



Accreditation of laboratories and sampling entities with sampling units at multiple sites

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SCOPE

This document defines the requirements for the sampling units acting under the responsibility of an ISTA accredited laboratory or a sampling entity.

RELATED DOCUMENTS

ISTA Accreditation Standard for Seed Sampling and Testing
Acc-D-07, ISTA Accreditation and Scope of Accreditation Policy
Acc-D-01, Termination-Suspension-Withdrawal of ISTA Accreditation
Acc-P-02, Procedure for ISTA auditors for the on-site assessment
Acc-SOP-08, Audit visit arrangement
Acc-F-09B, Application Form for (Re)Accreditation

RESPONSIBILITY

ECOM Accreditation Working Group (ECOM-AWG): will decide the suitability of each request for the (re)accreditation of a laboratory or sampling entity with multiple sampling units.

Head of Accreditation and Technical Department (HoAT): will ensure that the requirements of this directive are applied.

ISTA Secretary General (SG): will supervise the process.

ISTA auditors: will perform the audit according to the related procedure.

Audit administrator: will support the audit team in organising the audit dates, travel, accommodation.

DEFINITIONS

Site: a permanent location where an accredited laboratory carries out activities listed in its accreditation scope.

Sampling unit: a unit that is voluntarily separated from the main accredited laboratory/sampling entity and that takes samples for the issuance of ISTA Orange Certificates under the responsibility of the main ISTA accredited laboratory or sampling entity. The separate sampling unit can be located either in the same or a different country to the main laboratory or the sampling entity.

PROCESS DESCRIPTION

GENERAL CONDITIONS

The laboratory or sampling entity's (re)accreditation process follows the principles outlined in the documents listed in the section "Related Documents".

In the following sections, accredited laboratory or sampling entity work comprises all those activities covered by the laboratory's or sampling entity's existing scope of accreditation or proposed addition to the scope of accreditation. It is assumed that all these activities are carried out at the laboratory's or sampling entity's permanent facilities, except 'sampling from the seed lot', which is, by its nature, typically conducted outside the premises.

SAMPLING UNITS INSIDE OR OUTSIDE THE NATIONAL BORDERS UNDER THE RESPONSIBILITY OF AN ACCREDITED LABORATORY OR SAMPLING ENTITY

ISTA accredited laboratories for testing and sampling, or sampling entities, can have approved sampling units belonging to a main laboratory/sampling entity even when the sampling involves different locations in the same country or crossing of international borders. This includes but is not limited to international seed companies with processing plants at several sites in the same country or different countries. There is no limitation due to the geographical areas or continents.

Any approved sampler out of the country of the main location must be part of a sampling unit.

An ISTA member laboratory or sampling entity cannot be a sampling unit of another ISTA accredited laboratory /sampling entity.

A main laboratory or sampling entity can have a maximum of 18 sampling units, providing evidence that the activities performed at all sampling units are under full control of the main location.

A minimum of one third of the sampling units of a laboratory or sampling entity will be evaluated at each ISTA audit. At least one sampling unit will be evaluated with an on-site assessment.

A partially remote audit or a complete remote audit can only be performed upon request of the HoAT in consultation with the SG and must be approved by the ISTA ECOM-AWG.

Conditions for approving a partially or complete remote audit are:

- ISTA auditors are not allowed to travel in a country/ distinct economy where there is an official advice against travel by the official website of the Swiss Federal Department of Foreign Affairs, and/or the country which the ISTA auditors belong to, due to unpredictable security situations (travel warnings).
- If the evaluation of the main location and the sampling units will take longer than one working week (5 days), excluding travel days

A representative of the main laboratory/sampling entity should be available to participate in the evaluation of the sampling units.

On the application for the laboratory or sampling entity (re)accreditation of the locations where sampling units are located and where sampling is performed must be listed, and their name and the address should be clear, and unambiguous.

The Accreditation Certificate is issued with the main laboratory or sampling entity name and address. The sampling units and their address must also be listed on that Certificate. There must be an unambiguous link between the main laboratory or sampling entity and the sampling units falling under the same ISTA accreditation.

There will be only one single unique code assigned by ISTA for the testing laboratory or sampling entity and on the ISTA Certificates the unique code and the contact details of the accredited laboratory or sampling entity must be stated.

A formal agreement between the accredited laboratory or sampling entity and the sampling units must be available.

An up-to-date list of sampling units and their sampling scope must be maintained.

