods. Statistical evaluations for establishing the equivalence of ready-to-use methods and standard methods are only mentioned briefly.

As the available ready-to-use methods are based on different analytical principles and also show different degrees of accuracy, they are classified into several groups. The aim of this International Standard is to set up criteria as to when the different kinds of ready-to-use methods may be applied for the analysis of distinct parameters in water samples (e.g. potable water, river water, process water, waste water) and which steps are necessary to prove their suitability for a certain application.

Ready-to-use methods have to meet special requirements because they are often used by non-chemists. This International Standard lists requirements for the producers of these tests, concerning safety and environmental aspects as well as handling and a description of the procedure. There are also several requirements concerning the training and supervision of the users of ready-to-use methods.

2 Normative references

The following referenced documents are indispensable for the application 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 8466-1, *Water quality — Calibration and evaluation of analytical methods and estimation of performance characteristics — Part 1: Statistical evaluation of the linear calibration function*

ISO 8466-2, *Water quality — Calibration and evaluation of analytical methods and estimation of performance characteristics — Part 2: Calibration strategy for non-linear second-order calibration functions*

ISO/TR 13530, *Water quality — Guide to analytical quality control for water analysis*

3 Terms and definitions

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

3.1
reference method
analytical method that is stipulated by law and is usually standardized

3.2
ready-to-use method
analytical method that is ready-made for use, and may be employed in the field with no need for a laboratory

NOTE A more familiar name is "field method".

3.3
decision value
discrete indication of concentration derived from legal, technical and other requirements

3.4
accuracy
degree of agreement of the observed value with the true value of the quantity of interest

NOTE Both random and systematic errors can contribute to a reduction in accuracy.

4 Classification of ready-to-use methods

Ready-to-use methods are characterized by their readiness for use and their suitability for use in the field. As a rule they require less expenditure, less technical equipment and less expertise than the corresponding reference method. Depending upon the nature of the task involved and the method employed, the quality of the analytical results obtained using ready-to-use methods may equal the result gained when applying the corresponding standardized methods.

Ready-to-use methods may be classified according to various different aspects:

a) according to the type of method (e.g. photometric cuvette test, comparator test, test sticks, simple volumetric determination);

b) according to the accuracy of the reading

— of a discrete analytical finding, or

— of a range of results.

Ready-to-use methods are frequently based on standard methods that have been miniaturized to allow their direct application. They may also differ in part from the standard method in their method of detection.

5 Typical areas for the application of ready-to-use methods

5.1 General

Case studies outlining the use of ready-to-use methods in the different areas of application are contained in Annex B. Ready-to-use methods constitute a useful addition to standard procedures in the following areas.

5.2 Screening

Ready-to-use methods may be used for

- preselection of samples for analysis in the laboratory, and
- selection of the most suitable analytical method (concentration range, interferences).

5.3 Faults in waste-water facilities

Ready-to-use methods may be used for rapid detection of the uncontrolled ingress of pollutants in waste-water facilities.

5.4 Accidents with damaging consequences for surface water and ground water

Ready-to-use methods are a particularly useful means of limiting the amount of damage in the event of accidents, due to the rapid availability of the analytical information that they provide.

5.5 Control measurements in waste water, drinking water, swimming-pool water, surface water, water containing fish, and water for maintaining aquatic animal and plant life

Ready-to-use methods are employed, for example, for monitoring compliance with the permissible concentration range for a given parameter.

5.6 Monitoring of processes

Ready-to-use methods can be used to monitor and control processes (e.g. in waste-water facilities, production plants, internal water treatment plants and disinfection systems).

5.7 Testing for the presence of a given substance

The question as to whether or not a given substance (e.g. cyanide in waste water) is present may also be answered by means of ready-to-use methods. The desired detection limit and ability of the test to overcome possible interference from other components in the test sample are the decisive factors in selecting the most suitable ready-to-use method.

6 Selecting an analytical method

6.1 Selection criteria

The following criteria should be taken into consideration when selecting the appropriate analytical method. The decision-making process (see flow chart in Annex A) shall be documented.

A prerequisite is a known parameter.

a) Basic premises:
   - question posed by analysis/aim of determination;
   - parameter definition (individual species, e.g. total Fe, Fe^{2+}, Fe^{3+}).

b) Field of application:
   - concentration range;
   - matrix;
   - method limitations/interferences.

c) Boundary conditions:

— rapidity (in relation to aim of determination);

— mobility (in the field, etc.);

— cost;

— quality target of analysis;

— frequency of use (continuous, once only);

— qualification of personnel;

— legal stipulations;

— availability and/or ease of acquisition.

