



INTERNATIONAL SEED TESTING ASSOCIATION (ISTA)

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Procedure How to develop Quality Documentation

Note: Any copies of this document are not subject to change service

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SCOPE

This document provides guidance for the development, preparation and control of quality manuals tailored to the specific needs of the user. The resultant quality manuals should reflect documented quality system procedures required by the ISTA Laboratory Accreditation Standard. Examples are used to show one or several possibilities how requirements of the ISTA Laboratory Accreditation Standard may be considered appropriately. All these examples originate from existing laboratory quality manuals; 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, customized solutions reflecting the laboratory's daily work. This document is considered to be a guideline and may not be complete as the continual improvement approach is assumed.

RELATED DOCUMENTS

ISTA Seed Testing Laboratory Accreditation Standard

RESPONSIBILITY AND ABBREVIATIONS

Q: Quality

QM: Quality Manual

SOP: Standard Operating Procedure

PT: ISTA Proficiency Test

PROCESS DESCRIPTION

A. STRUCTURE AND FORMAT OF QUALITY MANUALS

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)**

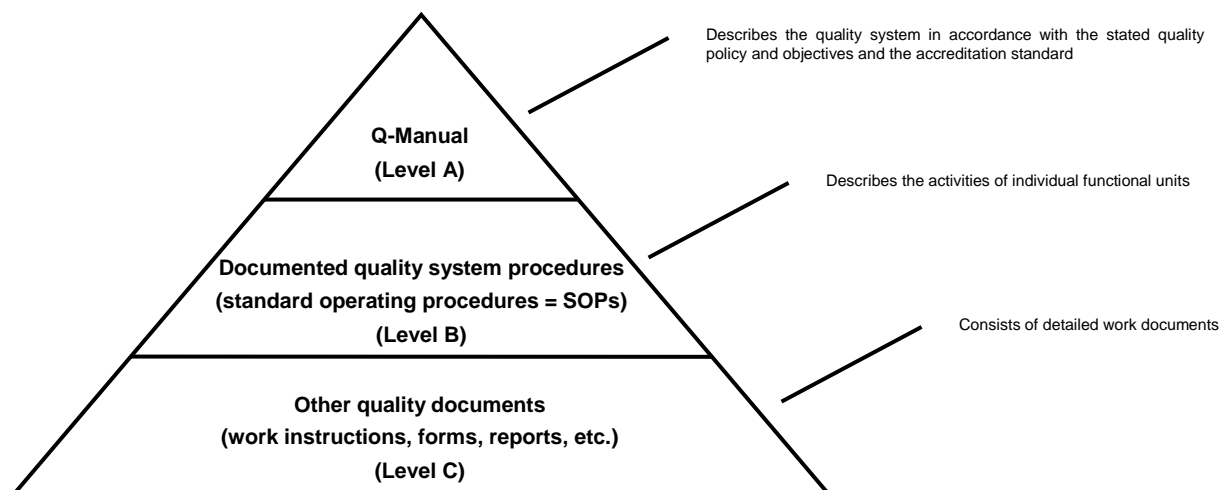
The purpose of a Q-Manual is to outline the general policies and procedures for staff, customers, accreditation bodies and/or legal bodies to provide an overview of the laboratory's quality system.

II. **Documented quality system procedures** such as **Standard Operating Procedures (SOPs)**

Standard Operating Procedures describe standard procedures in a concise manner to provide sufficient information to carry out the work concerned. The volume depends on the size of the laboratory, number of tests, number and qualification of staff and kind of equipment in use.

III. **Other quality documents** such as working instructions, forms, reports

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 quality manuals, however, it should convey accurately, completely and concisely the quality policy, objectives and governing documented procedures of the laboratory. It can be prepared in a book/booklet format or in a ring binder format. Each solution has its advantages and disadvantages:

Book/booklet

Advantage: easy control of distributed copies

Disadvantage: revisions of existing documents requires replacement of the whole document and all its copies

Ring binder

Advantage: revisions of existing documents by replacing single pages/chapters or entire SOPs, less time and cost consuming

Disadvantage: it may be more difficult to control distributed copies. A thorough document change service needs to be established

Cover-sheet 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](#)).

