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How to Respond to Audit Findings

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How to Respond to Audit Findings

PURPOSE AND SCOPE

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

REFERENCES

ISTA Seed Testing Laboratory Accreditation Standard and the ISTA Rules

DEFINITIONS

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 (\neq **Correction:** action to eliminate a detected non-conformity).

Document: Information and its supporting medium.

- **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.
- **Substantial non-conformities** are non-conformities that have a significant influence on the quality of the work. 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 are not followed. Non-substantial non-conformities from the former audit which have not been dealt with become substantial at the next audit.
- **Recommendation:** Statement based on an audit finding that does not affect the integrity of a laboratory's work but is deemed valuable information. Errors which do not give an indication for systematic deviations.

PROCESS

CORRECTIVE ACTION PROCEDURE

Non-conformities must be addressed through a formal corrective action procedure following the audit (10.6. in the ISTA Accreditation Standard).

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

The laboratory must:

- decide which action it will take to ensure that this non-conformity does not re-occur.
- decide how to implement the corrective action e.g. change of documents (SOPs, WI, QA-manual); is training needed, is additional calibration of equipment needed, is purchase of new equipment needed etc.
- implement the corrective action.
- decide how to measure the effectiveness of corrective action taken
- keep records on file for the next audit.

The laboratory is recommended to use the same procedure for remarks.

REPORTING TO THE ISTA ACCREDITATION DEPARTMENT

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

The laboratory should:

- Find the word-file with the detail of the audit detail reports in ("Final audit detail report NNX_Y_200X").
- In the appropriate place write its finding for each non-conformity, e.g. root cause, investigations, 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 would be appreciated if the documents are named using the audit detail number at the beginning of the file name.

Documents should be submitted electronically via e-mail, cd or memory-stick if possible. 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 of the deadline shall be submitted 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 etc.

To facilitate the auditors' evaluation, the changes must be highlighted.

- The implementation of the changes can be documented via minutes from staff meetings, invoices (e.g. in case of purchase of new equipment), training records, control charts, photographs (e.g. of how the temperature is measured, sealing systems), newly issued certificates etc.

Amended procedures in case of non-conformities related to the quality documentation and declarations of intent are in general not sufficient corrective measures.

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

Unless otherwise agreed to in the accreditation process, 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.

RECOMMENDATIONS FOR NON-SUBSTANTIAL NON-CONFORMITIES

The lab 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. 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 instructed to provide additional information.

APPROVAL OF CORRECTIVE ACTIONS

When the Accreditation Department of the ISTA secretariat has received the corrective action, it will be evaluated with the assistance and input of the technical auditor. In the document "Final audit detail report NNX_Y_200X" the auditors will state if the corrective actions taken are approved or not.

Example:

CONFIDENTIAL

(Step 1) Audit Detail Report

Date of visit **24.10.2008** ISTA lab code **XY01**

Detail report No. **2.4**

Division/department/activity assessed **Technical**

Accompanying lab representative **Responsible for equipment calibration**

Reporting assessor **Ms Check**

NS/S/Rec*	Non-substantial Non-conformity; S = Substantial Non-conformity, Rec = Recommendation (COMPLETED BY THE AUDITORS)	Reference	
S	Title: Temperature check in germination chambers	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

Langtbortistan 24.10.2008

Mr Quality

Ms Check

Place and date

Signature lab representative

Signature reporting assessor

(Step 2) Laboratory's Follow-up Corrective Action

Description THE LABORATORY IS RESPONSIBLE FOR FILLING OUT:	Reference to Quality Manual	Reference to annex attached
<p>Identified root cause :</p> <p>We have not realised 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.</p> <p>Investigation :</p> <p>During the closing meeting at the end of the audit we were made aware of how important and necessary it is that we check temperature in the germination boxes and have carried out corrective actions as detailed below.</p> <p>Corrective action :</p> <p>We updated our temperature checking plan/procedures to include a temperature check at the sample level in the germination boxes (SOP-TEMP-1). Photographs of position of the position of thermocouples that measure temperate in the air and in the boxes are enclosed Temperature records and charts of the temperature in the air and in the boxes are enclosed</p>	Page 3 from SOP-TEMP-1	<p>2.4-1 Photographs</p> <p>2.4-2 Periodical checklist</p> <p>2.4-3 Temperature records</p>

(Step 3) Approval of Follow-up Corrective Action

Description of observed facts: <i>TO BE FILLED IN BY THE ISTA ACCREDITATION DEPARTMENT ONLY</i>	Approved	Not approved
The corrective actions taken are appropriate and the documents provided clearly demonstrate that the corrective actions are implemented.	10.01.2009	