



ISTA

Seed Quality Assurance

ISTA Secretariat

Richtiarkade 18, 8304 Wallisellen, Switzerland

Phone: +41 44 838 60 00 | Fax: +41 44 838 60 01

Email: ista.office@ista.ch

www.seedtest.org

ISTA Accreditation and Scope of Accreditation Policy

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CREATED	REVIEWED	APPROVED
27.09.2013	February 2026	20.02.2026
Head of Accreditation and Technical Department (HoAT)	ISTA Accreditation Working Group (AWG)	ISTA Executive Committee (ECOM)

SCOPE

The scope of this directive is to explain the ISTA accreditation procedure in detail.

It provides information as to how laboratories, laboratories with facilities at multiple sites, laboratories and sampling entities with sampling units at multiple sites, and sampling entities can generate the scope of accreditation.

For the purpose of this Directive, the term ISTA “accredited member” refers to an accredited laboratory, laboratories with facilities at multiple sites, laboratories and sampling entities with sampling units at multiple sites, and accredited sampling entity. It clarifies the accreditation for sampling, or/and testing and also for which tests a laboratory must be accredited to be able to obtain accreditation for other related tests.

Information is also provided about how the scope of accreditation can be changed, how suspended or withdrawn tests can be reinstated.

GENERAL CONDITIONS

The scope of accreditation comprises testing and sampling methods for which a member holds accreditation.

An ISTA member can only be accredited for species and methods covered by the ISTA Rules. Accreditation cannot be granted for in-house methods or methods described in ISTA handbooks or other references only.

In a specified field, laboratories may be eligible to attain accreditation for tests that are not standardised in the Rules as the performance approved methods e.g. Chapter 19 of the ISTA Rules.

The same applies to the Semi-Performance-Based Approach methods in chapter 8 of the ISTA Rules.

Only ISTA accredited laboratories may issue ISTA Certificates. To issue ISTA Certificates the requirements as stated in the ISTA Accreditation Standard and in the ISTA Rules must be followed.

The blank ISTA Certificates (paper format and eCertificates) can be provided only by the ISTA Secretariat to the ISTA accredited laboratories.

RELATED DOCUMENTS

The Articles of the International Seed Testing Association (ISTA)

ISTA Accreditation Standard for Seed Sampling and Testing

ISTA International Rules for Seed Testing

Acc-D-01 Procedures for Termination, Suspension and Withdrawal of ISTA Accreditation

Acc-D-02 Use of ISTA Logo

Acc-D-04 Principles and Conditions for Laboratory Accreditation under the Performance Based Approach

Acc-D-06A Accreditation of laboratories with facilities at multiple sites

Acc-D-06B Accreditation of laboratories and sampling entities with sampling units at multiple sites

Acc-P-10 How to perform an ISTA partially or complete remote audit

Acc-P-08 How to develop Quality Documentation

Acc-P-09 How to respond to audit findings

Admin-05 Appeals and Complaints Procedure

PT-P-01 ISTA Proficiency Test Programme

Mark-P-01 Copyright Policy and Procedure

RESPONSIBILITIES

Performing the audits: ISTA Auditors

Submitting of documents and Corrective actions: candidates for accreditation and accredited members

Organizing 'Mini PT': ISTA Secretariat

Organizing 'Comparative test': concerned laboratories

ECOM and SG : accreditation and re-accreditation approval

HoAT: coordinate the (re)accreditation process

Audit administrator: support the process

ABBREVIATIONS

ECOM-AWG: ECOM Accreditation Working Group

BMP: Below Minimum Performance

GMO: Genetically Modified Organism

ISTA: International Seed Testing Association

PDE: Performance Data Evaluation

PT: ISTA Proficiency Test

OSD: Other Seed Determination

ECOM: ISTA Executive Committee

SG: ISTA Secretary General

HoAT: Head of Accreditation and Technical Department

SOPs: Standard operating procedures

SH: ISTA Seed Health testing

DEFINITIONS

Accreditation: Formal recognition of technical competence to carry out specific tasks .

Accreditation audit: first audit conducted to verify suitability of the quality management system and the member 's compliance with the ISTA Accreditation Standard

Accreditation body: Body that conducts and administers a member accreditation system and grants accreditation (ISTA).