The criteria shall be weighted differently depending on the intended application. In the case of tasks which are frequently repeated, the most suitable ready-to-use method should be determined, the necessary equipment kept ready, and the procedure documented in a standard work guideline.

6.2 Quality targets

The general quality target of analytical questions is to be able to establish the relationship between the analytical result and its confidence interval on the one hand, and the decision values on the other.

This relationship with the decision values means that the analytical method to be used is subject to requirements regarding the quality of the analytical results. These requirements are task related and shall be defined before the ready-to-use method is applied. The definition of these quality targets forms the basis for the selection of the appropriate method.

7 Requirements for the application of ready-to-use methods

7.1 Requirements for the environment

The environmental conditions and technical facilities should be adequate for the analytical method selected. The relevant laws concerning health and safety at work shall be observed.

Operating procedures for putting methods into practice and the documents mentioned in Clause 8 regarding the quality assurance of analysis shall be kept to hand at the site of analysis.

7.2 Requirements for personnel

7.2.1 Requirements for decision makers

Decision makers are responsible for selecting the analytical method to be employed and for making sure that it is performed correctly, by ensuring that personnel are trained and familiarized with their tasks and by encouraging further training or providing this themselves. They shall also monitor execution of the analysis and the quality assurance measures. The necessary prerequisite for decision makers is that they have recognized qualifications and/or competencies and experience gained in the specific field of work.

Decision makers shall ensure that basic training courses and further training measures for personnel performing analyses are documented in a suitable manner and in such a way that they can be verified at any time.

Together with their subordinate personnel, decision makers determine measures for quality assurance and documentation and agree suitable control measures.

7.2.2 Requirements for personnel performing the analysis

Persons entrusted with performing analyses in accordance with this International Standard shall have passed a basic training course (provided by the manufacturer or the company) demonstrating abilities in and knowledge of the following items:

— performance of tests;

— scope of parameters and matrix influences;

— method limitations/interferences;

— sampling;

— dangers and how to avoid them;

— disposal of waste and waste water;

— quality assurance.

The personnel performing the analysis should attend regular further training courses.

7.3 Requirements for the product

7.3.1 General

This subclause deals with the most important points that should be apparent from the accompanying documentation of a method. All information, either supplied or separately obtainable (enclosed leaflet, application documents, etc.) shall be easily comprehensible and should be written in the country's national language.

7.3.2 Field of application

— parameters (e.g. oxidation state of ion);

— measurement range/graduation; "zero" may not be stated for the lower limit of the operating range;

— matrix;

— matrix interferences, measures to be taken for their prevention or elimination;

— temperature range, pH range;

— storage;

— shelf life.

7.3.3 Basis of the method

— principle of reaction.

7.3.4 How to use the product

— description of supplied reagents (e.g. composition, indications of danger);

- description of supplied equipment, such as test vessel, metering device or colour scale;
- description of how and with which measuring instrument the evaluation may be performed;

and particularly important:

- additional reagents required for the application (e.g. acid for pH adjustment);
- additional equipment required for the application (e.g. thermoreactor for COD).

7.3.5 Sampling and samples

- description of sampling and of sample preparation, if required;
- description of sample quantity and volume.

7.3.6 Performance of measurement

- health and safety;
- handling, step-by-step (pictogram), introduction, training if necessary;
- reaction time (interval);
- ascertainment of results;
- cleaning and maintenance instructions.

7.3.7 Statement of results

- resolution;
- number of figures after the decimal point;
- confidence interval of results; precision;
- conversion table; conversion factors;
- recommended methods of assessing the results.

7.3.8 Disposal instructions

- waste, waste water, hazardous waste;
- return to the manufacturer.

7.3.9 Characteristic data of the method

- calibration in accordance with ISO 8466-1 or ISO 8466-2;
- available certificate of analysis;
- reference to products for quality assurance by the user (control standard, interlaboratory tests).

7.3.10 Literary references

- description of procedure;
- additional information, examples of possible applications.

8 Quality assurance

As is the case with routine procedures which are employed in the laboratory, quality assurance of ready-to-use methods is subject to very different requirements, depending upon the handling and nature of the method in question. In the case of a method which is used regularly (e.g. more than once per week), the same quality assurance measures may basically be used as for the reference method.

