ISTA
Seed Quality Assurance

ISTA Secretariat
Richtiarkade 18, 8304 Wallisellen, Switzerland
Phone: +41 44 838 60 00 | Fax: +41 44 838 60 01
Email: ista.office@ista.ch
www.seedtest.org

How to Develop Quality Documentation

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CREATED	REVIEWED	APPROVED
17.12.2014	OCTOBER 2019 / JULY 2021	NOVEMBER 2021
QUALITY MANAGER	HEAD OF ACCREDITATION AND TECHNICAL DEPARTMENT	SECRETARY GENERAL

SCOPE

This document provides guidance for the development, preparation and control of the quality documentation tailored to the specific needs of the user, testing laboratories or sampling entities.

The resultant quality documentation should reflect the documented quality system procedures required by the ISTA Accreditation Standard for Seed Testing and Seed Sampling.

Examples are used to show one or several possibilities how the requirements of the ISTA Accreditation Standard for Seed Testing and Seed Sampling may be considered appropriately.

All these examples originate from some existing laboratory quality documentation; for confidentiality reasons references to the laboratories have been deleted. Another purpose of these examples is to show the great variety of possible solutions and to demonstrate that what may be appropriate for one laboratory does not necessarily represent the best solution for another one. This should encourage laboratories in finding suitable, customised solutions reflecting the laboratory's daily work. This document is a guideline and may not be complete as the continual improvement approach is assumed.

RELATED DOCUMENTS

ISTA Accreditation Standard for Seed Testing and Seed Sampling

RESPONSIBILITY

n.a

ABBREVIATIONS

Q: Quality

QM: Quality Manager

Q-Manual: Quality Manual

SOP: Standard Operating Procedure

PT: Proficiency Test

PROCESS DESCRIPTION

STRUCTURE AND FORMAT OF THE QUALITY DOCUMENTATION

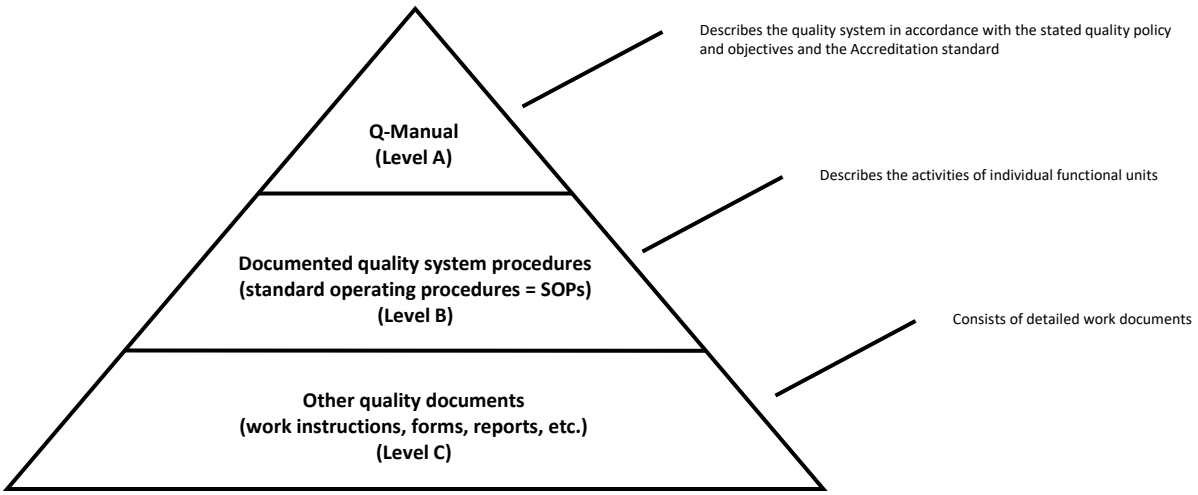
The Q-documentation must reflect all activities related to the ISTA accreditation scope.

The Q-documentation consists of at least the following three levels or parts also referred to as Document Hierarchy:

I. **Quality Manual (Q-Manual)** + annexes or appendices (comprising approximately 10-30 pages)
   The purpose of a Q-Manual is to outline the general policies and procedures for staff, customers, accreditation bodies and/or legal bodies to provide an overview of the laboratory's quality assurance system.

II. **Documented quality assurance system procedures** such as **Standard Operating Procedures (SOPs)**
   Standard Operating Procedures describe standard procedures in a concise manner to provide enough information to carry out the work concerned. The volume of work depends on the size of the laboratory, number of tests, number and qualification of staff and kind of equipment in use.

III. **Other quality assurance documents** such as working instructions, forms, reports
The Working instructions give details on the standard procedure concerned. This may be e.g., species related information on a specific test method. Forms, checklists, reports related to a standard procedure should be provided where appropriate. Working instructions or specimen forms may be directly attached to the respective SOP if applicable.



There is no required structure or format for the quality documentation, however, it should convey accurately, completely and concisely the quality policy, objectives and governing documented procedures of the laboratory.

It can be a hard copy or an electronic format.

Coversheet of the Q-Document is the first page of a document.

This page should give minimum information such as laboratory's name and contact details, name of document, indication of approval ("approved by: "), copy number, i.e., a unique number for each controlled copy and - if applicable, an indication "controlled document" – "uncontrolled document". The rationale behind this is to facilitate identification and control of all the single elements forming the Q-documentation (Example 1).

HOW TO START WITH THE PREPARATION OF A Q-MANUAL

The process of establishing the quality assurance system documentation should begin with the appointment of the coordination task to management-delegated competent personnel, who may be an individual or a group of individuals.

The appointee or the group of appointees is responsible for the following tasks:

- to obtain data on the actual state of the quality assurance system
- to plan the documentation system/structure
- to collect and compile existing documentation and require additional documentation where necessary
- to review the documentation to ensure clarity, suitability, and proper structure
- to develop a distribution policy
- to incorporate the necessary changes
- to act as contact person/s in all matters of the quality assurance system
- to assure that the quality system is always implemented and followed,
- to assure the continuous improvement as required in the ISTA Accreditation Standard for Seed Testing and Seed Sampling.

THE Q-MANUAL

- Q-Manual may be developed and used by an organisation for purposes including, but not limited to the following:
- communicating the laboratory's quality policy, procedures, and requirements
- describing the quality assurance system
- providing documented bases for auditing a quality assurance system
- providing continuity of the quality assurance system and its requirements during changing circumstances; must be updated regularly
- training personnel in the quality assurance system requirements and methods of compliance
- presenting the quality assurance system for external purposes, such as demonstrating compliance with the respective accreditation standard

WHAT TO INCLUDE IN A QUALITY MANUAL

1. **Scope and field of application**
   In the scope and field of application it shall be clearly stated for which activities/departments of the laboratory the Quality Manual is applicable.

2. **Table of contents** (indicating title of chapters/sections and subchapters/subsections)
   The numbering or coding system of sections, subsections, pages, figures, exhibits, diagrams, tables, working sheets, etc., should be clear and logical

3. **Definitions and explanation of the laboratory specific abbreviations**

4. **Quality Policy and Quality Objectives**

4.1. In this section, intentions and objective targets of the laboratory including a statement that the seed testing laboratory/sampling entity's standard of service will be in accordance with the requirements of the ISTA Accreditation Standard for Seed Testing and Seed Sampling and the current version of the ISTA Rules (Example 2 and 3) are stated. It should also describe how the **Quality Policy** is made known to, and understood by, all employees and how it is implemented, maintained and improved at all levels.
NOTE: A description of the activities of the laboratory/sampling entity is not a substitute for the Quality Policy statement.

4.2. Based on the Quality Policy, the **Quality Objectives** shall be determined. Objectives shall be quantifiable (current value, target value, period) to facilitate a target/actual value comparison (Example 4). The Q-objectives need not necessarily to be included in the Q-Manual; a reference to the document where they are to be found, for instance an annual plan, would be sufficient. Determination and verification of achievement of the objectives is to be made at least annually in the management review, or in other relevant planning documents.

5. **Description of the Q-Assurance System and the Document Control Procedure**

5.1. Explanation of the structure of the **Q-documentation**, e.g., how many levels, what kind of documents are used (Q-Manual, SOPs, if applicable work instructions (WI), forms, logbooks, checklists, loose sheet copies, etc.), format (electronic or hard copy). The description should ensure that somebody using the document understands the way it is to be used (Example 5).

5.2. There should be a description of the document identification system (e.g., "SOP 01" or "SOP A01", e.g. "A" stands for Administration, or "F1" for the form number 1).

