INTERNATIONAL STANDARD

ISO 5667-24

First edition 2016-04-01

Water quality — Sampling —

Part 24: Guidance on the auditing of water quality sampling

Qualité de l'eau — Échantillonnage —

iTeh STPartie 24: Lignes directrices pour l'audit de l'échantillonnage de la qualité de l'eau (standards.iteh.ai)

<u>SIST ISO 5667-24:2018</u> https://standards.iteh.ai/catalog/standards/sist/83dba047-8530-4cb8-af05-723fb99b698d/sist-iso-5667-24-2018



iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>SIST ISO 5667-24:2018</u> https://standards.iteh.ai/catalog/standards/sist/83dba047-8530-4cb8-af05-723fb99b698d/sist-iso-5667-24-2018



COPYRIGHT PROTECTED DOCUMENT

© ISO 2016, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office Ch. de Blandonnet 8 • CP 401 CH-1214 Vernier, Geneva, Switzerland Tel. +41 22 749 01 11 Fax +41 22 749 09 47 copyright@iso.org www.iso.org

| Contents | | | | |
|----------|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|-----|--|
| Fore | word | | v | |
| Intro | oduction | 1 | vii | |
| 1 | Scope | 3 | 1 | |
| 2 | Norm | ative references | 1 | |
| 3 | Term | s and definitions | 1 | |
| 4 | | ple audits | | |
| 5 | | ing objectives | | |
| 6 | | nal audit objectives | | |
| 7 | | nal audit objectives | | |
| 8 | Identification of the critical factors in the water quality sampling process | | | |
| | 8.1 | Identification of critical operational steps | | |
| | 8.2 | Audit prioritization exercise | 7 | |
| | 8.3 | Unscheduled observations | | |
| | 8.4 | Follow-up actions | | |
| 9 | | based versus judgement-based approaches to auditing | | |
| | 9.1 9.2 | General Pick based auditing | | |
| | 9.2 | Risk-based auditing DARD PREVIEW Judgement-based auditing DARD PREVIEW | 0 | |
| | | Auditing assumptions | 9 | |
| 10 | Docu | Auditing assumptions and ards.iteh.ai) ment auditing | 9 | |
| | 10.1 | Sampling programme and sampling practitioner/operative instruction documents | 9 | |
| | 10.2 | Sampling manual streh ai/catalog/standards/sist/83dba047-8530-4cb8-af05- 10.2.1 General 723fb99b698d/sist-iso-5667-24-2018 | 9 | |
| | | 10.2.1 General 723fb99b698d/sist-iso-5667-24-2018 | 9 | |
| | | 10.2.2 Contents 10.2.3 Format | | |
| | | 10.2.4 The laboratory interface | | |
| | 10.3 | Training policy | 13 | |
| | 10.4 | Sampling record sheets | | |
| | 10.5 10.6 | Labels | 13 | |
| | 10.0 | Laboratory receipts | | |
| | 10.8 | Assessment of documents before the field assessment | | |
| | 10.9 | Assessment of completed documents | | |
| | 10.10 | Policy on statements of uncertainty | 16 | |
| 11 | Real-time audit | | | |
| | 11.1 | Audit forms | | |
| | 11.2 11.3 | Field observation | | |
| | 11.4 | Real-time judgement-based auditing (see also 9.3) | | |
| | 11.5 | Evidence of internal audits | | |
| 12 | Design of an audit plan | | | |
| | 12.1 | Consultation with the responsible person | 17 | |
| | 12.2 12.3 12.4 | Pre-audit questionnaire | | |
| | | Plan design | | |
| | | 12.4.1 Staff competence assessments | | |
| | | 12.4.2 Supervision | 18 | |
| | | 12.4.3 Equipment | | |
| | | 12.4.4 Handling of samples | 19 | |

ISO 5667-24:2016(E)

| | | 12.4.5 Individual sample records | 19 | |
|--------------|--------------------------------------------|--------------------------------------------------------------------------|-----|--|
| | | 12.4.6 Tracking of samples | 20 | |
| | 12.5 | Quality assurance and control issues (see ISO 5667-14) | 20 | |
| 13 | Conduct of field assessments | | | |
| | 13.1 | General | 20 | |
| | 13.2 | Sample location verification | 21 | |
| | 13.3 | Identification | 22 | |
| | 13.4 | The use of photographs in field assessment | 22 | |
| 14 | Audit methodology | | | |
| | 14.1 | General | 22 | |
| | 14.2 | Conduct of the audit | 22 | |
| | 14.3 | Reviewing the audit plan | 23 | |
| | 14.4 | Real-time assessment | 24 | |
| | | 14.4.1 General | 24 | |
| | | 14.4.2 Pre-audit meeting | 24 | |
| | | 14.4.3 Opening meeting | 24 | |
| | | 14.4.4 Traceability assessments before real-time audit | 24 | |
| | | 14.4.5 Observation procedures | | |
| | | 14.4.6 Assessing conformity with temperature control during the audit | | |
| | | 14.4.7 Auditing of photographic evidence | | |
| | | 14.4.8 Interpretation of audit data | | |
| | | 14.4.9 Recording nonconformity | | |
| 15 | Assig | udit report and statement of findings The report (standards.iteh.ai) | 26 | |
| 16 | The audit report and statement of findings | | | |
| 10 | 16.1 | The report (standards iteh ai) | 2.7 | |
| | 16.2 | Statement of findings | 28 | |
| | 16.3 | Audit conclusions SIST ISO 5667-24:2018 | | |
| | 16.4 | Statement of recommended actions/standards/sist/83dba047-8530-4cb8-af05= | 28 | |
| 17 | Outli | ne flow diagram of audit process 698d/sist-iso-5667-24-2018 | | |
| Annex | | ormative) Audit forms | | |
| | | ormative) Suggested procedures for monitoring temperature control | | |
| | - | ormative) Measurement of uncertainty associated with sampling practices | | |
| Bibliography | | | | |

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).

SIST ISO 5667-242018

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

723fb99b698d/sist-iso-5667-24-2018

- 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

ISO 5667-24:2016(E)

- 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

iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>SIST ISO 5667-24:2018</u> https://standards.iteh.ai/catalog/standards/sist/83dba047-8530-4cb8-af05-723fb99b698d/sist-iso-5667-24-2018

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 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 atalog/standards/sist/83dba047-8530-4cb8-af05-

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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>SIST ISO 5667-24:2018</u> https://standards.iteh.ai/catalog/standards/sist/83dba047-8530-4cb8-af05-723fb99b698d/sist-iso-5667-24-2018

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.

Standards.iteh.ai

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 and procedures are reports on conformity to these and procedures are reports on conformity to these are reports on conformity to the reports of the reports of

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.

information provider

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

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 (standards.iten.ai) reagents, etc.

3.16

nonconformity

SIST ISO 5667-24:2018

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

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

iTeh STANDARD PREVIEW

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

SIST ISO 5667-24:2018

https://standards.iteh.ai/catalog/standards/sist/83dba047-8530-4cb8-af05-

uncontrolled document

723fb99b698d/sist-iso-5667-24-2018

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.

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.

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. ARD PREVIEW

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.

SIST ISO 5667-24:2018

https://standards.iteh.ai/catalog/standards/sist/83dba047-8530-4cb8-af05-723fb99b698d/sist-iso-5667-24-2018

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 <u>Annex A</u>.

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.

SIST ISO 5667-24:2018

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