



ISTA

Seed Quality Assurance

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ISTA Accreditation Standard for Seed Sampling and Testing

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ISTA Accreditation Standard for Seed Sampling and Testing

This standard specifies the criteria which must be fulfilled by laboratories, laboratories with facilities at multiple sites, laboratories and sampling entities with sampling units at multiple sites, and sampling entities in order to obtain ISTA accreditation, and to maintain their status as an ISTA accredited member and their authorisation to issue ISTA certificates. This standard covers all the steps from sampling to issuance of ISTA certificates.

For the purpose of this standard, 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.

ISTA only accredits laboratories and/or sampling entities that meet the requirements of this Standard. ISTA does not accredit or authorise individual analysts or individual samplers.

Accreditation of laboratories with facilities at multiple sites must comply with the requirements specified in the ISTA Directive Acc-D-06A: Accreditation of laboratories with facilities at multiple sites.

Accreditation of laboratories or sampling entities with sampling units at multiple sites must comply with the requirements specified in the ISTA Directives Acc-D-06B: Accreditation of laboratories with sampling units at multiple sites.

A laboratory or sampling entity located in a country cannot have approved ISTA samplers based in another country unless the laboratory or sampling entity is accredited under the ISTA Directive Acc-D-06B: Accreditation for laboratories with sampling units at multiple sites.

ISTA Certificates can be issued only by accredited laboratories having seed testing methods included in their scope of accreditation.

Technologies new to the ISTA Rules are accepted, whether these are the basis of new methods or new tools within existing methods, provided they can meet the specific requirements that are prescribed case by case.

Application forms are obtainable from the ISTA Secretariat. In order to obtain accreditation duly completed application forms must be lodged with the ISTA Secretariat. The applicant must meet the requirements outlined in this Standard, show competence by successfully completing the pre-accreditation proficiency testing, and demonstrate competence during the assessment of the candidate for accreditation/accredited member's facilities by auditors appointed by the ISTA Head of the Accreditation and Technical Department.

Applicants pay for the services rendered during the accreditation assessment (i.e., proficiency assessment, on-site assessment, partially remote assessment or remote assessment in specific conditions, and evaluation of documents), and also pay an annual fee for being an accredited member of ISTA.

A partially remote audit or a complete remote audit can only be accepted on an exceptional basis and must be approved by the ISTA Executive Committee (ECOM).

ISTA accreditation is formally granted by ISTA after the Executive Committee is satisfied that the accreditation process has been properly executed, and that the candidate for accreditation/accredited member has met the requirements of this Standard.

1. Purpose and scope

- 1.1. This ISTA Accreditation Standard has been prepared to meet the specific needs of ISTA, its accredited members and the international seed trade. It has been approved by the ISTA Executive Committee under provisions of Article 15(c)15 of the Articles of the International Seed Testing Association.
- 1.2. The current version of the ISTA International Rules for Seed Testing forms an integral part of the Standard, as the Rules define the methods which must be used for the issuance of ISTA Certificates by accredited members. Accreditation can only be granted for methods stated in the ISTA Rules including new technologies and performance approved methods as defined therein.
- 1.3. Care has been taken to make this Standard suitable for accredited members in different countries, and to require only that is necessary to confirm that sampling and testing ensure that the test results reported on the ISTA Certificates are reliable.
- 1.4. Only the English version of this Standard is official.
- 1.5. It is the responsibility of the accredited member to carry out its work in such a way as to meet the requirements of ISTA.

- 1.6. It is the responsibility of the accredited member to 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.

2. Definitions

The following terms are used in this Standard:

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

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

Auditors: Persons appointed by or recognised by the Association to carry out audits.

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

Certificate: Document that presents test results and other information relevant to a test.

Documents: Information and its supporting medium, e.g., policy statements, procedures, specifications, calibration tables, charts, books, notices, memoranda, work instructions, drawings, plans, etc. Information may be on different media such as hard copy or electronic, digital, analogue, photographic or handwritten.