B. HOW TO START WITH THE PREPARATION OF A Q-MANUAL?

The process of establishing quality assurance system documentation should begin with appointment of the coordination task to a management-delegated competent body, which 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
- 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 pertinent changes

- to act as contact person/s in all matters of the quality assurance system

C. THE Q-MANUAL

Q-manuals 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 system
- providing documented bases for auditing quality systems
- providing continuity of the quality system and its requirements during changing circumstances
- training personnel in the quality system requirements and methods of compliance
- presenting the quality system for external purposes, such as demonstrating compliance with respective accreditation standard

D. WHAT TO INCLUDE IN A QUALITY MANUAL?

1. **Scope and field of application**

In the scope or field of application it shall be clearly stated for which activities/departments of the laboratory the Quality Manual is valid.

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 laboratory specific abbreviations**

4. **Policy and Quality Objectives**

4.1. In this section, intentions and objective targets of the laboratory incl. a statement that the seed testing laboratory's standard of service will be in accordance with the requirements of the ISTA Laboratory Accreditation Standard and the current version of the ISTA Rules ([Example 2](#)) ([Example 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 and maintained at all levels. **NOTE:** A description of the activities of the laboratory is not a substitute for the Q-policy statement.

4.2. Based on the Quality Policy, **Quality Objectives** shall be determined. Objectives shall be quantifiable (current value, target value, time period) to facilitate a target/actual value comparison ([Example 4](#)). The Q-objectives need not necessarily to be included in the Q-manual; a mere 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, see below or in other relevant planning documents.

5. **Description of the Q-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, log books, checklists, loose sheet copies, etc.). 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 change control are essential to ensure that the content of the quality documentation is properly authorized. 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. 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 Laboratory Accreditation Standard).
- 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 ensures that the new versions were received. This may be done by listing the documents on a **master list of controlled documents** (or document 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 document
 - approval date
 - recipients (can be person(s) and/or a place, e.g. room number)
 - person responsible for distribution of new or revised documents

6. Organisation and Management

- 6.1. Description of the organization, responsibilities and authorities: In this section the laboratory 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 and sampling unit in the overall context within a larger organisation, e.g. the institute within the ministry of agriculture, or the seed testing laboratory unit within a seed company, and the organisational structure within the laboratory ([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 seed testing activities: The laboratory must describe how it meets these requirements of the ISTA Laboratory Accreditation Standard.
- 6.3. Defining the responsibility of the management, i.e. providing resources (human and financial resources), determining the Q-policy and Q-aims, management review, promoting quality assurance system to increase awareness, motivation and involvement.

7. Staff and Training

- 7.1. Description of responsibilities and authorisations of laboratory functions and positions (e.g. head of the laboratory, technical manager, quality manager, supervisors, technicians/analysts, administrative personnel, trainees, etc.)
- 7.2. Laboratory staff matrix showing responsibilities and deputies in key activities ([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 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 training needs identified and recorded? How is 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 for new staff members. ([Example 12](#))

8. Laboratory Premises

- 8.1. In this section the laboratory 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. testing of coated seed). A brief description how good housekeeping in the testing laboratory is ensured should be included.
- 8.2. Definition of appropriate regulations for access and use of the laboratory premises by the staff during working hours and off-time and definition how entry of persons external to the laboratory (staff of foreign sections, clients or other visitors) is controlled and how it is ensured that external persons are not left unattended in the laboratory premises.
- 8.3. Sample storage: This section contains a description of the sample storage system (i.e. where, how, how long the samples are stored and which components of the samples, i.e. only remainder of submitted samples or with the other seeds and inert matter found, are stored), control/treatment and recording of pests and diseases, control and recording of relative humidity and temperature. Definition of procedures for disposal of stored samples (e.g. treated versus untreated seeds).

9. Purchasing of Services and Supplies

- 9.1. General description of the procedure for the selection and purchasing of laboratory services and supplies including description of records in place.
- 9.2. Services and supplies that affect the quality of tests must be identified. 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 compliance prior to use.
- 9.3. Explanation on how and when the supplier of critical services and supplies are evaluated and how suppliers are approved.

