



ISTA Laboratory Accreditation Standard

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ISTA Laboratory Accreditation Standard

This Standard specifies the criteria which must be fulfilled by laboratories in order to obtain and maintain their status as an International Seed Testing Association (ISTA) accredited laboratory and their authorisation to issue ISTA Certificates. This Standard covers all steps from sampling to issuance of ISTA Certificates.

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 required organisational and other requirements outlined in this Standard, show competence by successfully completing the pre-accreditation proficiency testing, and demonstrate competence during the on-site assessment of the laboratory's facilities by auditors appointed by the ISTA Executive Committee.

Applicants pay for the services rendered during the accreditation assessment (proficiency assessment, on-site assessment, and document evaluation), and pay an annual fee for being an accredited member of ISTA.

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.

1. Purpose and scope

- 1.1. This ISTA Laboratory Accreditation 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. It has been approved by the ISTA Executive Committee under provisions of Article VII(c)15 of the Constitution 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 laboratories. Accreditation can only be granted for methods stated in the ISTA Rules including performance approved methods as defined therein.
- 1.3. Care has been taken to make the Standard suitable for laboratories in different countries, and to require only that which is necessary to ensure that test results are reliable.
- 1.4. Only the English version of this Standard is official.
- 1.5. It is the responsibility of the laboratory to carry out its work in such a way as to meet the requirements of ISTA.

2. Definitions

The following terms are used in the Standard:

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

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

Auditors (Assessors): 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: 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 hand written.

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.

Laboratory: entity performing seed sampling and/or testing.

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, i.e. the ISTA Proficiency Test Programme.

Quality manual: Collection of documents which describes quality policy, quality systems and quality practices in the laboratory.

Reference materials: Materials which provide essential traceability and are used to demonstrate the accuracy of results, to calibrate equipment, to monitor laboratory 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 authorised by a laboratory to obtain seed samples..

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

SI units of measurement: 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 laboratory must:

- 3.1. be an entity that can be held legally responsible for its work.
- 3.2. define the involvement and responsibilities of key personnel, if the laboratory is part of an organisation performing activities other than seed testing, in order to identify potential conflicts of interest.
- 3.3. have a laboratory management system able to cover work carried out in the laboratory's 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 laboratory, 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 laboratory are excluded.
- 3.9. ensure that access to and use of all laboratory test areas is controlled in a manner appropriate to their purpose, and that entry by persons external to the laboratory is defined and controlled.
- 3.10. provide a list of species or groups of species and analyses for which the laboratory claims competence, i.e. the scope of accreditation.
- 3.11. ensure that if subcontracting is necessary a laboratory is used which adheres to this Standard and holds ISTA Accreditation for the work in question. The laboratory must advise the client of any subcontracting in writing and, when appropriate, gain the approval of the client, preferably in writing. The laboratory is responsible to the client for the subcontractor's work. It shall 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 clients 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 laboratory.
- 3.15. have a nominated person who is responsible for quality management in the laboratory. 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 laboratory policy or resources.
- 3.16. appoint suitable deputies in the absence of senior technical staff
- 3.17. The management of the laboratory must formulate goals with respect to the education, training and skills of the laboratory personnel. The laboratory 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 laboratory.
- 3.18. The management must appoint specific personnel to perform particular types of work and to issue ISTA Certificates. The laboratory 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.

4. Staff

- 4.1. Laboratory staff and samplers must have and maintain the necessary education, training, technical knowledge, demonstrated skills and experience for their assigned functions.
- 4.2. The laboratory must use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory must ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system.
- 4.3. There must be a job description for each laboratory staff member and sampler. 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 laboratory must provide adequate supervision of testing staff and samplers, including trainees, by persons familiar with methods and procedures, the purpose of each test and assessment of the results.

5. Environment, equipment and calibration

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, steam, vibration, electromagnetic disturbance, interference, and must be maintained accordingly. They 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. Laboratory 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 laboratory is accredited.
- 5.2.2. Equipment must be run by authorised 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 laboratory 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 operating, maintaining, calibrating and monitoring of sampling and testing equipment. Whenever practicable, all equipment under the control of the laboratory and requiring calibration must be labelled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration 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 or otherwise to be defective, must be taken out of service and clearly labelled until it has been repaired and then shown by test or calibration to be performing its function satisfactorily again.
- 5.2.7. Each equipment and its software used for testing and 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 reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of the next calibration
 - (g) checks that the equipment complies with the specification
- 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, reference and testing materials

- 5.3.1. All sampling, measuring and testing equipment, for which this is possible, must be adequately calibrated before being placed into service and regularly afterwards, and a log book kept in which is recorded the results of each calibration, service and repairs (see 5.2.7e and f). Calibration and servicing of equipment must be performed according to an established programme.
- 5.3.2. The overall programme of calibration of equipment must be designed and operated so as to ensure that, wherever applicable, measurements made in the laboratory 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 laboratory, and be used for calibration and reference purpose only. 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. Reference materials must, if necessary, be verified by an authority nominated by the ISTA Secretariat.
 - 5.3.5. Calibration samples for the blowers must be provided by arrangement with the ISTA Secretariat.
 - 5.3.6. The laboratory must examine the effect of defective equipment on any previous tests, and withdraw and re-issue certificates where faulty results are suspected.
 - 5.3.7. The laboratory 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 laboratory 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 laboratory consumable materials relevant for the tests.
 - 5.4.2. The laboratory 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 laboratory 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 laboratory 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 laboratory 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 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.