Accredited test: Test covered by a laboratory's scope of 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

Audit evidence: records, statements of fact or other information which are relevant to the audit criteria and verifiable

Audit criteria: set of policies, procedures, and requirements

Auditor/Assessor: person appointed by or recognised by the Association to carry out audits

Authorisation: approval by the ISTA Executive Committee that an ISTA accredited laboratory may issue ISTA Certificates or that a sampling entity can sample for issuance of ISTA Certificates

ISTA Crop group: Classification of species into 8 groups with similar features

ISTA Accreditation Standard for Seed Sampling and Testing (referred to as 'Accreditation Standard'): document approved by the ISTA Executive Committee where requirements of the quality management system are laid down. The audited members are assessed against this standard

ISTA International Rules for Seed Testing: published by the Association and referred to as 'ISTA Rules'.

On-site assessment/on-site audit: 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.

Note: Partially or complete remote audits can be performed for both accreditation and (re)accreditation audits under specific circumstances.

Proficiency Test Programme: schedule of inter-laboratory trials aimed at confirming the laboratory testing performance.

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 and compliance with the ISTA Accreditation Standard.

Re-audit: additional audit 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 member is accredited in terms of sampling and testing methods from the current version of the ISTA Rules performed on species or crop groups, including methods for which a laboratory can be accredited under the Performance Based Approach.

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.

The (re)accreditation is granted when both S non-conformities and NS non-conformities have been addressed.

PROCESS DESCRIPTION

1. ISTA Membership

Membership in ISTA is open to laboratories, laboratories with facilities at multiple sites, laboratories and sampling entities with sampling units at multiple sites, and sampling entities supporting the Association's aims as laid down in 'The Articles of the International Seed Testing Association'. Laboratory membership and sampling entities services include receipt of the ISTA Rules, free copies of new publications, participation in the 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 ([Member Search - International Seed Testing Associationhttp://www.seedtest.org/](http://www.seedtest.org/)).

Only ISTA members may apply for accreditation.

2. The Scope of Accreditation

The ISTA Accreditation Standard requires a list of species and/or sampling method/ analyses for which the member claims competence. By granting accreditation to a member based on that list, ISTA approves the list as an unambiguous reference to what the accredited member is competent to do, which infers that the accreditation assessment covered the elements of that scope to an appropriate extent.

The accredited member's scope of accreditation will be administrated through the Accreditation and Technical Department data base.

Prior to an ISTA audit, each candidate for (re)accreditation will receive a generic application form, which contains all possible methods. They will have to select the methods to be covered by accreditation and return the completed document. This is the basis for the assessment in order to ensure that the audit team and the candidate for (re)accreditation have a common understanding of what will be subject to assessment.

The scope of accreditation in which the candidate for (re)accreditation is interested in should be known by a laboratory as soon as possible as they need to indicate in which PT rounds, they have to participate in. Where accredited tests are defined by groups of species (e.g. 'Cereals'), this grouping also applies to PT

participation. If for instance, a laboratory's accreditation includes germination of a particular cereal species, then it is mandatory to participate in any proficiency test round which includes the crop group 'Cereals' and the related tests purity and other seed determination. When individual species need to be stated to define an accredited test, a laboratory must participate in a proficiency test only if a species used in a test round is also included in its scope of accreditation for that test objective (e.g., accreditation for accelerated ageing test for *Glycine max*).

Where accredited tests involve activities that are also subject to potential accreditation (e.g., moisture determination in an Accelerated Ageing Test or retrieving the pure seed fraction for all determinations made on pure seed), an accredited laboratory must demonstrate its competence and hold accreditation for each of the procedures concerned.

The following are some details thereof:

- Laboratories interested in being accredited for purity must also be accredited for other seeds by number and vice versa.
- Laboratories interested in being accredited for germination must also be accredited for purity and other seed determination as the germination test is based on the use of pure seeds.
- Laboratories interested in being accredited for Thousand Seed Weight (TSW) must also be accredited for purity and other seed determination as the TSW test is based on the use of pure seeds
- An exception is a tetrazolium test or embryo excision performed on the fresh seeds which remain after a germination test: laboratories accredited for germination may perform a viability test on the seeds identified as fresh seeds if present by 5% or more using tetrazolium or excised embryo without being accredited for these tests. However, this only applies for this particular circumstance.
- Another exception is the Thousand Seed Weight (TSW) performed during sample preparation for GMO testing. Laboratories accredited for GMO testing does not need to be accredited for TSW but must follow the ISTA Rules for TSW determination when preparing the samples.
- The same applies for calculating the sample size of pelleted seeds in number of pellets. The laboratory does not need to be accredited for Thousand Seed Weight (TSW) but must follow the ISTA Rules for TSW when calculating the sample size.
- Members seeking accreditation for automatic sampling must also be accredited for manual sampling.