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 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. function check, calibration). The laboratory must describe how it examines the effect of defective equipment on any previous tests, and withdraw and re-issue certificates where faulty results are suspected.
- 10.3. General description of the laboratory's calibration programme to ensure that measurements made in the testing laboratory are traceable to national or international standards of measurement. Reference to records kept on these measures must be provided.
- 10.4. The testing and measuring equipment must 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 calibration 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, log book, 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. This may be supplemented by an organizational chart.
- 11.2. What are the provisions to ensure independence of ISTA sampling/ISTA samplers? An example of a declaration that there are no conflicts of interest in regards to sampling may be provided.
- 11.3. How are the testing laboratory and the samplers affiliated? A list of authorized/recognized ISTA samplers (name and address of ISTA sampler, authorisation number, category of ISTA sampler, specimen signature/initials) must be provided. A list of authorised ISTA automatic samplers (name and address of the owner, authorisation number, unique identification).
- 11.4. What are the requirements to obtain and maintain formal authorisation as an ISTA sampler? This section should describe procedures and criteria how ISTA samplers are authorized and how authorisation is maintained, i.e. initial training, refresher 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](#)).
- 11.5. Specification of applied sampling procedures, i.e. national seed regulations and/or ISTA sampling procedures including date of the latest revision.
- 11.6. 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. Description of automatic sampler authorisation and monitoring process.
- 11.7. Handling of samples: A description of how the laboratory handle the sample when it is received has to be elaborated. The ISTA Laboratory Accreditation Standard has described in detail what is needed for safe handling of samples. This includes the unique identification, labelling, transport, storage and disposal, as well as that 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.
- 12.2. Definition of 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. Ideally a detailed list of species with reference to the applicable test methods is joined.
- 12.3. Description of the policy of sub-contracting of sampling and tests being reported on ISTA Certificates including a description how suitable sub-contractors are identified and monitored. If sub-contracting is not applicable a short indication that no sub-contracting for ISTA purposes is made is sufficient.

13. Process management (work flows) ([Example 15](#))

- 13.1. Work flow 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 samplers and laboratory staff, 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, plausibility, completeness, correctness and accuracy.
- 14.3. Specification of responsibilities or authorisations to make corrections in the computer (e.g. password protection) and laboratory work cards.
- 14.4. Description on the process of how to records (inscriptions must be made by using inerasable pen) and how to proceed if mistakes must be corrected (on laboratory work cards, on records but also in the computer).
- 14.5. Description of the verification process of up-dated computer software on correct calculations and tolerance checks if applicable.
- 14.6. Description of the laboratory's concept (back-up frequency, media) to retain computerized data and to ensure that back-ups of computerized 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, the seed lot is sampled by different seed samplers.
- 15.2. Check testing: Is a monitoring of reproducibility of results, different employees test the same sample. This monitoring shall be done on all tests for which the laboratory holds accreditation.
- 15.3. In the procedure explanation should be given on how the results are recorded and evaluated.
- 15.4. A description of how trends are observed and a systematic follow up on the performance of the testing and sampling staff over time should be included in this description.

E. STANDARD OPERATING PROCEDURES (SOPs) INCL. WORK INSTRUCTIONS

For those operations of the Q-Manual that need to be described in detail SOPs should be elaborated on. SOPs serve the staff members 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 reality 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 particular laboratory shall 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.

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 Customer Complaints
- Non conforming work and Corrective Action Procedure ([Example 16](#))
- Preventive Action Procedure
- 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:

