INTERNATIONAL SEED TESTING ASSOCIATION (ISTA)

Secretariat, Zürichstrasse 50, 8303 Bassersdorf, CH-Switzerland
Phone: +41-44-838 60 00, Fax: +41-44-838 60 01, Email: ista.office@ista.ch, http://www.seedtest.org

Procedure

How to Respond to Audit Findings

Note: Any copies of this document are not subject to change service

	Created by	Reviewed by	Approved by
Date:	01.09.2014	01.09.2014	03.09.2014
Name:	Rasha El-Khadem HoAT	Branislava Opra SA2	Rasha El-Khadem HoAT
Signature:			
Valid from: 20.09.2014			

SCOPE

This document provides information on how to report on corrective actions taken and measures implemented following an ISTA accreditation assessment.

RELATED DOCUMENTS

ISTA Laboratory Accreditation Standard

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

ISTA Rules

RESPONSIBILITY AND 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 either conformity or non-conformity with audit criteria or opportunity for improvement.

Corrective action: action to eliminate the cause of a detected non-conformity or undesirable situation.

Correction: action to eliminate a detected 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 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 (10.6. in the ISTA Laboratory Accreditation Standard).

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 action 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.

REPORTING TO THE ISTA ACCREDITATION AND TECHNICAL DEPARTMENT

When at least the corrective actions for the substantial non-conformities have been implemented the laboratory must report to the ISTA Accreditation and Technical Department.

The laboratory should:

- Find the word-file with the detail of the audit detail reports in ("Final audit detail report").
- In the appropriate place write its finding for each non-conformity, e.g. root cause investigation, corrective action e.g. change of SOPs, and how it implemented the corrective actions.
- In the appropriate column refer to which SOP, highlight the changes, (see the example).
- In the appropriate column refer to which documents provide proof of the implementation e.g. photos, training records, (see the example).

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 and 2.3.4).

Documents should be submitted electronically via e-mail, CD or memory-stick. Paper copies should be avoided.

TIMING

Corrective action measures pertaining to non-conformities rated 'substantial' must be reported by the agreed date stated in the audit report.

Submitted documents have to be at the ISTA Secretariat by that time.

Requests for extensions <u>of the deadline</u> (if any) shall be submitted to the system auditor before the agreed-upon deadline.

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 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 have to 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.

APPROVAL OF CORRECTIVE ACTIONS

When the Accreditation and Technical Department has received the corrective action, it will be evaluated with the assistance and input of the technical auditor. In the document "CA Final audit detail report" the auditors will state if the corrective actions taken are approved or not.

ANNEX

Example of the Final Audit detail report

DISTRIBUTION LIST

Audited laboratory

ISTA laboratory code	**XY01**	Detail Report Number	2.3

Division/department/activity assessed: Technical

Accompanying laboratory representative/s: Name of staff member/s

Reporting assessor/s: S. Check

(Step 1)

S/NS/Rec	S: Substantial non-conformity; NS: Non-substantial non-conformity; Rec: Recommendation **(COMPLETED BY THE AUDITORS)**	**Reference**	
S	*Title*: **Temperature check in Germination chamber**	ISTA Accreditation Standard	ISTA Rules
	Description: The temperature in the germination chamber is measured in the air and not at the level of the samples or in the substrate.		5.6.2.3

(Step 2)

Laboratory's Follow-up Corrective Action

Description ***The laboratory is responsible for filling out:***	Reference to Quality Manual	Reference to annex attached
Identified root cause: We have not realised that this is a requirement of the ISTA Rules. We also did not expect that there would be difference in temperature between the air and germination boxes in a chamber. Therefore we just checked and monitored the air temperature of the germination chamber. **Investigation:** As a correction we updated our SOP (SOP-TEMP-1) and measured the temperature in the germination chamber where the seed is exposed. We also provided training to our staff about this change. **Corrective action:** As corrective action we informed our laboratory leaders to analyze once more the ISTA Rules to make sure we are aware of the requirements. Effectiveness will be measured by our internal auditor who will check if we comply with the ISTA Rules.		**2.3.1** SOP-TEMP-1 **2.3.2** Training records of staff **2.3.3** Temperature records **2.3.4** Communication with laboratory leaders

(Step 3)

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**