5.3. Purpose of document control procedures is to guarantee that each page of the Q-documentation is identifiable and attributable. Document issue and changes control are essential to ensure that the content of the Q-documentation is properly authorised.
The document control system defines who and in which way suggestions for changes in the documents can be made, who decides on necessary amendments and the time frame when changes are due, periodicity of revision. It is recommended to create a form where suggestions/revisions are noted and brought to the attention of the person responsible for the revision (Example 6).

5.4. Each page of the Q-documentation should at least contain (Example 7):

- Name of the document
- Page number: It is recommended to number the pages of each QM-chapter or SOP separately rather than numbering the pages consecutively for the whole document. The format must be as “page X of Y” instead of only “page X”
- Revision status
- Version number (or “valid since date”)
- Control indication such as “*This is a controlled document* ” or “*This document is not subject to change service*”.

5.5. A description should also be given about how external documents are controlled (e.g. ISTA Rules, ISTA Accreditation Standard for Seed Testing and Seed Sampling, List of Stabilised Plant Names).

5.6. The distribution concept outlines the addressees/recipients for controlled or uncontrolled copies of the document. If documents are distributed electronically or by mail, explanation must be given on how the laboratory/sampling entity ensures that the new versions were received. This may be done by listing the documents on a **master list of controlled documents** (or documents matrix) (Example 8).
A master list of controlled documents should at least contain the following:

- name of the document (and document code)
- version number of current documents (or “valid since date”)
- approval date
- recipients (can be person(s) and/or a place, e.g., room number)
- person responsible for distribution of new or revised documents
- retrieval of the obsolete version

6. Organisation and Management

6.1. Description of the organisation, responsibilities and authorities: in this section the laboratory/sampling entity should provide a description of the high-level structure of the organisation. This may be preferably made by an organisational chart, where responsibilities, authorities and interrelationship structure are included (Example 9). It puts the laboratory/sampling entity in the overall context within a larger organisation, e.g. the institute within the ministry of agriculture, or within a seed company, and the organisational structure within the laboratory/sampling entity (Example 10) to define and show sections/departments (staff administration, financial department, how sampling is linked to the laboratory), functions or positions, (technical manager, quality manager), sample reception/registration, testing sections, issuance of ISTA Certificates.

6.2. Independence of judgement and integrity in relation to sampling and testing activities: the laboratory/sampling entity must describe how it meets these requirements of the ISTA Accreditation Standard for Seed Testing and Seed Sampling.

6.3. Defining the responsibility of the management, i.e., providing resources (human and financial resources, equipment), determining the Q-policy and Q-objectives, management review, promoting quality assurance system to increase awareness, motivation and involvement.

7. Staff and Training

7.1. Description of responsibilities and authorisations of the laboratory/sampling entity functions and positions (e.g. head of the laboratory, technical manager, quality manager, supervisors, technicians/analysts/samplers, administrative personnel, trainees etc.)

7.2. Laboratory/sampling entity staff matrix showing responsibilities and suitable deputies (Example 11).

7.3. Description of the general policy concerning internal and external training (i.e. workshops, instruction, on-the job training etc.). How does the laboratory/sampling entity management determine the individual training needs? What are the criteria (e.g. based on annual performance appraisals)? What is the basis to set up an annual training plan or how are the training needs identified and recorded? How is a training recorded?

7.4. Description of a general training procedure for new staff members. This general description is supplemented by a more detailed SOP describing the training programme, acceptance criteria, approval of the new staff members for the independent work. (Example 12)

8. Laboratory/Sampling entity Premises

8.1. In this section the premises should be described, if possible, including a floor plan. If applicable, provisions taken against excessive temperatures and moisture, vibration (stable work benches and tables) should be mentioned as well as measures taken to protect the staff in terms of health and safety (e.g. seed health tests). A brief description how good housekeeping is ensured should be included.

8.2. Description of the appropriate internal regulations for access and use of the laboratory/sampling entity premises by the staff during working hours and off-time and definition how entry of the external persons (staff of foreign sections, clients or other visitors) is controlled; how it is ensured that external persons are not left unattended in the laboratory/sampling entity premises.

8.3. Samples storage: This section contains a description of the sample storage system before and after testing (i.e. where, how, how long the samples are stored and which components of the samples are stored) control/treatment and recording of pests and diseases, control and recording of relative humidity and temperature, the procedure for disposal of the stored samples (e.g. treated versus untreated seeds).

9. Purchasing of Services and Supplies

9.1. Services and supplies that affect the quality of tests must be identified.

9.2. General description of the procedure for the selection and purchasing of services and supplies including a description of the records in place.

9.3. Those critical services (e.g. external calibration of weights needed for the balances) and critical supplies (e.g. germination substrate, chemicals) must be checked to verify their compliance with the requirements prior to use.

9.4. Explanation on how and when the supplier of critical services and supplies are evaluated and how suppliers are approved/acceptance criteria.

10. Equipment and Calibration

10.1. General description of maintenance, servicing, labelling, and handling and repair of testing and measuring equipment. Records of maintenance, servicing and repair pertaining to each item of equipment may be stored with the respective item or at an appropriate place.

10.2. Description of the general procedures on how to deal with cases where any item of equipment has been subjected to overloading or mishandling or where it gives suspect results or has been shown by calibration or otherwise to be defective. General procedures include but are not limited to, taking out of service, labelling, and advising the responsible person and procedures to be followed to put the devices in operation again after repair (i.e. functional check, calibration). The laboratory/sampling entity must describe how it examines the effect of a defective equipment on any previous tests and withdraw and re-issue the ISTA certificates where faulty results are suspected.

10.3. General description of the verification/calibration programme to ensure that measurements made in the testing laboratory are traceable to national or international standards of measurement when required. Reference to records kept on these measures must be provided.

10.4. The sampling, testing and measuring equipment may be listed and columns with the following specifications should be included (Example 13):

- kind of equipment (e.g. balance, soil divider, calibration weight for balances)
- date of purchase
- manufacturer
- unique serial and/or inventory number
- range of measurement (e.g. thermometer: 0–70 °C; balance: 0.001-50 g; moisture oven: 50-230 °C) and precision (e.g. sieve: 0.50 mm mesh size, working thermometer: 0.1 °C)

- internal check or verification interval (e.g. daily, weekly, monthly) and external calibration if certified* reference standards of measurement (e.g. yearly, every two years)
- maintenance interval
- room number and/or location (e.g. purity section, room no. 125)
- reference document number (SOP, logbook, user manual)

11. Sampling

11.1. In this section, the organisation and management of (ISTA) sampling is described, i.e. how is the sampling integrated in the laboratory's organisation and management (when is not a sampling entity). This may be supplemented by an organisational chart.

11.2. What are the provisions to ensure independence of ISTA sampling/ISTA samplers? An example of a declaration/commitment, that there is no conflict of interest regarding sampling, may be provided.

11.3. How are the testing laboratory and the samplers affiliated? A list of authorised ISTA samplers (e.g. name of the ISTA sampler, authorisation number, status, specimen signature/initials, unique identification) must be provided.

11.4. A list of authorised ISTA automatic samplers (name and address of the owner, authorisation number, unique identification) and the ISTA sampler/s responsible for the automatic sampler must be assigned. Description of automatic sampler authorisation and monitoring process.

11.5. What are the requirements to obtain, to maintain and to suspend the formal authorisation as an ISTA sampler? This section should describe procedures and criteria how the ISTA samplers are authorised and how their authorisation is maintained, i.e. initial training, refreshing training, monitoring such as internal auditing and/or check sampling; indicate frequency, scope and responsibilities of training and monitoring activities (**SOPs of authorisation, training programme, monitoring programme**) (Example 14).

11.6. Specification of applied sampling procedures, i.e. national seed regulations and/or ISTA sampling procedures including date of the latest revision. When both sampling for national and for ISTA are described in the same SOP, a clear differentiation must be made.

11.7. Description of seed lot identification system to ensure that each seed sample is traceable to the respective seed lot by a unique seed lot number.

11.8. Handling of samples: a description of how the laboratory/sampling entity handle the samples must be elaborated. The ISTA Accreditation Standard for Seed Testing and Seed Sampling has described in detail what is needed for safe handling of samples. This includes the unique identification, labelling, transport, storage, and disposal. Records must be kept on samples showing any unusual condition.

12. Scope of testing

12.1. This section specifies the scope of testing to distinguish between ISTA and non-ISTA tests. Applied test methods, i.e., national seed regulations and/or ISTA test methods including date of their latest revision should be specified. When both, national and ISTA tests are described in the same SOP a clear differentiation must be made.

12.2. Defining the scope of ISTA Accreditation:
The specification must allow the seed analyst and interested parties to identify the species X test combination the laboratory is accredited for and consequently is entitled to issue ISTA International Seed Analysis Certificates. A detailed list of species with reference to the applicable test methods is recommended.

