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Water quality — Sampling —

Part 24: Guidance on the auditing of water quality sampling

Qualité de l'eau — Échantillonnage —

Partie 24: Lignes directrices pour l'audit de l'échantillonnage de la qualité 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.

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 147, *Water quality*, Subcommittee SC 6, *Sampling (general methods)*.

ISO 5667 consists of the following parts, under the general title *Water quality — Sampling*:

— *Part 1: Guidance on the design of sampling programmes and sampling techniques*

— *Part 3: Preservation and handling of water samples*

— *Part 4: Guidance on sampling from lakes, natural and man-made*

— *Part 5: Guidance on sampling of drinking water from treatment works and piped distribution systems*

— *Part 6: Guidance on sampling of rivers and streams*

— *Part 7: Guidance on sampling of water and steam in boiler plants*

— *Part 8: Guidance on the sampling of wet deposition*

— *Part 9: Guidance on sampling from marine waters*

— *Part 10: Guidance on sampling of waste waters*

— *Part 11: Guidance on sampling of groundwaters*

— *Part 12: Guidance on sampling of bottom sediments*

— *Part 13: Guidance on sampling of sludges*

— *Part 14: Guidance on quality assurance and quality control of environmental water sampling and handling*

— *Part 15: Guidance on the preservation and handling of sludge and sediment samples*

— *Part 16: Guidance on biotesting of samples*

— *Part 17: Guidance on sampling of bulk suspended solids*

— *Part 19: Guidance on sampling of marine sediments*

— *Part 20: Guidance on the use of sampling data for decision making — Compliance with thresholds and classification systems*

— *Part 21: Guidance on sampling of drinking water distributed by tankers or means other than distribution pipes*

— *Part 22: Guidance on the design and installation of groundwater monitoring points*

— *Part 23: Guidance on passive sampling in surface water*

— *Part 24: Guidance on the auditing of water quality sampling*

Introduction

The sampling and analysis of drinking water supplies is one of the key elements in the protection of public health. Environmental sampling from rivers and other surface waters; sampling of discharges such as treated sewage effluents and trade discharges; and sampling of water used for non-potable purposes can also have a significant impact on public health, occupational hygiene and asset durability.

One of the major sources of error in gathering water quality monitoring data can be the sampling process. Poor sampling practices create problems for those interpreting results and can lead to costly and incorrect decisions. Failure to manage factors such as *Cryptosporidium* levels in drinking water, pneumonia caused by Legionella and heating system corrosion are examples of where failures of quality control/assurance in the sampling process can lead to expensive and potentially life-threatening consequences.

Auditing of water quality sampling identifies both positive and negative attributes of the management chain. Thus, the goal of a sampling audit is to emphasize the effectiveness of "best practice" and to build up a knowledge base to allow its dissemination within the organization.

No audit is ever intended to cover every aspect of water quality sampling and it is advisable to adopt a risk-based approach to designing the audit programme to ensure that high-risk issues are covered more frequently, and in greater depth, than low-risk issues. For example, it is essential that all high-level documentation, which covers sampling policy and strategy, training policy and health and safety policy, is checked during the first audit, along with its implementation on the ground. Where implementation documents are also produced at a high-level (sampling manuals, training manuals, etc.) they might be regarded as high-level documents for the purpose of designing the audit programme. Providing there are no issues arising, this documentation would only need detailed checking on subsequent audits if any changes have been made during the interim. However, it would still be prudent to check that any issues identified during the initial audit have been addressed satisfactorily; that any other changes are appropriate; and that the circumstances of sampling have not changed in such a way that a revision of these high-level documents is needed.

Larger organizations might wish to either audit fully high-level documentation at regular interims (e.g. every four years) or to audit different parts of the documentation on a rolling programme. They might also wish to consider a regular programme of auditing the dissemination of changes to high-level documentation as these could take time to work their way down to the sampling practitioners/operatives and their managers, especially where there is a large geographical spread and sampling is not the main function. This is rarely a problem in small organizations where the person responsible for writing the high-level documents is usually also responsible for managing, if not carrying out, the sampling.

Risks of nonconformity at sampling locations can vary markedly, and the frequency and extent of each audit needs to reflect this. Some organizations sample only in very closely controlled environments, where purpose-built sampling taps are provided. Here the risk of nonconformity is very low, but, at the same time, a very high degree of conformity can be expected. Other organizations take samples in environments which vary and which are often far from ideal, making compromise necessary. The audit might identify a number of risks of nonconformity with the documented procedures, but allowances have to be made for any guidance given to the sampling practitioner/operative and the process by which a satisfactory compromise is reached and recorded.

The key point in designing an audit programme is to ensure that the effort spent on auditing is proportional to the risk and the size of the organization. The programme is therefore refined in the light of experience.

Water quality — Sampling —

Part 24: Guidance on the auditing of water quality sampling

IMPORTANT — It has been assumed in the preparation of this International Standard that the execution of its provisions will be entrusted to appropriately qualified and experienced people, for whose use it has been produced.

1 Scope

This part of ISO 5667 provides an audit protocol to monitor conformity with declared, or assumed, practices in all areas of water quality sampling. Specifically, this part of ISO 5667 provides guidance on the systematic assessment of sampling practices and procedures in the field, and assessing conformity with those given in the organization's sampling manual. It is applicable to the audit of sampling activities from the development of a sampling manual through to the delivery of samples to the laboratory.

NOTE 1 The design of the sampling manual is the prerogative of the data user and this part of ISO 5667 is not intended to deliver criticism of a manual's structure.

This part of ISO 5667 is applicable to sampling practices associated with wastewaters, including discharges to water bodies, environmental monitoring, potable water supplies from source to tap, commercial and industrial uses of water, and power generation.

This part of ISO 5667 is applicable to the auditing of sampling practices relevant to the management of water stored in containers, such as temporary supply tanks and bottled supplies. However, it is not applicable for the auditing (or calibration and maintenance) of on-site test equipment or kits.

NOTE 2 BS 1427 covers water test kits used "in the field".

The following sampling occasions are excluded from both the field- and desk-audit procedures set out in this part of ISO 5667:

a) chemical and microbiological incidents, which are investigated by agencies such as the emergency services, e.g. where an immediate risk to the health of the sampling practitioner/operative is evident;

b) radiochemical sampling of water quality, other than that specified as a routine requirement under the UK Water Supply (Water Quality) Regulations,[9][10][11][12] i.e. radiochemical incidents which are investigated by agencies such as the emergency services.

Informative Annex A contains a series of forms to assist with auditing. These are for guidance only. Informative Annex B gives procedures for monitoring temperature control, while Informative Annex C provides guidance on measuring the uncertainty associated with sampling practices.

2 Normative references

There are no normative references cited in the document.

3 Terms and definitions

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

3.1
audit
formal examination of the organization's processes and procedures as a means of identifying critical operational risk to sample and data integrity generated during the collection of samples

Note 1 to entry: ISO 19011 can be used for auditing of sampling.

Note 2 to entry: ISO/IEC 17025:2005, 5.7, introduces specific requirements for sampling.

3.2
audit conclusion
overall conclusion of the impact of water quality sampling practice on data quality

Note 1 to entry: Such a statement can be judgemental rather than based on any statistical consideration, and depends on the audit plan.

3.3
audit coordinator
member of the audit team nominated to liaise with the responsible person and to coordinate the overall audit process where an audit involves more than one auditor

3.4
audit detection risk
probability that the audit will not identify a nonconformity during the period of assessment

Note 1 to entry: BS 4778–3.1:1991 defines risk as a "combination of the probability, or frequency, of occurrence of a defined hazard and the magnitude of the consequences of the occurrence." A mathematical interpretation of this definition is risk = hazard × probability of the hazard happening.

3.5
auditor
person who undertakes an audit of the organization's documented water quality sampling practices and procedures and reports on conformity to these

Note 1 to entry: Ideally, the auditor will have operational experience of the type of work being carried out by those being assessed.

3.6
audit plan
plan designed to evaluate conformity with a predetermined set of criteria

Note 1 to entry: The plan can be solely or a combination of risk-based and judgemental components.

3.7
audit prioritization
process where, for the purposes of constructing an audit plan, a single or multiple risk factor is identified in the sampling regime as requiring further investigation

3.8
conformity
occasion when the observed practice matches the objectives and prescribed techniques set out in the relevant sampling procedure/policy

3.9
controlled document
document controlled as part of a quality assurance scheme

3.10
data quality risk
expression of a failure in sampling practice(s) likely to impact on the results of the sample testing and/or their interpretation

3.11
data user
person who uses information gathered during the sampling process

3.12
delivery
transport and custody transfer of the sample as accounted for by a documented process

Note 1 to entry: This can take the form of a sign-off sheet (including that for field measurements) or a vehicle log. Where unattended overnight storage of the samples is deemed the point of handover to the laboratory, custody proof of delivery is regarded as documentary evidence of deposit.

3.13
information provider
person, who can be the responsible person, from whom an auditor can obtain information during the execution of an audit

3.14
judgement-based auditing plan
plan where the audit detection risk cannot be measured statistically

3.15
laboratory
location where a sample is assessed or analysed for the parameter of interest

Note 1 to entry: This could include, for example, the point at which a field test is performed, and covers mobile laboratories. BS 1427 distinguishes between tests that can be performed without a dedicated room as on-site tests and tests that need a designated test room/facility because the tests require high temperatures, hazardous reagents, etc.

3.16
nonconformity
occasion when the observed practice does not meet the objectives and prescribed techniques set out in the sampling policies and procedures, and requires mitigation

3.17
real-time audit
audit processes separate from document auditing

Note 1 to entry: For example, observing practices and processes in the field.

3.18
responsible person
person nominated by the organization to provide the appropriate interface with the auditor

Note 1 to entry: The responsible person may or may not have overall control of sampling quality and logistics.

Note 2 to entry: A responsible person in the context of ISO 5667-24 is not the same as the responsible person under good manufacturing practice.

3.19
risk-based auditing plan
plan where the audit detection risk can be statistically measured

3.20
sampling
collection of water or related material for quality determination purposes

3.21
sampling manual
document or series of written protocols which set out the manner in which samples are to be collected

Note 1 to entry: A sampling manual, which precisely defines how the data will be collected by the sampling practitioner/operative(s) is necessary to ensure the data are provided in the correct form to conform to a sampling programme. It is prescriptive to the organization and provides detailed instructions to the sampling practitioner/operative taking the samples. The document(s) may or may not be controlled.

3.22
sampling occasion
process of collecting a sample from a designated point, starting at the point of receiving an instruction to take the sample and ending with the delivery of the sample to a laboratory

3.23
sampling operative
person who takes samples, but not necessarily at practitioner level

3.24
sampling practitioner
person who specifies the sampling requirements, but is also able to take samples

3.25
sampling programme
scheme which sets out a data need and how it is to be used

3.26
sampling schedule
written instruction which defines the number and type of samples to be taken within a defined geographical area over a predetermined period of time, usually based on the sampling programme

3.27
uncontrolled document
document not controlled as part of a quality assurance scheme

3.28
unscheduled action
breach of procedure documented in the sampling manual, which has not been identified as a risk factor but which (in the judgement of the auditor) represents a nonconformity

EXAMPLE For example, a sampling practitioner/operative might carry out a practice which (in the opinion of the auditor) is a risk to sample integrity but is not prohibited by the sampling manual.

3.29
unscheduled observation
observation made by the auditor to allow a categorical statement to be made in the audit report to address a specific concern

EXAMPLE Stating that a particular process was completed satisfactorily on all observed occasions.

4 Multiple audits

Most audits are likely to involve a single auditor. However, situations might arise when an audit involves more than one auditor; for example, where multidisciplinary audits or multiple audits are being carried out. In such cases, a member of the audit team should be nominated to liaise with the responsible person and to coordinate the overall audit process. They would be the main point of contact between the audit team and the responsible person and would be responsible for arranging the various meetings, for consolidating the audit report, and for coordinating responses to any follow-up actions on recommendations arising from the audit.

Prior to the audit the audit coordinator and the responsible person would need to set out the audit objectives, which would then be communicated to the other members of the audit team along with an outline audit plan. The audit team would then need to prepare a consolidated pre-audit questionnaire so that the audit coordinator can arrange with the responsible person for the various documents to be distributed as appropriate. Each team member would be responsible for completing the relevant audit assessment forms for their section(s) of the audit and the completed forms would be brought together by the audit coordinator to form the audit report and statement of findings. All members of the audit team should attend the opening and closure meetings.

5 Auditing objectives

Before drafting an audit plan, the auditor (or audit coordinator in the case of an audit team) and the responsible person need to agree on the objectives of the audit. This would usually take the form of an iterative process between both parties.

The primary purpose of setting such objectives is to determine whether the process of sampling imposes any adverse impacts on data integrity. Thus, the objectives should be specific to the organization, although, in general, auditing objectives tend to fall into two categories, namely:

a) those for internal audits used to examine the efficacy of standard operating procedures and management control of a sampling process;

b) those for assessing conformity with stated objectives by a third party, such as an accreditation body, or a different department within an organization.

The depth of the proposed audit also needs to be agreed; for example, establishing whether the audit is intended to be a high-level assessment of the management system or a specific assessment of training uptake in the field. A modular approach might therefore be more appropriate. This would reduce the need for unnecessarily frequent reviews of the entire management process, where a shortened audit for routine operator screening would be sufficient. It is recognized that some auditing objectives represent standing issues, irrespective of the organization's specific needs. For example, the need to ensure data integrity to achieve the organization's primary function (e.g. maintenance of public health). Conversely, a floating, or transient, objective might be to concentrate the audit on the influences of a particular parameter grouping, such as sampling for pesticides or microbiological quality in relation to a standing objective.

The objectives for an audit being carried out by an external body are likely to be defined by a need to assess conformity with minimum requirements, possibly set out in a contract or as a statutory obligation. However, for internal use the auditor is likely to be assessing matters for related, but different, reasons (for example, determining training needs, or process preparedness in advance of an external audit, or in response to a management objective for key performance indicators). Both external and internal audits have the same primary objective of determining whether the process of sampling imposes any adverse impacts on data integrity.

Examples of possible objectives are given as follows, although this is not an exhaustive list or a minimum set of criteria:

a) to examine the efficacy of standard operating procedures and management control of a sampling process for both routine and non-routine sampling;

b) to follow an audit plan designed to evaluate conformity with a predetermined set of criteria;

c) to identify strengths and weaknesses in training;

d) to check on the efficacy of established processes and protocols;

e) to address a particular problem identified through some other means, e.g. data quality issues;

f) to ensure that appropriate procedures and practices exist for different sample types;

g) to take account of sampling practitioner/operative health and safety;

h) follow-up from a previous audit to determine whether actions put in place have addressed nonconformities identified;

i) in the case of external audits, for assessing conformity with stated objectives by a third party, such as an accreditation body, or a different department within an organization;

j) to assess conformity to minimum requirements, possibly defined in a contract or as a statutory obligation.

It is recommended that audit objectives are documented within the audit plan, using, for example, Form A2 in Annex A.

6 Internal audit objectives

Internal audit objectives should recognize the need to improve sampling efficiency in terms of logistics, while ensuring that sample integrity is maintained. Internal audit objectives should also include consideration of the health and safety of the sampling practitioners/operatives. While these factors are important to an organization, they might not be the primary concerns of a third party auditor whose brief is to consider sampling in the context of a specific goal of the organization.

When planning an internal audit, agreement should be reached between the auditor and the manager responsible for sampling so that the organization can gain the maximum benefit from the exercise. For example, if a stated objective of the audit is to identify training needs, then it is important to have prior agreement with the line manager on how the outcome of the audit is reported, so that staff communication issues can be managed effectively.

It is equally important to establish audit objectives for conformity with the needs of opportunistic or unscheduled sampling; for example, an incident involving a trade effluent spillage. Given the relative rarity of such occasions, the process should always be evaluated if such an event occurs during an internal audit.

7 External audit objectives

Third parties are likely to have undisclosed criteria for the detail of the audit and are unlikely, therefore, to discuss detailed objectives with line managers. However, it is reasonable to expect broad audit objectives to be given, which are either stated or obvious; for example, the protection of public health though sampling integrity.

8 Identification of the critical factors in the water quality sampling process

8.1 Identification of critical operational steps

The auditor should identify critical operational steps in the sampling manual and adopted technical guidance to highlight the most vulnerable sampling step in terms of:

a) chain of custody, as appropriate;

b) sample integrity;

c) introduction of unnecessary deviations of uncertainty;

d) whether the sample is representative of the body being sampled;

e) data transfer to data users;

f) storage, sample container, transport, sample conditions, and time from sample collection and analysis;

g) maintenance of sampling locations and sample characteristics.