3. Demonstrating laboratory's technical competence

It is a precondition for members interested to become ISTA accredited to have appropriate evidence of their competence. Competence may be demonstrated by participating in the ISTA Proficiency Test Programme, in the so called 'Mini' Proficiency Testing or by self-organising a comparative test.

Note: This does not apply to entities performing sampling only.

3.1 Participation in the ISTA Proficiency Test Programme

If the tests desired for accreditation are covered in the ISTA Proficiency Test Programme, then participation in this is a precondition. Laboratories interested to apply for accreditation must participate in at least one PT round for each crop group or species in question. Test results of all tests that the laboratory is interested in must be available. The laboratory must obtain ratings of either 'A' or 'B'.

ISTA runs a proficiency test programme covering tests such as: Purity, Other Seed Determination, Germination, Viability Testing, Moisture Determination, Vigour, Thousand-seed weight determination (TSW), Variety testing, GMO Testing, Seed Health Testing. The programme also covers the reporting of test results on ISTA Certificates. The performances of laboratories are rated using 'A', 'B', 'C' and 'BMP' ratings, with 'A' reflecting a very good performance. Explanations on how the ratings are calculated are described in the document 'ISTA Standard Proficiency Test' which can be downloaded from the ISTA website ([Proficiency Test Documents - International Seed Testing Association](#)).

3.2 Participation in the 'Mini' Proficiency Testing

In case there is no PT round scheduled for the next 12 months for the tests/crop groups in question, the laboratories can contact the ISTA Accreditation and Technical Department to see if a 'Mini Proficiency Test' round can be scheduled. A Mini-PT round is usually organised by the chair of the Proficiency Test Committee and ISTA accredited laboratories participate on a voluntary basis acting as a reference. Completing tests on these Mini-PT samples can reduce the time for laboratories to apply for accreditation.

Member laboratories are not eligible for participation in a Mini Proficiency Test round unless they are asked by the ISTA Accreditation and Technical Department, and Mini-PT rounds are not organised for non-members. They are usually also not organised for species and tests which have been dispatched as part of the normal PT programme just few months before or will be organised just few months after the laboratory requested to participate.

3.3 Participation in the comparative testing

In case that there is no ISTA test provided within the PT programme and organisation of the 'Mini' Proficiency Testing is not possible, the laboratory seeking ISTA accreditation is requested by the HoAT to organise a comparative test with minimum two other laboratories accredited by ISTA for the combination of the crop groups/tests of interest. The ECOM-AWG is informed.

It is duty of the laboratory seeking ISTA accreditation to make all communication and testing arrangement with the accredited laboratories who accept the collaboration. List of ISTA accredited laboratories is published at the ISTA website (see [Member Search - International Seed Testing Association](https://www.seedtest.org/en/membership/member-search.html)<https://www.seedtest.org/en/membership/member-search.html>).

An accredited laboratory who agreed to take part in the comparative test needs to organise it in a way that the quality parameters, (the composition of the other seed added, the level of seed infection/GMO presence) are not known to the laboratory who seeks ISTA accreditation or the extension of its accreditation scope.

All laboratories in the comparative test need to apply ISTA Rules for testing and can use their own working cards for reporting the results.

The Comparative test results must be evaluated statistically by the laboratory seeking ISTA accreditation and submitted to the ISTA Accreditation and Technical Department for review. All records need to be transparent (original data recorded, as well as method used and data verification principle).

If required, the Accreditation and Technical Department may seek advice of the statistics committee and may involve other technical auditors for the review.

