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 become an

ISTA Accredited Laboratory

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

	Created by	Reviewed by	Approved by
Date:	30.03.2015	01.04.2015	01.04.2015
Name:	Branislava Opra System Auditor	Florina Palada System Auditor	Branislava Opra System Auditor
Signature:			
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SCOPE

The scope of this document is to explain the procedure for becoming an ISTA accredited member laboratory. This guideline will be distributed to laboratories interested in attaining ISTA accreditation.

RELATED DOCUMENTS

- ISTA Seed Testing Laboratory Accreditation Standard
- The Articles of the International Seed Testing Association
- PT-P-01-ISTA Proficiency Test Programme
- Acc-P-08-How to develop Quality documentation
- Acc-F-09-Application Form for (Re-)Accreditation
- Acc-D-01-Termination-Suspension-Withdrawal
- Acc-D-02-Use of the ISTA Logo
- Acc-D-04-Accreditation under the PBA
- Acc-D-06-Multiple-site laboratory accreditation
- Acc-D-07-Scope of Accreditation Policy

RESPONSIBILITY AND ABBREVIATIONS

Accreditation: procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

Accreditation body: body that conducts and administers an accreditation system and grants accreditation.

Audit: systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

Auditor/Assessor: person with competence to conduct an audit.

Authorisation: approval by the ISTA Executive Committee that an ISTA accredited laboratory may issue ISTA International Seed Analysis Certificates.

ISTA Laboratory Accreditation Standard: document provided by the ISTA Secretariat and approved by the Executive Committee where requirements of the quality management systems are laid down. Seed testing laboratories are assessed against this standard.

ISTA Rules: ISTA International Rules for Seed Testing, published by the Association.

Laboratory Proficiency Test Programme: determination of laboratory testing performance by means of inter-laboratory comparisons.

On-site assessment: part of the audit conducted by an ISTA audit team to verify compliance of the current quality management system with the requirements of the ISTA Laboratory Accreditation Standard which takes place in the premises of the laboratory.

Quality Manual: document specifying the quality management system of an organisation.

Re-accreditation audit: audit conducted every three years after the first audit to verify maintenance of the quality management system.

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Repeat audit: additional assessment conducted after a (re-)accreditation audit to verify the suitability of corrective actions taken to address audit findings. This might be necessary when major non-compliances occur and removal cannot be verified through submission of documents.

Scope of accreditation: The scope of accreditation gives details of activities for which the laboratory is accredited in terms of methods in the current version of the ISTA Rules and species mentioned there, including methods for which a laboratory can be accredited under the Performance Based Approach. It cannot comprise methods described only in ISTA Handbooks or Working Sheets. The scope of accreditation must be documented and communicated to the staff members.

PROCESS DESCRIPTION

1. Aim of the ISTA Accreditation

The aim of ISTA Accreditation is to verify if a seed testing laboratory is technically competent to carry out seed testing procedures in accordance with the ISTA Rules. Accredited laboratories must show that they run a quality management system fulfilling the requirements of the ISTA Laboratory Accreditation Standard.

2. ISTA Membership

Only ISTA member laboratories may apply for accreditation. Laboratories that are not ISTA members must apply for membership prior to accreditation. In general, membership in ISTA is open to all persons or laboratories supporting the Association's aims as stipulated in the Articles of the International Seed Testing Association. Membership services include receipt of free copies of all new publications, participation in the inter-laboratory proficiency test programme and access to ISTA's international network of seed scientists and technologists. A directory of all ISTA members is published on the ISTA website (http://www.seedtest.org).

Detailed information on membership and application forms is available from the ISTA Secretariat upon request.

3. Participation in the ISTA Inter-Laboratory Proficiency Test Programme

Participation in the Proficiency Test Programme is obligatory for laboratories accredited by ISTA and a precondition for applying for accreditation. It is voluntary for non-accredited member laboratories that want to bench mark their performance with that of accredited laboratories and prepare themselves for accreditation some day.

