



Accreditation of laboratories with facilities at multiple sites

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AWG	AWG	ECOM

SCOPE

This document establishes the requirements to be accomplished by the accredited laboratories with facilities on multiple sites.

RELATED DOCUMENTS

ISTA Accreditation Standard for Seed Testing and Seed Sampling

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-09A, Application Form for (Re)Accreditation for laboratories at multiple sites

PT-P-01, ISTA Proficiency Test Programme

RESPONSIBILITY

ECOM- Accreditation working Group: will decide the suitability of each request for the (re)accreditation of a multiple sites' laboratory.

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

ISTA Secretary General: will supervise the process.

ISTA auditors: will perform the audit

Audits administrator: will support the organisation of the audit

DEFINITIONS

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

Multiple sites laboratory: a laboratory having a declared central function (the main accredited laboratory or primary site) at which the activities are planned, controlled and managed and a network of local sites (local accredited laboratories) at which such activities are fully or partially carried out, as defined in the accreditation scope. For ISTA accreditation, the main laboratory and the local laboratories should be identified with the same ISTA code, provided that the number of the local sites are not more than 2 and that the requirements defined below are fulfilled.

PROCESS DESCRIPTION

GENERAL CONDITIONS

The laboratories accreditation process follows the principles outlined in the documents listed as reference.

For laboratories with facilities in multiple sites the approach outlined below applies.

The special case of sampling units acting under the responsibility of an ISTA accredited laboratory based in the same or a different country is dealt with in the Acc-D-06B-Accreditation of laboratories with sampling units at multiple sites.

In the following, **accredited laboratory work** comprises all those activities covered by the laboratory'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 permanent facilities, except 'sampling from the seed lot', which is, by its nature, typically conducted outside the laboratory premises.

ISTA Accreditation of a Multiple sites' laboratory

In relation to the quality management system, multiple sites laboratory can be regarded as equivalent to a single site laboratory, if the requirements defined in this procedure are fulfilled. It has its facilities for conducting accredited laboratory work within one site or on nearby multiple sites. Nearby means that each of the facilities can be easily reached from the main site and should not involve the crossing of national or international borders excepting the case when they are part of the same company/organisation/owner. This includes seed companies with testing laboratories at several sites in the same country or different countries.

A laboratory with multiple sites must be a unique legal entity. A formal agreement between the main laboratory and the local sites must be available. An up-to-date list of local sites and their accreditation scope must be maintained.

On the application for (re)accreditation all facilities must be listed and the name and the address of all should be made clear. Their intended or existing scope of accreditation must be listed clearly and unambiguously for each site. The main laboratory must be mentioned.

The Accreditation Certificate is issued with the main laboratory name and address. The local sites and their accreditation scope must be listed on that Certificate. There must be an unambiguous link between the main laboratory and the local facilities falling under the same ISTA accreditation.

THERE WILL BE ONLY ONE SINGLE UNIQUE CODE ASSIGNED BY ISTA AND ON THE ISTA CERTIFICATES MUST BE STATED THE UNIQUE CODE AND THE CONTACT DETAILS OF THE SAMPLING AND TESTING UNITS (MAIN AND LOCAL LABORATORY/LABORATORIES) RESPONSIBLE FOR THE SPECIFIC ACTIVITIES ON THE CERTIFICATE.

(RE)ACCREDITATION PROCESS

The same process applies irrespective of whether a laboratory operates from one or many sites.

Each location included in the accreditation application/scope of accreditation is visited at the initial accreditation audit and every three years as per the re-accreditation cycle.

The audit fee will include the evaluation of the multiple sites.

Over the course of the (re)accreditation process the laboratory has to provide information concerning their organisational and legal setup. The laboratory's management system must be centrally controlled.

As the units are part of one organisation, at a minimum the following criteria have to be met:

- There has to be a single quality management system applicable in the fields relevant to ISTA accreditation,
 - The laboratory has to provide evidence that it is able to implement its policies to the required degree in all locations involved in accredited laboratory work,
 - The laboratory's appointed technical manager assumes full responsibility for the accredited laboratory work carried out in the main and at the separate sites,
 - 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 have to be centrally managed:
 - Internal audits
 - Management review
 - Staff training and monitoring
 - Evaluation of corrective actions
 - Complaints

- Changes to the system

PARTICIPATION TO THE PROFICIENCY TESTS PROGRAMME

All testing sites (the main laboratory and the local laboratories) must participate in the Proficiency Tests Programme to demonstrate their competence when applying for accreditation for the crop groups and tests they are accredited. The same policy applies for the suspension or termination of accreditation when poor results are obtained whether a laboratory operates from one or multiple sites.

Note:

The ISTA membership fee includes as a benefit the participation in the PT rounds for one laboratory, the participation of the additional laboratories will be at a cost for which the laboratory will be invoiced.

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

EXTENSION AND REDUCTION OF THE ACCREDITATION SCOPE

Voluntary extension or reduction of the accreditation scope of the main laboratory will automatically involve a full consideration of the implication(s) for the laboratory accreditation as a whole.

Voluntary extension of the accreditation scope at one local site will not be possible if the new test/method or crop group is not included in the accreditation scope of the main laboratory or requested at the same time by the main laboratory.

Reduction of the scope of one local site can be accepted as agreed by the main laboratory.

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 main laboratory will automatically involve a full consideration of the implication(s) for the laboratory as a whole, i.e., the main laboratory **and** local sites.

The same policy applies for the suspension and termination of accreditation whether a laboratory operates from one or multiple sites.

Note:

Multi-site establishments that are based in different countries and require substantial effort or time to reach the individual facilities conducting accredited laboratory work have to apply for individual accreditation for each of the single site units intended to carry out accredited work. Membership status must be obtained for each site before accreditation may be sought.

DISTRIBUTION LIST

Published at the ISTA website

REVISION HISTORY

Version #	Changes
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2.0	Complete revision
3.0	Responsibilities update General conditions update Nearby means that each of the facilities can be easily reached from the main site and should not involve the crossing of national or international borders excepting the case when they are part of the same company/organisation/owner. This includes seed companies with testing laboratories at several sites in the same country or different countries.