(RE)ACCREDITATION PROCESS

The same process applies irrespective of whether a laboratory or sampling entity sample in the country where it is located or has sampling units over the international borders.

At the initial accreditation audit of the laboratory or sampling entity a minimum of one third of the sampling units are audited. Afterwards, the assessment at the sampling units is organised so a minimum

of one third of the sampling units of a laboratory or sampling entity should be assessed every three years as per the re-accreditation cycle.

Over the course of the (re)accreditation process the laboratory or sampling entity must provide information concerning the organisational and legal setup and take full responsibility for all of its sampling units. The laboratory's or sampling entity's management and document control system must be centrally controlled.

The audit fee will include the evaluation of main location and the multiple sampling units.

The cost will be advised to the laboratory at the time of their application for multisite (re)accreditation.

When applying for ISTA (re)accreditation with sampling units at multi-sites the following criteria must be met:

- There must be a single quality management system that complies with the requirements of the ISTA Accreditation standard,
- The laboratory or sampling entity must provide evidence that it is able to implement its policies in the sampling units,
- The laboratory's or sampling entity's appointed technical person responsible for sampling assumes full responsibility for the work carried out in the sampling units,
- There must be one position assuming the overall responsibility for operating the quality management system and its compliance with the ISTA Accreditation standard,
- Key functions that must be centrally managed:
 - Internal audits
 - Management review
 - Sampler's training and monitoring
 - Evaluation of corrective actions
 - Complaints
 - Changes to the quality management system
 - Risks and opportunities

The laboratory or sampling entity must keep the following records for the samplers of the sampling units they approve to take samples for the issuance of ISTA OICs:

- How many samples each person takes
- The location including the country where the samples were taken
- Which ISTA accredited laboratory the samples are sent to for testing
- Feedback from the ISTA laboratories that receive the samples of any sample non-conformities, e.g. received submitted sample was underweight, sample bag was not sealed.

EXTENSION AND REDUCTION OF THE ACCREDITATION SCOPE

Voluntary extension or reduction of the accreditation scope for sampling of the laboratory or sampling entity will automatically involve a full consideration of the implication(s) for the activity of the sampling units.

Voluntary extension of the accreditation scope of one sampling unit will not be possible if the new sampling method or crop group is not included in the scope of the main accredited laboratory or sampling entity or requested at the same time by the accredited laboratory or sampling entity.

Adding a new sampling unit is considered extension of the scope. This can be requested at the reaccreditation audit time or in period between two ISTA audits. As long as the sampling unit is not listed

in the main location accreditation scope, the sampling unit cannot sample for issuance of ISTA Orange Certificates.

Reduction of the scope of one sampling unit can be accepted as agreed by the main laboratory or sampling entity.

The accepted changes of the accreditation scope will be reflected in the valid quality management system. If necessary, a new accreditation scope will be issued.

SUSPENSION, TERMINATION OF THE ACCREDITATION SCOPE

Suspension or termination of accreditation of the accredited laboratory or sampling entity will automatically involve the full consideration of the implication(s) for the laboratory or sampling entity as a whole.

The same policy applies irrespective of whether a laboratory or the sampling entity sample only in the country where is located or has sampling units over international borders.

DISTRIBUTION LIST

Published at the ISTA website

REVISION HISTORY

Version #	Changes
2.0	The Directive is restructured
3.0	<p>Additions:</p> <p>Any approved sampler out of the country of the main location must be part of a sampling unit.</p> <p>An ISTA member laboratory or sampling entity cannot be a sampling unit of another ISTA accredited laboratory /sampling entity.</p> <p>A main laboratory or sampling entity can have a maximum of 18 sampling units, providing evidence that the activities performed at all sampling units are under full control of the main location.</p> <p>Conditions for approving a partially or complete remote audit: If the evaluation of the main location and the sampling units will take longer than one working week (5 days), excluding travel days.</p> <p>Adding a new sampling unit is considered extension of the scope. This can be requested at the reaccreditation audit time or in period between two ISTA audits. As long as the sampling unit is not listed in the main location accreditation scope, the sampling unit cannot sample for issuance of ISTA Orange Certificates.</p> <p>At Key functions, added: Risks and opportunities</p> <p>A correction was done at the requirement that a formal agreement between the accredited laboratory or sampling entity and the sampling units must be available.</p> <p>Minor edits for clarity.</p>