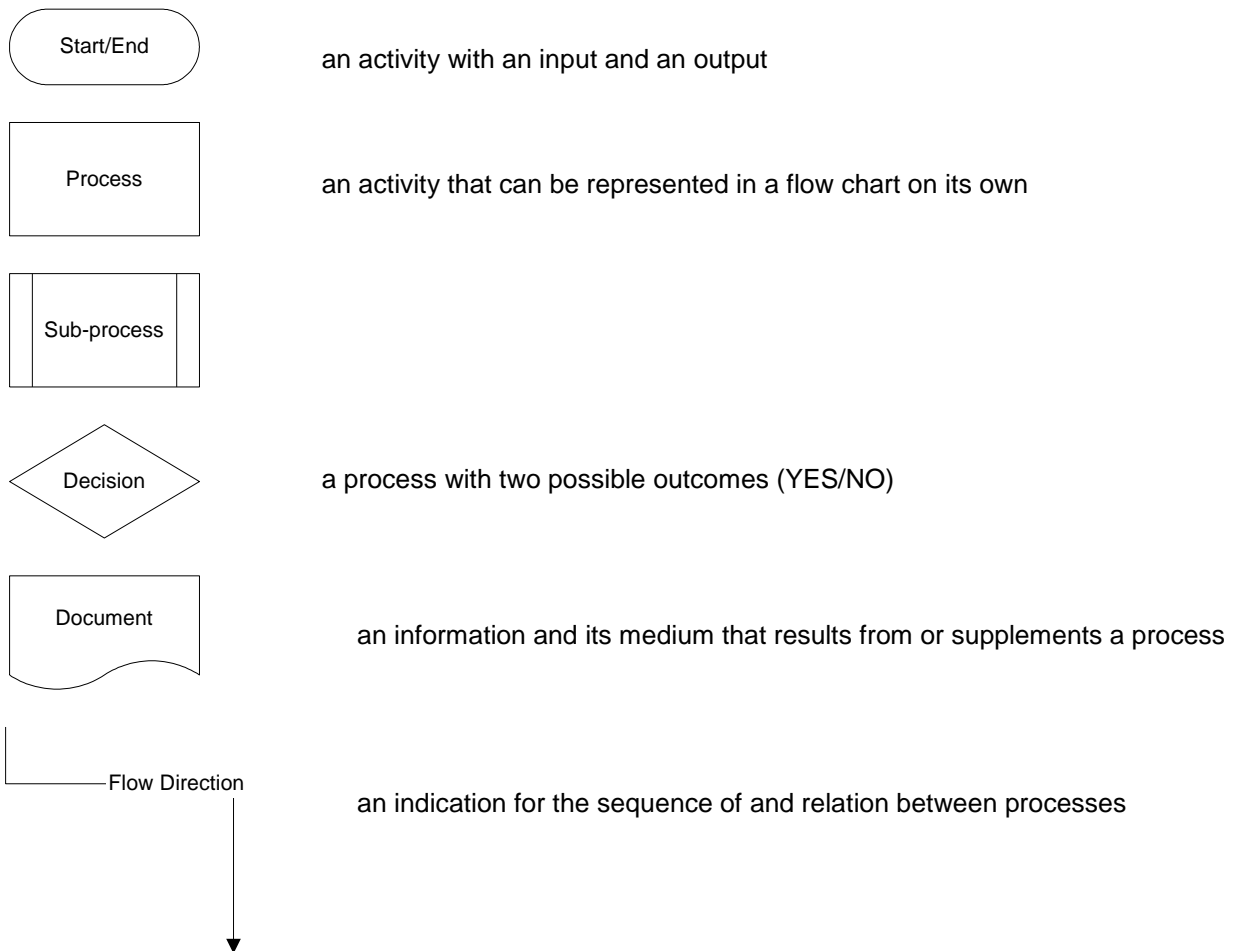
- Maintenance, repair, control or internal calibration for each item or group of equipment (e.g. balances, working thermometers, pH-meters, seed blower, grinder, moisture oven, germinators, dividers, etc.)
- Storage and disposal of samples
- Control and disposal of chemicals
- Maintenance and description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

- Mixing and dividing of samples in the 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 SOP to avoid redundancy and inconsistency.

A flow chart is particularly helpful to visualize 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 general consensus a very limited number of symbols is used, which facilitates its generic application and makes it a tool that is easily understood:



With those few elements most processes, interrelations and even complicated procedures can be represented. A number of additional “shapes” is available, but one has to bear in mind that there is always a certain risk of jeopardizing the greatest asset of this tool: its simplicity.

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

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.

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

unique QM #	location	responsible	signature
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QUALITY MANUAL OF

“ LAB NAME”

“CONTACT DETAILS”

Example 1: Quality Manual cover page

Controlled document

Author:	Up-date:	Authorisation:
Name:	Name:	Name:
Designation:	Designation:	Designation:
Date:	Date:	Date:
Document name, acronym, file reference etc.		

Institution	Quality Manual	Section: 00
Department	_____	Version: 03
	Quality Policy	Page: 3 of 20

F. QUALITY-POLICY

Policy statements

Customer Focus:

We maintain close contact with 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 strive at all times 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 operates a documented quality system which meets the requirements of the ISTA Accreditation Standard for Seed Testing Laboratories and the current ISTA International Rules of Seed Testing.