12.3. Description of the policy of sub-contracting for ISTA tests being reported on the ISTA Certificates including a description how suitable sub-contractors are identified and monitored. If sub-contracting is not applicable a short indication/statement, that no sub-contracting for ISTA purposes is made, is sufficient.

* Certified reference standards of measurement are periodically calibrated by an accredited national calibration service

13. Process management (workflows) (Example 15)

13.1. Workflows of all relevant laboratory procedures and tests can be depicted, preferably by means of flow charts to show sequentially the single steps from sample entry to reporting of results on the certificate.

14. Recording and Archiving

14.1. Description of the records used and completed by the staff of the ISTA accredited laboratory, i.e. sampling application form, sampling report, laboratory work cards including records of original observations, calculations and derived data, equipment log books, including calibration data, maintenance and repair of equipment, records on monitoring activities such as auditing, check sampling and check testing results, management review reports, training, staff performance appraisals, test reports including ISTA Certificates, etc.

14.2. Description of procedures to check test results (can also be included in the related technical SOP). This includes answers to the questions by whom and at which stage test results are checked on allowed tolerances, completeness, correctness and accuracy.

14.3. Specification of responsibilities and authorisation to make corrections in computerised systems (e.g. password protection) and laboratory work cards.

14.4. Description on the process of how to record and protect data (inscriptions must be made by using inerasable pen) and how to proceed if mistakes must be corrected (e.g., on the laboratory working cards, on records but also in computerised systems)

14.5. Description of the verification process of computerised systems and other electronic working tools e.g. on correct calculations and tolerance checks if applicable, ISTA sampling calculator etc.

14.6. Description of the concept (back-up frequency, media) to retain computerized data and to ensure that back-ups of computerised data remain legible once the computer software has been changed.

14.7. Description of the archiving system of the documents to ensure that they are kept and legible for at least six years. It is recommended to provide all relevant information by means of a table containing: type of document, intermediate/final depository, retention time, way of disposal.

15. Quality control procedures

Quality control procedures must be defined related to seed lot identification, sampling arrangements and laboratory testing procedures. This monitoring must be planned and reviewed (responsibilities, frequency of monitoring, way of evaluating the results, thresholds, and way to follow-up).

15.1. Check sampling: is a monitoring of reproducibility of results, if the seed lot is sampled by different seed samplers. The monitoring shall be done on all crop groups for which the laboratory holds accreditation.

15.2. Check testing: is a monitoring of reproducibility of results, if different employees test the same sample. This monitoring shall be done on all tests and crop groups for which the laboratory holds accreditation.

15.3. In the procedure an explanation should be given on how the results are recorded and evaluated.

15.4. A description of how possible trends are identified; a systematic follow up on the performance of the testing and sampling staff over time should be included in this description, and the actions to be taken when a trend is detected.

STANDARD OPERATING PROCEDURES (SOPS) INCLUDING WORK INSTRUCTIONS

For those operations of the Q-Manual that need to be described in detail, SOPs should be elaborated. The SOPs serve the staff as a practical working aid for their daily use. They should be compiled in such a way that they can be used like a “cooking recipe”.

It is recommended to keep the SOPs concise. They should be exact, to the point and should represent the practice by using simple wording. Where necessary, SOPs may be supplemented by work instructions, describing single aspects even more detailed or giving examples.

Reasons for having SOPs instead of just referring to the ISTA Rules:

- The ISTA Rules do not always describe the tests to be conducted sequentially.
- ISTA Rules provide different options for a specific test type (e.g. different germination substrates, different temperature ranges, different sampling and dividing methods etc.), in the SOP only the information relevant for the laboratory should be available.
- Most laboratories conduct various test procedures depending on the test report to be completed (test methods of ISTA Rules versus in-house or national methods). A SOP shall clearly indicate which specific test method is to be used for the issuance of an ISTA Certificate and for the national certification.
- The ISTA Rules are not translated in all languages.

SOPs should be provided for, but not be limited to, the following subjects:

System SOPs:

- Document Control Procedure
- Sample receipt and registration
- Issuance of ISTA Certificates
- Training of new and experienced laboratory staff (for sampling and testing activities) including authorisation/recognition, training of new and experienced staff, procedure of warning, suspension, and withdrawal of authorisation of ISTA samplers and testing staff
- Internal Audit Procedure
- Dealing with the Customer Complaints
- Non-conforming work and Corrective Action Procedure (Example 16)
- Preventive Action Procedure if is the case
- Purchasing of Services and Supplies
- Management Review Procedure
- Quality Control Procedure (Monitoring by e.g. check sampling and check testing)
- Proficiency Testing Procedure (Example 17)

Technical SOPs:

Maintenance, repair, control or internal calibration for each item or group of equipment (e.g. balances, working thermometers, pH-meters, seed blower, grinder, moisture oven, germinators, dividers etc.)

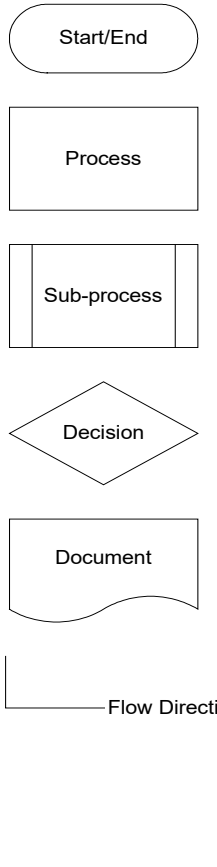
- Storage and disposal of samples
- Control and disposal of chemicals
- Maintenance and description of seed collection(s) and how the verification of species is accomplished incl. a list of seeds
- Testing of new batches of germination substrates

Testing SOPs:

- Sampling of the seed lots
- Mixing and dividing of samples in the warehouse/laboratory
- For each test method the laboratory claims ISTA Accreditation (e.g. purity analysis, germination test, determination of other seeds by number, determination of moisture content, testing of coated seed etc.)

NOTE: The general policy and procedures already described in the quality manual should not be mentioned again in the SOPs to avoid redundancy and possible risk of inconsistency.

A flow chart is particularly helpful to visualise a process and to represent the essential elements of a given procedure on a single page. It may be supplemented by explanatory notes or be itself the summary to a textual description. By consensus a very limited number of symbols is used, which facilitates its generic application and makes it a tool that is easily understood:



an activity with an input and an output

an activity that can be represented in a flow chart on its own

a process with two possible outcomes (YES/NO)

an information and its medium that results from or supplements a process

an indication for the sequence of and relation between processes

With those few elements most processes, interrelations and even complicated procedures can be represented.

ANNEX

Example 1: Quality Manual cover page

Example 2: Quality Policy statement

Example 3: Quality Policy

Example 4: Quality Objectives

Example 5: Quality Manual, structure

Example 6: Changing a procedure

Example 7: Quality Manual page

Example 8: Master list-controlled documents

Example 9: Organisational structure

Example 10: Organisational structure

Example 11: Staff Matrix

Example 12: Training Guide

Example 13: Equipment list

Example 14: Training Guide

Example 15: Process flow charts

Example 16: Corrective Action Procedure

Example 17: PT SOP

DISTRIBUTION LIST

Any part interested in ISTA Accreditation

ISTA website

REVISION HISTORY

Version #	Changes
1.4	ISTA Accreditation Standard defined as 'ISTA Laboratory Accreditation Standard' Text reformulated on page 3 Second example of Annex 15 removed as containing erroneous information.
1.5	Sampling entity added Amendments to some aspects treated in this procedure
2.0	Layout change Content updated, restructured

Organisation:	QUALITY MANUAL	Version:
	Name of document	Original/copy:

unique QM #	location	responsible	signature

QUALITY MANUAL OF

"Laboratory /Sampling Entity NAME"

"CONTACT DETAILS"

Author: Name: Position/Function: Date:	Up-date: Name: Position/Function: Date:	Authorisation/Approval: Name: Position/Function: Date:
Document name, acronym, file reference etc.		

QUALITY-POLICY

Policy statements

Customer Focus:
We maintain close contact with our customers in order to keep abreast of their requirements and expectations and provide independent, timely, reliable and traceable analysis results which are essential for their businesses.

Excellence and performance:

We always strive for superior performance. We systematically promote the skills and knowledge of all staff members by appropriate training, internal/external quality control and information. The staff are fully aware of their authorities and responsibilities and are committed to self-reliance, self-control, and error prevention.

Accreditation Standard/Effectiveness:

The Laboratory/Sampling entity operates a documented quality assurance system which meets the requirements of the ISTA Accreditation Standard for Seed Testing and Seed Sampling.

Sampling and testing for the issuance of the ISTA Certificates are always carried out in accordance with the current ISTA Rules.