NOTE These steps are not listed in any particular order.

8.2 Audit prioritization exercise

Before the real-time audit commences, it is recommended that the sampling process is examined as a paper exercise in order to identify clearly the primary technical factors to be assessed during an audit. Each step identified in the various data capture forms can then be allocated an audit prioritization. Examples of such forms (A3, C1, C2 and C3) are provided in Annex A.

Ideally, the allocation of significance to these steps should be based on high or low risk to sample integrity if the operation is not carried out as intended.

EXAMPLES

— High risk: washing preservative from a pre-prepared sample container.

— Low risk: the use of ice packs in a cool box, rather than a specified temperature-controlled compartment in a vehicle.

The final assignment of significance should be based on the professional judgement of the auditor, taking into account the specific sampling practice under examination. In the case of a multiple audit, the auditing team would need to adopt a uniform approach towards their calibration of risk prioritization in order to avoid introducing personal bias. This exercise could be carried out as a one-off occurrence by an auditor or audit team and the risk levels assigned in advance for all subsequent audits, to be reviewed periodically as required (e.g. at the beginning of a major audit exercise or when the audit team changes).

Consideration of health and safety matters requires qualification of special risk assessments; specifically, whether safety considerations compromise the sampling event, or vice versa. No sample is worth breaching health and safety requirements.

Audit prioritizations should be documented and recorded within the data capture forms in order to gain maximum benefit, especially if corrective actions are required. They should also link back to the audit objectives (see Annex A, Form A2).

The auditor (or audit team) needs to look at situation-specific audit prioritizations when carrying out the pre-audit exercise, as these might identify critical deviations that require immediate action on completion of the audit. This is in contrast to other nonconformity rankings, which would need amendment before the subsequent assessments.

EXAMPLES

— Correcting a particular sampling practitioner/operative’s habit of washing preservatives from a pre-prepared bottle (high priority ranking) compared to certain types of labelling errors, which might attract a lower ranking.

— Illegible labelling of routine samples, while a nuisance to the organization, can be regarded as a low risk to data quality, because it is detectable and would allow the laboratory to reject the sample.

It is also recommended that the audit prioritization exercise includes a comparison by the auditor(s) of the sampling locations visited against records and assessments made by the organization as part of its sampling manual.

8.3 Unscheduled observations

During the course of an audit, situations could arise that are not covered fully by the audit objectives. For example, a data set might exhibit a higher variability in the results for certain metals, which cannot easily be explained by examination of analytical procedures. One of the objectives of the audit could therefore be to examine all parts of the sampling process that might influence the presence of metals, such as copper, in the sample. Thus, the audit plan should be designed to examine likely causes of contamination, or relative dilution arising from the sampling process. In an ideal situation, the sampling practitioner/operative

should report any problems observed with the sampling line and/or tap that might affect the result. However, if the sampling practitioner/operative is unaware that there could be a problem and there is no requirement in the sampling manual for them to report on the condition of the sampling line or tap, then it might be left to the auditor to subsequently report evidence of corrosion. Such unscheduled observations should be addressed within the audit report (see, for example, Form D.2 in Annex A).

NOTE All unscheduled observations are likely to have the same significance in terms of addressing problems identified to those which an audit has been designed to assess.

It is not anticipated that unscheduled observations be prioritized in general. However, their significance can be prioritized, in terms of the urgency of the mitigation measures that might be required.

8.4 Follow-up actions

The onus is on the responsible person to ensure that the organization is made aware of, and takes appropriate follow-up actions on, any deficiencies identified during the audit. Such actions should be carried out within an acceptable timescale, agreed with the auditor(s).

9 Risk-based versus judgement-based approaches to auditing

9.1 General

A decision should be taken on the evaluation of observations made during the audit which could pose a risk to the integrity of the sampling process. A risk-based approach provides a measurable and controllable audit detection risk, whereas a judgemental approach does not provide the same degree of numerical clarity of audit detection risk.

Auditing of the sampling occasions is the same, whichever approach is used, as both require the auditor to exercise judgement during the development and subsequent execution of the plan. In other words, the use of statistical methods does not eliminate the need to exercise judgement.

In most situations, a judgement-based approach is likely to be taken for audits of single sampling occasions. However, in some circumstances, a risk-based approach could be more appropriate. Therefore the audit objectives should first be determined before deciding which approach to adopt.

9.2 Risk-based auditing

A decision on the approach to use should be taken after identifying the population characteristics of interest and determining the acceptable degree of nonconformity risk (for example, whether or not it is acceptable that fewer than 95 % of sampling occasions conform to the prescribed procedures).

If an organization seeks to audit a range of sampling occasions (for example, routine and/or ad hoc), it is inevitable that some processes need to be judgementally assessed while other more routine monitoring is more amenable to risk-based assessments. However, risk-based auditing requires a well-defined data set in order to provide sufficient information for statistical analysis, and this tends to limit its use to larger organizations that have carried out, or intend to carry out, multiple audits. It is likely that there will be justification for mixing the two types of approach with any audit plan. The audit report therefore needs to identify clearly which types of auditing are referred to, relative to the findings, conclusions and recommended corrective action.

The risk-based approach adds value to a quality assurance scheme by providing assurances that the overall sampling processes, controls and outcomes are effective at reducing the influence of sampling errors. This evidence might be provided in the form of numerical statements of confidence that can be applied to the audit outcome. However, the use of a risk-based plan does not mean that the auditor will alter the procedures designed to collect evidence.

9.3 Judgement-based auditing

Judgemental auditing is a necessary technique when observations are made on the basis of a single sample being taken. This could be during a routine sampling occasion or a one-off situation (for example, to demonstrate a breach of a trade effluent consent). A judgement-based audit plan in this context might be that each individual responsible for sampling such events is assessed annually for conformity with a written procedure. In this case, the primary audit is likely to be carried out by a line manager, or peer, who happens to be nearby when the sampling event occurs. An external audit might then be required to find the evidence of such an assessment and the associated document trail recording the conformity or otherwise.

9.4 Auditing assumptions

A list of assumptions should be constructed during the development of the audit plan, which will allow a rational qualification of any numerical or subjective claims made in the final audit report. Such an assumption might be that all sampling practitioners/operatives are trained and, if not, that the audit is carried out accordingly.

Ideally, the number of individual sampling practitioner/operatives audited should be representative of the total number within the organization. Where possible, the number assessed should reflect a 95 % confidence level that a nonconforming sampling practitioner/operative could be identified. These priorities might change with follow-up audits or through regular internal audits. However, an external auditor might only be in a position to inspect the findings of such evaluations to assess conformity with a desired standard.

10 Document auditing

NOTE This area of auditing is entirely desk-based. It comprises the examination of documents relating to the seven key areas of interest (described in 10.1 to 10.7), which are required to ensure a continued chain of custody and effective transmission of site information in respect of sampling processes. Included in this are documents relating to the taking of formal samples in the case of breach of a statutory duty.

10.1 Sampling programme and sampling practitioner/operative instruction documents

Any individual or organization with water quality data requirements should produce a sampling programme that defines, as a minimum, the material identity and the date and location of the samples to be taken. This information forms the basis of the sampling schedule, which, along with any requirements for ad hoc samples, provides specific instructions to the sampling practitioner/operative. The audit should ensure that the documentation presented to the sampling practitioner/operative clearly identifies any variations required by the data user, relative to dependent options on the sampling schedule. This should include details about the sample that allow specific definitions to be used in the interpretation of the laboratory results.

EXAMPLE

“The drain should be sampled at the point of discharge to the river. An additional sample of the river should also be collected upstream of the confluence with the pipe, when the drain is flowing.”

10.2 Sampling manual

10.2.1 General

The sampling manual should address the specific sampling requirements of the organization. It should conform to appropriate guidance, such as ISO 5667-1, and provide detailed instructions to sampling practitioners/operatives. The manual can be a single document or consist of a series of standard operating procedures or protocols (SOPs) that address a variety of sampling functions (for example, potable water, wastewater and marine or industrial waters). A section dealing with generic

requirements such as health and safety should be available, but not necessarily form an integrated part of the manual.

The manual may be in hard copy or held electronically. Ideally, it should be a controlled document and contain a log sheet to record all amendments, who implemented them, and the date they were distributed to authorized holders. A master record sheet should be maintained by the process owner, who might or might not be the responsible person. This should detail who has received amendments and when they were issued to them.

In small organizations, the sampling manual might take the form of a project-specific collection of documents from various sources; for example, instructions from the laboratory on how to fill sample bottles.

The manual should be issued to all personnel who are likely to be involved in the taking of samples, along with any other documents related to the project that provide relevant or required information for the sampling practitioner/operative.

Where the sampling manual is issued as a controlled document, a detailed assessment should be carried out during first audit. If no nonconformities are identified, subsequent audits would need only to assess any revisions or updates.

10.2.2 Contents

The contents of the manual should identify

a) the sample type (e.g. water, sludge, sediment) and the test parameters for which information is to be gathered,

b) equipment requirements,

c) time and spatial requirements,

d) preservation (including the type of sample and instruction for the sample pre-treatment method) and handling needs (including instructions on bottle filling and decontamination needs for collection equipment between locations),

e) procedures and techniques to be deployed (e.g. aseptic collection, dip samples, uncertainty estimation),

f) on-site testing needs, with specific instructions on sample handling for that purpose, together with instructions on how reporting is to be carried out, and

g) health and safety requirements and constraints.

The manual may also specify

— how, and where, equipment is to be cleaned and stored between sampling occasions,

— the chain of management communication and reporting, and

— an operating procedure for the storage of containers prepared/purchased for specific uses; such a protocol should document how storage facilities are to be maintained commensurate with those intended uses and by whom.

The auditor should exercise judgement on 3 items above, giving due regard to the size of the organization, the frequency at which samples are taken, and the location where the sampling equipment is stored. On some occasions, the sampling equipment and bottles are delivered by a laboratory, or by a contractor, and are used within a short period. Unused bottles and equipment are then returned to the laboratory with the samples. In such cases, the auditor should exercise discretion with regard to the robustness of the documentation required. For example, courier dispatch notes might be sufficient evidence to demonstrate the date of receipt of time-sensitive containers and the absence of any stock will demonstrate that there is no risk of future samples being taken in out-of-date containers.

The auditor should refer to ISO 5667-3 for requirements on the preservation and handling of water samples.

10.2.3 Format

10.2.3.1 The format and list of specimen data needs for the sampling manual should be as follows:

a) the generic content, including:

   1) the update record for amendments, unless the manual has been assembled for a single use (and marked as such, e.g. “uncontrolled copy”);

   2) an index of protocols or procedures contained within the manual, if appropriate;

   3) a glossary, if appropriate; however, abbreviated terms specific to the organization should be avoided or explained, e.g. reference to a pipe outlet using an acronym should not be used unless the sample point carries a label with the same identifying phrase;

   4) guidance documents or procedures which might be contained in the manual or held centrally at a location specified in the manual; for example:

      i) COSHH[13] guidance;

      ii) health and safety requirements and associated risk assessments;

      iii) violence at work;

      iv) lone worker procedures, covering both routine and remote situations;

b) other key information, including:

   1) details of sample locations or sampling points;

   2) an inventory of sampling kit, e.g.:

      i) bottle type, with photograph(s) of bottle(s);

      ii) other types of sample containers;

      iii) equipment needed for taking specific types of samples;

      iv) equipment needed for on-site measurements, including copies of operating instructions;

      v) chemicals needed for on-site measurements;

      vi) chemicals needed for on-site preservation of samples;

c) protocols or procedures on sampling, e.g.:

   1) selection of sample taps (if appropriate);

   2) type of sample to be taken;

   3) the sequence for sampling (this could be critical in some circumstances);

   4) the taking of samples;

   5) sample-specific guidance; for example, for microbiological samples;

   6) details of sample preservation techniques, if required;

   7) the carrying out of on-site tests, including analytical quality control requirements;

   8) procedures for cleaning and disinfecting the sample tap, as appropriate;

9) procedures for amending site record sheets, as appropriate;

10) storage and transport conditions, and time allowed before commencement of the analysis for time-critical parameters;

11) recording and reporting on-site information;

d) good housekeeping, e.g.:

1) cleanliness of equipment;

2) the need to avoid cross-contamination;

3) cleanliness of sample van;

4) cleanliness of the sample storage boxes and related facilities, including any transit refrigerators used to store samples en route to the laboratory;

5) legibility of records and labels.

10.2.3.2 The manual may also contain a number of specimen forms to assist the sampling practitioner/operative when completing their records; for example:

a) temperature recording of the cool box, sample van refrigerator, and any transit refrigerators likely to be used by the sampling practitioner/operative;

b) when the cool box, sample van refrigerator, and transit refrigerator are cleaned;

c) an ad hoc sampling sheet;

d) examples of labels;

e) chain of custody records in the event of a sealed evidence bag being required;

f) specimen form for quality control sheets for on-site tests, as appropriate.

10.2.3.3 The manual should also refer, where appropriate, to:

a) training and competence, e.g. a permit-to-work required for health and safety reasons;

b) the use of chemicals or heat for decontamination or cleaning (and where/when hot works are permitted);

c) sampling in emergencies/pollution incidents;

d) reference documents.

10.2.3.4 The manual should provide guidance on sample storage requirements in the event of prolonged breaks in journey time, or when the sampling schedule requires collection periods in excess of that specified for time sensitive parameters. In the case of biological sampling, the manual should provide information for the maintenance of animal welfare, where appropriate.

10.2.4 The laboratory interface

When assessing the sampling manual, the auditor should consider the problems that might occur when a third party organization (for example, the receiving laboratory) supplies the sample bottles/containers. There might be anomalies in the quality and depth of documents provided by the third party organization, especially in areas that ought to form an integral part of the sampling manual; for example, the filling instructions for bottles containing preservatives, transit temperatures for specific parameters, and provision of adequate identification of containers in respect of their filling instructions. Problems could also occur with the supply of safety documents, such as material safety

data sheets for preservatives. The re-use of such documents might not be appropriate for returning the samples since the dilute form of preservatives such as acids require distinctly different safety considerations. Such issues might be outside the control of the organization, especially in the case of the short-term sampling exercises that are common in commercial situations.

The auditor should seek to identify a good practice model by ensuring that the depth of information in the sampling report provides the data user with a comprehensive statement of factors which could affect the information to be derived from the samples (for example, the uncertainty of the resulting measurements). However, it is recognized that such mitigation cannot compensate for the inappropriate use of material safety data sheets, which could mislead a sampling practitioner/operative when taking samples in an emergency. The auditor should treat this issue with appropriate regard to the safety implications on a case-by-case basis. For example, a person confronted with safety information for concentrated hydrochloric acid in a 30 mL vial, which actually contained 50 µL of acid diluted with the sample, might overreact.

10.3 Training policy

All sampling practitioners/operatives should have appropriate training in the areas of sampling in which they operate. Ideally, the organization should have a documented policy on the selection of sampling practitioners/operatives and their training requirements. The policy should also include details on

a) the competence of personnel carrying out the training,

b) the level of performance monitoring of individual practitioners/operatives,

c) the frequency of any internal audits, and

d) a means of identifying the need for re-training/refresher training.

A detailed assessment of the policy should be carried out during the first audit. If no nonconformities are identified, then subsequent audits need only assess any revisions or updates.

Generic training records and/or competency records might also be assessed at this stage of the audit, although further checks should be performed during the field assessment to ensure that the sampling practitioner/operative being audited is fully trained and competent in their field of operations.

10.4 Sampling record sheets

The auditor should pay particular attention to the form of sampling record sheets and the manner in which they are used, as problems can occur in the way that they prompt the sampling practitioner/operative for information. For example, important information, such as exceptional climatic conditions or an unusual demand on a distribution system, might not be recorded simply because it is not requested on the sheet. The auditor should ensure that any pre-printed sample record sheets adequately reflect the data needs of the data user.

10.5 Labels

Labels are an essential link in the transmission of information about a sample to the data user. The auditor should assess information chains with rigour, ensuring that sample labels are traceable to all field records. It should also be possible that, on receipt at a laboratory, the data user can be directed to all the information recorded about a sample.

The auditor should be satisfied that all label information is legible and transparently transferable. Account should be taken of the size of the label or the associated container, which might restrict the amount of information that can be transferred. It is particularly important for the auditor to assess the effectiveness of traceability and supplementary site recording requirements where small containers are used, e.g. vials used for the collection of trihalomethane samples.

Certain information on a sample label is essential, irrespective of the size of the label or container. Such information includes the following:

a) a unique identification number which can be traced back to the individual who took the sample, the location and the time and date it was taken;

b) safety information relative to any preservative in the bottle before filling;

c) safety information relative to the content of the bottle when filled; for example, sewage sludge is a biohazard;

d) the quality of the bottle before filling; for example, with microbiological samples, sterile until opened during sample collection.