ISTA Rules: ISTA International Rules for Seed Testing, published by the International Seed Testing Association; includes standardised definitions, methods and principles to be used in evaluating seed for transactions in international trade.

ISTA Certificates: Blank paper ISTA Certificates and access to blank electronic ISTA eCertificates for seed analysis is controlled by ISTA. Both blank paper, and access to blank electronic certificates, are only provided to and can only be issued by accredited laboratories.

Accredited member: Entity performing a) seed testing and sampling, b) seed testing only or c) sampling only.

Sampling entity: An ISTA member accredited/authorised by ISTA for seed sampling only.

Method: Generic description of a logical sequence of operations used in a particular test, specifying the attribute to be examined, the species, the measuring principles used as well as the possible range, dimension and unit of results.

Proficiency testing: Methods of checking laboratory testing performance by means of inter-laboratory tests, e.g., the ISTA Proficiency Test Programme.

Quality manual: Collection of documents which describes quality policy, quality management system and quality practices of the accredited member.

Reference materials: Materials which provide essential traceability and are used to demonstrate the accuracy of results, to calibrate/verify equipment, to monitor accredited member performance, to validate methods, and to enable comparison of methods by use as transfer standards.

Sampler: A person trained and experienced in seed sampling who is approved by an accredited member to obtain seed samples.

Sampling: A defined ISTA procedure whereby a representative part of a seed lot is taken to obtain a sample of suitable size.

SI units of measurement (International System of Units): The SI is founded on seven SI base units for seven base quantities assumed to be mutually independent, e.g., length (m), mass (kg).

Validation: The confirmation of conformity with specified requirements for an intended use.

3. Management Requirements

An accredited ISTA member must:

- 3.1. be an entity that can be held legally responsible for all accredited activities as listed in their scope including that of their sampling units and/or laboratories at multiple sites.
- 3.2. define the involvement and responsibilities of key personnel, if the accredited member is part of an organisation performing activities other than seed testing, in order to identify potential conflicts of interest.

- 3.3. have a quality management system able to cover work carried out in its permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.
- 3.4. define the organisation and management structure of the accredited member, including its place in any parent organisation, and the relationships between management, technical operations, sampling operations, support services and the quality management system (use organisational charts, as necessary).
- 3.5. be able to demonstrate that it does not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to sampling and testing activities.
- 3.6. be able to demonstrate that staff members and samplers are not subjected to undue pressure or inducement that might influence their judgement or results of their work.
- 3.7. be able to demonstrate that the remuneration and conditions of employment of the personnel do not depend on the results of accredited work.
- 3.8. be able to demonstrate that any commercial, financial or other undue influence on the results of the examinations and tests exercised by persons or organisations on the accredited member are excluded.
- 3.9. ensure that access to and use of all accredited member test areas is controlled in a manner appropriate to their purpose, and that entry by persons external to the accredited member is defined and controlled.
- 3.10. provide a list of species and analyses for which the accredited member claims competence.
- 3.11. ensure that if subcontracting is necessary an accredited member is used which adheres to this Standard and holds valid ISTA Accreditation for the work in question. The accredited member must advise the client of any subcontracting in writing and, when appropriate, gain the approval of the client, in writing. The accredited member is responsible to the client for the subcontractor's work. It must maintain a register of all subcontractors that it uses and a record of the evidence of compliance with this Standard for the work in question.
- 3.12. have policies and procedures to ensure the protection of its client's confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results.
- 3.13. specify the responsibilities, authorities and interrelationships of all personnel who manage, perform, or verify work affecting the quality of the tests.
- 3.14. have a technical manager (however named) who has overall responsibility for the technical operations of the accredited member.
- 3.15. have a nominated responsible for quality management system of the accredited member. The quality manager must have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the quality manager must have direct access to the highest level of management at which decisions are made on accredited member policy or resources.
- 3.16. appoint suitable deputies.
- 3.17. ensure the management of the accredited member formulates goals with respect to the education, training and skills of the personnel. The accredited member must have a policy and procedures for identifying training needs and providing training of personnel. The training must be relevant to the present and anticipated tasks of the accredited member.
- 3.18. ensure the management appoints specific personnel to perform particular types of work and to issue ISTA Certificates. The accredited member must maintain records of the relevant appointment(s), educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information must be readily available and must include the date on which authorisation and/or competence is confirmed.
- 3.19. provide any additional documentation and/or survey information relating to its accreditation, as requested by the ISTA Secretariat.
- 3.20. 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.
- 3.21. immediately discontinue the use of ISTA Certificates and return any unused blank paper ISTA Certificates and the Certificate of Accreditation to the ISTA Secretariat in the event of withdrawal or termination of accreditation.

