ISTA
Seed Quality Assurance

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How to Respond to Audit Findings

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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 Sampling and Testing

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

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

RESPONSIBILITY

Audited member: for following the procedure

ISTA auditors: for verifying that the procedure is followed

Audit administrator: for supporting the process

Head of Accreditation and Technical Department (HoAT): for supervising the process

ISTA Secretary General (SG): for supporting the process

ECOM Accreditation Working Group (AWG): for supporting the HoAT and SG for any special decision related to the audit process

DEFINITIONS/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 root 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 (S): non-conformities that have a significant influence on the quality of the work. This could be, e.g., a requirement given by the ISTA Accreditation Standard not implemented and described or described but not yet implemented. Substantial non-conformities have to be rectified not later than 6 months after the ISTA audit has been performed
- Non-substantial non-conformities (NS): non-conformities that are not expected to have a significant influence on the quality of the laboratory's work. Non-substantial non-conformities have to be rectified not later than 9 months after the ISTA audit has been performed.
- **Recommendation (Rec):** a statement that does not affect the integrity of the audited member's work but is providing valuable information.
- **For accreditation being granted all non-conformities must be addressed.**

PROCESS DESCRIPTION

CORRECTIVE ACTION PROCEDURE

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

The audited member must use its own procedure for each non-conformity given at the audit. The identified root cause and details on the corrective action investigation and evaluation of effectiveness shall be stated.

The audited member must:

- where necessary apply an immediate correction related to the non-conformity
- investigate the root cause for the identified non-conformity
- decide which action/s 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
- implement the corrective action
- decide how to measure the effectiveness of corrective action taken
- measure the effectiveness and keep records
- define responsible and due date for the established steps

REPORTING TO THE ISTA ACCREDITATION AND TECHNICAL DEPARTMENT

When the corrective actions for the identified non-conformities have been implemented but not later than the agreed due date at the closing meeting of the ISTA audit, the audited member must report to the ISTA Accreditation and Technical Department.

For reporting, the audited member 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 and when the effectiveness of the corrective action is implemented and evaluated.
- in the appropriate column refer to which documents of the audited member Quality Management System (QMS) the change belongs.
- in the appropriate column refer to the provided documents as a proof of implementation (e.g. photos, training records, revised paragraph of an SOP, new SOP, new form).

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 audited member 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. It will also facilitate the evaluation if the revised paragraph/information is highlighter (e.g. a different colour, a sign to mark the change/addition).

Documents should be submitted electronically.

TIMING

Corrective action measures pertaining to all identified non-conformities must be reported.
The submission must not be later than the date agreed at the closing meeting of the assessment day. Usually, the first corrective action (CA1) is submitted not later than three months after the audit date, however, may be extended upon request. A new deadline may be approved in justifiable cases, and after consultation with the Head of the Accreditation and Technical Department and the lead Auditor. If more than 14 days are requested a second deadline may be granted by ECOM-AWG which may not exceed a period of 1 month after the first deadline. Each subsequent CA period is given on a monthly basis thereafter.

Any exception to the above will be considered on a case-by-case base (e.g. justified reasons provided by the audited member, force majeure) and will be discussed and approved or not by the ECOM-Accreditation Working Group.

OBJECTIVE EVIDENCE

The corrective action taken can be documented e.g. via a change in the Quality Manual, changes in SOPs, working instructions, forms, including the audited member'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.

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 audited member corrected the non-conformity and not the corrective action.

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 (Quality 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. The corrective actions are uploaded to the related Audit SharePoint. The access to the audited member is granted by the Accreditation and Technical Department.

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.

REPORTING

Laboratories receive a formal follow-up corrective action report including the auditors' comments with respect to the corrective actions reported. If necessary, the audited member 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. The evaluation of any corrective action must be submitted back to the audited member in maximum 10 working days after the corrective action receipt.

The substantial non-conformities(S) must be address not later than 6 months and the non-substantial non-conformities (NS) not later than 9 months after the audit date.

APPROVAL OF (RE-)ACCREDITATION

(Re-)Accreditation can only be granted after all non-conformities are properly address and approved.

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 if the Accreditation Standard Elaborating the timing Updating the Annex 1
3.0	Layout change
4.0	Update to reflect the ISTA policy regarding the non-conformities identified during an ISTA audit
5.0	The change is due to the updated policy and also the format for reporting the non-conformities (Responsibilities amended, Chapter “Timing” amended, Annex 1 updated)
6.0	ISTA Accreditation Standard title updated “Accreditation” to “approval” wording change in the Annex 1 “laboratory” to “audited member” wording change Note1 and 2 included in the Annex 1 Clarification on the corrective action due date given Definitions for S and NS as in the revised Directive Acc-D-07 Due date prolongation for 14 days and more according to the revised Acc- D-07 Auditee changed to audited member to be align with the term from the Accreditation Standard

Annex 1. Example of the Final Audit detail report

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

S/NS/Rec	S: Substantial non-conformity; NS: Non-substantial non-conformity; Rec: Recommendation	
S	**Submitted sample for Moisture testing**	
Description: The sampler did not take a minimum of three subsamples from different positions of the composite sample. Only one large scoop was taken.		
Reference	ISTA Accreditation Standard	6.2.2, 7.2
	ISTA Rules	2.5.1.5

Follow-up Corrective Action

Description **(The audited organisation is responsible for filling out)**

Identified root cause:

- Sampling demonstration has been performed by a sampler in the approval process;
- Insufficient knowledge of the ISTA Rules;
- The SOP describing the sampling for moisture test was not detailed enough.

Corrective action:

The sampler was removed from the list of the approved ISTA samplers as he was in the appproval process; his training still in progress.

The related SOP has been revised and distributed to the staff involved in the sampling process (approved and in the approval process)

A refreshing training for the ISTA Rules – Sampling aspects and the revised SOP was organized for all ISTA samplers (approved and in the approval process)

Evaluation of effectiveness:

A questionnaire was completed by the trained staff. The answers they provided demonstrate that the training was effective.

The List of approved samplers was verified and contains the approved samplers only.

Reference to QMS	Standard operational procedures
Reference to annex attached	**2.3.1** SOP-Sampling, revised, **2.3.2** Training records of staff, **2.3.3** Results obtained by the trainee **2.3.4** Communication with the next internal auditors, **2.3.5** List of approved ISTA samplers

Approval of Follow-up Corrective Action

Description of observed facts (To be filled in by the ISTA Auditors)	**Approved**	**Not approved**
The laboratory provided detailed evidence of corrective actions established and implemented: the related SOP is now revised; the list of ISTA samplers is update, and the ISTA samplers are trained and evaluated for the updated procedures. **The non-conformity is appropriately addressed.**	01.02.2025	

Note 1

Identified root cause:

this aspect is not for repeating the non-conformity formulated by the auditors, but it requires statement of laboratory internal investigation of the cause for the identified non-conformity

Note 2

Evaluation of effectiveness:

this field is not be left empty but requires explanation of how the effectiveness of the corrective action was verified, including the related attached evidence of verification