NOTE Where sample vials are too small or it is not otherwise judged practical for all this information to be included on the label, then the minimum requirement is the unique identifier and a secondary reference to a document carrying all the requisite information. This could take the form of a box label, or site file.

Other desirable information is site- and discipline-specific and can take the form of any or all of the information that appears on the sampling report.

10.6 Chain of custody records

Chain of custody documents are vital to demonstrate the integrity of a sample between the point of sampling and arrival at the laboratory. The auditor should therefore ensure that

a) the chain of custody procedures and documentation are robustly cross-referenced,

b) there is documentation that explicitly covers storage conditions in the sampling practitioner/operative's vehicle or the courier's vehicle, and at any transfer points between the sample being taken and delivered at the laboratory,

c) there is documentation on the precise time that samples were left in secure conditions outside the sampling practitioner/operative's control, and who has/had responsibility for their security, and

d) the documents record that specific sample preservation requirements for chemical additions have been complied with, as well as those requirements for time and temperature.

The chain of custody documentation is particularly important if the sample is likely to be used as evidence in a court of law. It then becomes essential that there is an unbroken chain of custody to demonstrate that the sample was stored under correct conditions and delivered to the analysing laboratory within the required timescale. Any inconsistencies in the chain of custody documents could result in the collapse of a case or in questions of safety where health issues are involved, e.g. samples to be examined for *Legionella*.

NOTE Readers are reminded of the desirability of following good laboratory and good manufacturing practice.

It should be possible to construct a complete timeline from the date and time of taking the sample to the date and time of the sample being delivered to the laboratory. Under normal circumstances this chain of custody relating to sampling practices ends when the sample is booked in at the receiving laboratory. Thereafter, it becomes the responsibility of the laboratory's quality management system in terms of ongoing chain of custody. It is also for the laboratory to ensure that procedures are in place to facilitate the receipt and timely analysis of unscheduled samples outside normal working hours. However, if the sample being audited relates to a potential offence, the auditor might also wish to check that the analysis commenced within the required timeframe.

10.7 Laboratory receipts

The manner in which a laboratory documents the receipt of a sample is an essential continuity step for the data user. The auditor should ensure that the system can allow anyone involved in the sampling chain to confirm that a sample has been received by a laboratory and that

a) the date and time of sampling have been recorded throughout,

b) the date and time of receipt have been recorded,

c) the condition of the samples on receipt has been recorded; for example, the container and/or any formal seal is intact,

d) transport conditions, sufficient sample amount for analysis, and

e) site observations are recorded with the sample information.

NOTE The specific nature of some parameters can also require that a time-dependent nonconformity is recorded and notified to the sampling practitioner/operative or the data user. For example, the receipt of microbiological samples outside a predefined time window after sampling.

10.8 Assessment of documents before the field assessment

The auditor(s) should carry out an assessment of the sampling documentation as a desk-top exercise before the field assessment. The time required to do this exercise will depend on the depth and complexity of the audit and the quality of the documentation available. However, sufficient time and resource need to be built into the audit programme and, ideally, all requested documents should be available to the auditor(s) at least four weeks before the planned field assessment date. Form A3 in Annex A is intended to highlight the areas that might need to be covered as part of the document assessment process. Although this looks at the implementation of policies and practices, any relevant observations should also be entered on an observation record form (see, for example, Form C5 in Annex A).

The auditor needs to determine whether the information required by the sampling schedule can be consistently and effectively entered on the site record. The presence of a comments field on the record is not regarded as sufficient for this purpose. If the assessment being carried out is to follow-up a previous audit to validate mitigation, then it might only be necessary to check any amendments to the documentation.

The auditor should check that the sampling manual contains sufficient detail, including the information in 10.2.3.4, for the sampling practitioner/operative to meet the requirements of the sampling schedule in terms of sample collection and delivery, assuming they have the correct equipment available. It is also recommended that the auditor coincidentally requests copies of relevant health and safety risk assessments and site-specific instructions. These can be cross-referenced to safety advice given in the manual in terms of handling preservatives and other health and safety issues.

For location-dependent options, as defined in the sampling schedule, the site record documents should carry written prompts to ensure essential information is collected. For example, if sample temperature and stream flow rate are required as mandatory data fields, they should be marked for compulsory data collection on the sampling record or indicated as such in the sampling manual.

Documents not available before the audit can be reviewed on-site at the beginning of the real-time audit. However, it needs to be recognized that, in some situations, documentation could be basic or might not even exist. In such instances the auditor should verify with both the responsible person and the sampling practitioner/operative the degree of training received and the way in which instructions on sampling are transmitted between the relevant parties.

10.9 Assessment of completed documents

When assessing the impact of completed records or documents on the transfer of information, the auditor should check that all sampling information as recorded is transmitted with the sample and

delivered to the data user. Delivery to the data user may be coincidental with, but separate from, the sample at the laboratory. Alternatively, it may be a simultaneous recording with the laboratory results. The allocation and continuity afforded by the unique sample identifier should be assessed on every audit occasion.

10.10 Policy on statements of uncertainty

It is generally accepted that incorrect taking, handling and preservation of samples is likely to contribute the largest element of uncertainty to the measurements.

If the organization has a declared policy on statements of uncertainty of measurement, the auditor should ascertain whether a reference to uncertainty due to sampling is included. If such a reference is included, then any systematic and random errors identified during the audit should be quantified separately and the resulting uncertainty included in the statement of findings for the audit. Estimating the level of uncertainty due to sampling is discussed in Annex C.

If there is no reference to uncertainty due to sampling, the auditor may highlight this to the responsible person and recommend that an evaluation be carried out to see whether conformity of sampling could be included for future audits.

11 Real-time audit

11.1 Audit forms

Annex A contains a series of forms to assist the auditor. These forms are for guidance only and need to be tailored to the specific needs of the audit being carried out. They also need to reflect the type(s) of water being sampled.

For example, if previous audits have shown management systems to be satisfactory, it will not be necessary to undertake a further full process review unless parts of the process have been amended. In such cases a modular approach might be more appropriate, with only selected parts of this auditing protocol being applied and the appropriate forms used. The following are examples of scenarios where this might be suitable, together with the associated forms in Annex A.

— The auditing of sample point locations: Forms C3 and C5

— The auditing of sampling practice: Forms C2 and C5

— The auditing of training status: Forms C1 and C5

— The auditing of temperature monitoring: Forms C4 and C5

11.2 Field observation

Observation of practices in the field is the second stage of any audit process; this can be applied to risk-based as well as judgement-based assessments. The aim is to determine

a) the degree to which the sampling manual is being followed,

b) the appropriateness of the training received,

c) the degree to which the sampling schedule and sampling manual reflect the practicality of sampling points and their ability to deliver a representative sample,

d) the efficacy of the documentation relating to sample records and adherence to documenting chains of custody, and

e) conformity with storage time requirements, relative to the required test parameters (including the measurement of temperature on site).

11.3 Real-time risk-based auditing (see also 9.2)

Risk-based auditing is applied to multiple, repetitive sampling occasions, e.g. observing routine microbiological sampling of a potable water distribution system. The process is documenting observations of repeated practices, which on their own could only be evaluated on a judgemental basis. Nonconformity on such occasions may be recorded on Form C5 in Annex A.

11.4 Real-time judgement-based auditing (see also 9.3)

Judgement-based auditing is usually applied to a single sampling occasion, which might occur during an unscheduled event, or on occasions where infrequent sampling is required. Assessment of conformity with required practices should be based on assessing the sampling practitioner/operative's actions against that set out in the sampling manual and the requirements of any supporting procedures, such as documenting field observations. Nonconformity on such occasions may be recorded on Form C5 in Annex A.

11.5 Evidence of internal audits

When carrying out an external audit, the auditor can request the outputs from any internal assessments that have been undertaken, subject to agreement with the organization. This would then form part of the scope of the audit. This is particularly relevant where evidence of assessment of internal judgemental audits is required.

12 Design of an audit plan

12.1 Consultation with the responsible person

Before or at the outset of the audit, the auditor should request that the organization nominates a responsible person within the management structure to interface with the auditor. The responsible person should be made aware that their responsibilities during the audit are

a) liaising with the auditor (or audit coordinator in the case of an audit team),

b) setting up meetings,

c) organizing the documents required for the audit and arranging their timely delivery to the auditor(s), and

d) arranging for the real-time assessments to be carried out.

The responsible person should not be in a position to dictate the direction of the audit, but they may influence the audit objectives where, for example

— it increases the stringency of the audit by asking for specific areas to be covered,

— additional objectives are added to address local concerns relative to conformity, or

— training requirements need to be assessed against the organization's internal competence standards.

The auditor should provide a brief description of the conduct of the audit at the pre-audit meeting (see 14.4.2) to assist the responsible person in allocating sufficient resources to the provision of the required information.

12.2 Pre-audit questionnaire

The information provided by the pre-audit questionnaire forms a fundamental part of the record of the assessment.

NOTE Form A1 in Annex A provides the basis of the questionnaire; it is not an exclusive or minimum set of requirements.

The type of sampling to be assessed and the location of the sampling practitioner/operative's base of operations might dictate that additional information is required to assist in effectively planning the audit.

12.3 Plan design

The audit plan should describe the scope, objectives and timeline of the audit. The plan should clearly explain the relationship of the audit objectives to the organization's water quality goals and to the areas of highest nonconformity risk, e.g. public health or corrosion protection.

The plan should demonstrate that the audit resources can be used efficiently and effectively. The audit resources should be sufficient to demonstrate that the assumed audit failure risks are realistic. Depending on the depth and complexity of the audit, a first time audit could take four or more days of applied time if a full assessment of all documentation and sampling practice is required. Subsequent audits are likely to require less time, especially when key policies and procedures have not been amended during the interim.

Audit plans should be presented on documentation (see, for example, Form A2 in Annex A).

12.4 Audit practice

12.4.1 Staff competence assessments

The auditor should check the training records of each of the sampling practitioners/operatives being audited to ensure that they have received appropriate training for the tasks being assessed. These might take the form of records required by the organization's training policy or, in some cases, a job description. The auditor is encouraged to exercise judgement as to the relevance of an individual's training experience and academic qualifications in relation to the type of samples being taken.

Where the sampling manual is issued as a controlled document, the auditor should ensure that each sampling practitioner/operative being audited has access to the most up-to-date version and that it covers the tasks being audited. Where the sampling manual is not a controlled document, records of the sampling procedures that each sampling practitioner/operative is competent to carry out should be assessed and cross-referenced to the duties assigned by supervisory staff.

The training assessment Form C1 in Annex A sets out the minimum information required for verification of the assignment of trained personnel. Any relevant observations should also be entered on an observation record form (see, for example, Form C5 in Annex A).

NOTE For some sampling practitioners/operatives, evidence of competency can be provided in parallel to other data collection needs, such as that required for continued professional development (CPD), or membership of relevant peer groups or committees dealing with technical matters.

12.4.2 Supervision

The auditor should record sufficient evidence to demonstrate that the sampling practitioner/operative is aware of whom to contact about such matters as health and safety, problems with sampling points, and all issues relating to the preservation and handling of samples, including storage.

A record identifying the responsibilities of staff nominated to control technical and quality matters relating to sampling should be available.

NOTE This can be a standalone document or form part of the sampling manual. Assessment of the efficacy of technical supervision can also be made by documenting interviews with the organization's sampling staff.

The auditor should not comment on managerial practice or the background or qualifications of the line managers, but confine the assessment to the degree to which technical information is transmitted via verbal briefings and feedback meetings, and how such occasions are formalized for record keeping purposes.

12.4.3 Equipment

Where the receiving laboratory is not part of the organization but supplies the sample bottles, the auditor should review the procedures for identifying the bottle types, filling instructions, and any checks carried out to ensure that the bottles are within their use-by date. The auditor should then verify during the real-time assessment that these procedures are being implemented. This is particularly important for ad hoc samples.

When undertaking the field assessments, the auditor should assess the following general items as a minimum in each case:

a) cleaning of equipment at prescribed intervals during the sampling process and prior to storage (including the effectiveness of the cleaning process, with a view to the subsequent use of equipment, i.e. contamination risk);

b) the type and any unique identity reference of sampling equipment and its appropriateness for use for the task at hand;

c) records of calibration for field equipment (e.g. pumps/flow measurement) and on-site testing equipment (e.g. thermometers, residual chlorine monitors and dissolved oxygen monitors);

d) cleaning of sample boxes, vans, and transit refrigerators at prescribed intervals.

12.4.4 Handling of samples

During the field assessments, the auditor should verify that the sample meets the technical requirements for testing and record the conformity (or otherwise) of practice relating to:

a) container damage;

b) contamination risks;

c) temperature control;

d) labelling;

e) security/tamper-proof evidence.

12.4.5 Individual sample records

The auditor should verify that the following, as a minimum, are recorded for each sampling occasion observed:

a) each sample carries a unique identifier traceable to the date, time and location;

b) the sampling report is traceable to the individual sampling practitioner/operative who took the sample;

c) any field-based measurements are traceable to the sample they are associated with;

d) any field-based measuring equipment is fit-for-purpose, with appropriate calibration and quality control as necessary.

The auditor should also record environmental conditions that could significantly compromise the integrity of the sample and note adherence of the practitioner/operative to this principle. If the sampling manual requires records of this nature to be kept, then any nonconformity should be identified and recorded as a breach of the requirement of the sampling manual.

The sampling practitioner/operative is not necessarily conversant with all the environmental issues that could affect sample quality, so a thorough sampling record is essential for review by data users. If the auditor determines that the sampling practitioner/operative is not fully aware of these issues, then nonconformity against any stated training requirements should be recorded.

Completion of good quality negative information on sampling reports is also important. For example, leaving a record field blank because it was not raining might not be sufficient to indicate that it was a clear day, unless this is a laboratory information management system (LIMS) default condition. Any long-term benefit of this additional information to the data user might therefore be lost over time. The auditor should establish at the outset of the audit what the system default options are, if any, before making an observation of a failure to record. The auditor should also recognize that, in some circumstances, information requirements become progressive throughout a monitoring programme and, therefore, that data needs might change. The audit should reflect the assessment of adequate documentation of these changes and effective communication of these needs to the sampling practitioner/operative.

12.4.6 Tracking of samples

The auditor should verify that there are appropriate procedures in place to track the condition of each sample at every intermediate stage from the point of being taken to the point of delivery at the receiving laboratory. This is particularly important where the organization uses third party courier services for transporting samples.

12.5 Quality assurance and control issues (see ISO 5667-14)

Results obtained from the deployment of replicate sampling and the use of trip blanks should be managed with particular care, as this is the principal tool used by laboratories to judge sampling error and measurement uncertainty. Special regard should be given to the instructions in the sampling manual on the way in which such samples should be taken. Although instructions on container labels are likely to be regarded as effective communication, the auditor should examine the quality of this communication.

If the organization operates a sampling quality control scheme, such as that described in ISO 5667-1 or an equivalent standard, it is recommended that the auditor considers the following key questions.

a) To what degree is the sampling manual effective in communicating the requirements of quality control to the sampling practitioner/operative?

b) To what degree is the sampling practitioner/operative aware of the reason for the collection of replicate samples?

c) To what degree is the sampling practitioner/operative aware of the reason for the distribution of trip blanks?

d) Are the results of sampling quality control samples communicated to the sampling team?

e) If the sampling team receives the results, how are they evaluated and what significance is applied to them? For example, do they lead to sampling practice being modified?

f) If corrective action is applied, how and at what frequency are subsequent checks carried out?

g) If corrective action is required, are data users informed in a way that allows them to consider the potential impact on the information they are using?

If the organization operates a quality control scheme, the audit report should take into account the conformity with the required rigour and the efficacy of communication of any data quality risk to the data user. Similarly, if the organization has a policy on measurement of uncertainty relating to sampling, then this should be taken into account in the audit report.

13 Conduct of field assessments

13.1 General

The different degrees of technical expertise or experience of individual auditors need to relate to the types of sampling being assessed. In organizations where sampling needs vary, different technical

disciplines should be assessed in line with a consistent administrative and behavioural protocol by all the auditors involved. Auditing can be carried out by a team of individual specialists or a single person, if appropriate experience has been demonstrated.

NOTE An example of appropriate experience would be an established peer review of their practice.

Sampling practitioners/operatives should be briefed prior to the audit to ensure that they understand the need to maintain a single administrative process when undertaking field assessments. Where appropriate, the auditor may obtain their signature as a record of their understanding.

The auditor should provide the sampling practitioner/operative with a copy of the audit objectives that have been agreed with the responsible person: any decision not to divulge the purpose of the audit should reside with the responsible person.