4. Staff

- 4.1. Accredited member staff and samplers must have and maintain the necessary education, training, technical knowledge, demonstrated skills and experience for their assigned functions.
- 4.2. The accredited member must use staff who are employed by, or under contract to, the accredited member. Where contracted and additional technical and key support personnel are used, the accredited member must ensure that such staff are supervised and competent and that they work in accordance with the accredited member's quality management system.
- 4.3. There must be a job description for each accredited member's staff (i.e. analysts and samplers). A job description should include an outline of the key tasks, and the required levels of education, training, technical knowledge and experience.
- 4.4. The accredited member must provide adequate supervision of testing staff and samplers, including trainees, by staff familiar with methods and procedures, the purpose of each test and assessment of the results.
- 4.5. In general, any stand-alone machinery designed for replacing the human analyst during testing of seed samples may be used in an ISTA accredited laboratory. The machinery has to be fit for purpose.
- 4.6. The machinery has to be trained, verified before first use and then periodically verified and routinely monitored as the laboratory personnel who are approved to do the same testing task.

5. Environment, equipment, calibration, and verification

5.1. Environment

- 5.1.1. The environment in which the laboratory tests are undertaken must not invalidate the test results or adversely affect the accuracy of measurement. The testing premises must be protected as required from excessive conditions such as excessive temperature, dust, moisture, vibration, electromagnetic disturbance, interference, and must be maintained accordingly. The environment must be sufficiently spacious to limit the risk of damage or danger and to allow operators to make practical and precise movements. The laboratory must have the equipment and energy sources needed for the testing. When the testing so requires, the laboratory must be equipped with appropriate devices to monitor the environmental conditions.
- 5.1.2. There must be effective separation between neighbouring areas in which there are incompatible activities. Measures must be taken to prevent cross-contamination.
- 5.1.3. Adequate measures must be taken to ensure good housekeeping in the laboratory.
- 5.1.4. The samplers must ensure that the environment of the premises where sampling is carried out meets the requirements of the sampling procedure and does not affect the validity of the sampling or subsequent test results. The premises must have the equipment and energy sources necessary for sampling. There must be adequate light and space to allow for safety and access to the seed to be sampled.

5.2. Provision and maintenance of equipment

- 5.2.1. Accredited member staff and samplers must be furnished with or have access to all items of equipment required for correct performance of sampling and testing for which the member is accredited.
- 5.2.2. Equipment must be run appropriately by approved staff. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) must be readily available for use by the appropriate accredited member staff.
- 5.2.3. Equipment and its software used for testing and sampling must be capable of achieving the accuracy required and must comply with specifications relevant to the tests concerned.
- 5.2.4. There must be documented procedures for calibrating, operating, maintaining, verifying, and monitoring of sampling and testing equipment. Whenever practicable, all equipment under the control of the accredited member and requiring calibration or verification must be labelled, coded, or otherwise identified to indicate the status of calibration/verification, including the date when last calibrated/verified and the date or expiration criteria when recalibration or reverification is due.
- 5.2.5. All equipment must be properly maintained to ensure protection from corrosion and other causes of deterioration.