The Management is committed to and the analysts are conversant with the laboratory's quality system as described in this quality documentation. The quality system 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.

DEPARTMENT

SEED TESTING STATION QUALITY SYSTEMS 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 Station 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 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 (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.

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 systems and quality management. Compliance with the procedures and principles presented in the present Quality Systems 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 STATION
QUALITY SYSTEMS DOCUMENT
Appendix to DocNo XXXYYY

G. 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 Laboratory Accreditation Standard in relation to document control by a mentioned date and in relation to ...

Document name, acronym, file reference, Revision status/version	page # of total #
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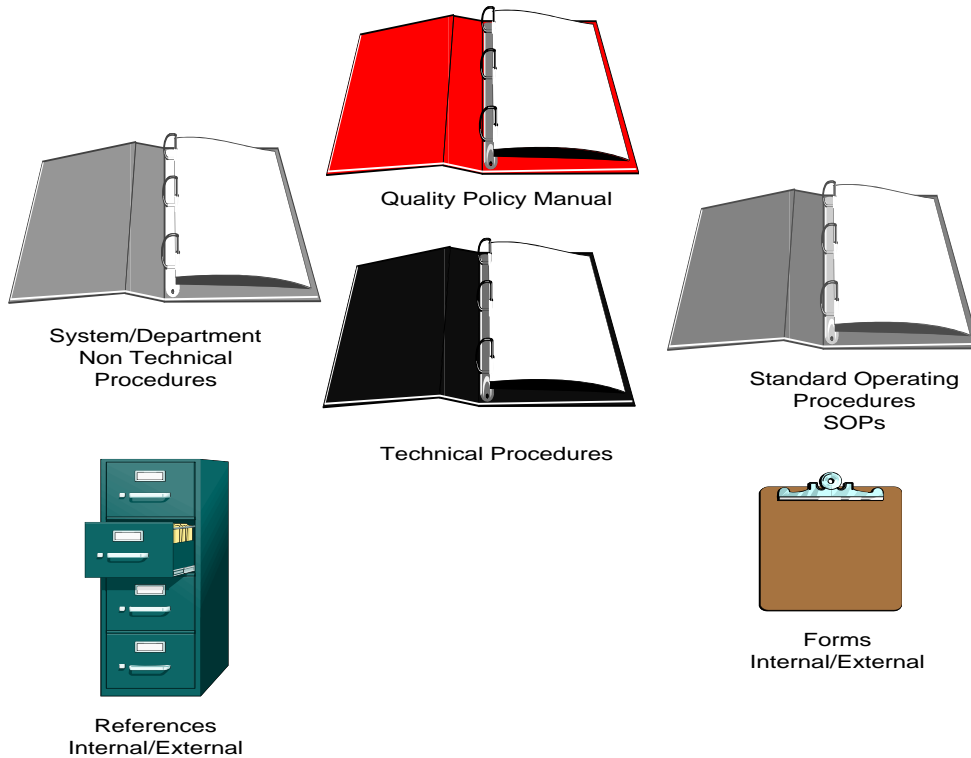
A. INSTITUTE	B. QUALITY POLICY MANUAL
Section:	Approved by
Page:	
Document No. : QPM/001/12584	Designation

3.2 Management System Documents

3.2.1 Structure and Document Format

Documents which are part of the Laboratory'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's Management System.



C. INSTITUTE	D. QUALITY POLICY MANUAL
Section:	Approved by
Page:	
Document No. : QPM/001/12584	Designation

Policy Manual - provides an overview of the Laboratory's business. It defines its Policy, refers to the business objectives and states the laboratory's commitment to quality in respect of the International Seed Testing Association and National standard. 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 activities conducted by the Analytical Laboratories. The format for Technical Procedures (Appendix 4.3) is based on the National Standard: Test Methods - Guide to the format, style and content.

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.

Forms - are used to record information as evidence that activities have been completed as described within procedures. Completed forms are retained as records.

