"Further strengthening of capacities of phytosanitary sector in the fields of plant protection products, plant health and seeds and seedlings, including phytosanitary laboratories and phytosanitary inspections"
(TWINNING BA/12/IB/AG 01)

Component 3: Seeds and propagation materials

ISTA ACCREDITATION STANDARD FOR SEED TESTING AND SEED SAMPLING

Rita Zecchinelli

QUALITY MANAGEMENT MODELS

Organization/Company requirements

Regulatory framework

Recognised best laboratory practices

National Accreditation Standards

International Standards

ISTA ACCREDITATION STANDARD

ACTUAL VERSION:

ISTA ACCREDITATION STANDARD FOR
SEED TESTING AND SEED SAMPLING
Version 6.0
Effective as of 01.08.2015

The presentation is aimed to provide an overview.
It is not a valid copy of the document.
For accreditation purposes, please refer to the actual version available on the ISTA website.

www.seedtest.org

ISTA ACCREDITATION STANDARD FOR SEED TESTING AND SEED SAMPLING

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ISTA Accreditation Standard for Seed Testing and Seed Sampling

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ISTA ACCREDITATION STANDARD

DESIGN:

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ISTA ACCREDITATION STANDARD

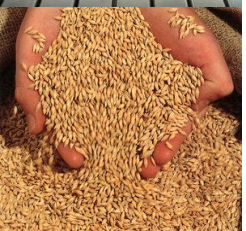
Introduction 1/2

This standard specifies the criteria which must be fulfilled by laboratories in order to maintain their status as an ISTA accredited laboratory and their authorisation to issue ISTA certificates. This standard covers all steps from sampling to issuance of ISTA certificates. This standard applies also to entities performing sampling only. ISTA Certificates can be issued only by accredited laboratories having seed testing methods included in their scope of accreditation.







ISTA ACCREDITATION STANDARD

Introduction 2/2

Application forms are obtainable from the ISTA Secretariat.… The applicant must meet the required organisational and other requirements outlined in this Standard, show competence … and demonstrate competence …

Applicants pay for the services …..

ISTA accreditation is formally granted by ISTA after the Executive Committee has been satisfied that the accreditation process has been properly executed, and that the applicant laboratory has met the requirements of this Standard.

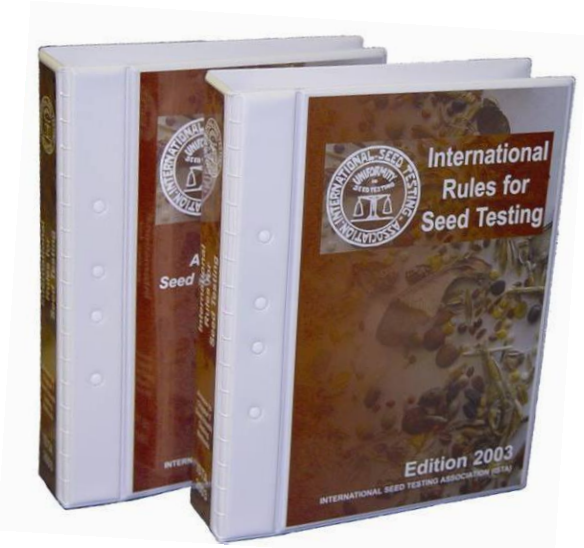
ISTA ACCREDITATION STANDARD
1. Purpose and scope

- The standard has been prepared to meet the specific needs of ISTA, its member laboratories and the international seed trade. It is based on internationally accepted principles for accreditation (i.e. ISO/IEC 17025).
- Accreditation is granted only for methods stated in the ISTA Rules, including performance approved methods; the current version of the ISTA Rules is part of the Standard
- The standard is suitable for seed testing laboratories in different countries
- Official version: English
- The laboratory is responsible to carry out its work in such a way as to meet ISTA requirements

ISTA RULES

The ISTA Rules for Seed Testing provide standardized definitions and methods to be used in evaluating seeds.

They define the methods which must be used for the issuance of ISTA certificates by accredited laboratories.