These include (see ISO/TR 13530):

- multiple testing;
- measurements of standards and possible reference materials;
- plausibility tests by means of dilution and standard addition;
- comparative tests with reference methods;
- interlaboratory tests;
- keeping a control chart.

NOTE In the case of methods delivering discrete analytical results, Shewhart or Range type control charts (ISO/TR 13530) may be employed, whereas a target value chart is suitable for methods stating result ranges. In the first case, the control values are subject to statistical evaluation. In the latter, the control values are not subjected to statistical evaluation (mean value, standard error, control limits, warning limits) but instead it is decided whether or not they lie within a predefined tolerance range (yes/no decision). In this way, target value charts for blank values, mean values, recovery rates and range can be maintained.

In the case of occasional use (e.g. in the event of a fault in a waste-water facility), the points mentioned above would necessitate an excessive, not goal-oriented, degree of time and expenditure. However, personnel should, as far as possible, be practised in use of the method and it should be characterized in terms of its performance characteristics before it is used for the first time. In certain individual cases, multiple testing, the measurement of standards and plausibility checks through dilution or standard addition are available as simple measures.

Finally, the selection of suitable quality assurance measures depends upon the specific aim of the analysis. The decision concerning the extent of the measures to be implemented, the results of these measures and their assessment, shall be documented.

9 Documentation

The application of this International Standard enables a qualified decision to be made regarding the most appropriate method of analysis for the task at hand. At the same time, however, the decision-making process shall be transparent and verifiable to outsiders. For this reason, thorough documentation is especially important, starting at the beginning of the test and lasting until assessment of the analytical results. Systematic documentation provides objective proof of the quality of analysis.

The minimum requirements for documentation include:

- presentation of decision criteria in accordance with Clause 6 (see examples in Annex B);
- documentation of the qualifications of decision makers and personnel performing analysis;
- documentation of individual quality assurance measures;
- documentation of continuous quality assurance measures;
- sampling record;
- written report of the analysis, including
  - indication of measured values with clear identification of samples, and
  - indication of the product used;
- deviations from the operating procedure, if applicable;
- assessment of results.

Annex A
(informative)