The Management is committed to, and the analysts are conversant with the laboratory's quality assurance system as described in this quality documentation and is regularly reviewed on effectiveness. It shall be pragmatic, efficient, and up to date.

Integrity/Confidence:

We carry out independent seed sampling and testing. We pride ourselves on being honest, trustworthy, and completely reliable in all our dealings.

Management representative
Signature/date

DEPARTMENT

Laboratory/Sampling Entity Name

QUALITY MANUAL

SECTION 1 QUALITY SYSTEMS AND POLICY

1.1 MISSION STATEMENT

To maintain and promote the clean green image of National agriculture as it applies to seeds by providing totally independent seed testing, quality verification and quality assurance tests. The outcome will be a strong, viable seed industry contributing to the National economy.

1.2 QUALITY POLICY STATEMENT

The Manager, Department of XYZ, the Quality Systems Manager, and the staff of the Seed Testing Laboratory are fully committed to the provision of an independent and accurate seed testing service to the National seed industry thereby maintaining and promoting the image of National agriculture.

In providing quality seed sampling or/and testing services, we will:

- provide export opportunities for National seed growers through the issuance of internationally accepted certificates (ref.),
- maximise the opportunities for the National seed industry and National seed growers producing all classes of seed through the provision of accurate and timely seed testing (ref.),
- support the operations of the National Quarantine and Inspection Services (ref.),
- maintain and continue to develop present activities concerned with the development of seed testing and related protocols for new species of herbage plants under evaluation locally,
- comply with, and assist all elements of the National seed industry to comply with, the provisions of National seeds legislation (ref.),
- maintain a level of expertise amongst the staff such as to ensure the Station continues to meet the criteria for ISTA accreditation standard and ISTA Rules for the issuance of the ISTA Certificates (ref.),
- support the National seed industry in their promotion of good quality seed,
- support the National seed industry in educating farmers to the value of planting clean seed,
- provide a seed testing service for any other clients and organisations who might require such a service.
- Sampling and testing for the issuance of the ISTA Certificates are always carried out in accordance with the current ISTA Rules.

The achievement of these objectives depends on the maintenance of a well organised and professionally focussed Seed Testing Laboratory in which staff are committed to the provision of accurate and timely analysis and total commitment to the principles of quality management systems. Compliance with the procedures and principles presented in the present Quality Manual and future versions of this manual will ensure that all of the objectives are met.

The key criteria by which the objectives will be achieved are presented in “Doc-code” (key criteria document).

SEED TESTING LABORATORY

QUALITY SYSTEMS DOCUMENT

Appendix to DocNo XXXYYY

QUALITY OBJECTIVES FOR PLANNING PERIOD 20XX

1.4.1 Testing

Review of all seed health test standard operational procedures in order to adapt them to the new format.

1.4.2 Interlaboratory test participation 20XX

Participation in three comparative interlaboratory tests for purity analysis with test results within the limits of <DEFINE MEASURABLE LIMITS>

1.4.3 Customer satisfaction

Decrease the average turn-around time for submitted samples for purity tests from 10.1 days to 8.5 days. Turn-around time is based on the date of sample entry and date of laboratory card completion.

1.4.4 QM System

Fully comply with the current ISTA Accreditation Standard for Seed Testing and Seed Sampling in relation to document control by a mentioned date and in relation to …

A. INSTITUTE	*B. QUALITY POLICY MANUAL*
Section:	Approved by
Page :	
Document No. : QPM/001/12584	Function /Position

3.2 Management System Documents

3.2.1 Structure and Documents Format

Documents which are part of the Laboratory/Sampling Entity's Management System have been documented on the basis of the complexity of the tasks described, the methods used, and the skills and training required by staff involved in carrying out the activity.

Documents will refer to additional documents that provide more detail about the activity where appropriate. The following is a schematic representation of Laboratory/Sampling entity's Management System.

Can be a hard copy or electronic format.

C. INSTITUTE	*D. QUALITY MANUAL*
Section:	Approved by
Page:	
Document No. : QPM/001/12584	Position/Function

Quality Manual - provides an overview of the Laboratory/Sampling entity's business. It defines its Policy, refers to the business objectives and states the commitment to quality in respect of the International Seed Testing Association. This document is used to introduce potential stakeholders (customers, staff, suppliers) to the Laboratory's work.

Non-technical procedures - are divided into two types:

1. System non-technical procedures (Appendix 4.1) are those which describe activities common to all departments e.g., purchasing, document control, internal auditing.

2. Department non-technical procedures (Appendix 4.2) describe activities specific to a department or where, due to geographical limitations, there are site-specific variations for activities described in System non-technical procedures.

Technical Procedures - describe testing/sampling activities conducted by the Laboratories/Sampling Entities. The format for Technical Procedures (Appendix 4.3)

Standard Operating Procedures (Appendix 4.4) - documents activities such as start-up, shutdown, calibration (as appropriate) and troubleshooting for specialised equipment.

References - include standards, specifications and acceptance criteria that provide additional information to assist understanding and completion of activities described in non-technical, technical, or standard operating procedures. Can be with external or internal origin.

Forms - are used to record information as evidence that activities have been completed as described within procedures. Completed forms are retained as records. Can be with external or internal origin.

ADMINISTRATION PROCEDURE		Document No.
Department Seed Testing Station	**Title: Changing a Procedure** Page 1 of 1 Authorised by:(Signature).....	Purpose: A high standard of efficiency and accuracy within the Seed Testing Laboratory/Sampling Entity, can only be maintained if the documented procedures are continually under scrutiny by all who use them. All members of staff are encouraged to critically examine the documented procedures and, whenever a potential error, omission or improvement is identified, to bring such error, omission or improvement to the notice of their line manager. This procedure details the steps required for effecting changes to a Procedure. Scope: Applied to all documented procedures

	Step	Procedure	Responsibility	Form	What if.....?
1	Obtain appropriate form	The original form is to be found in this Manual. Make a copy of it, making sure to return the original to the Manual.	Staff Member		
2	Identify the problem	Identify the Procedure to which you are recommending a change. Fill in the Procedure Number and Title (*To be found on the header of the Procedure)*	Staff Member		
3	Describe what needs changing	Fill in Section 1 on the form, giving brief details as to what needs changing (e.g., "*Step 4 needs changing to include a further checking step"*)	Staff Member		
4	Describe why it needs changing	Fill in Section 2 on the form, giving brief details as to why the changes are required, (e.g., "*As it is, it is possible to overlook the reading on the meter when taking off the sample"*)	Staff Member		
5	Describe how the Procedure can be improved	Fill in Section 3 on the form, giving brief details as to what action needs to be taken to effect the required changes in order to improve the Procedure (e.g., "*Introduce a step between Step 3 and Step 4 which requires the operator to check and record the reading on the meter before taking off the sample"*)	Staff Member		
6	Does it comply with the ISTA Rules	Does the proposed change still comply with the ISTA Rules? (*Basically a "Yes/No" answer*)	Staff Member, Supervising Seed Analyst		
7	Consider proposal	The proposal for changing the Procedure is then considered by the appropriate people.	Nominated personnel (*Nominated by QSM)*		
8	Changes approved	If they proposed changes are approved, they are authorised by the appropriate person, the proposal is signed and passed on the Quality Systems Manager for action.	Quality Systems Manager		...changes not approved. The decision is recorded on Form/003 and filed.
9	Amend Procedure Print off Replace old with new.	The Procedure is amended, and two copies run off. Both copies are signed by the authority, one being given to the Quality Systems Manager, the other to the Supervising Seed Analyst. The copies are placed into the Manual as the old versions are removed and destroyed.	QSM Supervising Seed Analyst Appropriate personnel		
10	Record amendment	Amendments to the Procedures must be recorded as the new version is placed in the Manual.	QSM Supervising Seed Analyst		