ISTA ACCREDITATION STANDARD
2. Definitions

- Accreditation
  - Formal recognition of technical competence to carry out specific tasks
- Accreditation body (ISTA)
  - Body that conducts and administers a laboratory accreditation system and grants accreditation

……..

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

……..

- Laboratory
  - Laboratory: “entity performing: a) seed testing and sampling or b) seed testing only ”

ISTA ACCREDITATION STANDARD
3. Management requirements

An accredited ISTA laboratory MUST:

Fulfil legal requirements
Define its organizational structure:
- Externally (vs parent organization)
- Internally (technical manager, quality manager, responsibilities, deputies)

Manage any conflict of interest, avoid undue pressures and influence
Define subcontracting policies
Ensure proper employment conditions and remunerations
Ensure access control to all laboratory's areas
Ensure:
- Independence and integrity
- Impartiality
- Confidentiality
- Competence

Staff: made a training programme available, keep records
Scope: define a list of species and tests

ISTA ACCREDITATION STANDARD
4. Staff

Laboratory staff and samplers (employed or under contract) must have, maintain and demonstrate necessary education, training, technical knowledge and skills (depending on the assigned functions).

The laboratory must define a job description for each staff member and for each sampler.

The laboratory must provide adequate supervision of testing staff and samplers, including trainees.

ISTA ACCREDITATION STANDARD
5.1 Environment

The environment must not invalidate the test results or affect the accuracy of measurement. Interference due to excessive conditions of temperature, dust, moisture, steam, vibration, electromagnetic disturbance must be under control. Enough spacious is required, together with the needed equipment and energy sources.

Incompatible activities must be separated and cross contamination prevented.

Good housekeeping is required.

Samplers must ensure that the environment of the premises where sampling is carried out meets the requirements of the sampling procedure. There must be enough light and space and access to the seed to be sampled must be fully enabled.








ISTA ACCREDITATION STANDARD
5.2 Provision and maintenance of equipment

Staff and samplers must have access to all items of equipment required for correct performance of their tasks.

Equipment must be run by authorized staff; up to date instructions on the use and maintenance of equipment must be available.

Equipment must be capable of achieving the accuracy required.

There must be documented procedures for operating, maintaining, calibrating, monitoring the equipment; equipment must be identifiable (coded and labeled).

Equipment must be properly maintained.

Defective equipment must be taken out of service until they are repaired and checked.

Each equipment must be uniquely identify.

For each item of equipment and its software, the relevant information must be recorded.







ISTA ACCREDITATION STANDARD
5.3 Calibration, reference and testing materials

All sampling, measuring, testing equipment (for which it is possible) must be calibrated before use and regularly afterwards; there must be a calibration programme and calibration results must be recorded. Whenever applicable, the calibration programme must ensure traceability of measures to national and international standards of measurement.

The laboratory must hold appropriate calibration samples, reference materials and standard of measurement (e.g. blower calibration samples, pH standard buffer solutions, weights, seed reference collection); they should be certified or traceable to SI units of measurement; some reference materials must be provided/verified by ISTA.

The laboratory must examine the effect of defective equipment; where faulty results are suspected, the laboratory must withdraw previous results and re-issue certificate.

The laboratory must protect the integrity of reference standards and materials (procedures for use, handling, transport, storage).

ISTA ACCREDITATION STANDARD
5.4 Purchasing services and supplies

The requirements concern services and supplies that affect the quality of the tests.

The laboratory must have a policy for the selection of services and supplies (procedure/s: purchase, reception and storage of reagents and consumable materials).

The laboratory must check or otherwise verified reagents and consumable materials before the use; services and supplies must comply with the specified requirements and the records must be maintained.

Purchasing documents for items affecting the quality of tests must contain data describing the services and supplies (they must be reviewed and approved prior to release).

The laboratory must evaluate the suppliers and must maintain records of these evaluations and list those approved.

ISTA ACCREDITATION STANDARD
6.1 Lot identification and sampling

The laboratory MUST be able to demonstrate that:

It has a system for the approval of lot identification.