Decision-making process

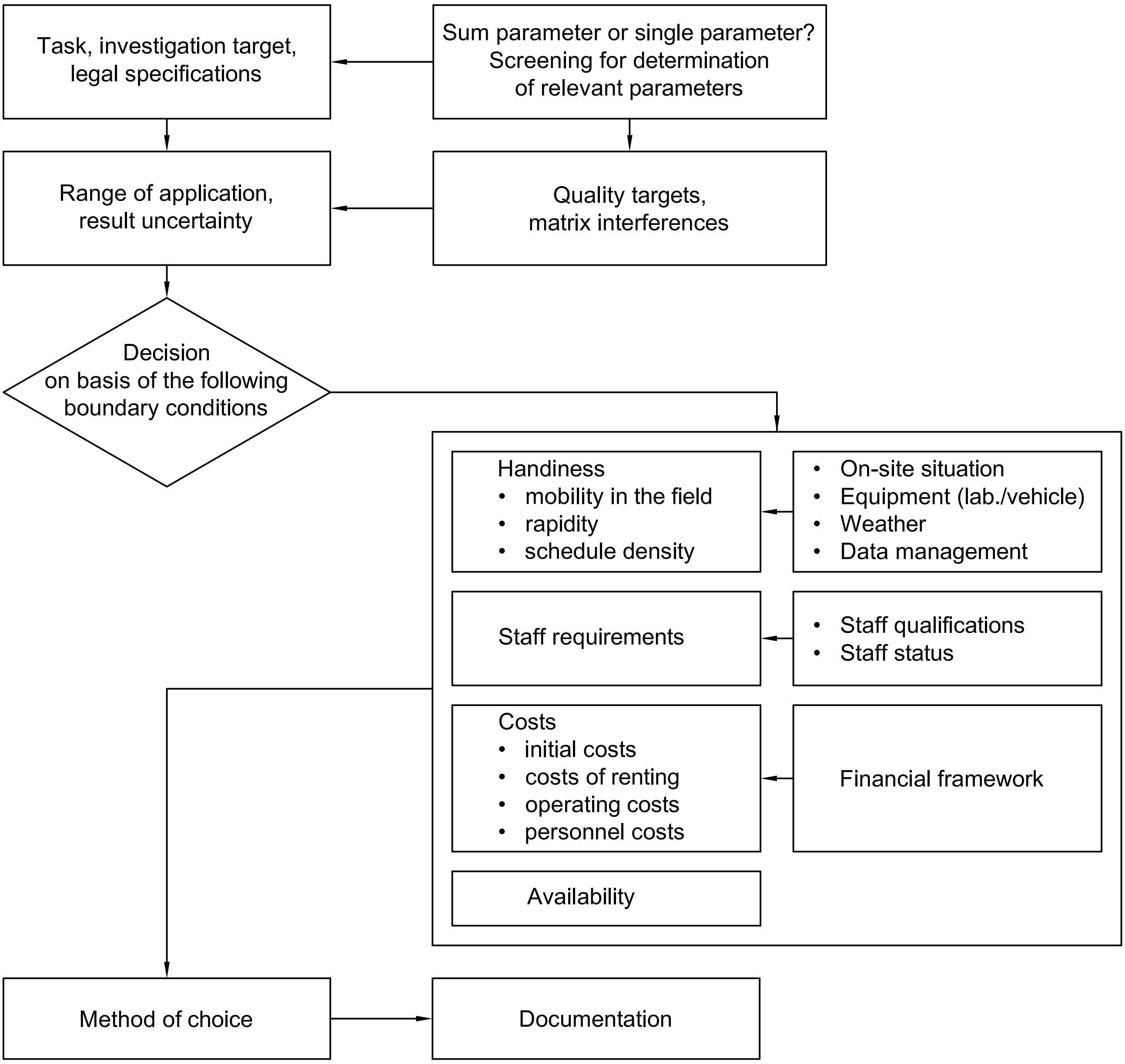

Figure A.1 — Flow chart

Annex B
(informative)

Case studies for the decision-making process

B.1 Case 1: Routine operational monitoring of treatment process (potable water)

B.1.1 Task

To monitor frequently the residual coagulant iron(III) sulfate in final water leaving a water treatment works, to check the efficiency of the treatment process.

B.1.2 Question/Investigation target and definition of parameters

A test kit is required that can determine the concentration of the coagulant ferric sulfate.

B.1.3 Range of application

This needs to cover a range of concentrations from a value near to the limit of detection of the reference method for that determinand to a concentration which is greater than the prescribed concentration or value (pcv), i.e. 0,2 mg/l of Fe.

B.1.4 Boundary conditions

Rapidity:	results within a few minutes.
Mobility:	should be portable.
Cost:	minimal purchase cost plus reagents.
Frequency of use:	variable, from hourly to occasionally.
Legal specifications:	national regulations.
Availability:	photometer or comparator type from laboratory suppliers.
Quality target:	to assure that the decision value is not exceeded.
Personnel:	no formal qualifications, basic training course provided by the manufacturer.

B.1.5 Decision-making process performed by the head of the laboratory (e.g. a chemical engineer)

A simple, easy-to-use test is required that can be used by non-scientific staff to provide regular information on the efficiency of the treatment process.

Regular samples are submitted to a laboratory performing the reference method, but only daily at most, and often only once per week.

Hence the test is used to monitor any changes in residual coagulant during the daily operation of the plant, and the staff have the back-up of the laboratory results and their own quality checks, to monitor the performance of the “ready-to-use” method.

The following tests are selected:

cuvette test: iron (0,05 mg/l to 4,00 mg/l);

colorimetric test: iron (0,05 mg/l, 0,1 mg/l, 0,2 mg/l, 0,4 mg/l, 0,6 mg/l, 0,8 mg/l, 1,0 mg/l).

B.1.6 Quality assurance

Where the test kit or meter is in continuous use, a weekly check should be carried out as follows.

Blank, low and high standard solutions are run to check operator and reagent performance and compared with laboratory results. Standards should be within 20 % and 80 % of range of application.

Where occasional use is required, the above checks should be carried out prior to use, by the person about to carry out the tests.

B.1.7 Documentation

The quality assurance measures, results of analysis, person performing tests, laboratory comparison and any action taken to effect the treatment and its consequences are documented.

B.2 Case 2: Waste-water control

B.2.1 Task

To frequently determine the nutrients ammonium, nitrite and nitrate in waste water, as an important part of the control of sewage treatment plants.

B.2.2 Question/Investigation target and definition of parameters

Test kits are required with the ability to determine the concentration of ammonium-N, nitrite-N and nitrate-N in waste water.