The auditor should not disclose an opinion of the outcome of an audit to anyone other than the responsible person, or any other party nominated by the responsible person. In addition, the auditor should not respond to requests for comment on the correctness of practices carried out by the sampling practitioner/operative, or respond to questions regarding opinion on the acceptability of work carried out. The single overriding exception is where observed practices represent a clear risk to the health and safety of the auditor and/or the sampling practitioner/operative. For example, failure to act upon signs requiring protective clothing to be worn or restricting access for safety reasons.

When questioning the sampling practitioner/operative during the field assessment, the auditor should ensure that the process does not distract the individual from carrying out the intended task. Questions like the following should be avoided in order to avoid the risk of biasing an assessment.

— “Are you sure you want to do that?”

— “Is that the correct preservative for the bottle you are using?”

— “Is that label correct?”

Where possible, open rather than closed questions should be used and the auditor should ensure that responses to questions are recorded correctly. For example, when assessing the impact of an organization’s training programme, asking if an individual has been trained to undertake a specific task might produce an answer “No”. It is important that such a simple answer is recorded in conjunction with the question rather than simply concluding that there might not be a training programme in place.

Interviews carried out during the field assessment and practice observations should be recorded on field assessment forms (see, for example, Form C2 in Annex A). Any relevant observations should also be entered on an observation record form (see, for example, Form C5 in Annex A).

The auditor needs to ensure that adequate copies of the required forms are available for each stage of the audit. If appropriate, the auditor might obtain the signature of the sampling practitioner/operative on completion of each observation or assessment record, to ensure that the record is factually correct.

13.2 Sample location verification

The auditor should verify that the method by which the sampling practitioner/operative identifies the sampling location is as specified in the sampling plan, and is documented and traceable. If sample locations are new and previously unrecorded, an audit trail is needed to demonstrate clearly that the same location can be identified by other sampling practitioners/operatives on future occasions. In situations where technological aids are used to identify sample locations (for example, a photograph or a global positioning device), relevant documentation should be available to show the date and time that the location was recorded, along with any relevant equipment serial numbers and calibration record, to enable another person to find the same location on a subsequent occasion. Audit information gathered in the field in this context should be recorded on a location record sheet (see, for example, Form C3 in Annex A). Any relevant observations which are identified as nonconformities should also be entered on an observation record form (see, for example, Form C5 in Annex A).

13.3 Identification

Where samples are being taken from private premises, the auditor should verify that the sampling practitioner/operative carries and shows appropriate identification before entering the premises. If the auditor does not carry similar proof of identity, the responsible person should provide them with a letter of authority from the organization.

13.4 The use of photographs in field assessment

The value of photographs when undertaking field assessments should be stressed to the responsible person. However, the auditor should only take photographs in circumstances permitted by the organization and with the written consent of the responsible person. The consent should be recorded (e.g. Form B2 in Annex A) before commencing any field assessments.

Any camera used should preferably be able to identify the date and time of the photograph and the unique location identifier should, if possible, be included in the frame. Alternatively, the picture should include a board marked with a unique identifying code, which is traceable to the date, time and location visited. Records should be kept in a photographic record log (see, for example, Form B2 in Annex A), and cross-referenced to the field assessment and real-time audit form. Where it is not possible to predefine a picture, such as the opportunistic observation of poor practice (for example, failure to use a funnel to fill a bottle causing the wash-over to damage labels), then the photographic record should be described on the audit form such that it can be clearly identified later. This can be done by taking a subsequent picture using a marker board.

On completion of the photographic record of each observation or assessment, the auditor should obtain the signature of the sampling practitioner/operative to ensure that a correct record of the fact(s) has been made.

BS 10008 may be consulted, as a best practice model, where electronically stored information is used; it might also be useful for physical (film) photographs.

14 Audit methodology

14.1 General

The fundamental task of the auditor or audit team is to determine whether a system is in place for each declared process and whether it is adequately documented and consistently implemented. The auditor's duty is also to ensure that any nonconformity is objectively recorded; is considered in the context of the report to be produced; and is consistent with risks to the monitoring requirements of the organization when recommendations for mitigation are made. The auditor should always have due regard to the data quality risk presented by any nonconformity observed.

Irrespective of the type of audit being carried out, the conduct of the assessment should follow the procedures outlined in 14.2 and 14.4. It might not be possible to adhere always to some of the practices advocated, given the circumstances that might occur under field conditions.

All correspondence relevant to the pre-audit assessment should remain confidential between the auditor or the audit team and the responsible person to avoid the risk of bias being introduced by prior knowledge of the details of the documents sent for assessment.

14.2 Conduct of the audit

The first phase of the audit is the assessment of the sampling manual and other relevant documents. This should be done not less than one week before any real-time assessment is made. However, the size of the sampling operation being audited dictates the volume of documentation to be assessed. The auditor might therefore need to exercise judgement as to the period required for assessment of such documents.

The request for documentation should be formally made to the responsible person, stating clearly what should be provided. [An example form for this purpose (Form A1) is provided in Annex A.] This should include the following:

a) a statement of the data needs associated with the type of sampling to be assessed (this can be as simple as, "To evaluate potable water quality, or test for environmental impact."), signed by the responsible person, and attached to the audit report by the auditor;

b) an example sampling schedule;

c) a relevant related example of a sampling report or sample record sheet;

d) a relevant example of laboratory custody confirmation;

e) a copy of the organization's sampling manual or documented procedures, if relevant materials are assembled on a job-specific basis;

f) a copy of any training programme relating to sampling and attended by staff whose records will be assessed;

g) an example of the relevant training records of staff members from the sampling team to be assessed;

h) copies of relevant health and safety assessments and any site-specific instructions; and

i) incident procedures specific to the sampling practitioners/operatives to be assessed.

On completion of the evaluation of this documentation, the auditor(s) should

— amend the audit objectives if required, and

— compile the audit plan.

The draft audit plan should then be sent to the responsible person in confidence to ensure that sufficient resources are available during the real-time assessment. The responsible person should comment on the plan with regard to matters of fact, clarity and logistical issues.

The auditor should suggest (in the draft audit plan) the number of practitioner/operatives to be audited. The number should relate to the nature of the audit and whether the audit is to be judgement- or risk-based; this number should be agreed between the auditor and the responsible person.

NOTE The names of the practitioners/operatives can be finalized at the pre-audit meeting.

If possible, the individuals to be audited should be named on the day of the audit, as this avoids the moral hazard of them being briefed in advance, thereby biasing the outcome.

This might be feasible for an internal audit, especially if the auditor is based in the same premises as the auditee(s). However, the logistics become more complex if the audit is to be carried out over several days or if the auditor has to travel some distance to the sampling team's premises, or even join the auditee part way through their sampling round. In such situations, the auditor should select the practitioners/operatives to be audited in advance of the real-time assessment, and arrange with the responsible person the timing and location of the audit with as little notice as possible for the auditee.

14.3 Reviewing the audit plan

It is recommended that at this stage the auditor discloses the names of the individuals to be assessed in order to allow the responsible person sufficient notice to make arrangements. If the real-time assessment is to be carried out at some distance from the location of the meeting, this information might have to be imparted in advance, but within a timeframe that should not allow briefing of the sampling practitioner/operative to be audited. The auditor should also ensure that the responsible person is briefed on how nonconformities and unscheduled actions will be recorded and brought to the attention of the accompanying staff member.

14.4 Real-time assessment

14.4.1 General

At the time the audit plan is agreed, the auditor or audit team should request access to a private room at a convenient location where documents can be reviewed and from where the assessment can be administered.

NOTE Ideally, this is the same location that the practitioners/operatives are based.

In addition, the auditor should request access to a member of staff, the information provider, who will assist in the retrieval of requested documents. During on-site document assessments, the auditor should present observations of nonconformity to this nominated staff member.

It is important that those who are the subject of an audit do not treat the process as a training exercise. Thus, the responsible person should advise staff not to seek sanctions for their actions from the auditor during the assessment process, although the auditor might still need to remind individuals of this during the field assessment.

14.4.2 Pre-audit meeting

It is recommended that the auditor or audit coordinator and the responsible person meet privately, prior to any opening meeting, to review the audit plan and agree any changes dictated by issues such as staff absences or other logistical arrangements. The purpose of the pre-audit meeting is also to ensure that both parties are clear about the audit process, objectives, reporting needs and required outcomes.

14.4.3 Opening meeting

Following the meeting in private, it is recommended that an opening meeting is held with all staff involved in the audit, at which the responsible person should introduce the auditor or audit team. The auditor(s) should then describe the audit procedure and answer questions about the assessment process and how any nonconformities observed during the audit will be recorded and reported to the responsible person. The auditor should make it clear that conformity will be judged against the organization's stated objectives, and not necessarily those of a statutory or other controlled framework conformity requirement, e.g. UKAS or other accreditation bodies.

It should also be explained at this stage that there will be a closure meeting at which any recommended mitigation measures will be disclosed.

A recommended minimum agenda and record of the opening meeting is given as Form B1 in Annex A.

14.4.4 Traceability assessments before real-time audit

The auditor or audit team should conduct a traceability assessment by asking the information provider to provide records for assessment in a private room, rather than the auditor having to search for records and disrupting the normal work of the organization.

If necessary, the auditor(s) may request interviews with the data user so that the transfer of data from the sample site records to the data user can be assessed. For example, they might not have automatic access to information about the condition of formal seals on bottles taken for regulatory purposes. It is essential that such information is transmitted to the data user, but it might not be provided automatically on a laboratory report.

14.4.5 Observation procedures

When recording nonconformities, the following practice is recommended for the auditor(s).

a) Do not interrupt the sampling practitioner/operative during the task in hand; to do so might be a distraction, which could have safety implications.

b) When the nonconforming task has been completed, document the process without comment.

On completion of the scheduled task(s) the auditor should inform the sampling practitioner/operative that nonconformities have been observed and recorded, and provide them with the details. Such observations should be recorded (see, for example, Form C5 in Annex A). Neither party should enter into discussion about the merits of the matter being recorded. The auditor should not engage in any debate as to whether or not the person under assessment has passed or failed any kind of test.

The auditor should complete a location record sheet (see, for example, Form C3 in Annex A) to register all sampling locations visited and indicate to what degree these locations are representative of:

— the water body as a whole, where relevant;

— the prevailing flow and load conditions, where relevant;

— mixing of flows, where relevant.

The relevance of the manner in which the sample is taken should also be recorded in this context. For example, the sample might be representative of water in the location chosen but the sampling point might not be representative of the body as a whole. Negative results need not necessarily be interpreted as nonconformity because the sampling plan might recognize the limitations identified, e.g. sampling the periphery of a lake shore to examine the influence of wind on near surface diatom bloom movement. Observations of this nature should be cross-referenced with sampling plans as necessary (the use to which these data are put depends largely on the audit objectives).

14.4.6 Assessing conformity with temperature control during the audit

If an organization routinely carries out temperature monitoring of storage and transport conditions, the auditor may consider it sufficient to assess the documentation associated with such record-keeping. The auditor should also verify temperature-monitoring arrangements when third-party couriers are involved in delivering samples to the receiving laboratory.

If temperature monitoring is a prerequisite for specific parameters in a sample taken during the real-time assessment, then the auditor should observe the sampling practitioner/operative carrying out the appropriate checks and complete a temperature record sheet (see, for example, Form C4 in Annex A). Similar observations should be made where temperature monitoring is carried out at transit points, such as refrigerators at depots.

If there is no evidence of temperature monitoring being carried out, the auditor might wish to initiate checks during the audit using the protocols suggested in Annex B. In such cases the auditor should apply judgement as to the efficacy of any documented consideration of risk to data quality transmitted to the data user arising from a lack of monitoring of storage and transport conditions.

The degree to which the auditor cross-checks temperature measurements will be determined by the judgements made during the pre-audit document assessment.

14.4.7 Auditing of photographic evidence

During investigations into water quality incidents that could result in criminal prosecution or civil action, photographic evidence can be gathered in addition to samples. In extreme cases, criminal standards of evidence apply to such photographs. Thus, courts are entitled to be presented with photographic records that have been maintained in accordance with appropriate standards, e.g BS 10008.

The auditor should determine whether the organization has a written policy, or standard operating procedure, on the management of photographic evidence. This is likely to take the form of an overarching policy, or procedure, relating to the evidential weight and legal admissibility of electronic information, given that most photographs taken in these circumstances will be digital photographs. Further information on this can be found in BS 10008.

When assessing conformity with the management of photographic evidence, the auditor should ensure that

a) the organization's policy on the handling of photographic evidence has been complied with,

b) the documentation generated with the chain of custody for the photographs is traceable to sampling documentation,

c) there is a fully documented report of any manipulation of the photographs, such as stamping location information into the image, and

d) the photographs are securely stored on uneditable media with all the relevant custody and manipulation records for transmission to the data user.

The auditor should exercise discretion as to the precise timing of assessing photographic evidence; it could be carried out as part of the pre-audit document assessment or as a random check as part of the real-time audit.

14.4.8 Interpretation of audit data

Before convening the closure meeting (see Clause 6) the auditor(s) should formally assess the nonconformities observed in line with the predetermined audit prioritization performed at the outset of the audit. It is also recommended that the auditor record any nonconformities and drafts the audit report in private. In the case of a multiple audit, this process would have to be coordinated and agreed by all members of the audit team.

A numerical summary might be provided at this stage. Such summaries can be useful for managers of sampling operations as they allow monitoring of quality management issues over time. They can also be useful in highlighting priorities for action.

14.4.9 Recording nonconformity

Detailed report forms need to be completed and all documentation associated with a nonconformity copied and attached to illustrate the extent of nonconformity. It is recognized that copying documents might not always be practical and the auditor is advised to make use of a camera under such circumstances.

Report forms should contain the following:

a) details of where the observation was made;

b) a reference to any documents involved;

c) a record of the nonconformity observed, including any repeats of the nonconformity;

d) the name of the person who acknowledged the nonconformity was recorded;

e) the signature of the person who acknowledged the nonconformity was recorded.

Subsequently, each observation should be classified in terms of the rankings previously identified in the audit prioritization exercise.

15 Assignment of the audit report and the closure meeting

At the end of the audit a closure meeting should take place, at which:

a) the audit findings (including nonconformities), both verbal and in the report, are communicated to the responsible person by the auditor, or audit coordinator in the case of an audit team;

b) the statement of recommended actions and the timetable for their implementation are agreed.

A minimum recommended agenda for the closure meeting is given Form D1 in Annex A, which may also be used to create a record of the meeting.

NOTE The statement of findings may be presented to an extended audience if the responsible person deems it desirable.

During the meeting, the auditor or audit coordinator should provide a verbal or written summary of their findings. This may consist of a series of numerical statements on the number and type of observed nonconformities identified during the audit in relation to the number of samples taken by the organization, the number of sampling practitioners/ operatives involved and the number audited. Where appropriate, the auditor should clearly set out and describe the auditing risk, i.e. describe the confidence levels that can be applied to the numerical statements and differentiate between auditing approaches taken (i.e. risk-based versus judgemental).

The auditor should also validate with the responsible person any assumptions made during the audit before including them in the final report. For example, if the audit identified the possibility of proximate discharges to a stretch of river close to a sampling location used for routine monitoring, then the report should note if the sampling practitioner/operative observed and recorded whether there was any flow from these discharges at the time of sampling. This could be reported by way of either a scheduled or an unscheduled observation.

The auditor should agree with the responsible person on the timetable for producing a draft audit report. This is particularly important when more than one auditor is involved, as the audit coordinator will need time to prepare a consolidated draft. The responsible person will then have the opportunity to comment on matters of fact and clarity before the final report containing all completed audit documentation is submitted. The final report should be signed by the responsible person and the auditor, or audit coordinator, before being copied to all other interested parties.

The auditor or audit coordinator should also agree with the responsible person on a timetable for follow-up actions to any recommendations arising from the audit.

16 The audit report and statement of findings

16.1 The report

The audit report should comprise the collated documentation recording nonconformities and any accompanying evidential paperwork. It should contain a summary of manifest unmitigated nonconformities and those that were observed but mitigated, thereby allowing the audit to reflect the number of occasions a sampling process captures and mitigates data quality risk, rather than singling out negative attributes. The report should also contain a formalized statement of findings which distinguishes between

a) observations made, but not deemed to be critical to the integrity of the sampling process (for example, safety issues such as broken glass in vehicle storage compartments),

b) nonconformities which are significant (but not critical) to the immediate integrity of the sampling process, and

c) nonconformities which present a critical risk to the integrity of the sampling process.