Samples, prepared by the Proficiency Test Leader are distributed by the ISTA Accreditation and Technical Department on the beginning of February, June and October each year. A programme plan of proficiency tests is drawn up every three years and distributed to member laboratories. Laboratories accredited for the generic species group being tested in a particular test round are asked to carry out tests according to their preferred ISTA method and report the results on reporting sheets provided within a given deadline. The ISTA Accreditation and Technical Department collects and evaluates the proficiency test results after the deadline. Participating laboratories receive report, showing their performance in comparison with the mean performance of accredited laboratories participating in the test.

Laboratories applying for accreditation can request a package of pre-accreditation proficiency test samples. Completing tests on these samples can minimise the time between application and completion of accreditation.

The document 'The ISTA Proficiency Test Programme' may be obtained from the ISTA Secretariat or can be downloaded from the website (http://www.seedtest.org).

4. Establishment of a Quality Management System

A laboratory applying for accreditation must establish a quality management system according to the ISTA Laboratory Accreditation Standard. The quality management system shall be documented in a quality manual that also includes standard operating procedures (SOPs) and work instructions. The Secretariat compiled a guideline 'How to develop Quality documentation' which may also be downloaded from the website (http://www.seedtest.org).

5. Application for Accreditation

Application for accreditation is made by submitting a completed Application Form for (Re-)Accreditation. The laboratory is required to specify the scope of accreditation it claims competence for (i.e. methods and species tested). Authorisation for the issuance of ISTA Certificates can only be granted in accordance with a relevant scope of ISTA Accreditation.

6. Document Review

Laboratories audited for the first time will be requested to submit their quality documentation or parts of it to the Secretariat. These documents are subject to review by the ISTA Auditors to verify if the requirements concerning the documentation are appropriately addressed. In case of major non-conformities, the auditors may require corrective action to remove them prior to the on-site assessment. If the documents are considered appropriate for the purpose of an audit, the audit date is arranged. Accredited laboratories that are re-audited will be approached by the Secretariat well in advance to arrange the audit date and to ask for a completed Application Form for (Re-)Accreditation. They have to submit their quality documentation at least four weeks prior to the arranged audit date, as electronic versions.

The documents must contain a general description of the laboratory, e.g. an organisational chart, and a description of the responsibilities of individual members of staff, e.g. management, administration, testing, reporting, etc. The laboratory's standard operating procedures (SOPs) and work instructions must also be provided. The appointed audit team will examine the documents and, if necessary, ask for more detailed documents and/or have corrective actions carried out prior to the audit. Where the language used in the laboratory is not English, ISTA requires a copy of the quality documents table of contents to be translated into English. The lead auditor will choose which parts of the quality documents have to be translated prior to the audit. Translation is the responsibility of the laboratory.

7. ISTA Audit

An ISTA audit is usually performed by two auditors, the system auditor and the technical auditor. The system auditor is the lead auditor. As such he/she is responsible for all steps in the accreditation process. He or she examines the quality management system in general and whether it is applied in the every-day work. Technical auditors are seed experts and trained in assessing testing laboratories. He or she examines the technical aspects of the laboratory (e.g. calibration procedures, application of testing procedures, performance of the laboratory in inter-laboratory comparative tests, etc.). The auditors verify the status of the laboratory concerning its involvement in other activities as well as the appropriateness of its scope of accreditation.

The **appointment of auditors** is the responsibility of the ISTA Accreditation and Technical Department and depends on the scope of accreditation and the availability of an auditor. The **on-site assessment** in the premises of the laboratory will be arranged in consultation with the laboratory by the ISTA Accreditation and Technical Department. The assessment usually starts with an opening meeting between the auditors, the head of the laboratory and the staff members involved. This meeting gives the auditors the chance to meet the laboratory staff and to explain the purpose of the audit and the process involved. After the opening meeting, the laboratory is inspected, documents are studied and staff members are interviewed. After that, the auditors will have a meeting to compile facts and data gathered

during the inspection. In a final meeting the auditors present their overall results to the staff members.

Depending on the size of the laboratories scope of accreditation, an on-site assessment takes between one to one and a half working days.

During the on-site assessment, audit findings are recorded in the **Audit Detail Report**, and signed by the respective auditor and the head of the laboratory. The overall result of the assessment will be reported in an **Audit Report**, which includes a **Checklist** of items covered during the audit.