- 5.2.6. Any equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by calibration, verification or otherwise to be defective, must be taken out of service and clearly labelled until it has been repaired and then shown by test, calibration, or verification to be performing its function satisfactorily again.
- 5.2.7. Each equipment and its software used for testing that is significant to the result must, when practicable, be uniquely identified. Records must be maintained of each major item of equipment and its software. Each record must include:
- (a) the name, type, identification, and serial number or other unique identification, of the item of equipment and its software
 - (b) details of maintenance and monitoring
 - (c) the current location, where appropriate
 - (d) the manufacturer's instructions, if available, or reference to their location
 - (e) details of any damage, malfunction, modification, or repair to the equipment
 - (f) dates, results and copies of verification reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of the next calibration or verification
 - (g) checks that the equipment complies with the specification, before first use and then periodically verified
- 5.2.8. Each record may also include:
- (h) the names of the manufacturer, supplier and service agent, date received, and date placed in service in current location, as appropriate.
- 5.3. Calibration, verification, reference, and testing materials
- 5.3.1. All sampling, measuring, and testing equipment, for which this is possible, must be adequately calibrated, verified and approved as fit for purpose before being placed into service and monitored regularly afterwards. A document must be kept in which are recorded the results of each calibration, verification, service, and repairs (see 5.2.7e and f). Calibration, verification and servicing of equipment must be performed according to an established programme.
- 5.3.2. The overall programme of calibration/verification of equipment must be designed and operated so as to ensure that, wherever applicable, measurements made in the accredited member are traceable to national and international standards of measurement.
- 5.3.3. Appropriate calibration samples, reference materials and reference standards of measurement must be held by the accredited member, or a service provider, and be used for calibration and reference purposes. They should, where possible, be traceable to SI units of measurement, or to certified reference materials. Examples include calibration samples for seed blowers, standard buffer solutions for pH meters, calibration weights for balances, and reference collections of seed.
- 5.3.4. Calibration samples for the blowers must be provided by arrangement with the ISTA Secretariat.
- 5.3.5. The accredited member must examine the effect of defective equipment, and any non-compliant material used for testing (e.g. substrate) on any previous tests and withdraw and re-issue certificates where faulty results are suspected.
- 5.3.6. The accredited member must have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.
- 5.4. Purchasing services and supplies
- 5.4.1. The accredited member must have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests. Procedures must exist for the purchase, reception and storage of reagents and consumable materials relevant for the tests.
- 5.4.2. The accredited member must ensure that purchased supplies and reagents and consumable materials that affect the quality of tests are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests concerned. These services and supplies used must comply with the specified requirements. Records of actions taken to check compliance must be maintained.

- 5.4.3. Purchasing documents for items affecting the quality of accredited member output must contain data describing the services and supplies ordered. These purchasing documents must be reviewed and approved for technical content prior to release.
- 5.4.4. The accredited member must evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and sampling and must maintain records of these evaluations and list those approved.

6. Lot identification, sampling, and handling of samples

6.1. Lot identification and sampling

The accredited member must be able to demonstrate that:

- 6.1.1. it has a system for the approval of lot identification.
- 6.1.2. it has procedures and practices to monitor the uniformity of seed lots and to refuse sampling and testing where doubt exists concerning uniformity.
- 6.1.3. it has a system for the authorisation of its samplers, including the approval and/or provision of sampler training programs, and arrangements for maintaining and distributing up-to-date lists of samplers.
- 6.1.4. adequate procedures and practices exist to monitor the performance of individual samplers with respect to adherence to the ISTA Rules and that provisions exist to cancel the authorisation of individual samplers who for any reason fail to meet the requirements of the Standard.
- 6.1.5. it has a system for the approval of automatic samplers.
- 6.1.6. adequate procedures and practices exist to monitor the performance of automatic samplers.
- 6.1.7. the current protocol for the approval of the automatic seed samplers is applied