Form D2 in Annex A can be used to identify key points of the audit findings. It might also constitute an acceptable report, especially for internal audits. For detailed written reports, it is recommended that the auditor produce a draft for comment by the responsible person on matters of fact (which may include a copy of Form D2 if used), within four weeks of the closure meeting. On receipt of any comments, the auditor should produce and sign a final report, which should also be signed by the responsible person.

16.2 Statement of findings

A single audit is unlikely to pick up all nonconformities, and any report or statement of findings should mention this limitation. A number of factors might be detected that could give rise to systematic or random errors in the determination of the results requested by the data user. Therefore, the report should, where possible, identify and comment on these impacts. For example, if a nonconformity occurs once, it might be deemed random, whereas if it occurs more than once it might be indicative of poor practice developing and should be deemed systematic.

The statement of findings should contain a caveat stating, for example, that:

"This report, its conclusions and its recommendations are based on the audit of a small selection of records, documents and locations. The conclusions, therefore, are not necessarily widely applicable and the absence of critical comment or recommendations on any matter does not mean that it was found to be satisfactory, nor does it relieve the organization, department or section of responsibility for the consequences of any deficiency which might exist or subsequently arise. Any statement of satisfaction represents the auditor's opinions at the time, based on the information available to and inspected by them, and does not constitute a general endorsement of the adequacy of the organization's, department's or section's procedures or practices."

If the organization has a policy on statements of uncertainty of measurement then an appropriate evaluation should be included in the statements of findings. Information on the measurement of uncertainty associated with sampling practices is given in Annex C.

16.3 Audit conclusions

The auditor(s) should be clear when stating their findings at the closure meeting and in the documentation left at the organization's premises. Documented conclusions should state

a) the degree to which the organization has demonstrated conformity with declared sampling practice,

b) the degree to which the number of high, medium and low nonconformity observations has influenced the conclusions drawn, and

c) how the level of nonconformity has affected the quality of data collected via the sampling process assessed.

The conclusions should also set out the timetable for mitigation agreed with the responsible person and how such mitigation will improve/maintain the quality of data collected via the sampling process.

The audit conclusions should clearly state whether

— this was the first audit to be carried out, or

— if a previous audit was undertaken, where the conclusion of that audit can be viewed.

The conclusions should also state clearly whether any corrective action arising from the previous audit, and assigned for completion before the current audit, was completed. Obvious positive attributes of the sampling operation identified during the audit should be highlighted in the report. However, the statement of conformity rests entirely on the degree to which conformity has been observed.

16.4 Statement of recommended actions

Any statement of recommended actions should include an agreed timetable for the rectification of errors, for example:

a) high (H) ranked unmitigated nonconformities need rectification immediately or as soon as practicable, i.e. within one month from the date of audit;

b) all other nonconformities (L) require attention within an agreed timeframe, which could be within three months from the date of audit or even before the next audit, when they would be subject to

special attention at that time; a process for re-evaluation of conformity should also be agreed with the responsible person.

The auditor should ensure that the statement of recommended actions addresses all the audit objectives and contains clear risk-based conclusions (where appropriate to the audit plan). If a nonconformity has not been rectified between audits and a subsequent audit identifies it as an ongoing problem, the auditor should consider raising its ranked status as a means of ensuring that errors do not persist in an organization's sampling practice.

The auditor should ensure that the responsible person is aware of the responsibility of taking the audit findings and associated actions forward within the organization.

17 Outline flow diagram of audit process

Organization decides to audit water quality sampling, possibly driven by:
a) training assessments;
b) regulatory requirements;
c) adoption of GLP, GMP, HAZOP, etc.
Organization nominates a responsible person (RP) (3.18) to take audit forward.

RP contacts auditor (whether internal or external).

Preliminary meeting (12.1) between RP and auditor to discuss:
a) reason for the audit and what needs to be covered;
b) type of audit required: risk- or judgement-based (Clause 9).

Auditor (or audit coordinator) agrees with RP:
a) draft audit objectives (Clause 5 to Clause 7);
b) pre-audit questionnaire (12.2 and Form A1);
c) outline audit plan (12.3 and Form A2);
d) audit assumptions (9.4);
e) policy on statement of uncertainty (10.10);
f) date of audit and associated meetings.

Auditor (or audit coordinator) receives key documents for assessment (Form A3), including:
a) sampling programme and instruction documents (10.1);
b) sampling manual (10.2);
c) training policy (10.3);
d) sampling record sheets (10.4);
e) labels (10.5);
f) chain of custody reports (10.6);
g) laboratory receipts (10.7).

Auditor (or audit coordinator):
a) amends audit objectives if necessary (14.2);
b) undertakes an audit prioritization exercise (8.2);
c) finalizes the audit plan with the RP and agrees:
1) the number of sampling practitioners/operatives to be audited;
2) the location for the audits; and
3) the date of the audits; (14.2 and 14.3);
d) obtains RP's consent to the use of photographs during the field assessment, as appropriate (13.4);
e) holds a pre-audit meeting, as necessary (14.4.2).

Opening meeting at start of real-time assessment between the RP, the auditor(s) and all staff involved in the audit (14.4.3 and Form B1).

Auditor(s) commences real-time assessment, including:

a) traceability assessment (14.4.4);

b) training records for the sampling practitioners/operatives being audited (10.3 and Form C1);

c) recording on-site observations as part of the field assessment (13.1, 13.2, 14.4.5, 14.4.6 and Form C2, Form C3, Form C4 and Form C5).

On completion of real-time assessment, the auditor(s):

1) assesses any nonconformities observed against the audit prioritization (14.4.8 and 14.4.9); and

2) drafts an outline audit report (Clause 15, Clause 16 and Form D2).

Closure meeting, at which the auditor (or audit coordinator) provides the RP and other interested parties with a verbal or written summary of the audit and a statement of findings (Clause 15, Clause 16, Form D1 and Form D2).

The auditor (or audit coordinator) and RP agree a timetable for follow-up actions to recommendations arising from the audit (16.4).

Final report agreed with RP and signed off by the auditor (or audit coordinator) and RP.

Annex A
(informative)

Audit forms

A.1 General

This Annex contains a series of forms to assist the auditor. These forms are for guidance only and need to be tailored to the requirements of the individual auditor or audit team. The references A1, B2, C3, etc. are form references, not references to clauses.

NOTE They are intended to be used in accordance with the guidance given in this part of ISO 5667.

A.2 Pre-audit questionnaire

A1	**PRE-AUDIT QUESTIONNAIRE**	Audit Ref. No.	
STATEMENT OF AUDIT NEEDS associated with the type of sampling to be assessed			
To be completed by responsible person This document will be returned to the responsible person if this section is left blank.			
Name of responsible person	Signature of responsible person		Date

ORGANIZATION INFORMATION *To be completed by responsible person*				
Office location of responsible person				
Contact details for responsible person				
Name of person assigned as information provider				
Location/office where the sampling practitioners/ operatives to be assessed are normally based				
Location where audit meetings will be held				
Location where document inspections can be carried out, as necessary				
Number of sampling practitioners/ operatives in the operational unit		Number of samples taken, on average per year, by the operational unit	Regulatory:	
Number of sampling practitioners/ operatives to be assessed			Operational:	
Number of samples taken by the sampling practitioners/operatives to be assessed			Unscheduled:	
Type of sampling to be assessed (e.g. potable water, environmental, sludge, closed systems, *Legionella*)				
Proposed dates for the audit/real-time assessments				

A1	**PRE-AUDIT QUESTIONNAIRE**	Audit Ref. No.	
LIST OF DOCUMENTS			
The responsible person should identify the documents that can be provided prior to audit and those which can only be accessed on the day of audit.			
No.	Document required *(include any additional documents required in list)*	Provided prior to audit *(please tick)*	Provided on day of audit *(please tick)*
1	Maps of office location(s); audit meeting locations; locations of operations to be assessed (for external auditors)		
2	Organizational chart (for external auditors)		
3	Descriptive documents of type of sample to be assessed		
4	An example sampling schedule		
5	An example bottle label, if pre-printed		
6	A relevant example sampling report or sample record sheet		
7	A relevant example of laboratory's custody confirmation		
8	A copy of the organization's sampling manual or documented sampling procedures		
9	A copy of the organization's training programme relating to sampling activities		
10	An example of the relevant training records of staff members from the sampling team to be assessed		
11	Copies of relevant health and safety risk assessments and any site-specific instructions		
12	Incident procedures specific to sampling practitioners/ operatives		
Complete rows below for any additional document requirements			
13			
14			
15			

QUESTIONNAIRE AND DOCUMENTS RECEIVED BY AUDITOR		
Name of auditor	Signature of auditor	Date documents received

A.3 Audit plan

A2	AUDIT PLAN	Audit Ref. No.	

GUIDANCE ON THE DESIGN OF AN AUDIT PLAN

Consultation with the responsible person

The auditor (or audit coordinator in the case of an audit team) should produce a draft audit plan for discussion with the responsible person. Once agreed, this plan forms the basis for the audit.

Audit plan design

The audit plan should describe the scope, objectives and timeline of the audit. The plan should clearly explain the relationship of the audit objectives to the organization's water quality goals and to those areas of highest water quality conformity failure risk, e.g. public health or corrosion protection. The plan should also demonstrate that the audit resources can be used efficiently and effectively.

Audit objectives

Before drafting an audit plan, the auditor (or audit coordinator in the case of an audit team) and the responsible person need to agree the objectives of the audit. These should be specific to the organization, but their primary purpose is to determine whether the process of sampling imposes any adverse impacts on data integrity.

Auditing assumptions

A list of assumptions should be constructed during the development of the audit plan, which will allow a rational qualification of any numerical or subjective claims made in the final report. Such an assumption could be that all sampling practitioners/operatives have been trained. If this proves to be founded, the audit is carried out accordingly.

Risk-based versus judgemental approaches to auditing

A decision should be taken on the evaluation of observations, which might pose a risk to the integrity of the sampling process, identified during the audit. A risk-based approach provides a measurable and controllable audit detection risk. A judgemental approach can also be used, but it does not provide the same degree of numerical clarity of audit detection risk, even with a perfectly designed plan.

Audit prioritization

In order to identify clearly the primary technical factors to be assessed during the real-time audit, the sampling process should first be examined as a paper exercise. Each step identified in the various data capture forms (A3, C1, C2 and C3 of ISO 5667-24:2016, Annex A) can then be allocated an audit prioritization.

The allocation of significance to these steps, if an operation is not carried out as intended, should be based on high or low risk to sample integrity. The risk might be considered 'high' if it is considered critical to the integrity of the sample data or "low" if it is not deemed significant. Such prioritizations allow identification of critical deviations that require immediate action on completion of the audit.

The final assignment of significance should be based on the professional judgement of the auditor, taking into account the specific sampling practice under examination. In the case of a multiple audit, the auditing team would need to adopt a uniform approach towards their calibration of risk prioritization in order to avoid introducing personal bias. This exercise could be carried out as a one-off occurrence by an auditor or audit team and the risk levels assigned in advance for all subsequent audits, with a review undertaken periodically as required.

Audit prioritization should be documented and recorded within the data capture forms in order to gain maximum benefit, if corrective actions are required.

Recording nonconformities/observations

Any nonconformities identified during the audit, which pose a risk to the integrity of the sampling process, can be cross-referenced to the audit prioritization predefined in the data capture forms.

The auditor should also note any unscheduled observations or actions arising during the audit which were not foreseen prior to the audit. These observations should be allocated a high ranking where they could be considered to have a significant effect or impact on sample/data integrity or a low risk ranking if they pose minimal risk. If appropriate, these observations may be included as assessment items in the data capture forms for future auditing occasions.

All observations are recorded on an observation record form (see, for example, Form C5 in ISO 5667-24:2016, Annex A).

A2	AUDIT PLAN		Audit Ref. No.	
SUGGESTED FORMAT FOR AN AUDIT PLAN				
Name and address of organization				
Name of responsible person (RP)				
Type of audit (*select one*)	Internal		External	
Scope of the audit (identified from the statement of audit needs on the pre-audit questionnaire)				
Audit objectives				
Auditing assumptions				
The organization's water quality goals and/or areas of highest water quality conformity failure risk				
Nonconformity evaluation (select one)	Judgement-based	Risk-based	Mixed	
Number of sampling practitioners/ operatives to be audited		No. of sampling occasions that will be observed during audit		
Audit detection risk (if risk-based audit, refer to ISO 5667-24 for method of calculation)				
Statement of uncertainty (if organization links its sampling audit to revised statement of uncertainty)				
Resources required from organization(including number of sampling practitioners/ operatives to be audited)				
Resources required by auditor (e.g. man hours, including numbers of days on-site, numbers of auditors, etc.)				

A2	**AUDIT PLAN** (continued)	Audit Ref. No.	
Audit preparation		Date planned	Date completed
Organization nominates an RP			
RP contacts auditor			
Preliminary meeting/discussions held between auditor and RP			
Draft audit objectives agreed			
Pre-audit questionnaire sent to RP			
Pre-audit questionnaire and relevant documents returned to auditor			
Draft plan developed and sent to RP			
Document assessment carried out by auditor			
Audit objectives and plan amended, if necessary			
Confirmed audit plan agreed with RP			
Audit on-site (it is recognized that these events might all take place on the same day)		Completed Y/N (include any comments)	
Real-time assessment visit			
Opening meeting			
Traceability assessments			
On-site/field assessment(s)			
Closure meeting			
Audit reporting		Date planned	
Draft outline audit report sent to RP			
Comments on matters of fact returned to auditor			
Final audit report sent to RP			
Additional events (*if required*)		Date planned	

Name of auditor	Signature of auditor	Date
Name of responsible person	Signature of responsible person	Date

A.4 Document assessment form

A3	DOCUMENT ASSESSMENT FORM	Audit Ref. No.	

- The auditor should formally request copies of the relevant documents from the responsible person before the audit commences, stating clearly what should be provided. (A suggested list is given in the pre-audit questionnaire, Form A1, in ISO 5667-24:2016, Annex A). The documents not available before the audit can be reviewed on-site at the commencement of the audit.
- As part of the audit planning exercise (Form A2 in ISO 5667-24:2016, Annex A) and while carrying out the document assessment, the auditor should assign high or low risk priorities to each item set out below. This exercise is intended to identify and prioritize the primary technical factors to be assessed during the audit, where the result shows that the operation does not conform to stated procedures and protocols and requires further investigation.
- Any nonconformities identified during the audit/assessment which pose a risk to the integrity of the sampling process can be recorded on an observation record form (see, for example, Form C5 in ISO 5667-24:2016, Annex A) and reference made to the relevant section of this form. Please do not leave any fields blank, apart from the comments section if not applicable.

No.	Assessment item	Y/N	N/A	Audit prioritization H or L	Comments (include references to any documents assessed)
1	Sampling schedules/sampling practitioner/operative instruction documents				
1.1	Does the documentation define, as a minimum:				
a)	the material identity of the sample?				
b)	the date of sampling?				
c)	the location where the sample is to be taken?				
1.2	Does the documentation clearly identify to the sampling practitioner/operative any variations required by the data user, relative to dependent options on the sampling schedule?				

Y/*N* = Yes/No N/A = Not applicable H/L = High/Low

A3	DOCUMENT ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments** (include references to any documents assessed)	
1.3	Does the documentation allow the sampling practitioner/operative to postpone or cancel scheduled samples as long as the reasons are recorded? If so, how?					
2	**Sampling manual**					
2.1	Does the organization have a sampling manual? *NOTE The manual can be in hard copy or held electronically, and can take the form of a project-specific collection of documents from various sources, e.g. instructions from the laboratory on how to fill sample bottles.*					
2.2	Does the manual address the specific sampling requirements of the organization and provide detailed instructions to sampling practitioners/operatives?					
2.3	Does the manual contain the following:					
a)	an index of the protocols or procedures contained therein (if appropriate)?					
b)	a section identifying the responsibilities of staff nominated to control all technical and quality matters related to sampling and identify a chain of management communication?					

A3	DOCUMENT ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments** (include references to any documents assessed)	
c)	a glossary (if appropriate)?					
	NOTE However, abbreviated terms specific to the organization should be avoided or explained. For example, reference to a pipe outlet using an acronym should not be used, unless the sample point carries a label with the same identifying phrase.					
d)	a section on reference documents (if appropriate)?					
e)	guidance documents or a section dealing with generic requirements, such as COSHH?					
f)	health and safety and associated risk assessments?					
g)	a section on violence at work?					
h)	lone worker procedures, covering both routine and remote situations?					
2.4a)	Is the manual a controlled document?					
b)	If so, is it subject to regular review?					
c)	Is there a nominated officer responsible for revisions of the manual?					
d)	Is a list available to show that it has been distributed to all appropriate members of staff?					