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, 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 (<i>To be found on the header of the Procedure</i>)	Staff Member		
3	Describe what needs changing	Fill in Section 1 on the form, giving brief details as to what needs changing (eg <i>"Step 4 needs changing to include a further checking step"</i>)	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. <i>"As it is, it is possible to overlook the reading on the meter when taking off the sample"</i>)	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. <i>"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"</i>)	Staff Member		
6	Does it comply with the Rules	Does the proposed change still comply with the ISTA Rules. (<i>Basically a "Yes/No" answer</i>)	Staff Member, Supervising Seed Analyst		
7	Consider proposal	The proposal for changing the Procedure is then considered by the appropriate people.	Nominated personnel (<i>Nominated by QSM</i>)		
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

Institution	Quality Manual	Section:	03
Department		Version:	03
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Content

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3.5	...	3
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3.8	Related documents	4

Example 7:
Quality Manual page

This is a controlled document

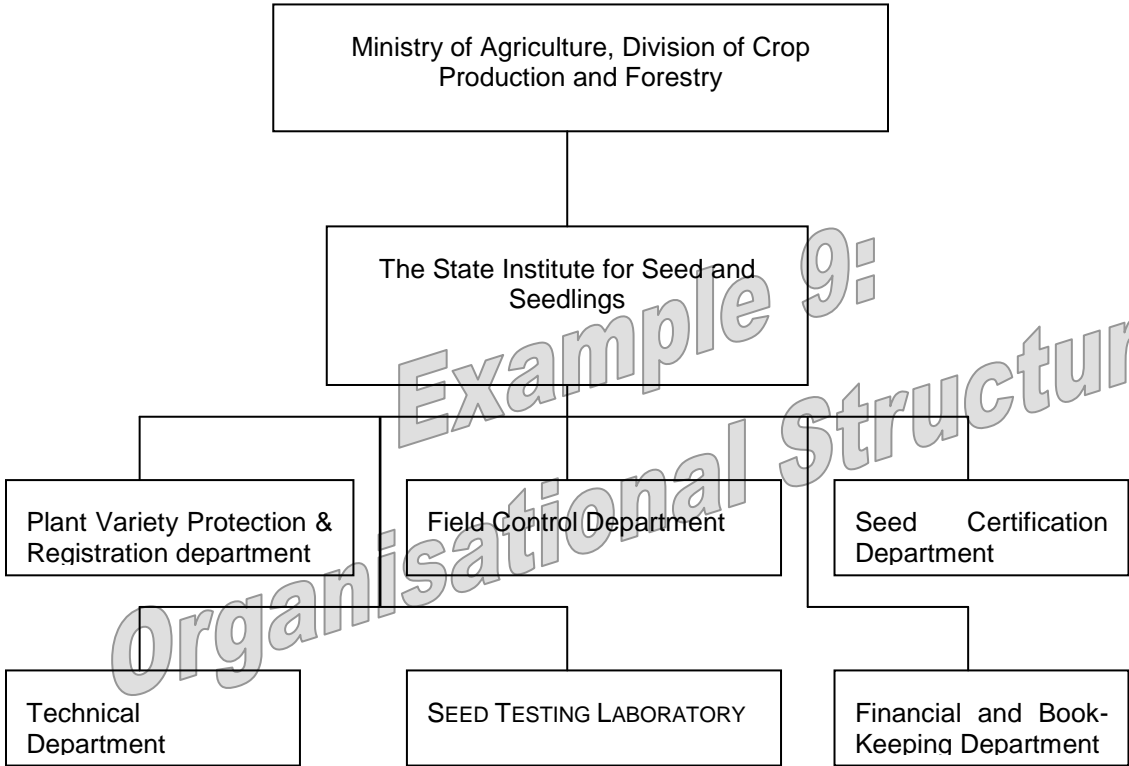
Master Document Register - Technical Procedures

Document title	Type of Doc	Doc Code	Revision Date	Approved by	Availability		Availability							
					Type	FQ	F S	S T	M S	AD	BD	R&D	G-Lab	
Document 1	SOP	SOP TP/001	01.05.2009	Supervisor, FQL	Hardcopy	1	1			1				1
Document 2	SOP	SOP TP/002	21.03.2008	Supervisor, MSL	Hardcopy	1				1				1
Document 3	SOP	SOP TP/003	01.03.2010	Manager, CCL	Online					1				
Document 4	SOP	SOP TP/004	20010618	Supervisor, MSL	Hardcopy					1	1	1	1	1
Form XY1	Form	F TP/001	01.05.2009	Supervisor, MSL	Hardcopy	1	1			1				1
Form XY2	Form	F TP/002	21.03.2008	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