4. Establishment of a Quality Management System

The member candidate for accreditation must establish a quality management system appropriate to its size and work range. It must define the organisation and management structure including its place in the parent organisation. All elements of the ISTA Accreditation Standard must be addressed in the quality management system. Suitable documents and procedures, forms for the system and technical part must be developed, available and used by the staff (Acc-P-08-How to develop Quality Documentation). The candidate for accreditation must have its quality management system implemented prior to the ISTA audit; at least an internal audit and a management review must already be performed and reports available. They should be competent to complete ISTA Certificates. This will be also checked by the assigned auditors prior the audit.

5. Application for Accreditation

Once the member candidate for accreditation has fulfilled the requirement to be an ISTA member, and have established a quality management system, it may contact the ISTA Accreditation and Technical Department to request the form 'Application for (re)accreditation'. In the application form, the candidate must select which activity they would like to include in their scope of accreditation.

The candidates' laboratories must have suitable PT results available for the crop group and tests of interest. This does not apply to entities performing sampling only.

The Accreditation and Technical Department will provide the current version of the application form and will also contact the laboratory to confirm that they have a quality management system implemented and that the related reports are available.

The HoAT will check the suitability of the application. If this is the case, the member candidate will be approached to submit its quality documentation for review.

6. Document Review

For the very first accreditation audit, the candidate for accreditation will be requested to submit its entire quality documentation related to ISTA accreditation in English (e.g., Quality Manual, Procedures, Work Instructions or however named, related forms) for review. The auditors will review the quality documentation to see if it addresses satisfactorily the elements of the ISTA Accreditation Standard. If major parts are not addressed or the quality documentation was found to be not suitable, the laboratory will be informed thereof. No further steps will be taken by the Accreditation and Technical Department towards accreditation unless the candidate for accreditation has provided documents which were reviewed and found to be suitable.

For all following re-accreditation audits due in a three-year cycle, the accredited member will be contacted and asked to submit the content list of its Quality Manual and the complete list of its documentation (SOPs, work instructions, forms, tables, however named). These lists provided in English shall contain the number of pages per document. Based on the application form and scope of accreditation, proficiency test results, audit report and follow-up reports of previous audits, the ISTA auditors will select quality documents to be provided for review.

All selected documents must be submitted in English language. They shall be sent to the Accreditation and Technical Department as electronic versions at the latest one month prior to the audit date.

If the laboratory performed a PDE for GMO detection/quantification or comparative tests for methods not covered in the Proficiency Test Programme, it must submit the results and its evaluation to the Accreditation and Technical Department at least one month prior to the audit.

To maintain the ISTA accreditation a laboratory or sampling entity must be re-evaluated not later than three years and three months after the last ISTA audit.

7. ISTA Audit

An ISTA audit is usually performed with on-site assessment. A partially remote audit or a complete remote audit can be exceptionally accepted and must be approved by ECOM-AWG.

The candidate for accreditation/accredited member will receive an invoice of the audit visit fee once the application for (re)accreditation has been accepted. The invoice must be paid at least one month prior to the audit.

The audits administrator suggests an audit date and provides the information about the composition of the audit team.

The audit team usually consists of a system auditor and a technical auditor. When necessary, another auditor or an ISTA expert for tests as GMO, Variety and SH can participate as part of the audit team. Changes to this composition may be decided depending on the necessity and availability of auditors.

In some cases, when appropriate, one single auditor can be assigned to perform the on-site assessment (e.g., laboratories/sampling entities with a very small accreditation scope). In this case the auditor must be approved as an ISTA system and technical auditor.

The candidate for accreditation/accredited member has the right to appeal in writing against the selection of the auditors if there are good reasons for that. If possible, a new audit team will be appointed. If the grounds for objection are unreasonable or a suitable alternative cannot be identified, the Accreditation and Technical Department reserve the right to appoint the auditors originally selected.

ISTA audits are conducted in English language, unless the auditors can speak the local language. In this case the whole audit or parts of it may be conducted in that language. The candidate for accreditation/accredited member is bound to organise translators for auditors if the staff members do not speak English. All reports prepared by the auditors are written and provided in English.

The audit duration depends on the scope of accreditation and other factors that might have an influence on the time needed. Usually, the audit duration is either 1 or 1.5 days. For the audit of the laboratories with facilities at multiple sites and laboratories or sampling entities with sampling units at multiple sites may take no longer than 8 working days excluding the travel day.