Version 2 *November 20XX*

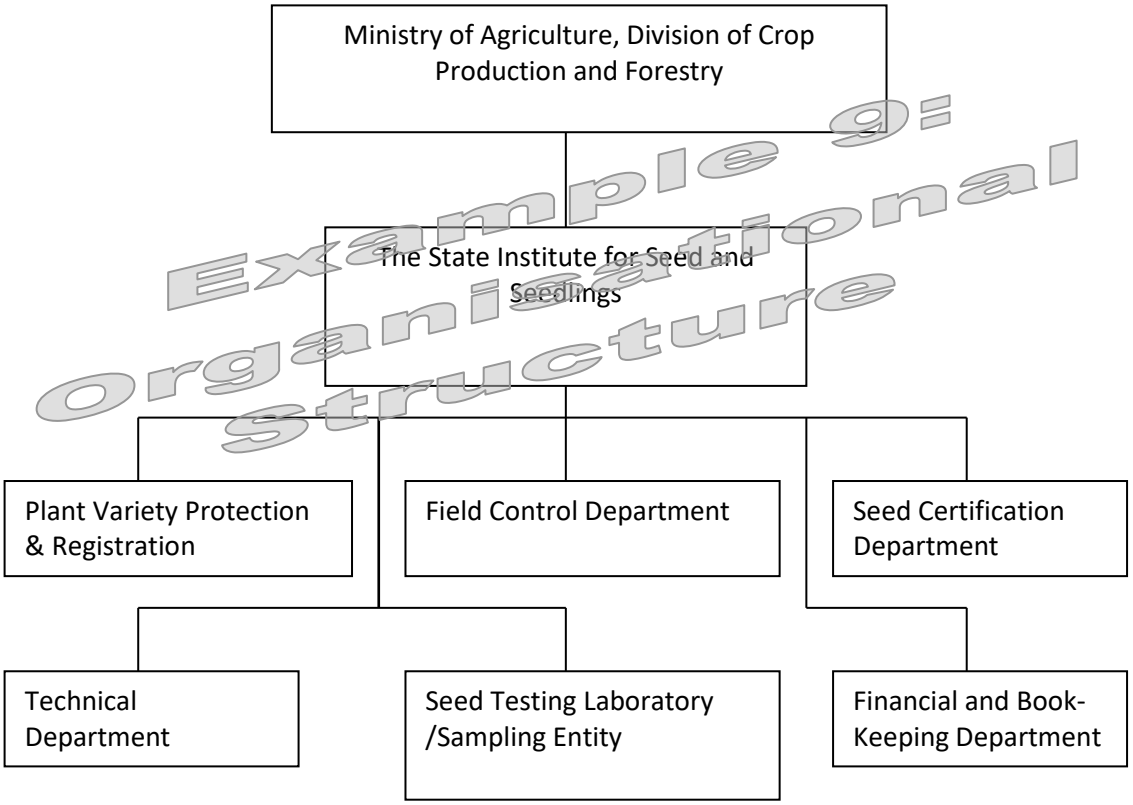
Content **page number**

This is a controlled document

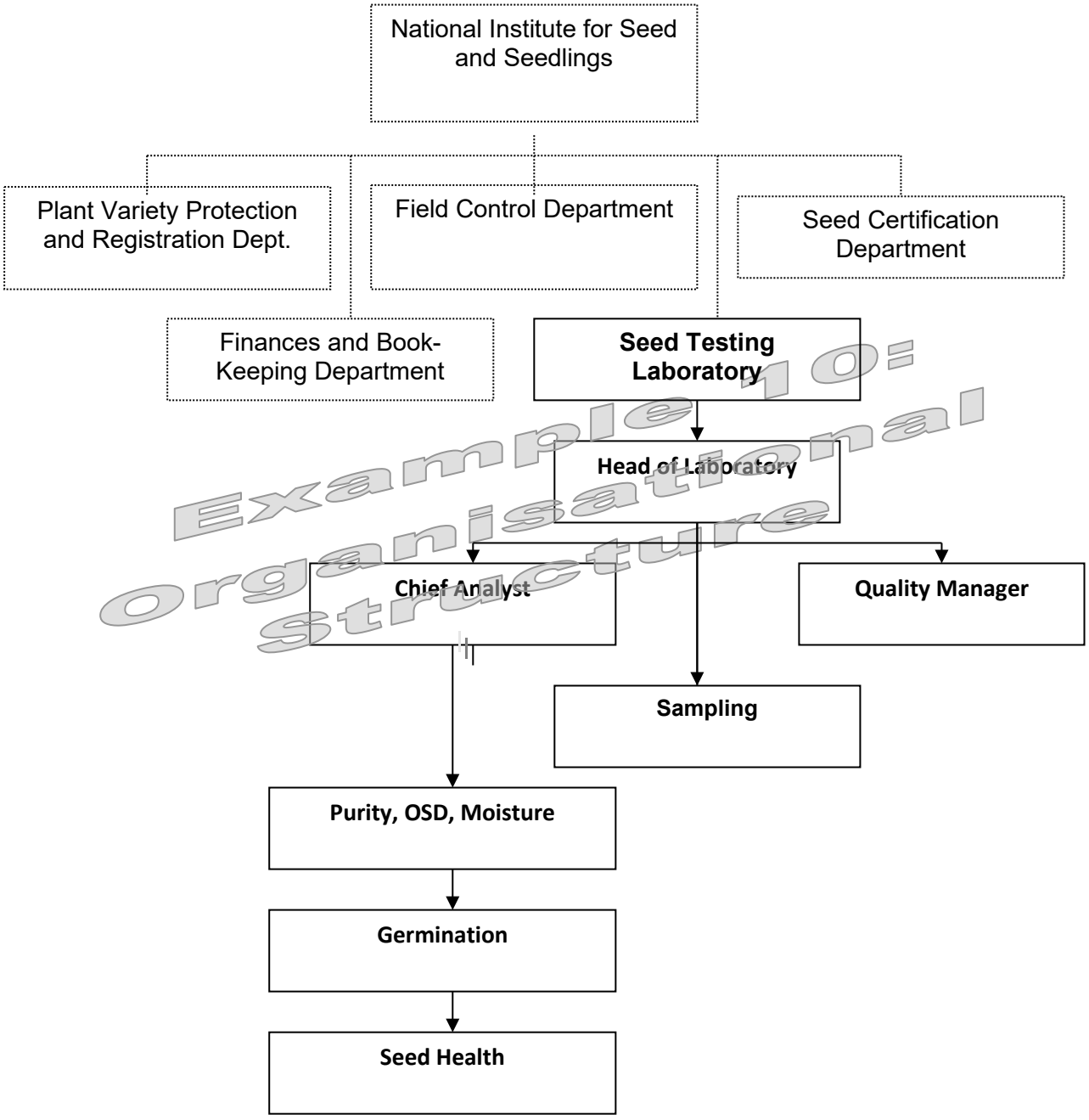
Master Document Register - Technical Procedures

					Availability	Availability							
Document title	**Type of Doc**	**Doc Code**	**Revision Date**	**Approved by**	**Type**	**FQ**	**[illegible]**	**S T**	**M S**	**AD**	**BD**	**R&D**	**G-Lab**
Document 1	SOP	SOP TP/001	01.05.2009	Supervisor, FQL	[illegible]	1	1		1	[illegible]	[illegible]		1
Document 2	SOP	SOP TP/002	21.03.2[illegible]	[illegible]ervisor, MSL	Hardcopy	1			1				1
Document 3	SOP	SOP T[illegible]	01.03.2010	Manager, CCL	[illegible]				1				
Document 4	SOP	SOP TP/004	200[illegible]1	Supervisor, MSL	Hardcopy				1	1	1	1	1
Form XY1	Form	T[illegible]	01.05.2009	Supervisor, MS[illegible]	[illegible]rdcopy	1	1		1				1
Form XY2	[illegible]	F TP/002	[illegible]03.[illegible]09	Manager, CCL	Hardcopy	1			1				1
ISTA Acc Standard	External	n.a.	2007	ISTA	Hardcopy	1				1	1	1	1
IST Rules	External	n.a.	2010	ISTA	Hardcopy	1							1

Organisational structure



ORGANISATONAL STRUCTURE



Staff responsibilities in Seed Testing

Name	Sampling	Purity and OSD	Moisture content	Germination	Vigour	Preparation, sowing media	Check sampling	Check testing	Calibration	Substrate check	Certificates	Quality Assurance	Supplies
Sasi	-	-	-	-	-	-	-	-	T	-	R	R	-
Dachada	R	T	-	-	-	-	R	R	T	-	-	D	-
Dlaska	D	R	-	-	-	-	T	D	T	-	D	T	R
Trudel	T	D	-	-	-	-	D	-	T	-	-	T	-
Timlar	T	T	-	-	-	-	T	-	T	-	-	T	-
Garat	T	T	-	-	-	-	T	-	T	-	-	T	-
Haina	-	IT	IT	IT	IT	-	-	-	T	-	-	-	-
Homer	IT	T	-	R	T	R	-	-	T	R	-	-	-
Pinsdorf	-	-	R	D	T	D	-	-	T	D	-	-	-
Tamara	-	-	D	T	D	T	-	-	R	T	-	-	-
Susanna	-	-	T	T	R	T	-	-	D	T	-	-	-
Dadiru	IT	-	T	-	-	-	-	-	T	-	-	-	D

R = Responsible
D = Deputy
T = Trained
IT = In training

page No /total page number

Training

Main headings for topics to be taught to new analysts in preparation for their licensing examination.