6.2. Handling of samples

- 6.2.1. A system for identifying samples to be tested must be applied, through marking samples and documentation, to ensure that there is no confusion regarding the identity of samples and the results of tests made.
- 6.2.2. At all stages of obtaining, dispatching, transporting, storing, handling, sub-sampling and testing of samples, precautions must be taken to prevent contamination, damage or deterioration which would invalidate test results. Handling instructions provided must be followed. When samples have to be stored or conditioned under specified environmental conditions, these conditions must be established, maintained, monitored and recorded. Where a sample is to be held securely, the accredited member must have arrangements for storage and security that protect the condition and integrity of the secured samples concerned.
- 6.2.3. Appropriate information relating to sampling of a seed lot must be included in the documentation sent to the accredited member, as follows:
 - (a) name / identification/ signature or unique identification of the sampler (or other means)
 - (b) name and address of the client/exporter/applicant/seed owner
 - (c) date of sampling
 - (d) unambiguous and unique reference number(s) identifying the seed lot. This may be a seed lot reference number or a sequence or sequences of label numbers
 - (e) the species and where relevant variety/cultivar of seed
 - (f) lot weight/size
 - (g) sealing of the lot
 - (h) number of containers
 - (i) tests required
 - (j) details of any environmental or other conditions during sampling which may affect the interpretation of the test results

- (k) any other available information requested by a client (e.g. the need for subplot certificates)
 - (l) any other information relevant for the testing laboratory (e.g. number of duplicate certificates to issue, duration of waterproofness of moisture samples containers)
- 6.2.4. There must be clear rules for the receipt, retention and disposal of samples. Sample retention must be for not less than one year after receipt of the sample. Exceptions of this retention time are defined in the ISTA Rules.
- 6.2.5. A record of any unusual condition of the sample at the receipt at the accredited member must be kept. When there is doubt as to the suitability of a sample for testing, or when a sample does not conform to the description provided, or the test required is not specified in sufficient detail, the accredited member must consult its approved sampler for further instructions before proceeding; records must be kept.

7. Methods and procedures

- 7.1. For the purpose of the issuance of ISTA Certificates, only the current edition of the ISTA Rules is applicable.
- 7.2. Accredited members must adhere to the methods and procedures of sampling and testing including technologies new to the ISTA Rules and performance approved methods, as published or referred to in the current version of the ISTA Rules.
- 7.3. All rules, handbooks, manuals, instructions, and reference data relevant to the work of the accredited member must be current, up-to-date and readily available to staff. Documents must be written as detailed as necessary to allow staff to perform their tasks.
- 7.4. All calculations and data transfers must be subject to appropriate checks in a systematic manner.
- 7.5. When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data, the accredited member must ensure that:
- (a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use
 - (b) procedures are established and implemented for protecting the data; such procedures must include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing
 - (c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test, calibration, validation, and verification.

8. Test reports and Certificates

- 8.1. The results of each test or series of tests carried out by the accredited member must be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the ISTA Rules.
- 8.2. Test results for which an ISTA Certificate is sought must be reported on an ISTA Certificate, obtainable from the ISTA Secretariat, in accordance with procedures prescribed in the ISTA Rules.
- 8.3. ISTA Certificates must only be issued on species which are listed in the ISTA Rules, and for which the member has been accredited. An ISTA Orange Certificate reflects the quality of the lot at the time of sampling.
- 8.4. When the test report contains results of tests performed by subcontractors, these results must be clearly identified. The subcontractor must report the results in writing or electronically and records must be kept.
- 8.5. An ISTA Certificate must contain a signature (note: this can be digital) and title or an equivalent designation of the person(s) accepting the responsibility of the test report and date of issue, e.g., authorised signatory.
- 8.6. The results reported on any ISTA Certificate must be kept confidential.

9. Documents and records

- 9.1. The accredited member must maintain an up-to-date record of names and addresses of all staff, including samplers, together with records of their training.
- 9.2. The accredited member must maintain a document and record system to suit its particular circumstances. It must retain records of the initial approval of automatic samplers, testing equipment, as well as records of method validation or verification until the device, the equipment or the method is no longer used for the issuance of ISTA certificate but not less than six years. All other records of original observations,

calculations and derived data and sufficient information to establish an audit trail, calibration records, staff records, and a copy of each test report issued, are retained for a defined period but not less than six years.