A3	DOCUMENT ASSESSMENT FORM					Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments** (include references to any documents assessed)		
e)	Is there a record of amendments with the name of the distributor and the dates of issue to authorized holders?						
2.5	Are there any other controlled documents associated with sampling, e.g. bottle book, driver's handbook, safe systems of working handbook?						
2.6	Does the manual identify the following:						
a)	the sample type (e.g. water, sludge, sediment) and the test parameters for which information is to be gathered?						
b)	equipment requirements (as appropriate)?						
c)	time and spatial requirements (as appropriate)?						
d)	preservation and handling needs, including instructions on bottle filling and decontamination needs for collection equipment between locations?						
e)	safety requirements and constraints (as appropriate)?						
f)	chemicals needed for on-site measurements?						
g)	chemicals needed for on-site preservation of samples?						
2.7a)	Does the sampling manual specify sampling locations and sampling points?						

A3	DOCUMENT ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments** (include references to any documents assessed)	
b)	If so, are maps/schematics included?					
c)	Is there a person/team responsible for maintaining and reviewing sample points?					
d)	Does the person responsible for setting sample points consider all relevant factors to ensure that the sampling point is representative and fit-for-purpose?					
e)	If the sampling point is not representative, is this recognized in the sampling plan?					
f)	Where relevant, is there any asset guidance available detailing specific requirements for sampling lines, e.g. appropriate material and length?					
2.8a)	Does the sampling manual contain an inventory of sampling equipment?					
b)	Does the inventory include the following: sampling kit, e.g. bottle type, with photographs?					
c)	other types of sample containers?					
d)	specialized equipment needed for taking specific types of samples?					
e)	equipment for on-site measurements, including operating instructions, calibration and quality control requirements?					

A3	DOCUMENT ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments** (include references to any documents assessed)	
2.9	Does the manual contain specimen forms to assist the sampling practitioner/operative when completing their records? For example:					
a)	specimen form for temperature recording of the cool box, van refrigerator or transit refrigerator;					
b)	specimen form for recording when the cool box, van refrigerator or transit refrigerator is cleaned;					
c)	examples of labels;					
d)	specimen form for an ad hoc sampling sheet;					
e)	specimen form for chain of custody records in the event of a sealed evidence bag being required;					
f)	specimen form for quality control sheets for on-site tests, as appropriate.					
2.10	Does the sampling manual set out the sampling procedures and techniques to be deployed for each type of sample? For example:					
a)	selection of sample taps, as appropriate;					
b)	the order of taking the samples;					

A3	DOCUMENT ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments** (include references to any documents assessed)	
c)	the requirements for taking microbiological samples aseptically, including disinfecting and flushing the sample tap, as appropriate;					
d)	details of on-site sample preservation, as required; *NOTE A reference to shelf life/use-by date needs to be included for pre-prepared sample bottles containing preservatives; likewise a reference to tamper-proof seals.*					
e)	information on the maintenance of animal welfare for biological samples.					
2.11	Does the sampling manual contain:					
a)	procedures or protocols for on-site tests?					
b)	instructions on sample handling for on-site tests, as appropriate?					
c)	the methodology for the test with requirements for uncertainty estimation and analytical quality control, as appropriate?					
d)	reporting of results?					
2.12	Does the sampling manual contain a section on sampling during emergencies/incidents?					
2.13	Does the sampling manual contain a section on good housekeeping? For example:					
a)	how and where equipment is to be cleaned and stored between sampling occasions.					

A3	DOCUMENT ASSESSMENT FORM					Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments** (include references to any documents assessed)		
b)	the storage of containers prepared/purchased for specific uses including how the storage facilities are to be maintained, commensurate with the intended use and by whom.						
c)	the need to avoid cross-contamination of samples during storage/transit, including cleaning processes for equipment.						
d)	routines for cleaning the sample van.						
e)	routines for cleaning sample storage boxes and related facilities.						
f)	routines for cleaning the cool box and refrigerators, including any transit refrigerators used for holding samples prior to delivery to the laboratory.						
2.14	Does the sampling manual contain a section on storage and transport conditions for samples and the time allowed before commencement of the analysis for time critical parameters?						
2.15	Does the sampling manual contain guidance on sample storage in the event of prolonged breaks in journey time, or when the sampling schedule requires collection periods in excess of that specified for time-sensitive parameters?						

A3	DOCUMENT ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments** (include references to any documents assessed)	
2.16	Has the organization an agreement in place with the laboratory for time-dependent nonconformities to be recorded and notified to the sampling practitioner/operative or data user?					
2.17	Does the sampling manual contain procedures for the following:					
a)	recording and reporting on-site information, including the need for legibility?					
b)	amending site details, as appropriate, where new information can be fed back to update records?					
2.18	If the manual is not issued as a controlled document, how are the relevant documents/procedures issued to personnel likely to be involved in the taking of samples?					
3	Training policy and programme					
3.1	Does the organization have a documented policy on the selection of sampling practitioners/operatives and their training requirements?					
3.2	Does the policy include details on:					
a)	criteria for personnel carrying out the training?					
b)	performance monitoring of individual sampling practitioners/operatives?					

A3	DOCUMENT ASSESSMENT FORM			Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments** (include references to any documents assessed)
c)	the frequency of any internal audits?				
d)	identifying the need for re-training/refresher training?				
3.3	Does the organization have a programme of regular refresher training for all sampling practitioners/operatives?				
3.4	Does the organization require temporary staff and/or contractors to be trained to the same level as permanent staff?				
4	Sampling record sheets				
4.1	Are the sampling record sheets laid out in a format that is user-friendly for the sampling practitioner/operative, and do they clearly set out the information required? *NOTE The sample record sheets can be problematic in the way that they prompt sampling practitioners/operatives for information.*				
4.2	If pre-printed sample record sheets are used, do they adequately reflect the data needs of the data user? *NOTE For example, the sampler might omit to record important information simply because it is not requested on the sheet.*				

A3	DOCUMENT ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments** (include references to any documents assessed)	
4.3	Can the information required by the sampling schedule be consistently and effectively entered on the sample record? *NOTE For location-dependant options, the sample record document should carry written prompts to ensure essential information is collected, e.g. where stream flow rate is a mandatory field.*					
5	Labels Assessed during pre-audit if pre-printed labels are available					
5.1	Do all pre-printed labels contain the following:					
a)	a unique identification number which can be traced back to the individual who took the sample?					
b)	the location and the time and date it was taken?					
c)	safety information relative to any preservative in the bottle before filling and the level to fill?					
d)	safety information relative to the content of the bottle when filled (e.g. sewage sludge is a biohazard)?					
e)	information regarding the quality of the bottle before filling (e.g. with microbiological samples, sterile until opened during sample collection)?					

A3	DOCUMENT ASSESSMENT FORM			Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments** (include references to any documents assessed)
5.2	Does the system allow for duplicate sample numbers to be used? If so how?				
6	Chain of custody records Some organizations could be required to take samples for use as evidence in subsequent legal proceedings. Sampling in these situations needs to be carried out under forensic conditions with a full chain of custody, including all the relevant documentation. Procedures and protocols relating to chain of custody records may form part of the sampling manual or make up a standalone document.				
6.1	Does the organization have procedures for dealing with chain of custody samples and the associated documentation?				
6.2	Is there explicit documentation to demonstrate an unbroken chain of custody between the sample being taken and being delivered to the analysing laboratory within the required timescale, including the following:				
a)	recording that specific sample preservation requirements have been complied with relative to chemical additions, as well as those requirements for time and temperature?				
b)	showing that the sample was stored under correct conditions in the sampler's or courier's vehicle and at any transfer points between the sample being taken and delivered at the laboratory?				
c)	dealing with situations where samples have to be left in secure conditions outside the sampler's control, and who has/had responsibility for their security?				

A3	DOCUMENT ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments** (include references to any documents assessed)	
6.3	Does the organization have a policy on the management of photographic evidence? If so, do the procedures include the following.					
a)	A chain of custody for the photographs traceable to the sampling documentation?					
b)	A fully documented report of any manipulation of the photographs, such as stamping location information into the image?					
c)	Secure storage of photographs so that they cannot be edited, with all the relevant custody and manipulation records for transmission to the data user?					
6.4	Is there a policy/procedure in place for the organization to negotiate with the analysing laboratory to facilitate the receipt and timely analysis of unscheduled samples outside normal working hours?					
7	Policy on statements of uncertainty					
7.1	Does the organization have a declared policy on statements of uncertainty in measurement? If so, the auditor should ascertain whether a reference to uncertainty due to sampling is included in the statement.					

A3	DOCUMENT ASSESSMENT FORM					Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments** (include references to any documents assessed)		
Name of organization			Name of organization's responsible person				
Date(s) of pre-audit document assessment			Date(s) of document assessment on site				
Name of information provider			Evidence attached				
Name of auditor							
Signature of auditor							

A.5 Opening meeting record

B1	OPENING MEETING RECORD	Audit Ref. No.	
This form contains suggested items for the opening meeting or planning meeting between the auditor, the responsible person and all staff involved in the audit. It should be used in conjunction with the pre-audit questionnaire (Form A1 in ISO 5667-24:2016, Annex A).			
AGENDA AND RECORD OF OPENING MEETING The following is recommended as the minimum record of an opening meeting.			
No	**Agenda item**	**Record**	
1	Names of people attending the opening meeting		
2	Affirmation of the statement on the purpose and conduct of the audit		
3	Confirmation of administrative arrangements, such as housekeeping, health and safety matters and any other office or on-site requirements		
4	Confirmation that a staff member has been assigned to accompany the auditor to act as information provider		
5	Confirmation of availability of a private facility and other necessary resources such as photocopying machine		

B1	OPENING MEETING RECORD	Audit Ref. No.	

No	Agenda item	Record
6	Confirmation of the list of documents requested for assessment in advance of the real-time audit and confirmation that other documents will be made available as required during the course of the audit	
7	List of the likely participants in the audit with their titles for inclusion in the final report	
8	Any other business?	
9	Date of meeting	

CONFIRMATION:

At the end of the meeting a brief record of the meeting should be agreed and signed by the auditor (or audit coordinator for a team audit) and the responsible person to confirm that this is a true and accurate record of the meeting.

Name of responsible person	Signature of responsible person	Name of auditor	Signature of auditor
Use additional sheets, if required		No. of sheets added	

A.6 Photographic consent form

B2	PHOTOGRAPHIC CONSENT FORM	Audit Ref. No.	

PART 1: PHOTOGRAPHIC CONSENT

During the audit the auditor may wish to obtain a photographic or cinematographic record of a particular circumstance, e.g. failure to use a funnel to fill a bottle causing wash-over to damage label markings, to provide background information to the statement of findings in the audit report. Before taking such photographs, the auditor should obtain written consent from the responsible person as a matter of good practice.

A photographic record log sheet (Form B2, Part 2) should be used to record all photographs or video clips taken, along with the date and time the photograph/video clip was taken and a unique location identifier. The signature of the sampling practitioner/operative present during the audit should be recorded on this sheet to confirm that a correct record of the fact(s) has been made.

Conclusions drawn from photographic or cinematographic evidence and observations of work practices should be kept strictly confidential within the confines of the audit documentation.

NOTE Copyright of the photographs/video clips, which is vested in the auditor as the photographer, can be transferred to an employing organization by prior agreement. Any individual who can be reasonably identified in the photographs/video clips taken for the purposes of the audit has the right to refuse disclosure of the image to any party outside the context of their employment. This refusal might be overridden in the case of established legal precedence.

Consent statement

As the representative of the organization responsible for overseeing the audit, I agree that the auditor may use photographic or video evidence as part of the audit process. I understand that any photographs/video clips taken will remain the property of the auditor named below.

Name of responsible person	
Signature of responsible person	
Position held within the organization	
Date consent given	
Name of auditor to whom consent has been granted	
Signature of auditor	

B2	PHOTOGRAPHIC RECORD LOG SHEET				Audit Ref. No.	
This form should be used to record all photographic or cinematographic evidence taken during the audit (see Form B2, Part 1).						
PART 2: PHOTOGRAPHIC RECORD LOG SHEET						
Date and time taken	Unique location identifier	Description				
Name of sampling practitioner/operative		Signature of sampling practitioner/operative		Name of auditor		Signature of auditor
Use additional sheets, if required				No. of sheets added		

A.7 Training assessment form

C1	TRAINING ASSESSMENT FORM	Audit Ref. No.	

- All sampling practitioners/operatives should have received appropriate training in the areas of sampling in which they operate. Training and/or competency records should therefore be checked to ensure that the sampler being audited is trained and competent in their field of operations. The auditor should exercise judgement as to the relevance of an individual's training experience and academic qualifications in relation to the type of samples being taken.
- As part of the audit planning exercise (Form A2 in ISO 5667-24:2016, Annex A) the auditor should assign high or low risk priorities to each item set out below. This exercise is intended to identify and prioritize the primary technical factors to be assessed during the audit, where the result shows that the operation does not conform to stated procedures and protocols and requires further investigation.
- This training assessment forms part of the real-time audit (as opposed to the document assessment; see Form A3 in ISO 5667-24:2016, Annex A) and should be carried out prior to the field assessment.
- Any nonconformities identified during the audit/assessment which pose a risk to the integrity of the sampling process can be recorded on an observation record form (Form C5 in ISO 5667-24:2016, Annex A) and reference made to the relevant section of this form. Please do not leave any fields blank, apart from the comments section if not applicable.

NOTE When assessing the impact of an organization's training programme, asking if an individual has been trained to undertake a specific task might produce an answer "No". It is important that such a simple answer is recorded in conjunction with the question rather than simply concluding that there might not be a training programme in place.

No.	Assessment item	Y/N	N/A	Audit prioritization H or L	Comments
1	Training records				
1.1	Does the sampling practitioner/operative have a personal training record, containing details of all relevant sampling training undertaken?				
1.2a)	Does the training record contain details and dates of all operational sampling training performed?				
b)	Is the record countersigned by both the sampling practitioner/operative and the trainer?				
Y/*N* = Yes/No N/A = Not applicable H = High / L = Low					

C1	TRAINING ASSESSMENT FORM					Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments**		
c)	Does the record include tasks for which the sampling practitioner/ operative is being assessed?						
1.3	Does the record include up-to-date personal details, such as relevant qualifications?						
1.4	Have details of any further ad hoc external training and/or other internal training relevant to sampling been correctly entered and signed?						
1.5a)	Has all equipment used in training been identified to ensure authorization/competence to use equipment?						
b)	Does this include the use of equipment/instrument instruction manuals?						
1.6	Does the training record contain details of any training reviews that have been carried out?						
1.7	Have all training events relevant to sampling been accounted for? *NOTE These omissions should be recorded during the audit.*						

C1	TRAINING ASSESSMENT FORM			Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments**
2	Competency records/knowledge and experience				
2.1	Can the sampling practitioner/operative provide evidence of the knowledge and/or experience needed to carry out sampling activities according to sampling procedures, either by:				
a)	cross-reference to the duties assigned by supervisory staff (which can take the form of a job description/specification)?				
b)	documentary evidence that a controlled copy of an appropriate sampling manual has been received?				
NOTE For some sampling practitioners/operatives evidence of competency can be provided in parallel with other data collection needs, such as that required for continued professional development (CPD), or membership of relevant peer groups or committees dealing with technical matters.					
3	**Other forms of training**				
3.1	Does the sampling practitioner/operative have a permit-to-work required for health and safety reasons?				
3.2	Has the sampling practitioner/operative received any legal-based training on the processes required for procurement of evidence presented at a court of law?				
3.3	Has the sampling practitioner/operative been trained in lone worker procedures?				
Y/*N* = Yes/No N/A = Not applicable H = High / L = Low					

C1	TRAINING ASSESSMENT FORM					Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments**		
4	**Supervision**						
4.1	Has the sampling practitioner/operative been audited previously? *If so, a copy of the audit form should be requested if it is not with the training records.*						
4.2	Does the sampling practitioner/operative know who to contact about health and safety matters, problems with sampling points and all issues relating to sample handling and storage, etc.?						
Name of sampling practitioner/operative			Name of auditor				
Name of line manager/supervisor			Signature of auditor				
Area(s) of responsibility			Date of assessment				

