ISTA Secretariat
Richtiarkade 18, 8304 Wallisellen, Switzerland
Phone: +41 44 838 60 00 | Fax: +41 44 838 60 01
Email: ista.office@ista.ch
www.seedtest.org

How to Respond to Audit Findings

Any hardcopy of this document is not controlled copy

CREATED	REVIEWED	APPROVED
01.09.2014	OCTOBER 2019/ JULY 2021	29.07.2021
HEAD OF ACCREDITATION AND TECHNICAL DEPARTMENT	QUALITY MANAGER HEAD OF ACCREDITATION AND TECHNICAL DEPARTMENT	SECRETARY GENERAL

SCOPE

This document provides information on how to report on corrective actions established and implemented following an ISTA (re)accreditation assessment.

RELATED DOCUMENTS

ISTA Rules

ISTA Accreditation Standard for Seed Testing and Seed Sampling

Acc-F-03A (Final) Audit Detail Report

Acc-F-03B (Re) Audit Detail Report

RESPONSIBILITIES

Audited member: for following the procedure

ISTA auditors: for verifying that the procedure is followed

HoAT: for supervising the process

ABBREVIATIONS

Audit/Assessment: Systematic, independent, and documented process for obtaining records, statements of fact or other relevant information and assessing them to determine the extent to which specified requirements are fulfilled.

Audit finding: Indicates the non-conformity with audit criteria or opportunity for improvement.

Corrective action: action to eliminate the cause of an identified non-conformity

Correction: action to eliminate an identified non-conformity.

Document: Information and its supporting medium (e.g. documented procedures, forms, records, extracts from databases)

- **Substantial non-conformities** are non-conformities that have a significant influence on the quality of the work or the data leaving the laboratory. This could be, e.g. a requirement given by the accreditation standard not implemented and described, or described but not yet implemented. In either case, the ISTA Rules and/or the Accreditation Standard are not followed. Non-substantial non-conformities from the former audit which have not been dealt with become substantial at the next ISTA audit.
- **Non-substantial non-conformities** are non-conformities that are not expected to have a significant influence on the quality of the laboratory's work, e.g. accreditation requirements that are implemented but insufficiently described in the laboratories' documentation.
- **Recommendation:** Statement based on an audit finding that does not affect the integrity of a laboratory's work but is deemed valuable information.

PROCESS DESCRIPTION

CORRECTIVE ACTION PROCEDURE

Non-conformities must be addressed through a formal corrective action procedure following the audit (Cp. 10.6. in the ISTA Accreditation Standard for Seed Testing and Seed Sampling).

The laboratory must use its own procedure for each non-conformity given at the audit. The identified root cause or details on the corrective action investigation shall be stated.

The laboratory must:

- where necessary apply corrections related to the non-conformity
- investigate the root cause for the non-conformity
- decide which action it will take to remove the root cause and to ensure that this non-conformity does not re-occur
- decide how to implement these corrective actions e.g. change of process steps, change of documents, is training needed, is additional calibration of equipment needed, is purchasing of new equipment needed etc.
- implement the corrective action
- decide how to measure the effectiveness of corrective action taken
- measure the effectiveness and keep records on file for the next audit
- define responsible and due date for the established steps

REPORTING TO THE ISTA ACCREDITATION AND TECHNICAL DEPARTMENT

When at least the corrective actions for the substantial non-conformities have been implemented but not later than the agreed due date, the laboratory must report to the ISTA Accreditation and Technical Department.

For reporting, the laboratory should:

- Use the word-file of the audit detail reports (“Final audit detail report”)
- In the appropriate place write its investigation for each non-conformity, (e.g. root cause), corrective action (e.g. changes of SOPs), and how the effectiveness of the corrective action is implemented and evaluated.
- In the appropriate column refer to which documents of the laboratory QMS the change belongs
- In the appropriate column refer to the provided documents as a proof of the implementation (e.g. photos, training records, revised paragraph of an SOP, new SOP)

To facilitate the auditors’ evaluation, it is necessary to use the audit detail number at the beginning of the file name of the documents. e.g. the laboratory addressed the non-conformity number 2.3 and has provided the auditors with four different documents; in this case the documents shall be named 2.3.1, 2.3.2, 2.3.3, 2.3.4, 2.3.5.

Documents should be submitted electronically.

TIMING

Corrective action measures pertaining to non-conformities rated as 'substantial' must be reported.

The submission must not be later than the date agreed at the closing meeting of the on-site assessment day. If an extension of the due date is necessary due to justified reasons, the Accreditation and Technical Department/assigned system auditor must be contacted.