- 9.3. The records for each test must contain sufficient information to enable the test, calibration, or verification to be repeated under conditions as close as possible to the original. The records must include the identity of personnel responsible for the sampling, performance of each test and checking the results. When machinery is used to replace human analyst, the machine's training and verification must be documented.
- 9.4. Documents and records must be legible and must be stored and retained in such a way that they are readily retrievable and are stored in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.
- 9.5. All records and test reports must be held secure and in confidence to the client, unless otherwise stipulated.
- 9.6. The accredited member must have procedures to protect, and back-up records stored electronically and to prevent unauthorised access to or amendment of these records.
- 9.7. When an error occurs in records, each error must be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records must be dated and signed or initialled by the person making the correction. In the case of records stored electronically, equivalent measures must be taken to avoid loss or change of original data.
- 9.8. Any notes or inscriptions must be made by using an inerasable pen.

10. Quality assurance system

10.1. Operation of the quality assurance system

- 10.1.1. The accredited member must design and operate a quality assurance system appropriate to the type, range and volume of work performed. The quality assurance system must ensure that the required degree of accuracy and precision is achieved, deficiencies are detected, and appropriate and effective corrective actions taken.
- 10.1.2. The quality assurance system must be documented in a quality manual (however named) which is available to the accredited member staff. The quality manual must be updated regularly. The overall objectives must be documented in a quality policy statement. The quality policy statement must be issued under the authority of the management team/person in overall charge of the accredited member. It must include at least the following:
 - (a) the accredited member management's commitment to good professional practice and to the quality of its testing in servicing its clients
 - (b) the objectives of the quality management system
 - (c) a requirement that all staff concerned with testing and sampling activities within the accredited member implement the quality documentation, policies and procedures in their work
 - (d) the accredited member management's commitment to compliance with this Standard and the ISTA Rules.
- 10.1.3. The quality policy statement should be concise and should include the requirement that tests for the purpose of ISTA Certificates must always be carried out in accordance with the ISTA Rules.
- 10.1.4. The quality manual must include or make reference to the supporting procedures including technical procedures (also referred to as standard operational procedures (SOPs) and working instructions (WI)). It must outline the structure of the documentation used in the quality management system.
- 10.1.5. The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with the ISTA Rules and this Standard, must be defined in the quality manual.

10.2. Document control

- 10.2.1. The accredited member must establish and maintain procedures to control all documents that form part of its quality management system (internal and external origin), such as regulations, standards, other normative documents, testing or sampling methods, etc.
- 10.2.2. All documents issued to the staff of the accredited member must be created, reviewed and approved by approved staff prior to use. A master list or an equivalent document control procedure identifying the

current revision status and distribution of documents in the quality system must be established and be readily available to preclude the use of invalid and/or obsolete documents.

10.2.3. The accredited member must ensure that:

- (a) authorised editions of appropriate documents are available at all locations where operations of the accredited member are performed
- (b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements
- (c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use
- (d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked

10.2.4. Quality system documents generated by the accredited member must be uniquely identified. Such identification must include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the documents, and the issuing authority.

10.2.5. Changes to documents must be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. Procedures must be established to describe how changes in documents are made and controlled.

10.3. Quality control procedures

10.3.1. The quality management system must define and document quality control procedures specific to seed lot identification and sampling arrangements, and accredited member testing procedures. These may include check sampling, check testing or other monitoring programmes. The resulting data must be recorded in such a way that trends are detectable and, where practicable, statistical techniques must be applied to the reviewing of the results. When machinery is used to replace the human analyst, the machine must be monitored.