A.8 Field assessment form

C2	FIELD ASSESSMENT FORM			Audit Ref. No.	
• The auditor needs to ensure that items identified at the document assessment stage of the audit are covered during the field assessment. Many of these items will be specific to the scope of the organization and the size of the sampling operation being audited. This form gives guidance on the key areas that should be covered. This form should be completed after a training assessment form (see, for example, Form C1 in ISO 5667-24:2016, Annex A) has been completed. • As part of the audit planning exercise (Form A2 in ISO 5667-24:2016, Annex A) and while carrying out the document assessment, the auditor should assign high or low risk priorities to each item set out below. This exercise is intended to identify and prioritize the primary technical factors to be assessed during the audit, where the result shows that the operation does not conform to stated procedures and protocols and requires further investigation. • Any nonconformities identified during the assessment which could pose a risk to the integrity of the sampling process can be recorded on an observation record form (Form C5 in ISO 5667-24:2016, Annex A) and reference made to the relevant section of this form. Please do not leave any fields blank, apart from the comments section if not applicable.					
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioriti-zation H or L**	**Comments**
1	Good housekeeping				
1.1	Is the sampling practitioner/operative's van used only for sampling? If not, what else is it used for?				
1.2	Is the vehicle clean and tidy?				
1.3	Are the sample containers correctly prepared, identified as to purpose and stowed free from possible contamination?				
1.4	If raw and treated water samples are carried, are they stored separately?				
1.5a)	Is the sampling equipment clean?				
Y/*N* = Yes/No N/A = Not applicable H = High / L = Low					

C2	FIELD ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioriti-zation H or L**	**Comments**	
b)	Is the sampling equipment in good order?					
c)	Is the sampling equipment correctly stored?					
1.6	Is provision made in the vehicle for keeping samples cool? If so, how?					
1.7	Is the temperature range suitable and how is it monitored (see also temperature record form, if used)?					
1.8a)	Are the cool boxes/refrigerator units regularly cleaned and maintained?					
b)	If so, how frequently and is this recorded?					
1.9	Are chemical samples stored in appropriate conditions (e.g. PAH samples in the dark; nitrite samples chilled)?					
2	**Pre-sampling checks**					
2.1	If necessary, has the sampling practitioner/operative carried out a site health and safety risk assessment prior to commencing sampling?					
2.2a)	Has the sampling practitioner/operative received, read and understood the sampling manual?					
b)	Is a copy of the sampling manual available and, if so, is it the most recent version?					
Y/*N* = Yes/No N/A = Not applicable H = High / L = Low						

C2	FIELD ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments**	
2.3	Has the sampling practitioner/operative a written work list (schedule) showing all samples to be taken and clearly identifying the sample type?					
2.4a)	If there is an inventory of sampling kit, has the sampling practitioner/operative complied with requirements?					
b)	If an inventory does not exist, does the sampling practitioner/operative have all the necessary equipment, bottles, etc., to perform the tasks required?					
2.5	Does the sampling practitioner/operative make checks on the condition of sampling equipment and bottles, etc., to determine any damage or contamination?					
3	**The sampling process**					
3.1	If the sample has to be taken at a property, has the sampling practitioner/operative shown his ID or otherwise established his credentials and authority?					
3.2	Has the sampling practitioner/operative carried out the sampling process in accordance with the documented procedures?					
3.3	Has the sampling process been carried out in a manner that has not compromised the integrity of the sample, e.g. washing preservatives from a pre-prepared bottle?					
Y/*N* = Yes/No N/A = Not applicable H = High / L = Low						

C2	FIELD ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments**	
3.4	Has the sampling practitioner/operative carried out appropriate rinsing of sampling apparatus and other relevant equipment to avoid contamination risks?					
3.5	If appropriate, have the rinsings been suitably disposed of to avoid contamination of sampling area?					
4	**The use of field instruments and other equipment**					
4.1	Are any on-site tests carried out? If so, what are they?					
4.2a)	Are the procedures for the field tests documented clearly?					
b)	Are these procedures available to the sampling practitioner/operative at the time of the field test?					
4.3	Is the calibration status checked for all field equipment (e.g. pumps/flow measurement) and on-site testing equipment (e.g. thermometers, residual chlorine monitors, dissolved oxygen monitors)?					
4.4	Is there clear guidance on the action to be taken if an instrument fails calibration?					
4.5	Are all field measurements and observations recorded at the time they are made and associated with the correct samples and containers?					
4.6	Does each piece of equipment carry a unique identity reference?					
4.7a)	Is any level of QC applied to the field tests?					
Y/*N* = Yes/No N/A = Not applicable H = High / L = Low						

C2	FIELD ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**		**Comments**
b)	Is the level of QC considered to be satisfactory, e.g. within acceptable tolerance limits?					
5	**Labels and sample records**					
5.1	Are appropriate labels and records available to record all the information required of the sampling activity?					
5.2	Is the sampling practitioner/operative aware of the need for specific labels containing pertinent safety information relating to potential risks? For example:					
a)	any preservative in the pre-prepared bottle before filling;					
b)	any biohazard arising from the bottle contents.					
5.3	If the labels are not pre-printed, does each sample carry:					
a)	a unique identifier traceable to the date and time of sampling?					
b)	the sampling location (cross-checked against any sampling point identified in the sampling schedule)?					
c)	identification of the sampler?					
5.4	Are sample labels traceable to all field records?					
5.5a)	Is the label information legible and transparently transferable?					
Y/*N* = Yes/No N/A = Not applicable H = High / L = Low						

C2	FIELD ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments**	
b)	If a sample label becomes illegible does the sampling practitioner/operative have any back-up procedure? If so, what is this?					
5.6	Are the sample labels always securely fixed to the sample container?					
5.7	Are adequate procedures in place to ensure that all label information is captured when the label has to be attached to a small sample container? *NOTE The auditor needs to assess the effectiveness of traceability and supplementary site recording requirements where small containers are used. For example, the vials used for the collection of trihalomethane sample.*					
5.8	Has all the relevant sample information been recorded on the samples sheets at the time of sampling?					
5.9	Does the sampling manual require environmental conditions to be recorded at the time of sampling (i.e. those appropriate to sample integrity)?					
5.9a)	Is the sampling practitioner/operative fully aware of these issues?					
5.10	If appropriate, are there suitable chain of custody records in the event of a sealed evidence bag being required to provide secure/tamper-proof evidence?					
Y/*N* = Yes/No N/A = Not applicable H = High / L = Low						

C2	FIELD ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments**	
6	**Quality assurance and control issues (other than for field tests)** **If the organization operates a quality control scheme the following areas should be considered for assessment.**					
6.1	Is the sampling manual schedule or the container labels effective in communicating the requirements of quality control samples to the sampling practitioner/operative? If so, to what degree?					
6.2	Is the sampling practitioner/operative aware of the reason for taking replicate samples? If so, to what degree					
6.3	Is the sampling practitioner/operative aware of the reason for the distribution of trip blanks? If so, to what degree?					
6.4	Are the results of uncertainty estimation and sampling quality control samples communicated to the sampling team? How?					
6.5	If the sampling team receives these results, are they evaluated and what significance is applied to them, i.e. do they lead to sampling practice being modified? If so, how?					
6.6	Is corrective action applied in response to the above assessment? How and at what frequency are subsequent checks carried out?					
6.7	If corrective action is required, are data users informed in a way that allows them to consider the potential impact on the information they are using? If so, how?					
Y/*N* = Yes/No N/A = Not applicable H = High / L = Low						

C2	FIELD ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments**	
7	**The use of photographs in field assessment**					
7.1	Has any photographic evidence been taken by the auditor during the field assessment? *NOTE Reference the photographic record log sheet no(s).*					
7.2	If any photographs have been taken, has consent been obtained from the responsible person organizing the audit process?					
8	**Sample transportation**					
8.1	Does the sampling practitioner/operative ensure that there is no cross-contamination of sample types during transit? How?					
8.2	Is there clear guidance on the action to be taken if the temperature during transit goes outside the ambient range?					
8.3	Are samples conveyed to the analysing laboratory with minimum delay?					
8.4	Is the sampling practitioner/operative aware of time-sensitive analyses?					
8.5	If samples are delivered to a collection point for onward transmission, are the storage arrangements satisfactory?					
8.6a)	If refrigerated storage is used when the samples are in transit, who is responsible for ensuring that it is cleaned regularly and who monitors and records the storage temperatures?					
Y/*N* = Yes/No N/A = Not applicable H = High / L = Low						

C2	FIELD ASSESSMENT FORM			Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments**
b)	Does storage in the transit refrigerator present a risk that samples could become contaminated?				
8.7	Is there a full chain of custody for onward delivery of samples to the laboratory, where required?				
9	**Laboratory receipts**				
9.1 a)	Is a system in place to allow the sampling practitioner/operative/ data user to confirm that: a sample has been received by a laboratory?				
b)	the date and time of receipt have been recorded?				
9.2	Is the condition of the samples on receipt at the laboratory recorded, e.g. that the container and/or the formal seal is intact?				
9.3	Are site observations recorded with the sample information?				
9.4	If the sample(s) being audited relates to a potential offence, did the analysis commence within the required timeframe?				
10	**Reporting of traceability assessments (Data transfer from the sample records to the data user)**				
10.1	Do sample records contain all the relevant information relating to the samples selected?				
Y/*N* = Yes/No N/A = Not applicable H = High / L = Low					

C2	FIELD ASSESSMENT FORM				Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments**	
10.2	Do laboratory registration records contain all the relevant information relating to the samples selected?					
10.3	Do LIMS/data archives records contain all the relevant information relating to the samples selected?					
10.4	Does sample analytical data contain all the relevant information relating to the samples selected?					
11	**Assessment of completed documents**					
11.1	When assessing the impact of completed records or documents on the transfer of information, has all recorded sampling information been transmitted with the sample and delivered to the data user? *NOTE Delivery to the data user can be coincidental with, but separate from, the sample at the laboratory. Alternatively, it can be a simultaneous recording with the laboratory results. The allocation and continuity afforded by the unique sample identifier should be assessed on every audit occasion.*					
11.2	Have any interviews been conducted with any of the organization's technical staff responsible for sampling to determine the mechanisms of technical information transfer and how such occasions are formalized for record keeping purposes? *NOTE Attach a copy of any interviews and collected information to this document.*					
Y/*N* = Yes/No N/A = Not applicable H = High / L = Low						

C2	FIELD ASSESSMENT FORM			Audit Ref. No.	
Name of sampling practitioner/operative		Name of auditor			
Name of line manager/supervisor		Signature of auditor			
Area(s) of responsibility		Date of assessment			
Y/*N* = Yes/No N/A = Not applicable H = High / L = Low					

A.9 Location record sheet

C3	LOCATION RECORD SHEET	Audit Ref. No.	

PART 1: SITE LOCATION INFORMATION

- This form should be used in conjunction with the field assessment form (Form C2 in ISO 5667-24:2016, Annex A). The information required on this form (Part 1) covers generic aspects of the sampling locations. The form should be adapted for any specific requirements related to different types of sampling points. All sampling points/locations visited during the assessment should be recorded on the log sheet (Part 2).
- As part of the audit planning exercise (Form A2 in ISO 5667-24:2016, Annex A) the auditor should assign high or low risk priorities to each item set out below. This exercise is intended to identify and prioritize the primary technical factors to be assessed during the audit, where the result shows that the operation does not conform to stated procedures and protocols and requires further investigation.
- Any nonconformities identified during the assessment which could pose a risk to the integrity of the sampling process can be recorded on an observation record form (Form C5 in ISO 5667-24:2016, Annex A) and reference made to the relevant section of this form. Please do not leave any fields blank, apart from the comments section if not applicable.

No.	Assessment item	Y/N	N/A	Audit prioritization H or L	Comments
1	**Site details**				
1.1 a)	Are there relevant health and safety risk assessments for the site/ sampling points?				
b)	Are copies available during the assessment?				
c)	Are there any issues arising from the site information recorded on these risk assessment forms? If so, please state what they are.				
1.2	If the sample locations are new and previously unrecorded, is there an audit trail to allow identification of the same location by a different sampler on future occasions?				

Y/*N* = Yes/No N/A = Not applicable H = High / L = Low

C3	LOCATION RECORD SHEET				Audit Ref. No.
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments**
1.3	Where technological aids are used to identify sample locations (e.g. a photograph or a global positioning system) is relevant documentation identified to enable another person to find the location again on a subsequent occasion?				
1.4	For location-dependent options, as defined in the sampling schedule, do the site record documents carry written prompts to ensure essential information is collected? *For example, if sample temperature and stream flow rate are required as mandatory data fields, they should be marked for compulsory data collection on the sampling record or indicated as such in the sampling manual.*				
2	**Sampling points**				
2.1a)	If for any reason the specified sample point/location cannot be used, is the sampling practitioner/operative directed to an alternative sample point/location, or is written guidance provided on selecting an alternative sample point/location? If so, where is this information recorded?				
Y/*N* = Yes/No N/A = Not applicable H = High / L = Low					

C3	LOCATION RECORD SHEET					Audit Ref. No.	
No.	**Assessment item**	**Y/N**	**N/A**	**Audit prioritization H or L**	**Comments**		
b)	Is the sampling practitioner/operative authorized to select another sampling point/location if the specified alternatives are not available? If so, under what conditions might another sample point be used?						
c)	Does the sampling practitioner/operative know whom to contact if further assistance is required in selecting another sample point?						
d)	Is the change in sample point recorded? If so, where?						
2.2	Does the sampling practitioner/operative know when the sample points/sampling locations were last reviewed?						
2.3	Does the sampling practitioner/operative know the person responsible for reviewing the details of sample points/locations?						

Name of auditor		**Name of practitioner/operative**		**Date of assessment**
Signature of auditor		Signature of practitioner/operative		
Y/*N* = Yes/No N/A = Not applicable H = High / L = Low				

C3	LOCATION RECORD SHEET	Audit Ref. No.	

PART 2: LOG OF SAMPLE POINT LOCATIONS VISITED DURING ASSESSMENT

This form is to be used to record all sampling points/locations visited during the assessment, with a separate input for each sampling location visited. This can be done by way of separate sheets or by copying this part to give a continuous and consolidated table for all the sampling points/locations to be visited.

Any pertinent details relevant to the location can be commented on and fed back to the responsible person for reviewing site information.

No.	Name and location of sampling point	Sample point description	Grid reference/ GPS reference/ sample point reference	Map/photo of sampling point available (Y/N)

Assessment item	Y/N	N/A	Comments
If relevant, has the sampling practitioner/operative signed any visitor's register or book at the site location?			
Are there any signs around the site that imply a safety restriction to sampling being carried out?			
Does the sampling practitioner/operative know that this is the correct sampling point location? How?			
Is the sampling point a tap?			
If a tap, is it easy to disinfect if being used to take a microbiological sample?			
If a tap, is there adequate drainage for when the tap is being flushed?			
Other relevant information, e.g. safety comments/environmental conditions	Comments		

Use additional sheets, if required	No. of sheets added	

Y/*N* = Yes/No N/A = Not applicable

A.10 Temperature record form

C4	TEMPERATURE RECORD FORM	Audit Ref. No.	
This form is for use by the auditor when carrying out manual temperature monitoring during the audit. The time and temperature reading should be taken before the field assessment commences, each time a sample is deposited in the sample transit container and at the end of the assessment when the samples are left in secure conditions or handed over to a laboratory. Use additional copies of this form, as required.			
Part 1: Manual temperature assessment		Record No.	
Sample transit container (e.g. cool box, fridge, refrigerated van)		Date of assessment	
Thermometer type (record any identifier)		Acceptable tolerance range	
Date of last thermometer calibration *(if applicable)*		Name of sampling practitioner/operative	

Time	Reading by auditor	Comments

Name of auditor	**Signature of auditor**

Use additional sheets, if required	No. of sheets added	

C4	TEMPERATURE RECORD FORM	Audit Ref. No.	

This form is for use by the auditor when carrying out temperature monitoring during the field assessment using an electronic data logger. The time should be recorded when the logger is placed into the sample transit container and again when the logger is removed from the container at the end of the assessment when the samples are left in secure conditions or handed over to a laboratory. Use additional copies of this form if more than one data logger is used during the assessment.