A. Basic training for new analysts in the laboratory

1. General organization of the laboratory
   - Introduction to the laboratory and organisation of the Institute
   - Quality Management System
   - Housekeeping in the laboratory
   - Safety in the laboratory

2. Introduction to the Quality Management System
   - Document control procedure
   - Recording in general and training requirements
   - Corrective action procedure
   - Internal audit procedure

3. Identification and Classification of Seeds
   - Introduction to scientific nomenclature, available books, lists, seed collection

4. Introduction to the "Methods and Procedures of Testing Seed"

   a. Principles Used in Purity Testing:
      - Drawing the working sample
      - Definitions:
        Pure Seed
        Inert Matter
        Other Seeds Seed
        etc.
      - Equipment used in the Purity laboratory
      - Conducting the purity analysis
      - Use of Checking limits
      - Recording the results of the purity analysis

   b. Introduction to Germination Testing
      - Germination Methods for Agricultural and Vegetable Seeds in ISTA Rules
      - Equipment and materials used in the Germination laboratory
      - Drawing the working sample for the germination test
      - Planting the seeds for the germination test
      - Essential structures of a seedling
      - Definitions:
        Normal seedlings
        Abnormal seedlings
        Not germinated
        Dormancy and how it may be broken
        etc.
      - Calculation of results and tolerance tables

5. Introduction to Elementary Botany
   - Definitions of Seeds
   - How they are formed and dispersed
   - Seed Morphology, i.e., characteristics by which seeds are identified
   - Seed Taxonomy

B. Advanced training

1. Identification and Classification of Seeds
   - Emphasis on seeds
   - Weed seeds with emphasis on weed seeds hard to separate
   - Complete familiarity with Scientific Nomenclature for those seeds commonly found in a seed laboratory
   - The use of the seed collection

2. A study of other seed testing rules that may be used in the seed laboratories so as to ensure that the analyst becomes familiar with them and knows when and how to use them.

   - International Seed Testing Association (ISTA) Rules for Seed Testing
   - International Seed Testing Association (ISTA) Handbooks
   - Internal Test Methods described in SOPs
   - Certificates
   - National Certificates
   - Orange International Seed Lot Certificate
   - Blue International Seed Sample Certificate
   - What are export tests and how they are carried out?

C. Authorisation of testing staff

1. Minimum requirements needed for authorisation for germination
   - Test 30 samples covering the needed crop croups with a large range of germination results
   - Compare the results with an authorised germination technician
   - Define thresholds for this comparison
   - If employee did not pass, define additional requirements
   - File records
   - Document date of authorisation

Similarly define requirements for other tests.

Subject	Date	Comments	Trainer / Trainee	Initials

TRAINING GUIDE

TRAINEE:	**TRAINER:**
DATE STARTED:	**DATE COMPLETED:**

The following is a summary of the course of study to be taken over the XX months. The order of appearance is in no way to imply order of importance or order of study.

	Date Training Initiated	Date Signed Off	
PURITY		**Trainer**	**Trainee**
Noxious weeds			
Cultivated crops			
Sow thistles - comparison of			
Small mustards - comparison of			
Brassicas - comparison of rapeseed and wild mustards			
Agropyrons - comparison of Couchgrass, slender wheatgrass, western wheatgrass, crested wheatgrass Tall wheatgrass and Intermediate wheatgrass			
Pure seed			
Fescues - comparison of			
Perennial ryegrass and meadow fescue			
Clovers			
Chicory and Endive			
Johnson's grass and Sudan grass			
Bluegrass (Poas)			
Bentgrass (Agrostis)			
Working knowledge of seed testing rules			
Seed collection and Names of species			

GERMINATION			
Detailed study of normal and abnormal seedlings by families			
Dicotyledons - illustration, label, define parts of seedlings			
Monocotyledons - illustration, label, define parts of seedlings			
The Root external and internal structure kinds of roots functions of roots			
The Stem - types and functions			
Seed Germination process in dormancy of seeds			
Leaves illustrations chlorophyll photosynthesis respiration transpiration stomata			

Authorisation data for germination

#	Species / Sample number tested	Test Day	Threshold: (define)
1	Species SX – sample 158621	03.05.2019	Within
2	Species SX – sample 158662	10.05.2019	Within
3	Species SX – sample 158701	11.05.2019	Within

REFERENCE			Document No.		
Department: Seed Testing Station:	**Title: Equipment Register.** Page 1 of 2 Authorised by:(Signature)……....		Purpose: Each item of laboratory equipment is registered for ease of reference. Scope: All items of laboratory equipment.		
LABORATORY No.	**ITEM & MODEL No.**	**MANUFACTURER & SERIAL No.**	**DATE OF PURCHASE**	**Maintenance interval and calibration**	**COMMENTS Location**
INC 01 (20°C)	Incubator	Labmaster No. 3137			
INC 03 (as req'd)	Incubator	Labmaster No. 2327			
INC 07 (15-25^{O}C)	Incubator	General Eletrico No TV0517			
INC 09 (as req'd)	Incubator	Labmaster No. 684 017			
Tanks 1-4 (20-30°C)	Germination Tanks	Waterwell No.1			
Tank 9 (as req'd)	Germination Tank	Manufacturer Lab-Man & Co No. 1523			
FRI 01	Refrigerator	Housefrigde & Co No. 54			
MOI 01	Moisture oven	Labmaster No. 428			
STER 01	Sterilizing oven	Speedy Company No. 5			
TRIER 1	Sampling trier	Casella, London; Serial No. 337			
GRIN02	Laboratory Mill	Granda Grinde Serial No. 104388.			

Version 2 *November 20XX*

Document code: Version: **1.0**
Date of Approval: Page: Copy No:

STANDARD OPERATING PROCEDURE

Training and Authorisation of Samplers

	Name	Position	Date	Signature
Written by:				
Approved by:				
Issued to:				

1. Object

This SOP describes procedure of training of new sampler for seed sampling according to ISTA Rules. It also describes formal authorisation of the sampler for drawing samples for ISTA Certificates, monitoring of sampler, as well as conditions for withdrawal of authorisation.

2. Related documents

ISTA Rules current edition
ISTA Accreditation Standard for Seed Testing and See Sampling, current version
Staff (doc code)
Sampling (doc code)
Check Sampling and Check Testing (doc code)
Internal Audit (doc code)
Training of New Analysts (doc code)
Staff Records and Staff Training (doc code)

3. Training of new seed samplers

3.1. Basic principles of training of new seed samplers

3.1.1. Training of seed samplers is performed by the Official Sampler and the Head of the Seed Testing Laboratory.

3.1.2. At the beginning of the training, a person who is trained in seed sampling has the status of 'sampler in training' or 'trainee'.

3.1.3. Training consists of theoretical and practical part. After training is concluded, the trainee has to pass the official exam.

3.2. Theoretical training

3.2.1. Theoretical part of training is conducted by the Head of the Seed Testing Laboratory/Samplers supervisor.

3.2.2. The Laboratory Samplers' supervisor, introduces the trainee to the importance of sampling in the process of seed quality testing, and issues her/his own copy of the document "Sampling" (doc code).

3.2.3. Theoretical part of training includes e.g.:
- introduction to ISTA Rules for seed sampling
- explanation of definitions of seed lot, primary, composite, submitted and working sample
- methods of packing, marking and sealing the seed lot
- procedure of applying the seed lot for sampling and testing
- filling in the *Sampling report*
- definition of homogeneity of the seed lot and methods for determination
- sizes of seed lots and submitted samples
- determining sampling intensity
- Laboratory/Sampling Entity ISTA accreditation scope

3.2.4. After completing theoretical training, the trainee can start with practical training.

3.3. Practical training

3.3.1. Practical training is performed by a senior Official Sampler of the Seed Testing Laboratory/ Samplers supervisor. (trainer).

3.3.2. Trainee is first introduced to characteristics sampling triers, methods of their proper use and choosing appropriate trier according to the species and type of containers.

3.3.3. Trainee becomes familiar with the other tools used for sampling (sample bags, seals, sealing pincers, sample divider, balance).

3.3.4. Trainee first practise taking primary samples in the Laboratory, using seed from the stocks, packed in paper or jute bags.

3.3.5. After the trainee has obtained basic skills, she/he starts accompanying a senior Official Sampler/ Samplers supervisor. at official sampling. During sampling, the trainer shows and explains to the trainee all the elements of sampling procedure.

3.3.6. When the trainer concludes that the trainee is ready, trainee starts drawing the official samples, under trainer's supervision. The trainer has to monitor and check every step done by the trainee and sign the Sampling Report together with her/him.

3.3.7. Estimation of competence of the trainee is performed based on 'the rule of 10 samples', in the same way as in the training of analysts (Training of New Analysts, doc code).

3.3.8. Each seed lot sampled by the trainee is recorded on the Form (doc code).

3.3.9. After the trainee has successfully performed sampling of 10 seed lots, under trainer's supervision, she/he can take the official exam.