Monitoring must be planned and reviewed and may include, but not be limited to, the following:

- (a) participation in the ISTA Proficiency Test Programme
- (b) replicate tests using the same or different methods
- (c) check sampling of a seed lot by the same or different samplers (parallel samples from the same seed lot)
- (d) testing of retained samples by the same or different analyst
- (e) individual audit assessment using a pre-established checklist
- (f) use of reference materials and/or internal quality controls

10.4. Control of nonconforming testing and sampling work

10.4.1. The accredited member must have a policy and procedures that must be implemented when any aspect of its testing and sampling work, or the results of this work, do not conform to ISTA Rules, its own procedures or the agreed requirements of the client. The policy and procedures must ensure that:

- (a) the responsibilities and authorities for the management of non-conforming work are designated and actions (including halting of work and withholding of test reports, as necessary) are defined and taken when nonconforming work is identified
- (b) an evaluation of the significance of the nonconforming work is made
- (c) corrections are made immediately, together with any decision about the acceptability of the nonconforming work
- (d) where necessary, the client is notified, and work is recalled
- (e) the responsibility for authorising the resumption of work is defined

10.4.2. To prevent that the non-conforming work will recur the corrective action procedures given must be promptly followed and reviewed for effectiveness.

10.5. Proficiency testing

- 10.5.1. The accredited member must actively participate in the ISTA Proficiency Test Programme and must be able to demonstrate that a poor result (i.e., results rated as C or BMP) or any inconsistencies are investigated, and corrective actions taken. The accredited member must also participate in any further follow-up tests arranged by the Proficiency Test Committee, if required.
- 10.5.2. When machinery is used to replace the human analyst, e.g., the machine performs the same tasks that a human analyst does, then the machine must be validated by participation in internal and ISTA Proficiency tests.

10.6. Corrective actions and complaints

- 10.6.1. The accredited member must establish a policy and procedures and must designate appropriate authorities for implementing corrective action when nonconforming work or deviations from the policies and procedures in the quality system or technical operations have been identified.
- 10.6.2. The procedure for corrective action must start with an investigation to determine the root cause(s) of the problem.
- 10.6.3. The accredited member must identify potential corrective actions. It must select and implement the action(s) most likely to eliminate the problem and to prevent recurrence. Corrective actions must be appropriate to the magnitude and the risk of the problem. The accredited member must document and implement any required changes resulting from corrective action investigations.
- 10.6.4. The accredited member must monitor the results to ensure that the corrective actions taken have been effective.
- 10.6.5. The accredited member must define and document arrangements for dealing with complaints and taking corrective action whenever discrepancies are identified.

10.7. Review of requests, tenders and contracts

- 10.7.1. The accredited member must establish and maintain procedures for the review of requests, tenders and contracts. This can be included in an application or request for testing form. The policies and procedures for these reviews leading to a contract for testing and sampling must ensure that:
 - (a) the requirements, including the methods to be used, are adequately defined, documented and understood and are listed in the ISTA Rules
 - (b) the accredited member has the capability and resources to meet the requirements
 - (c) the appropriate testing method is selected and capable of meeting the clients' requirements
- 10.7.2. Any differences between the request or tender and the contract must be resolved before any work commences. Each contract must be acceptable both to the accredited member and the client.
- 10.7.3. Records of reviews, including any significant changes, must be maintained. Records must also be maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract. A contract to test or sample could be for a single samples/test or a series of samples/tests.
- 10.7.4. The review must also cover any work that is subcontracted by the accredited member.
- 10.7.5. The client must be informed of any deviation from the contract.
- 10.7.6. If a contract needs to be amended after work has commenced, the same contract review process must be repeated, and any amendments must be communicated to all affected staff.

10.8. Audits

- 10.8.1. At least yearly, the accredited member must perform internal audits of its activities in accordance with a predetermined schedule and procedure. Audits must be performed in such a way that they verify the accredited member's continuous compliance with this Standard and its quality management system. The internal audit programme must address all elements of the quality management system, including the testing and sampling activities. It is the responsibility of the quality manager to plan and organise audits as required by the schedule and requested by the organisation management. Such audits must be carried out by trained and qualified staff who are, wherever resources permit, independent of the activity to be audited. The audit report and related checklist must be kept and available.