Part 2: Data logger temperature assessment		**Record No.**	
Sample transit container (e.g. cool box, fridge, refrigerated van)		Date of assessment	
Data logger type (record any identifier)		Acceptable tolerance range	
Date of any calibrations		Name of sampling practitioner/operative	

Time placed in storage container	Comments
Time removed from storage container	Comments

Name of auditor	Signature of auditor

Use additional sheets, if required	No. of sheets added	

C4	TEMPERATURE RECORD FORM	Audit Ref. No.	
This form is for use by the auditor when carrying out temperature monitoring at sample transit points during the field assessment. The time and temperature reading should be taken each time a sample is deposited at the sample transit point. Use additional copies of this form if required or more than one sample transit point is used during the assessment.			
Part 3: Temperature assessment at transit points		Record No.	
Sample transit point (e.g. fridge in depot)		Date of assessment	
Thermometer type (record any identifier)		Acceptable tolerance range	
Date of last thermometer calibration		Name of sampling practitioner/operative	

Time	Reading by auditor	Comments

Name of auditor	Signature of auditor

Use additional sheets, if required	No. of sheets added	

A.11 Observation record form

C5	OBSERVATION RECORD FORM	Audit Ref. No.	
This form is to be used in conjunction with the data capture forms A3, C1, C2 and C3 (see ISO 5667-24:2016, Annex A) for recording observations which are identified as nonconformities during the audit. The data capture form reference number may be recorded, e.g. A3-1.1, to enable cross-referencing of the activity to the observation. The audit prioritization of high (H) or low (L), allocated to each activity during the audit prioritization exercise, should be recorded against the observation. Any unscheduled action which is not covered in the data capture forms and is found to pose a risk to sample integrity should also be recorded and assigned an audit prioritization. On completion of the scheduled task(s) the auditor should inform the responsible person or sampling practitioner/operative that nonconformities have been observed and recorded and provide them with the details. Use as many copies of this form as required and allocate a record number to each sheet used. A summary of the observations made should be reported in the audit report			
PART 1: AUDIT DETAILS			
Name of organization		Audit location(s)	
Address of organization		Activities assessed	
Name of sampling practitioner/operative		Name of auditor	
Date of audit		Signature of auditor	
		No. of Part 2 records used	

C5	OBSERVATION RECORD FORM				Audit Ref. No.		
NOTE Refer to Part 1 of this form for additional information about completing this form. Use as many copies of this form as required.							
PART 2: OBSERVATION RECORD FORM			Report No.				
Observation. No.	Data Capture Form Ref. No.	Observation and description of finding (can be retrospectively cross-referenced to sampling documentation)	Audit prioritization High (H) or Low (L)		Unscheduled action High (H) or Low (L) Risk		Observation Mitigated Y/N
		Note: For audit prioritization, see data capture forms A3, C1, C2 or C3 in ISO 5667-24:2016, Annex A	H	L	H	L	
Totals							
Use additional sheets, if required		No. of sheets added					

A.12 Closure meeting record

D1	CLOSURE MEETING RECORD	Audit Ref. No.	
This form covers suggested items for the closure meeting. The responsible person should invite all relevant members of the organization to the closure meeting.			
AGENDA AND RECORD OF CLOSURE MEETING The following is recommended as the minimum record of a closure meeting.			
No.	**Agenda item**	**Record**	
1	Names of people attending closure meeting		
2	Affirmation of the statement on the purpose and conduct of the audit		
3	To note any deviations from the intended conduct of the audit on the grounds of safety or unforeseen circumstances, and the validation of any assumptions made during the audit		
4	Matters relating to non-completion of recommended action(s) from a previous audit (as appropriate)		
5	Summary of audit findings and observations made		

D1	CLOSURE MEETING RECORD	Audit Ref. No.	
6	Summary of outline conclusions and recommendations arising from the audit		
7	Agreement of the statement of recommended actions		
8	Agreement of the timetable for implementation of the recommended actions		
9	Confirmation of the participants in the audit to be documented in the final report		
10	Agreement of the timetable for delivery of the final report		
11	Arrangements for any further audits, if required		
12	Any other business		
13	Date of meeting		

CONFIRMATION:

At the end of the meeting, a short record of the outcomes should be agreed and signed by the auditor (or audit coordinator for a team audit) and the responsible person to confirm that this is a true and accurate record of the meeting.

Name of responsible person	Signature of responsible person	Name of auditor	Signature of auditor
Use additional sheets, if required		No. of sheets added	

A.13 Audit report and findings

D2	AUDIT REPORT	Audit Ref. No.	

GUIDANCE ON THE DESIGN OF AN AUDIT REPORT

The auditor(s) should produce a detailed written audit report not later than four weeks after the closure meeting. This report should bring together all the audit findings, collated documentation recording observations, and any other accompanying evidential paperwork. Relevant audit documentation should be attached as appendices, along with any other documents pertinent to the audit.

If there are any organization-specific requirements, the format of the report should be agreed between the auditor and the responsible person at the pre-audit meeting. Statements made in the report should also be agreed by both the auditor, or audit coordinator, and the responsible person before the final version is signed and distributed.

The following headings and guidance are intended to cover key points arising from most audits.

Title page

The title page of the report should provide a brief outline of the audit and the personnel involved in tabular format.

The title sheet should include a statement that, “This report should be read in conjunction with the requirements of ISO 5667-24”.

It should also contain the caveat that: “This report, its conclusions and its recommendations are based on the audit of a small selection of records, documents and locations. The conclusions, therefore, are not necessarily widely applicable and the absence of critical comment or recommendations on any matter does not mean that it was found to be satisfactory, nor does it relieve the organization, department or section of responsibility for the consequences of any deficiency which might exist or subsequently arise. Any statement of satisfaction represents the auditor’s opinions at the time, based on the information available to and inspected by them, and does not constitute a general endorsement of the adequacy of the organization’s, department’s or section’s procedures or practices.”

Appendices

All of the forms used during the audit and the associated documentation should be listed and attached as appendices to the report.

Executive summary

The executive summary should highlight the number of observations identified during the audit and their associated risks. It should also include a statement of findings and a statement of recommended actions.

Scope

The scope of the audit should be summarized, with the areas or activities covered during the audit, as defined in the audit plan. It should also be stated whether this is a first audit, whether the audit covers a particular area of activity, or whether it is a repeat audit.

D2	AUDIT REPORT	Audit Ref. No.	

Audit objectives

Reference should be made to the list of audit objectives, as identified in the audit plan, which should be attached as an appendix. A statement should be made as to whether or not each objective has been met. A similar statement should be made on any assurance objectives that might have been identified.

Any significant observations made in relation to achieving these objectives might have to be prioritized, in terms of the urgency of the mitigation measures that might be required.

Statement of findings

Audit outputs and findings may be summarized in a table quantifying identified unmitigated observations with risk rankings.

The following points could also assist the auditor in summarizing their findings.

- Has the audit been able to identify and quantify separately systematic and random errors and resultant uncertainty?
- Do the sampling activities witnessed during the audit provide a fair representation of the whole organization?
- Has the auditor formed an impression that the sampling practices observed demonstrate a sufficiently large number of observations to warrant a declaration that the sampling as assessed is unreliable and requires improvement?
- Is there an accumulation of low risk errors that could be regarded in isolation as having minimal effect on the process, but which, if they were related to the same area of work, might impose a greater risk?
- Identify and comment on the impacts of any errors in determination of the results requested by the data user.

What does the auditor believe to be the uncertainty arising from sampling and the resulting confidence level attributed to the sampling process as a whole for the occasions observed?

The confidence level can be determined from the quantitative information provided in the pre-audit questionnaire.

A formalized statement of findings can also distinguish between:

- observations made of, but not deemed to be critical to, the integrity of the sampling process;
- observations which are significant, but not critical, to the immediate integrity of the sampling process;
- observations which present a critical risk to the integrity of the sampling process.

Quality control scheme (if applicable)

If the organization operates a quality control scheme, take into account the conformity with the required rigour and the efficacy of communication of any data quality risk to the data users.

D2	AUDIT REPORT	Audit Ref. No.	

Statement of recommended actions

Any statement of recommended action(s) should include an agreed timetable for the rectification of errors, for example:

- high (H) ranked nonconformities need immediate rectification or as soon as practicable;
- all other nonconformities require attention within an agreed timeframe. This could be within three months of the date of audit or even before the next audit, when they would be subject to special attention at that time. A process for re-evaluation of conformity should also be agreed with the responsible person.

The auditor should ensure that the statement of recommended actions addresses all the audit objectives and contains clear risk-based conclusions (where appropriate to the audit plan). If a nonconformity has not been rectified between audits and a subsequent audit identifies it as an ongoing problem, the auditor should consider raising its ranked status as a means of ensuring that errors do not persist in an organization's sampling practice.

Audit conclusions and recommendations

The various forms associated with the assessment of documents and the field assessment should be attached as appendices. Conclusions arising from these assessments should be documented in the main body of the report and should take account of:

- the degree to which the organization has demonstrated conformity with declared sampling practice;
- the degree to which the number of high or low unmitigated observations has influenced the conclusions drawn;
- how the level of unmitigated observations has affected the quality of data collected via the sampling process assessed.

Reference should also be made to the executive summary in respect of quantifying identified unmitigated observations with risk rankings, with the outputs from the audit prioritization exercise attached as an appendix. Any unrecognized systematic effects, which might contribute to these errors but cannot be taken into account in uncertainty statements because they are not measurable, should be noted. Any assumptions made during the process of auditing should be validated.

If this is not a first time audit, reference should be made to the conclusions of the previous audit, which should be attached as an appendix. Any corrective actions arising from the previous audit should be commented on in terms of completion. Any obvious positive attributes of the sampling operation which are evident in the earlier report may be highlighted, but the statement of conformity should rest entirely on the degree to which conformity has been observed with the adopted criteria for judgement, e.g. sampling manual.

Recommended actions should:

- address all the audit objectives; and
- demonstrate clear risk-based conclusions, where appropriate to the audit plan.

D2	AUDIT REPORT	Audit Ref. No.	

SUGGESTED FORMAT FOR AN AUDIT REPORT

Name and address of organization		Audit location address (office)(if different)	
Name of organization's responsible person		Name of auditor(s)	
Type of audit(delete as appropriate)	Internal/External	Risk type of audit (delete as appropriate)	Judgement-based/Risk-based
Audit reference no.		Date(s) of audit	
Date of draft report		Date of final report	
Final report issued by: (auditor)		Signature of auditor	
Report received by:(responsible person)		Signature of responsible person	

This report should be read in conjunction with the requirements of ISO 5667-24.

This report, its conclusions and its recommendations are based on the audit of a small selection of records, documents and locations. The conclusions, therefore, are not necessarily widely applicable and the absence of critical comment or recommendations on any matter does not mean that it was found to be satisfactory, nor does it relieve the organization, department or section of responsibility for the consequences of any deficiency which might exist or subsequently arise. Any statement of satisfaction represents the auditor's opinions at the time, based on the information available to and inspected by them, and does not constitute a general endorsement of the adequacy of the organization's, department's or section's procedures or practices.

Appendices attached to this report (including any other evidential information collected during the audit)

No.	Document	Form Ref.	Attached Y/N?
1	Pre-audit questionnaire	A1	
2	Audit plan	A2	
3	Document assessment form	A3	
4	Opening meeting record	B1	
5	Photographic consent form	B2	
6	Training assessment form	C1	
7	Field assessment form	C2	
8	Location record sheets	C3	
9	Temperature record forms	C4	
10	Observation record forms	C5	
11	Closure meeting record	D1	
Complete the rows below for any additional evidence collected			
12			
13			

D2	AUDIT REPORT	Audit Ref. No.	
The executive summary			

Findings during audit	Mitigated	Unmitigated	Total
No. of predetermined high-risk findings			
No. of predetermined low-risk findings			
No. of unscheduled high-risk findings			
No. of unscheduled low-risk findings			
Total number of findings			
Percentage of all risks identified			
No. of same type breaches observed (where there is an accumulation of similar breaches which collectively could be significant, enter an explanation below)			

Scope (list any modification to the scope outlined in the audit plan)
Audit objectives (and any assurance objectives) (list any modification outlined in the audit plan)

D2	**AUDIT REPORT**	Audit Ref. No.	
Statement of findings *(data taken from audit)*			
No. of sampling practitioners/operatives in the operational unit			
No. of samples taken, on average per year, by the operational unit			
No. of sampling practitioners/operatives assessed during the audit			
No. of samples taken, on average per year, by the sampling practitioners/operatives assessed			
No. of sampling occasions/events observed during the audit			
Percentage of operational workload observed during audit			
Statement of recommended actions			
No.	Type of nonconformity	Date due for completion	
	High ranked nonconformities (i.e. need immediate rectification or as soon as practicable, within one month from the date of audit)		
	All other nonconformities (i.e. require attention within an agreed timeframe, within three months of the date of audit or even before the next audit, when they would be subject to special attention at that time)		

D2	**AUDIT REPORT**	Audit Ref. No.	
Audit conclusions and recommendations			

Annex B
(informative)

Suggested procedures for monitoring temperature control

B.1 General

If the auditor observes that temperature monitoring is not occurring during the audit and it is felt that such monitoring is relevant, the methodology outlined in this Annex may be followed.

Form C4 in Annex A is an example form for recording these procedures.

This form may also be used by the sampling practitioner/operative or adapted for use.

B.2 Thermometer with samples procedure

A thermometer is placed in the area in which samples are to be stored during transit, e.g. cool box, refrigerator in vehicle or refrigerated van. The temperature is then read and recorded on every subsequent occasion that the storage area is opened to deposit a sample, with the final reading being taken either when the samples are left in secure conditions outside the sampling practitioner/operative's control (e.g. a transit refrigerator or handed to a courier) or are formally handed over into the laboratory's custody.

B.3 Datalogger procedure

The auditor presents the sampling practitioner/operative with an electronic data logger, along with documented evidence to show that it has been set to operate as recommended by the manufacturer. This device is placed in a polyethylene bag, along with a record sheet showing the time and date of the sampling occasion, and signed by the auditor. The bag is sealed to prevent any ingress of liquid and placed in the area where samples will be kept during transit. When the samples are either left in secure conditions outside the sampling practitioner/operative's control or are formally received into the custody of the laboratory, the auditor again signs the sheet in the bag and indicates the date and time that custody was relinquished.

The temperature record for either procedure is then incorporated into the audit report. Where the electronic data logger is used, a presentation of "onscreen" displays during the closure meeting are acceptable demonstrations of audit evidence. Alternatively, the auditor may provide the organization with a paper copy later, unless arrangements have been made prior to the audit to provide an output at the time of the assessment.

B.4 Thermometers at storage points procedure

A thermometer is placed in the area in which samples will be stored at any transit points, such as refrigerators in depots. The temperature is then read and recorded by the auditor on every subsequent occasion that the storage area is opened to deposit a sample, with the final reading being taken either when the samples are removed and placed in secure conditions outside the sampling practitioner/operative's control (e.g. a transit refrigerator or handed to a courier) or are formally handed over into the laboratory's custody.

Annex C
(informative)

Measurement of uncertainty associated with sampling practices

In large organizations, samples can be taken throughout the year and it is not unusual to have numerous samples taken every day; often by several teams. An external audit, which would take place over one or two days, would only give a snapshot of all the annual sampling undertaken. As the audit would only observe a small portion of samples that are taken annually, the chance of observing an error on the day of the audit would be small, as illustrated by Table C.1.

Table C.1 — Example data for chance of observing an error

Parameter	Value
Number of samples taken annually by an organization	2 500
Number of errors in the samples (a hypothetical number; not generally known but assumed for this example)	20
Number of samples observed during the audit (over 1 to 2 days)	10
Chance of observing at least one error in the audit	8 %

Using the values in Table C.1, an external audit would have two chances in 25 of observing at least one error; on the other 20 three occasions no error would be observed.

The audit focuses on quality assurance; it is not just a binominal process (i.e. pass or fail), but also takes into account the practice of applying appropriate procedure.

The level of uncertainty of measurement can be estimated using frequentist and Bayesian statistical methods; although a full description is beyond the scope of this standard, references are given in the Bibliography on where to find further information.

Frequentist methods offer a conventional approach to the analysis in the uncertainty of measurement in sampling. This approach is based on the expected frequency that such data would be observed if the same procedure of data collection and analysis was implemented many times. Frequentist methods focus on the frequency with which the observed data are likely to be obtained from hypothetical replicates of sampling. Frequentist methods applied to the uncertainty of measurement in sampling is given in Eurachem.[14]

While conventional (frequentist) statistics are restricted to statements about long-run averages obtained from hypothetical replicates of sampled data, Bayesian methods can be used to make probabilistic predictions and, moreover, these are fully consistent with mathematical logic. Importantly, relevant prior information can be incorporated naturally into Bayesian analyses by specifying the appropriate prior probabilities for the parameters. Frequentist statistical methods are forced to ignore any relevant information other than that contained in the data. It is common in everyday life to combine prior information and new data to update knowledge. Bayesian methods explicitly recognize and combine components of knowledge. Prior knowledge and new data are combined using a model to produce posterior knowledge ("prior" and "posterior" refer here to before and after considering the data). Bayesian statistics provide a logically consistent, objective and repeatable method for combining prior information with data to produce the posterior. A review of Bayesian methods as applied in ecology is given in McCarthy 2007[15]; these methods could be adapted to the analysis in the uncertainty of measurement in sampling.

Bibliography

Standards publications

[1] ISO 5667-1, *Water quality — Sampling — Part 1: Guidance on the design of sampling programmes and sampling techniques*

[2] ISO 5667-3, *Water quality — Sampling — Part 3: Preservation and handling of water samples*

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