OBJECTIVE EVIDENCE

The corrective action taken can be documented via a change in the Quality Manual, changes in SOPs, working instructions, forms, including the laboratory’s completed corrective action form. Minutes from staff meetings, invoices (e.g. in case of purchase of new equipment), training records, other records (e.g. audit plan, audit reports), control charts, photographs (e.g. equipment), newly issued ISTA certificates might be suitable evidence for the auditors to see proper implementation.

<u>The changes must be highlighted.</u>

Amended procedures in case of non-conformities related to the quality documentation and declarations of intent are in general not sufficient corrective measures, as they only show how the laboratory corrected the non-conformity.

DOCUMENTS

Due to the nature of the follow-up of corrective action, the comprehensiveness of documents supplied by the auditee is crucial. However, a complete set of quality documents (Manual, Procedures, Instructions, Forms, and other relevant external documents) is not required.

If quality documents were amended as part of a corrective action, then only the revised section(s) should be made available, and the changes must be highlighted.

LANGUAGE

The reporting language for the covering letter and supporting documentation is English. This does not necessarily imply that all documents submitted as part of the corrective action report must be translated. The reporting laboratories are requested to adopt a common-sense approach. It is recommended to confer with the audit team when questions arise regarding the reporting process.

NON-SUBSTANTIAL NON-CONFORMITIES

The laboratory is also recommended to report on the non-substantial non-conformities. The auditors will give comments to the auditee as to whether the corrective actions are appropriate or not. For accreditation being granted the auditors will not require documentation of the implementation of the corrective action for the non-substantial non-conformities.

REPORTING

Laboratories receive a formal follow-up corrective action report including the auditors' comments with respect to the corrective actions reported. If necessary, the laboratory is requested to provide additional information. A new due date is fixed by the auditors.

APPROVAL OF CORRECTIVE ACTIONS

When the Accreditation and Technical Department has received the corrective actions, they will be evaluated with the assistance and input of both auditors and supported when needed by the HoAT. In the document “CA Final audit detail report” the auditors will state if the corrective actions taken are approved or not.

At least the substantial non-conformities must be fully address not later than 6 months after the on-site assessment.

ANNEX

Annex 1. Example of the Final Audit detail report

DISTRIBUTION LIST

ISTA website

Audited laboratory or sampling entity

REVISION HISTORY

Version #	Changes
2.6	Introducing responsibilities Introducing revision history Updating related documents Updating the name of the Accreditation Standard Elaborating the timing Updating the Annex 1
3.0	Layout change

Annex 1. Example of the Final Audit detail report

ISTA laboratory code	**XY01**	Detail Report Number	2.3
Division/department/activity assessed		Technical part	
Accompanying laboratory representative/s		Name of audited staff member/s	
Reporting assessor/s		Name of the system auditor	

(Step 1) Completed by the auditor

S/NS/Rec	S: Substantial non-conformity; NS: Non-substantial non-conformity; Rec: Recommendation	**Reference**	
S	*Title*: **Sample for Moisture Testing**	ISTA Accreditation Standard	ISTA Rules
	Description: The sampler did not take a minimum of three subsamples from different positions of the composite sample. Only one large scoop was taken.	6.2.2. 7.1.	2.5.1.5

(Step 2) completed by the laboratory Laboratory's Follow-up Corrective Action

Description ***The laboratory is responsible for filling out:***	Reference to QMS	Reference to annex attached
Identified root cause: - Sampling demonstration has been performed by a sampler in the authorization process; - Insufficient knowledge of the ISTA Rules; - The SOP describing the sampling moisture was not detailed enough. **Corrective action:** The sampler was removed from the list of the authorized samplers as he was in the authorization process; his training still in progress The related SOP has been revised and distributed to the staff involved in the sampling process (authorized and in authorization process) A refreshing training for the ISTA Rules – Sampling aspects and the revised SOP was organized for all ISTA samplers (authorized and in the authorization process) **Evaluation of effectiveness:** A questionnaire was completed by the trained staff. The answers they provided demonstrate that the training was efficient. The List of authorized samplers was verified and contains the authorized samplers only. The complete implementation will be checked at the next internal audit.	Standard operational procedures	**2.3.1** SOP- Sampling, revised **2.3.2** Training records of staff **2.3.3** Results obtained by the staff trained **2.3.4** Communication with the next internal auditors **2.3.5** List of authorised ISTA samplers

(Step 3) The auditors' evaluation Approval of Follow-up Corrective Action

Description of observed facts: ***To be filled in by the ISTA Accreditation and Technical Department only***	**Approved**	**Not approved**
The laboratory provided detailed evidence of corrective actions established and implemented: the SOP is now revised; the list of ISTA samplers is update, and the ISTA samplers trained and evaluated. **The non-conformity is appropriately addressed.**	21.11.2020	