Non-conformities are recorded during the audit in two different categories:

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.

Non-substantial non-conformities are non-conformities that are not expected to have a significant influence on the quality of the laboratory's work.

A date by which the observed substantial non-conformity will be discussed with the laboratory. Substantial non-conformities have to be rectified before the auditors recommend accreditation. Non-substantial non-conformities have to be rectified before the next audit three years later.

Accreditation approval procedure: After having fulfilled the requirements of the ISTA Laboratory Accreditation Standard, the auditors will recommend the granting of accreditation to the laboratory. The ISTA Executive Committee is responsible for decisions regarding accreditation on the basis of the information gathered during the accreditation process and the recommendations of the auditors.

Documentation: When accreditation is approved, the laboratory receives a confirmation letter and the **Certificate of Accreditation** which states the audit date, the scope of accreditation and the period of accreditation validity. A list of methods covered by accreditation is appended to the Certificate of Accreditation. The Certificate is signed by the ISTA President and is validated by applying a dated identification sticker at the bottom of the certificate. This sticker is obtained when the ISTA Secretariat has received payment of the annual accreditation subscription fee.

8. Authorisation to issue ISTA Certificates

Once the accreditation process is completed, the laboratory obtains authorisation to issue ISTA Certificates in accordance with its scope of ISTA accreditation. Authorisation is granted with a validity of three years starting at the date of the on-site assessment.

9. Re-assessment of Accredited Laboratories

Accreditation is valid for three years, starting from the date of the audit. A re-assessment should take place within three months of the third anniversary of accreditation.

10. Duties of an Accredited Laboratory

An ISTA accredited laboratory is obliged to:

- advise the ISTA Secretariat in advance of any significant changes to its ownership, affiliation, organisation, location, or any other matter relevant to its status as an ISTA accredited member laboratory. The ISTA Secretariat will then assess the effect of such changes, on a case-by-case basis, and if accreditation may be maintained or whether maintenance depends on the result of an audit.

- Provide any additional documentation and/or survey information relating to its accreditation, as requested by the ISTA Secretariat.

- continuously abide by the ISTA Laboratory Accreditation Standard once accreditation is granted.
- immediately discontinue the use of ISTA Certificates and return any unused ISTA Certificates and the Certificate of Accreditation to the ISTA Secretariat in the event of withdrawal or termination of accreditation. Conditions for termination, suspension and withdrawal of accreditation are defined in 'Procedures for Termination, Suspension and Withdrawal of ISTA Accreditation' obtainable from the website (http://www.seedtest.org).

11. Register of Accredited Laboratory

A directory of accredited laboratories is published on ISTA's web-site (http://www.seedtest.org), including the names of the laboratories and their scope of accreditation. Details of every new or re-accredited laboratory are published in Seed Testing International.

12. Keeping of Records

The documents concerning the accreditation process for individual laboratories are kept by the ISTA Accreditation and Technical Department.

13. Confidentiality

All information and documents regarding current accreditations and their results are kept confidential.

14. Use of ISTA Logo and the Way of Referring to the Accreditation Granted

ISTA accredited laboratories may refer to their accreditation status on letters and reports. The use of the ISTA logo, which is a registered trade mark, by members for example for public relations' purposes is restricted following the regulations of the Association.

15. Costs

A laboratory wishing to apply for accreditation must become an ISTA member laboratory first. The membership fees are stated below. Accredited laboratories pay an additional annual fee for their status. The audit visit fee is payable every three years prior to the audit.

Membership fees (in Swiss Francs CHF)	Current year
Annual laboratory membership fee (one personal member included)	5'214.-
Annual additional subscription fee for accredited laboratory	1'224.-
Audit visit fee	13'000.-

For further information please contact the ISTA Accreditation and Technical Department.

ANNEX

ISTA Accreditation Procedure flow chart

ANNEX 1

The ISTA Accreditation Procedure

Reference No.	The steps of the accreditation procedure	Related Documents
5.1		
5.2		
5.4		
5.5		
5.6		
5.7		

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DISTRIBUTION LIST

Any part interested in ISTA Accreditation

REVISION HISTORY

Version #	Changes
2.8	New layout. Small editorial changes.