The candidate for accreditation/accredited member must afford representatives and auditors of the accreditation body access to the premises, equipment and to all documents needed for the audit. It must be able to demonstrate all activities that they wish to include in their scope of accreditation. The audit starts with an opening meeting. The auditors will audit each activity to evaluate if the candidate for accreditation/accredited member is appropriately equipped and competent in performing these. At the closing meeting the auditors will present their overall impression and the identified non-conformities to the auditee.

The auditors and the auditee need to agree to a deadline until which the candidate for accreditation/accredited member, will submit the first corrective actions (CA1). This deadline is usually 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.

The non-conformities report will be handed over to the candidate for accreditation/accredited member representative for signing. When sign the identified non-conformities are agreed.

In case that the auditee and the auditors do not reach an agreement on a non-conformity, the auditee may submit a written complaint to the ISTA Accreditation and Technical Department (Admin-F-27-Complaints and Appeals form). If no written complaint is received within a period of one month after the audit date, it will be assumed that the auditee agreed with the non-conformities even if they were not signed by the candidate for accreditation/accredited member representative.

If the candidate for accreditation/accredited member did not settle the audit visit fee by the time of the audit, the non-conformities will not be shared with the laboratory during the closing meeting. However, the time to address the non-conformities will be defined and will start from the audit day. Thus, it is the interest of the auditee to settle the payment soon to have as much time as possible to address the non-conformities. Once the payment is received, the candidate for accreditation/accredited member will receive all audit records. In this case no signature of the auditee will be on the original records.

In case the auditors could not collect enough evidence that proving the suitability of the quality management system and/or the competence of the candidate for accreditation/accredited member and if the auditors were not confident that the laboratory is able to address the non-conformities in an appropriate way, they might recommend a re-audit. The approval for a re-audit is proposed by the HoAT to the ECOM-AWG. During the re-audit the auditors will use the records of the last ISTA audit. The effectiveness of the corrective actions taken by the candidate for accreditation/accredited member will be evaluated and recorded. It may be necessary that additional corrective actions will be requested.

The final format of an audit documents is approved by the HoAT.

The laboratory must cooperate in any pre- or post-accreditation audit or assessment, as requested by the ISTA Executive Committee, and permit access to the equipment, staff and records as required.

8. Addressing non-conformities

The auditors will prepare an audit report and an audit detail report with the description and rating of audit findings that will be sent to the laboratory. The candidate for accreditation/accredited member needs to address the Substantial non-conformities appropriately within a short-defined maximum timeline and not later than 6 months after the audit date and the Non-substantial non-conformities not later than 9 months after the audit date. Information about the root cause analysis and the corrective actions taken including related documents and records must be provided to the lead auditor as electronic version (see Acc-P-09-How to respond to audit findings). Both auditors will review the corrective actions and the supporting evidence and will evaluate them. The candidate for accreditation/accredited member will be informed whether the corrective actions were found to be suitable or if additional steps must be taken or additional evidence must be submitted. A new deadline for reporting the next Corrective action will be decided by the auditors. The final format of the corrective actions report is approved by the HoAT.

The auditee must cooperate in any pre- or post-accreditation audit or assessment, as required by the ISTA Executive Committee, and permit access to records as required.

If the candidate for accreditation/accredited member is not able to address the non-conformities related to one specific test or activity, it might want to consider reducing its scope of accreditation. In this case the non-conformity can be withdrawn, and the scope of accreditation will be reduced accordingly. The principles mentioned under '2. The Scope of Accreditation' will apply.

Once all non-conformities were approved by the auditors, the Accreditation and Technical Department will recommend granting accreditation to the ISTA Executive Committee.

9. Certificate of Accreditation

Once the (re)accreditation of a candidate for accreditation/accredited member has been approved by the ISTA Executive Committee (ECOM), the following steps will be taken:

- The accredited member will be listed on the ISTA website as “accredited”.
- As information about the scope of accreditation is of interest to a broad spectrum of the public including ISTA members, Technical Committees and laboratory customers, the scope of accreditation will be made available on the ISTA website.
- A Certificate of Accreditation will be issued and signed by the ISTA president. This Certificate indicates briefly the scope of accreditation. The certificate will be valid for three years starting from the audit date under the condition that the accredited member continues fulfilling its duties toward the Association (e.g., payment of fees, successful participation in obligatory ISTA proficiency test rounds and its compliance with the Accreditation Standard and ISTA Rules).