- 10.8.2. When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the accredited member's test results, the accredited member must take timely corrective action and must notify clients in writing if investigations show that the accredited member results may have been affected.
- 10.8.3. The area of activity audited, the audit findings, and corrective actions that arise from them must be recorded.
- 10.8.4. Follow-up audit activities must verify and record the implementation and effectiveness of the corrective action taken.
- 10.8.5. Additional audits must be held in case of any doubts on the accredited member's compliances with its own policies and procedures, or its compliance with this Standard. The accredited member must ensure that the appropriate areas of activity are audited as soon as possible.
- 10.8.6. The accredited member must cooperate in any pre- or post- (re)accreditation audit or assessment, as required by the ISTA Executive Committee, and permit access to documents and records as required.
- 10.8.7. The accredited member must afford representatives and auditors of the accreditation body access to the accredited member, accredited member staff, equipment and to all documents needed for a (re)assessment (re-accreditation or re-audit).

10.9. Reviews by management

- 10.9.1. In accordance with a predetermined schedule and procedure, the accredited member's executive management must periodically conduct a review of the accredited member's quality management system and testing and sampling activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review must take account of:
- the suitability of policies and procedures
 - reports from managerial and supervisory staff
 - the outcome of recent internal audits
 - corrective and continuous improvement actions
 - assessments by external bodies
 - the results of ISTA Proficiency Tests
 - changes in the volume and type of the work
 - complaints and any other relevant information (e.g. client feedback)
 - other relevant factors, such as quality control activities, resources and staff training
 - the outcomes of risk and opportunities actions
 - the outcome of previous management review

10.10. Continuous improvement

The accredited member should strive for continuous improvement and for improvements of efficiency.

10.11. Action to address risk and opportunities

The accredited member must establish a policy and procedures to address risks and opportunities.

Revision history

Version #	Changes
6.0	Title of the standard changed to include sampling entities Standard applies both for seed testing laboratories and for entities performing sampling only (clarification) Definition of the laboratory changed "revision history" introduced
6.1	1.1 Reworded for simplification 2. Definitions: Sampling entity: an ISTA member accredited/authorized by ISTA for seed sampling only
7.0	Use of term "accredited member" instead of accredited laboratory and "sampling entity" Partially and complete remote audits included ISTA electronic Certificates added at ISTA Certificates definition New technologies replacing the human analyst added in several sections Section 3: Management requirement, 3.19, 3.20, 3.21 added Sections: 5.2 and 5.3 terms "verification" added Section 6.2.3: additional clarification and 6.2.3 k) added Section 7.1: For the purpose of the issuance of ISTA Certificates, only the current edition of the ISTA Rules is applicable Sections 8.5 and 8.6: amended Section 9.2: Retention time for the initial approval of automatic samplers, testing equipment, as well as records of method validation or verification added Section 9.6: correction must be dated Section 10.3.1: amended Section 10.5.2: added Section: 10.9.1: amended Section 10.11: added
8.0	Title changed: ISTA Accreditation Standard for Seed Sampling and Testing Introductory part more detailed regarding ISTA accreditation Included as reference: Directive Acc-D-06A: Accreditation of laboratories with facilities at multiple sites and Acc-D-06B: Accreditation of laboratories with sampling units at multiple sites Use of term "approved" instead of "authorised" for the accredited members personnel Section 3.1 detailed for the responsibilities of an accredited member Section 1.6 Copy right policy included Section 5.3.5 testing materials included Section 6.1.7 protocol for the approval of the automatic seed samplers added Section 6.2.3: sealing of the lot (g) and duration of waterproofness of moisture samples containers (l) included Section 8.3. An ISTA Orange Certificate reflects the quality of the lot at the time of sampling, added Section 9.2 split in two sections (9.2 and 9.3) Section 10.2.2 "creating" of documents included Section 10.3.1 amended for more clarity of the monitoring process Section 10.9.1 the outcomes of risk and opportunities actions added For a better clarity in some other sections were done minor amendments