B.2.3 Range of application

Ammonium-N: the determinand shall be measured in concentrations above 1 mg/l.

Nitrate-N: the determinand shall be measured in concentrations above 1 mg/l

Nitrite-N: the determinand shall be measured in concentrations above 0,1 mg/l.

Depending on the type of waste water, other application ranges should be used.

B.2.4 Boundary conditions

Rapidity: results within a few minutes.

Mobility: should be portable.

Cost: low purchase cost plus reagents.

Frequency of use: variable, from hourly to occasionally.

Legal specifications: for example, according to the regulations of the Federal Republic of Germany, ready-to-use methods are admitted for

— *legal control*: effluent control by the environmental authorities of the state,

— *self control*: by the operator of the sewage treatment plant.

NOTE State regulations prescribe decision values for ammonium and TIN (total inorganic nitrogen). The TIN is calculated by the formula: TIN = NH_4-N + NO_2-N + NO_3-N.

Availability: small-scale/sealed tube photometric/colorimetric system or comparator type from laboratory suppliers.

Quality target: to test if the decision value

— is definitely exceeded, or

— is definitely not exceeded.

Personnel: referring to the *legal control*, the tests are performed by sampling teams consisting of two persons. One of them is a chemical or environmental engineer.

referring to the *self control*, the tests are performed by the staff of the obligatory effluent laboratories.

It is recommended that each effluent laboratory install a small test room (laboratory) for analysing field parameters.

Basic training course for the personnel should be provided by the manufacturer.

According to analytical quality control, the personnel of the *legal control* are frequently trained by the environmental agency of the state. The personnel of the effluents (*self control*) are trained by the environmental agency too, on a voluntary basis.

B.2.5 Decision-making process, performed by the head of the laboratory (e.g. a chemical engineer)

A simple, easy-to-use test is required that can be used by non-scientific staff to provide regular information on the efficiency of the waste-water treatment process.

Regular samples are submitted to a notified laboratory performing the reference method. Comparison tests between test kits and the corresponding reference methods are prescribed, but there is no prescription for the frequency of the comparison tests.

NOTE Notification is a special German procedure (comparable with accreditation) to confirm the competence of an analytical laboratory.

The results obtained by the ready-to-use tests are handled in the following way.

a) If the results assure definitely (considering the estimated inaccuracy of the results [see item d) of B.2.6]) that the decision value <u>is not exceeded</u>, a further analysis of the samples by reference methods is not necessary. The legal requirement is fulfilled. No further activities are undertaken.

b) If the results assure definitely (considering the estimated inaccuracy of the results [see item d) of B.2.6]) that the decision value <u>is exceeded</u>, a further analysis of the samples by reference methods is not necessary. The legal requirement is not fulfilled. According to the legislation, further activities are undertaken.

c) If the results (considering the estimated inaccuracy of the results [see item d) of B.2.6] do not definitely indicate whether or not the decision value is exceeded, the sample has to be analysed immediately with the corresponding reference method in a notified laboratory.

B.2.6 Quality assurance

Where the test kit or photometer is in continuous use, a weekly check should be carried out as follows.

a) In principle, AQC is performed in the same way as in the case of a reference method.

b) Blank, low and high standard solutions are run to check operator and reagent performance and compared with laboratory results. Standards should be 20 % and 80 % of the range of application.

c) Where occasional use is required, the above checks should be carried out prior to use, by the person about to carry out the tests.

d) An estimation of the expected/maximum inaccuracy of the ready-to-use tests should be available.

B.2.7 Documentation

The quality assurance measures, results of analysis, name of person performing tests, laboratory comparison and any action taken to effect the treatment and its consequences are documented.

B.3 Case 3: Ship accident

B.3.1 Task

A ship with a cargo, which probably consists of salts, sank in a river and broke apart. The alarm service of the responsible authority is informed and is to execute incident analysis.

B.3.2 Question/Investigation target and definition of parameters

The assumption that the accident involves the accidental spilling of salts is acknowledged. Downstream of the accident site, chloride and sulfate are to be determined, in order to be able to estimate the distribution process of the salts.

B.3.3 Range of application/Measuring range/Matrix/Interferences

Normal salt contents of the Rhine: approx. 150 mg/l chloride, less than 150 mg/l sulfate. Expectancy value of the analysis after accident: approx. 1 000-fold increase in salt contents. Therefore dilution probably necessary due to potential pollution by constituents of the cargo.