If an accredited member wishes to be re-accredited, it must allow a re-accreditation audit to take place within a period of 3 years and 3 months after the last ISTA accreditation audit. In this case the accredited member will continue to be accredited during the period of preparing the audit until the Accreditation and Technical Department comes up with a recommendation for the ISTA ECOM and the ECOM comes to a decision regarding the accreditation status.

If in doubt regarding the accreditation of an accredited member, the ISTA website [Home - International Seed Testing Association](#) shall be checked as it is the only controlled area to confirm accredited members and their scope of accreditation.

Once a member is accredited it can contact the ISTA Accreditation and Technical Department be provided with blank ISTA paper format or eCertificates.

ISTA accredited members may refer to their accreditation status on letters and reports. The use of the ISTA logo, which is a registered trademark, by members for example for public relations' purposes is restricted following the regulations of the Association (Acc-D-02, Use of ISTA Logo).

10. Keeping of Records and Confidentiality

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

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

11. Participation in the ISTA PT programme as accredited laboratory

Once a laboratory is accredited its participation in the ISTA Proficiency Test Programme will automatically be obligatory for the combination of test/crop groups or test/species in their scope of accreditation.

The ISTA Proficiency Test Programme is a monitoring tool for the performance of the laboratory. Poor performance in the ISTA Proficiency Test Programme may lead to suspension and/or withdrawal of ISTA accreditation. Similarly, non-participation in the obligatory proficiency test rounds may lead to suspension and/or withdrawal of ISTA accreditation. Details and the conditions are described in Acc-D-01, Procedures for Termination, Suspension and Withdrawal of ISTA Accreditation.

12. Changes in scope of Accreditation

If the scope of accreditation is changed (extension or reduction), a new version of the scope of accreditation will be issued. If necessary, a new Certificate of Accreditation will be provided.

11.1 Extension of scope to include new activities at the next re-accreditation audit

An accredited member may apply for an extension to its scope of accreditation when its regular audit due in a three years' cycle. It should give prior notice to the ISTA Accreditation and Technical Department if it intends to enlarge the scope of accreditation as this may affect the nomination of the auditors. Any extension must be indicated in the application form for re-accreditation. In some cases, the extension of the scope can be accepted at the latest if is requested by the member and agreed by the auditors at the audit opening meeting.

11.2 Extension of scope to include new activities in between two ISTA audits

It is also possible to extend the scope of accreditation prior to the next scheduled audit. This request shall be communicated in writing to the ISTA Accreditation and Technical Department. Extension to the scope of accreditation in between two audits is not possible for all ISTA activities. The requests will be reviewed on a case-by-case basis and depending on the content of the request it will be assessed by either the system auditors employed at the Secretariat or by appointed technical auditors. The laboratory will be charged with a fee.

Extension of the scope of accreditation for sampling: laboratories not accredited for sampling that wish to include sampling into their scope of accreditation must undergo an on-site assessment. Thus, an extension in between two audits is not possible just by submitting evidence and documents. However, the laboratory can ask to prepone their re-accreditation audit which then will take place in a period shorter than 3 years. In this case the procedure will apply as if the laboratory has asked for a regular re-accreditation audit and only the audit visit fee will be charged.

Laboratories/sampling entities accredited for manual sampling can claim the inclusion of automatic sampling into their scope of accreditation. They will be asked to provide documentations and data supporting the request. An on-site assessment may be necessary.

Extension of the scope of accreditation for sampling or testing: the accredited member will be asked to provide relevant documentation that supports the extension request. These are for example: standard operating procedures, work instructions, related forms, training records of staff, calibration and verification records of equipment. The laboratory is also asked to provide results of proficiency tests and/or comparative tests to show that it is competent in any methods and procedures applied. In some cases, an on-site assessment will be necessary. The laboratory will be charged with a fee.