3.4. Exam

3.4.1. Exam of the sampler in training is performed by the Head of the Seed Testing Laboratory.

3.4.2. The exam consists of theoretical and practical part. Theoretical part is conducted in the form of written exam, and practical part is sampling of the seed lot in the warehouse.

3.4.3. Data regarding exam of the sampler in training are recorded on the Form (doc code).

4. Formal authorisation of seed sampler

4.1. The Head of the Seed Testing Laboratory/Sampling Entity informs the trainee that he/she has successfully completed training and exam for seed sampling. The new sampler is registered into the Register of Authorised ISTA Seed Samplers.

4.2. The Head of the Seed Testing Laboratory/Sampling Entity issues the formal Certificate of proficiency in seed sampling to the new sampler. With this Certificate the new sampler is authorised to perform independently sampling of seed lots for ISTA Certificates.

4.3. The authorisation is also recorded on the Form (doc code, see Staff Records and Staff Training). She/he is given the identification number (ID), which is recorded on the Form (doc code), and a pair of sealing pincers, with her/his ID and Institute logo engraved on it. The new sampler is personally responsible for the sealing pincers. A copy of sampler's Certificate of proficiency is filed into her/his personal file.

5. Monitoring of seed sampler

5.1. Samplers authorised for sampling for ISTA Certificates are subjected to regular monitoring.

5.2. Monitoring includes check sampling (see Check Sampling and Check Testing, doc code) and internal audit (see Internal Audit, doc code).

5.3. After obtaining the authorisation, the new sampler must be check on at least 5% of the drawn samples (but at minimum on xx samples). Check sampling should be monitored over the entire year.

5.4. Results of check sampling must be recorded in a way that trends are detectable.

5.5. Every year the sampler has to take part in regular training, according to Annual training plan (see Staff Records and Staff Training, doc code).

5.6. Additional regular refreshing trainings are recommended.

6. Conditions for suspension or withdrawal of authorisation

6.1. In the following cases the Laboratory/Sampling Entity will formally warn the seed sampler:

- if the sampler does not participate in internal audit and /or check sampling for one year
- if the results of two check samplings within one year are out of tolerance or trends are visible
- if the sampler makes repeated unintentional mistakes in preparing the samples and filling the Sampling Report
- if it is obvious that the sampler does not follow strictly the prescribed SOPs/ISTA Rules for seed sampling

6.2. After receiving the formal warning, the sampler has to participate in additional training and frequency of check sampling is increased to xx% per year.

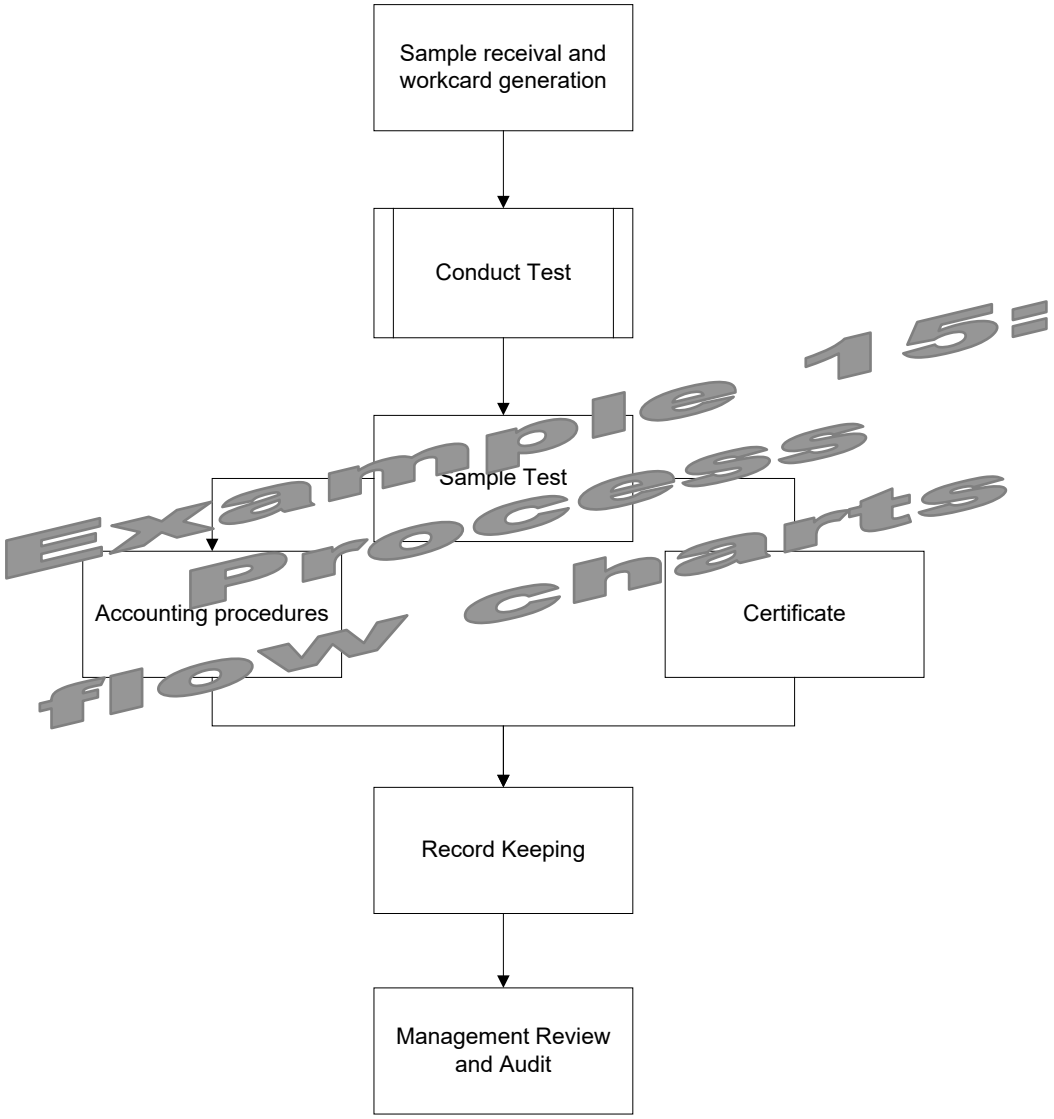
6.3. If the results of check sampling do not improve within the next 6 months or the problems mentioned under 6.1. are still present, sampler's authorisation for sampling seed lots for ISTA Certificates, will be temporarily suspended.

6.4. Sampler's authorisation may be reinstated if she/he passes again the complete initial training and participates successfully in the check sampling within the first year.

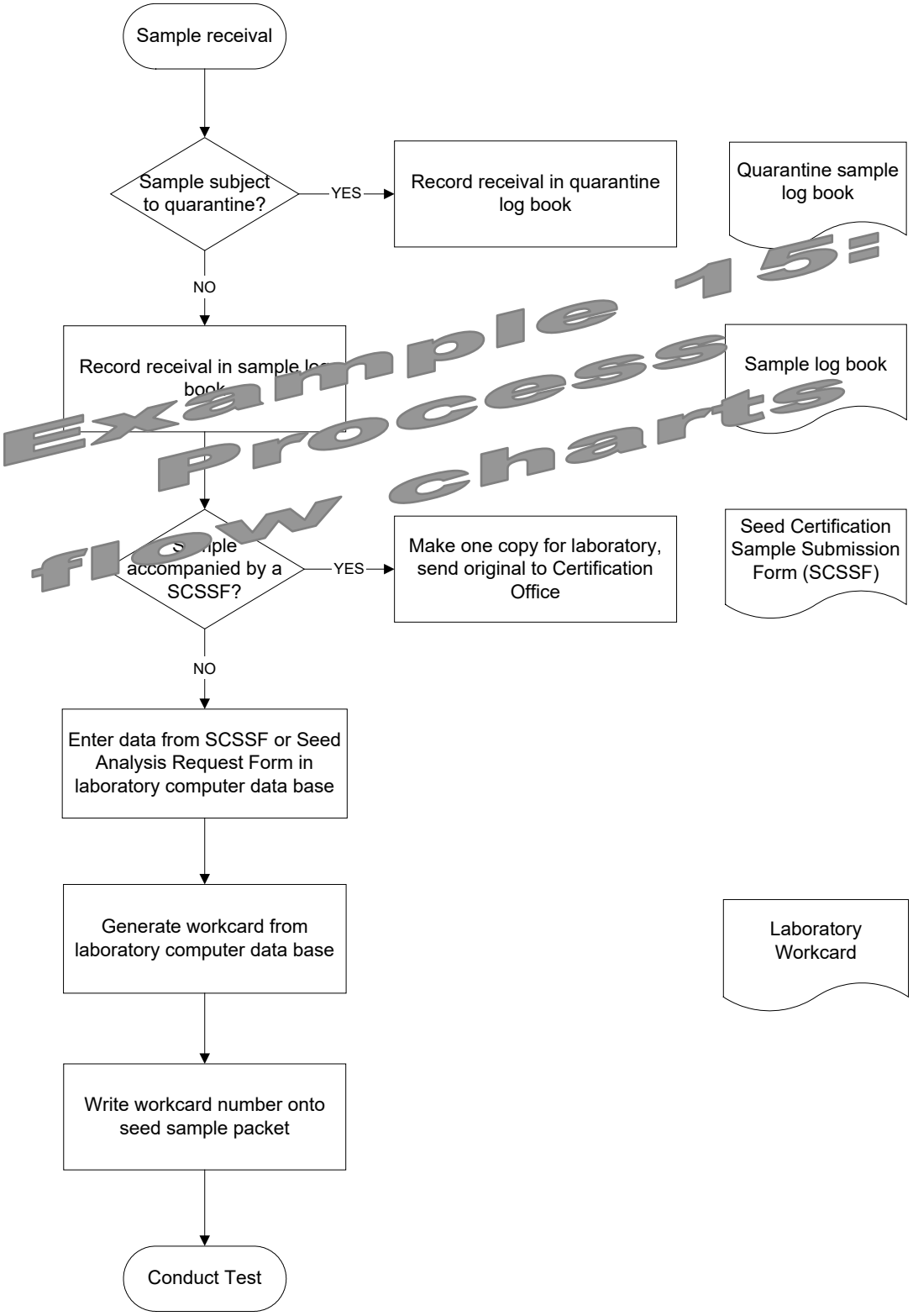
6.5. If the sampler's results do not improve even after repeated training or if the sampler refuses the repeated training, her/his authorisation will be permanently withdrawn.