It has procedures to monitor the uniformity of the lot and to refuse sampling in case of doubts.

It has a system for authorization and training of samplers; it must have an up-to-date list of authorized samplers.

It has procedures to monitor the performance of individual samplers, to cancel the authorization of individual samplers who fail to meet the requirements of the Standard.

It has a system for the authorization and the monitoring of automatic samplers.

ISTA ACCREDITATION STANDARD
6.2 Handling of samples

There must be a system to uniquely identify samples.

At all stages, precaution must be taken to prevent damage, contamination deterioration of samples; samples to be stored must be maintained under specified environmental conditions.

The sampling report must include all relevant information.

There must be procedures for receipt, retention, disposal of samples; sample retention must be for not less than one year after receipt.

A record of any unusual condition of the sample at the receipt must be kept; in case of any doubts, the client must be consulted and the discussion recorded.

ISTA ACCREDITATION STANDARD
7. Methods and procedures

To issue ISTA certificates, samplers and laboratory staff must adhere to the methods and procedures published in the current version of the ISTA Rules, including performance approved methods.

All instructions (manuals, handbooks, reference data..) to the staff must be available and up-to-date.

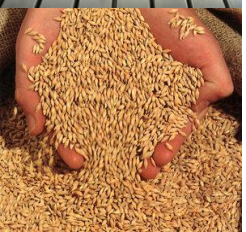
All calculations and data transfers must be checked in a systematic manner.

All computerized data must be protected, the software documented and validated as being adequate for use, the hardware maintained.







ISTA ACCREDITATION STANDARD
8. Test reports and certificates

Test results must be reported accurately, clearly, unambiguously, objectively, in accordance with the ISTA Rules.

ISTA certificates are provided by the ISTA Secretariat.

ISTA certificates must only be issued for species listed in the ISTA Rules and for which the laboratory has been accredited.

When the test report contain results of tests performed by subcontractors, these results shall be clearly identified; subcontractors shall report the results in writing.

ISTA certificates are signed by a person accepting technical responsibility of the test reported and date of issue.

ISTA certificate is property of the client and kept confidential.

ISTA ACCREDITATION STANDARD
9. Documents and records

The laboratory must maintain an up-to-date record of staff members and samplers (names, addresses) and of their training.

The laboratory must maintain a record system: original observations, calculations, derived data, calibration records, staff records, copy of each test report (min. 6 years); the records must enable to establish an audit trail and repeat the activity; the records must include the identity of personnel responsible for the sampling, performance of each test.

All records must be legible and stored adequately, in confidence with the client.

Records electronically stored must be protected and backed up; the access to these records is controlled.

Mistakes are not erased, but crossed out and the correct value is entered alongside; the correction is signed. Any note or inscription must be made by using an inerasable pen

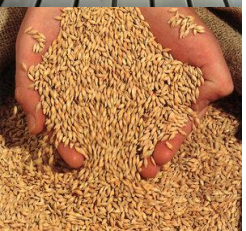
ISTA ACCREDITATION STANDARD
10. Quality Assurance System

10.1. Operation of the Quality Assurance System
10.2. Document control
10.3. Quality control procedures
10.4. Control of nonconforming testing and sampling work
10.5. Proficiency testing
10.6. Corrective actions and complaints
10.7. Review of requests, tenders, contracts
10.8 Audits
10.9. Reviews by management
10.10 Continuous improvement







ISTA ACCREDITATION STANDARD
10.1 Operation of the quality assurance system

The quality assurance system must be appropriate to the type, range and volume of the work; it must ensure the required degree of accuracy, deficiencies must be detected, corrective actions taken.

The quality assurance system must be documented in a quality manual available to the staff; this manual must be regularly updated and it must define the quality policy of the laboratory (overall objectives defined):

- the quality policy statement must include minimum information (referred to the laboratory's performance, objectives, staff, management, SOPs);
- it must make reference to the ISTA Accreditation Standard and to the ISTA Rules; it must state that ISTA certificate must be carried out in accordance to the ISTA Rules;
- it must define technical and quality responsibilities, including those to ensure compliance with the ISTA Rules and Accreditation Standard.

