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BSI Standards Publication

Water quality — Sampling

Part 24: Guidance on the auditing of water quality sampling

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National foreword

This British Standard is the UK implementation of ISO 5667-24:2016. It supersedes BS 8550:2010 which is withdrawn.

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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).

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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*

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— *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*

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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.

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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.

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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

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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

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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.

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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;

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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.

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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

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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.

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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

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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.

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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;

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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

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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.

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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.

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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

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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).

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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.

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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.

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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.

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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

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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).

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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.

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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.

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