6.6. If there are evidence that the sampler has intentionally and deliberately forged numbers of seed lots or seed samples or any other relevant data in the Sampling Report, her/his authorisation for sampling seed lots for ISTA Certificates, will be immediately and permanently withdrawn.

Overview of Management and Workflows



Sample receival and workcard generation



C. INSTITUTE	
Title: **Corrective Action Procedure**	**Document No: xxx** **Valid since** **Page x of y** **Approved by: _____** **Supervisor,**

Purpose

This procedure describes the process used to record feedback from customers, staff, audits, suppliers and others who have contact with “name of Laboratory/Sampling Entity”, to identify and implement solutions and report on their effectiveness and appropriateness

1 Scope

The procedure described in this document is to be used to record, investigate and follow-up on variation from documented procedures, equipment failures, inaccurate test results, problems with samples received for testing, purchased goods or services from suppliers, customer complaints, and identified improvement opportunities. The procedure can also be used to record praise from customers for noteworthy personal contributions.

2 References

Complaints Handling Procedure Doc #
Management Review and Statistical Techniques Procedure Doc #

3 Records

Document Title	Doc No.	File Name	Index Method #/A/D	File Location/ Responsibility	Retention Period (Years)

5 Responsibilities

All staff are required to be familiar with the requirements of this procedure.

5.1 Responsibility of Feedback Provider

5.1.1 Mark the appropriate boxes under Sources on the Feedback Form () that best describes the source of the feedback.

5.1.2 Record into the Description section the feedback origin, and a brief description of praise or problem to be resolved.

5.1.3 If the solution is known and investigation is not required, fill out the solution in the verification section and send the feedback form () back to the Manager, Laboratory Operations for signing off.

5.1.4 Feedback forms to be sent to the Investigator (if required) and a copy to the Manager, Laboratory Operations to register and allocate feedback numbers. In the case of electronic feedback communication, an electronic copy of the feedback form is to be sent to the Manager, Laboratory Operations and the investigator

5.1.5 Agree on the corrective action proposed by the investigator.

5.1.6 Record the required verification onto the Feedback Form (). This section may not be filled out if the proposed corrective action has been resolved to the satisfaction of both parties in 5.1.4.

5.1.7 All communications regarding feedback are to be copied to the Quality Manager, Laboratory Operations for filing with feedback forms ().

5.2 Responsibility of the Investigator

5.2.1 Identify the Root Cause using appropriate tools.

5.2.2 Provide a proposed short term and long term to address the problem in a timely manner. These are to be recorded on the feedback form ().

5.2.3 Agree on corrective actions. The Feedback Investigation Report () can be used, as a tool, to record actions taken.

5.2.4 Return finalised Feedback Forms () to the Quality Manager, Laboratory Operations and inform the feedback provider.

5.2.5 All communications regarding the feedback are to be copied to the Quality Manager, Laboratory Operations for filing with feedback forms ().

5.3 Responsibility of the Quality Manager, Laboratory Operations

5.3.1 Identify how and when effectiveness of the corrective actions will be measured.

5.3.2 Record measurement of effectiveness

5.3.3 If corrective actions showed to be not effective, additional investigation must be made and recorded to identify the appropriate root cause and additional corrective actions.

5.3.4 Report on outstanding and resolved feedbacks to the Management team monthly.

Sources:	☐ Customer	☐ Staff	☐ Audit	☐ Other _____
	☐ Equipment	☐ Supplier	☐ Test	☐ Improvement Opportunity

Description (Praise/Problem): *(Provider Only - cross out Praise or Problem which is not applicable)* (*Include Company, Feedback Provider Name, Phone, Audit # as appropriate)*

Signed: _____ Date: _____

Root cause analysis:

Signed: _____ Date: _____

Investigator Use only	☐ Supplier Capability	☐ Discipline	☐ Training	☐ Breakdown
				☐ Other _____

Short Term Fix / Correction (Proposed):
Investigator Use only

Signed: _____ Date: _____

Long Term Fix / Corrective Action (Proposed):
Investigator Use only

Signed: _____ Date: _____

Effectiveness: Date Due: _____

How is effectiveness measured:

Was corrective action effective: _____

If no what are the next steps:

Signed: _____ Date: _____

Close Off: (*Manager Laboratory Operations use only)*

Feedback Number

Signed: _____ Date: _____

Form code, version, date

STANDARD OPERATING PROCEDURE		Document No. STS/SOP/032
Department of ... Seed Testing Station	**Title: ISTA Proficiency Test Samples** Page 1 of 2 Authorised by:(Signature)	Purpose: The International Seed Testing Association, as part of its quality assurance program, monitors the operational standards of member laboratories. Samples are regularly received from ISTA as part of this program. his procedure deals with the registration, analysis and reporting of these samples. Scope: Applies to all ISTA Proficiency Samples.

	Step	Procedure	Responsibility	Form / Reference	What if.....?
1	Receive ISTA sample	ISTA proficiency samples are sent to the laboratory via AQIS. They are delivered to reception whereupon the appropriate form is completed, and the laboratory notified by phone.	Receptionist	F/006	
2	Collect sample	Nominated Analyst collects sample from Reception	Nominated Seed Analyst		
3	Register sample	Registered the ISTA sample as an Official Sample	Nominated Seed Analyst	SOP/001	
4	Check sample details	Check that the sample details against the details on the work card.	Nominated Seed Analyst		
5	Prepare working sample	Obtain one working sample of the prescribed weight, from the submitted sample using the appropriate seed divider. Record the weight of the working sample on the work card.	Refer ISTA Rules REF/002 REF/003		
6	Check ISTA Rules	If the species is one for which the laboratory does not claim competence, the Supervising Seed Analyst shall review the ISTA Rules as they apply to the species and discuss the procedures with the Seed Analysts.		ISTA Rules	
7	Test sample	The sample is subjected to the test(s) requested by ISTA. See appropriate SOP.	Nominated Seed Analyst	SOPs	
8	Double check sample	If carrying out a purity test, place components in separate, labelled, small Petri dishes for checking by a second analyst. If testing germination, the 'reading' of the sample is overseen by a second Analyst.			
9	Second analyst checks sample and initials workcard	Second analyst checks identification of 'Other Seeds' and 'Inert Matter' and satisfies him/herself that the 'Pure Seed' separation is accurate. Second analyst initials the workcard.			
10	ISTA Report completed	The Report Sheet accompanying the sample is completed and double checked before photocopying and filing the copy in locked cabinet No.2.			
11	Results to ISTA	Results are dispatched to ISTA.			
12	**Upon returned ISTA RESULTS** Discussion	On the return of the results from ISTA, Quality Systems Manager to discuss result with analysts. Any remedial action required by ISTA to be completed without delay. Report filed in locked cabinet No.2 In case of „C"or „BMP" rating: root cause analysis and establish corrective action	Quality Manager and Technical Manager		