B.3.4 Boundary conditions

Rapidity:	required.
Cost:	not relevant.
Mobility:	required, on-site investigation.
Frequency of use:	once.
Availability:	test sticks, cuvette tests.
Legal specifications:	none.

Quality target: sufficient to observe the concentration gradient.

Personnel: alarm service is provided by trained laboratory technicians.

B.3.5 Decision-making process, performed by an alert official (chemist)

High speed is required. It is not appropriate to wait for laboratory analysis but to use mobile methods available in the vehicle (cuvette test and test stick available). Since a concentration process is to be examined, preference is given to a cuvette test because of the higher accuracy. The application of test sticks would be less expensive. The test sticks are used nevertheless, in order to allow for a preliminary decision on the dilution. The staff fulfils the necessary qualification; legal specifications do not exist.

The following tests are selected:

test stick:	chloride (500 mg/l to 3 000 mg/l)	sulfate (200 mg/l to 1 600 mg/l).
cuvette test:	chloride (70 mg/l to 1 000 mg/l)	sulfate (150 mg/l to 900 mg/l).

B.3.6 Quality assurance

Since a single application is concerned, individual measures apply. For the test sticks, no quality assurance is necessary, since they serve only for the preliminary investigation. For the cuvette tests, a standard solution is used in the range of application of the tests. Because of possible matrix interferences, a plausibility check is made by dilution.

B.3.7 Documentation

The decision-making process, the quality assurance measures, the results of analysis and the evaluation are documented.

B.4 Case 4: Cooling lubricant

B.4.1 Task/Legal stipulation

Technical Regulations for Hazardous Substances (Technische Regeln für Gefahrstoffe) TRGS 611 describe restrictions regarding the use of cooling lubricants which may be or are mixed with water, during the use of which N-nitrosamines may occur.

B.4.2 Question/Investigation target and definition of parameters

Which are the means to avoid the formation of carcinogenic substances? Which triggering elements, such as secondary amines, nitrate and nitrite, are simple to monitor? The parameters nitrate and nitrite appear the obvious choice as their presence can be demonstrated using test sticks and their use is permitted.

B.4.3 Range of application

Nitrates and nitrites should be monitored in the ranges of application

NO_3^- : < 25 mg/l, < 50 mg/l, > 50 mg/l, and

NO_2^- : < 10 mg/l, < 20 mg/l, > 20 mg/l.

B.4.3.1 Matrix/Interferences

Cooling lubricants consist of emulsions, the milky nature of which has little influence on the colour reading of the test sticks. Reference to additional clarification precipitation using $K_4[Fe(CN)_6]$ and $ZnSO_4$ (Carrez's solution), as required for photometric measurements, may prove helpful.

B.4.4 Boundary conditions

Rapidity:	no preparation of samples, short reaction time (<1 min).
Mobility:	required.
Cost:	minimal purchasing costs only.
Frequency of use:	daily.
Legal specifications:	national regulations.
Availability:	obtainable from laboratory suppliers. Test sticks for nitrate and nitrite are also available everywhere at aquarium suppliers and in do-it-yourself stores.
Quality target:	to assure that the decided value is not exceeded.
Personnel:	no formal qualifications, basic training course provided by the manufacturer.

B.4.5 Decision-making process, performed by technical management under support of scientific consultant

Monitoring represents a *legal requirement*. The preparation of samples for the application of cuvette tests is extremely broad ranging. The accuracy and sensitivity that can be achieved are not required here. Checking the colour scales of the test sticks is sufficiently accurate. Test sticks are mobile, readily available and inexpensive. Employees do not need to be qualified.

B.4.5.1 Selected method

The following test sticks are selected:

— nitrate (e.g. 10 mg/l to 25 mg/l to 50 mg/l to 100 mg/l NO_3);

— nitrite (e.g. 5 mg/l to 10 mg/l to 20 mg/l to 40 mg/l NO_2).

B.4.6 Quality assurance

A once-only check requires an individual procedure. For regular use of test sticks (see Clause 8), comparability with the reference method should be checked regularly for the purpose of quality assurance. A plausibility test through addition of a standard is to be undertaken due to unwanted matrix interferences which may arise.

B.4.7 Documentation

The definition of quality assurance, the analytical results and the assessment are documented.

ICS 13.060.45

Price based on 15 pages