11.3 Re-instatement of accreditation on specific tests after suspension or withdrawal thereof

If the overall PT performance of the laboratory is poor the laboratory might be subject to suspension and withdrawal from ISTA accreditation. The suspension/withdrawal from accreditation might be limited to one test for which the poor PT results were obtained (e.g., suspension for germination). Following the directive 'Procedures for Termination, Suspension and Withdrawal of ISTA Accreditation' corrective actions must be taken by the laboratory, and their effectiveness must be corroborated by subsequent proficiency test rounds. Once enough subsequent PT results are obtained to result in a calculated overall rating of at least 'C', the laboratory can be re-instated for the specific test.

Poor performance may not be related to a systematic issue in the laboratory but can be related to the laboratory's competency in one specific area (e.g., the laboratory is performing well in germination on grasses and cereals; poor results were only obtained in germination on other agricultural crops). In this case the laboratory must participate in at least one PT round in this specific test/crop group combination and must obtain either an 'A' or a 'B' rating to be re-instated for the suspended/withdrawn test.

The suspension/termination of accreditation and reinstatement is approved case by case by the ECOM-AWG or by the full ECOM at the recommendation of the HoAT and the SG.

13. Duties of an Accredited Member

An ISTA accredited member 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. 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 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 Acc-D-01-Procedures for Termination, Suspension and Withdrawal of ISTA Accreditation from the ISTA website [Home - International Seed Testing Association](#) .
- respect the ISTA proprietary rights and copyright policy whenever referring to the ISTA documentation or part of documentation they may use (e.g. images, checklists, audit reports), see the document: ISTA-Copyright Policy and Procedure which is available on the ISTA website

ANNEX

N.A.

DISTRIBUTION LIST

Posted at the ISTA website

REVISION HISTORY

Version #	Changes
2.1	Revising the list of Annexes Separating responsibilities from abbreviations Introducing distribution list Elaborating comparative test conditions Elaborating records keeping Introducing GMO and SH experts in audit team Updating the name of ISTA Accreditation Standard Defining duties of accredited member Use of term "accredited member" for accredited sampling entities and accredited laboratories
3.0	Layout change
4.0	The directive is revised: <ul style="list-style-type: none">- to reflect the changes in the policy related to the non-substantial non-conformities- to reflect the practice of the laboratory's status according to the new ISTA website- the authority of ECOM-AWG and full ECOM are detailed- the complete remote or partially remote audits are introduced- Additional information about re-audit or extension of the accreditation scope are provided

5.0	<p>Scope: For the purpose of this Directive, the term ISTA “accredited member” refers to an accredited laboratory, laboratories with facilities at multiple sites, laboratories and sampling entities with sampling units at multiple sites, and accredited sampling entity. It clarifies the accreditation for sampling, or/and testing and also for which tests a laboratory must be accredited to be able to obtain accreditation for other related tests. Definitions aligned to the ISTA Accreditation Standard version 8</p> <p>More example at section 2: Laboratories interested in being accredited for Thousand Seed Weight (TSW) must also be accredited for purity and other seed determination as the TSW test is based on the use of pure seeds For calculating the sample size of pelleted seeds in number of pellets. The laboratory does not need to be accredited for Thousand Seed Weight (TSW) but must follow the ISTA Rules for TSW when calculating the sample size.</p> <p>Section 3: the laboratories candidate for accreditation should be competent to complete ISTA Certificates. This will be also checked by the assigned auditors prior to the audit.</p> <p>Section 4: The candidates' laboratories must have suitable PT results available for the crop group and tests of interest. This does not apply to entities performing sampling only.</p> <p>Section 6: For the audit of the laboratories with facilities at multiple sites and laboratories or sampling entities with sampling units at multiple sites may take no longer than 8 working days excluding the travel day.</p> <p>CA1: The deadline is usually three months after the audit date; however, it 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. Several sections: The final format of the corrective actions report is approved by HoAT.</p> <p>Section 11.1: In some cases, the extension of the scope can be accepted at the latest if is requested by the member and agreed by the auditors at the audit's opening meeting.</p> <p>Section 11.2 for extension of the scope: An on-site assessment may be necessary.:</p> <p>Section 12: respect the ISTA proprietary rights and copyright policy whenever referring to the ISTA documentation or part of documentation they may use (e.g. images, checklists, audit reports), see the document: ISTA-Copyright Policy and Procedure which is available on the ISTA website Minor edits for clarity.</p>
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