The quality manual must be concise and include or make reference to supporting procedures.

ISTA ACCREDITATION STANDARD
10.2 Document control

The laboratory must establish and maintain procedures to control all documents (internal and external origin) that form part of its quality system (e.g. standards, methods….).

All documents issued to the staff must be reviewed and approved. A master list to identify current versions and distribution must be available.

The laboratory must ensure that appropriate documents are available where necessary, they are periodically reviewed, when obsolete, they are removed from use and suitably marked.

All documents must be uniquely identified (date, revision, page X of Y, issuing authority/ies)-

Changes to documents must be reviewed and approved.

ISTA ACCREDITATION STANDARD
10.3 Quality control procedures

The quality system must define procedures specific to seed lot identification, sampling, testing; they must include check/monitoring sampling and testing programmes; resulting data must be recorded and where applicable evaluated by statistical techniques; trends must be detectable.

Examples of monitoring activities:

- regular use of reference materials
- participation in ISTA PT programme
- replicates tests (with the same o a different method)
- retesting

ISTA ACCREDITATION STANDARD
10.4 Control of non-conforming sampling and testing work

The laboratory must establish, maintain and implement a policy and procedures to control nonconformities (testing and sampling works, their results do not conform to the lab's procedures or to the agreed requirements of the clients), so that:

- management of nonconforming work is designed (including responsibilities and corrective actions);
- the significance of nonconforming work is evaluated;
- corrections are made immediately;
- the client is notified (if necessary);
- the resumption of work is under defined responsibilities;
- the indication of that the nonconforming work could recur is taken into account.

ISTA ACCREDITATION STANDARD

10.5 Proficiency Testing

The laboratory must participate to the ISTA proficiency test Programme; any inconsistencies are investigated.

ISTA ACCREDITATION STANDARD
10.6 Corrective actions and complaints

The laboratory must establish, maintain and implement a policy and procedures for implementing corrective actions when necessary; the procedure for corrective action must start with the determination of the root cause/s of the problem.

The laboratory must select the corrective action most likely to eliminate the problem; it must implement and document any changes resulting from the corrective action; the results of the corrective action must be monitored.

The laboratory must have a procedure to deal with complaints and take corrective actions whenever discrepancies are identified.

ISTA ACCREDITATION STANDARD

10.7 Review of requests, tenders, contracts

The laboratory must establish and maintain procedures for the review of request, tenders and contracts; when leading to a contract for sampling and testing , the procedures must ensure that the requirements (e.g. appropriate methods) are define, documented understood, the laboratory must have the capability and resources, any contrast between the tender or request and the contract is resolved before the work commences.

Records of reviews, changes, discussion with the client must me maintained.

The review must also cover sub-contracted works.

The client must be informed of any deviation from the contract.

Amendments to the contact made after work has commenced must be also reviewed and communicated to the staff.

ISTA ACCREDITATION STANDARD
10.8 Audits

Internal audits must be programmed and performed at least yearly, addressing all elements of the quality system and verifying the compliance with the ISTA Accreditation Standard; the quality manager is responsible for planning and organizing the audits, the auditors should be independent of the activities to be audited.

Corrective actions must be implemented when audit findings cast any doubts; the client/s must be notified in writing if there are any doubts on testing results.

The results of audits and of corrective actions must be recorded.

Corrective actions that arise from audit findings must be recorded and their effectiveness monitored.

Additional audits must be held in case of any doubts.

The laboratory must cooperate with ISTA auditors.

ISTA ACCREDITATION STANDARD

10.9 Reviews by management

The laboratory's management must periodically conduct a review of the quality system; the review must take account of:

- suitability of policies and procedures
- reports from the staff
- internal audit findings and assessments from external bodies
- corrective and preventive actions
- results of proficiency tests
- changes in the volume and type of work
- client feedback
- complaints
- other relevant factors (e.g. staff training, resources..)
- the outcome of previous management review.

ISTA ACCREDITATION STANDARD

10.10 Continuous improvement

The laboratory should strive for continuous improvement and for improvements of efficiency.