6.2. Handling of samples

- 6.2.1. A system for identifying samples to be tested must be applied, through marking 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 maintained, monitored and recorded. Where a sample is to be held secure, the laboratory 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 laboratory, as follows;
 - (a) name / identification/ signature of the sampler
 - (b) name and address of the client/exporter
 - (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 cultivar of seed
 - (f) lot weight
 - (g) number (and type) of containers
 - (h) tests required
 - (i) details of any environmental or other conditions during sampling which may affect the interpretation of the test results
 - (j) any other available information requested by a client

- 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 issue of the ISTA Certificate.
- 6.2.5. A record of any unusual condition of the sample at the receipt at the laboratory 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 laboratory must consult the client for further instructions before proceeding and must record the discussion.

7. Methods and procedures

- 7.1. For the purpose of the issuance of ISTA Certificates, samplers and laboratory staff must adhere to the methods and procedures of sampling and testing, as published in the current version of the ISTA Rules including performance approved methods according to chapter 8 of the ISTA Rules.
- 7.2. All rules, handbooks, manuals, instructions and reference data relevant to the work of the laboratory must be current up-to-date and readily available to staff.
- 7.3. All calculations and data transfers must be subject to appropriate checks in a systematic manner.
- 7.4. When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data, the laboratory 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 and calibration

8. Test reports and Certificates

- 8.1. The results of each test or series of tests carried out by the laboratory 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 International Seed Analysis 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 laboratory has been accredited.
- 8.4. When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.
- 8.5. An ISTA Certificate must contain a signature and title or an equivalent marking of person(s) accepting the technical responsibility of the test report and date of issue.
- 8.6. An ISTA Certificate is the property of the client, and must be kept confidential.

9. Records

- 9.1. The laboratory 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 laboratory must maintain a record system to suit its particular circumstances. It must retain all 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, for a defined period but not less than six years. The records for each test must contain sufficient information to enable the test or calibration 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.
- 9.3. All records must be legible and must be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.
- 9.4. All records and test reports must be held secure and in confidence to the client, unless otherwise stipulated.
- 9.5. The laboratory must have procedures to protect and back-up records stored electronically and to prevent unauthorised access to or amendment of these records.
- 9.6. When a mistake occurs in records, each mistake must be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records must be 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.
- 9.7. 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 laboratory 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 corrective actions taken.
- 10.1.2. The quality assurance system must be documented in a quality manual (however named) which is available to the laboratory 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 chief executive. It must include at least the following:
 - (a) the laboratory management's commitment to good professional practice and to the quality of its testing in servicing its clients
 - (b) the objectives of the quality system
 - (c) a requirement that all staff concerned with testing and sampling activities within the laboratory familiarise themselves with the quality documentation and implement the policies and procedures in their work
 - (d) the laboratory 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). It must outline the structure of the documentation used in the quality 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 laboratory must establish and maintain procedures to control all documents that form part of its quality system (internal and external origin), such as regulations, standards, other normative documents, test or sampling methods, etc.
- 10.2.2. All documents issued to the staff in the laboratory must be reviewed and approved for use by authorised staff prior to issue. 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 laboratory must ensure that:
 - (a) authorised editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory 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 laboratory 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(ies).
- 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 maintained in computerised systems are made and controlled.

10.3. Quality control procedures

- 10.3.1. The quality system must define and document quality control procedures specific to seed lot identification and sampling arrangements, and laboratory testing procedures. These may include check sampling, check testing and 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. This monitoring must be planned and reviewed and may include, but not be limited to, the following:
 - (a) regular use of certified reference materials and/or internal quality control using secondary reference materials
 - (b) participation in the ISTA Proficiency Test Programme
 - (c) replicate tests using the same or different methods
 - (d) retesting of retained samples

10.4. Control of nonconforming testing and sampling work

- 10.4.1. The laboratory 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 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. Where the evaluation indicates that the non-conforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given must be promptly followed.
- 10.5. Proficiency testing
- 10.5.1. The laboratory must actively participate in the ISTA Proficiency Test Programme and must be able to demonstrate that any inconsistencies are investigated and corrective actions taken. The laboratory must also participate in any further follow-up tests arranged by the Proficiency Test Committee, if required.
- 10.6. Corrective actions and complaints
- 10.6.1. The laboratory must establish a policy and procedures and must designate appropriate authorities for implementing corrective action when nonconforming work or departures 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. Where corrective action is needed, the laboratory 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 to a degree appropriate to the magnitude and the risk of the problem. The laboratory must document and implement any required changes resulting from corrective action investigations.
- 10.6.4. The laboratory must monitor the results to ensure that the corrective actions taken have been effective.
- 10.6.5. The laboratory 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 laboratory must establish and maintain procedures for the review of requests, tenders and contracts. 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
 - (b) the laboratory 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 laboratory 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.
- 10.7.4. The review must also cover any work that is subcontracted by the laboratory.
- 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 laboratory 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 laboratory's continuous compliance with this Standard and its quality system. The internal audit programme must address all elements of the quality 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 management. Such audits must be carried out by trained and qualified staff who are, wherever resources permit, independent of the activity to be audited.
- 10.8.2. When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test results, the laboratory must take timely corrective action, and must notify clients in writing if investigations show that the laboratory 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 laboratory's compliances with its own policies and procedures, or its compliance with this Standard. The laboratory must ensure that the appropriate areas of activity are audited as soon as possible.
 - 10.8.6. The laboratory 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.
 - 10.8.7. The laboratory must afford representatives and auditors of the accreditation body access to the laboratory and to all documents needed for an assessment.
- 10.9. Reviews by management
- 10.9.1. In accordance with a predetermined schedule and procedure, the laboratory's executive management must periodically conduct a review of the laboratory's quality 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 preventive actions
 - assessments by external bodies
 - the results of ISTA Proficiency Tests
 - changes in the volume and type of the work
 - client feedback
 - complaints
 - other relevant factors, such as quality control activities, resources and staff training