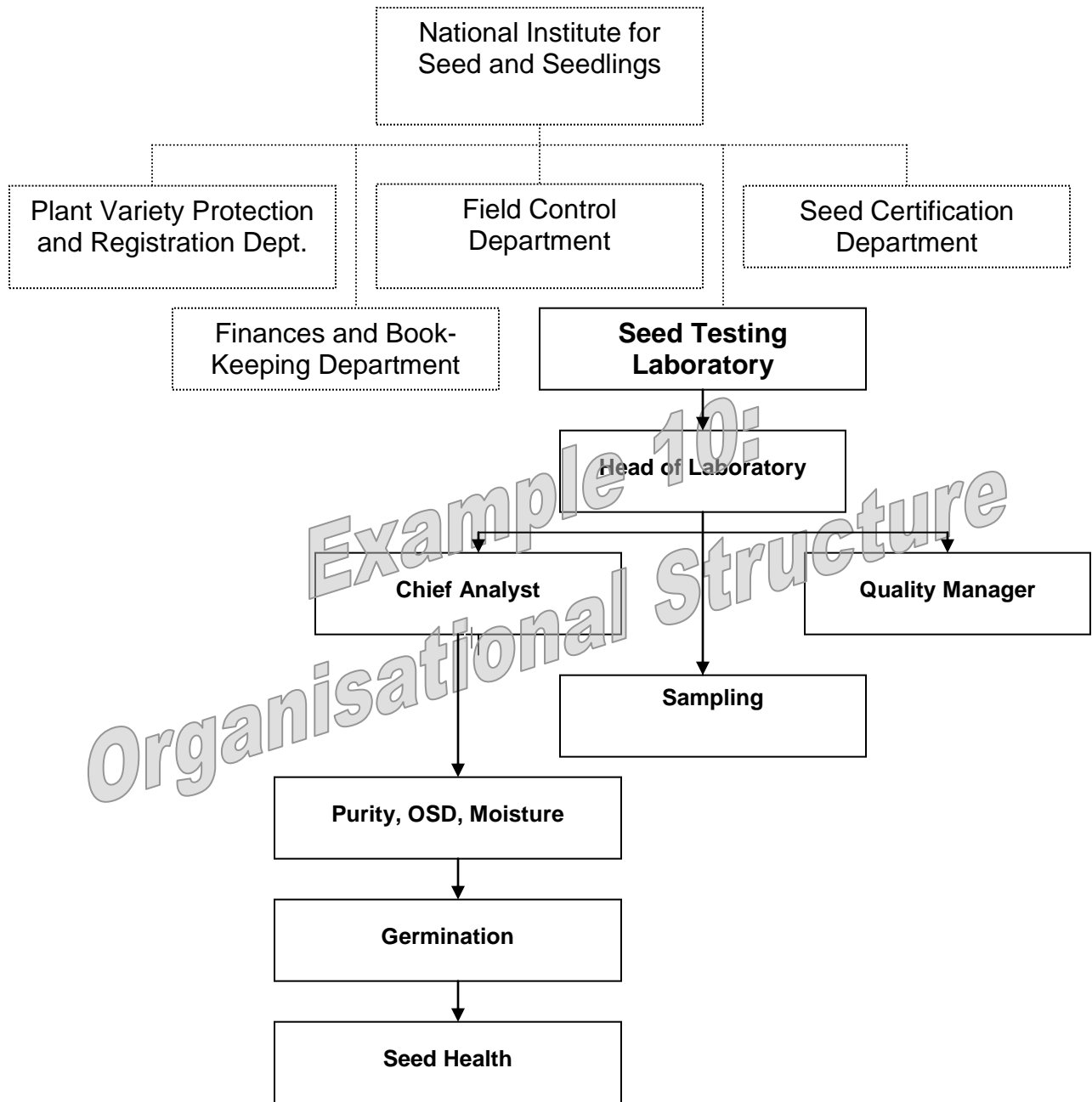
Master list controlled documents

Logo	QUALITY MANUAL	Doc. Code
	Subject:	Copy No.:
	Organisation and Management	Date:
	Version	Page:

Organisational structure



ORGANISATIONAL STRUCTURE



Example 10:
Organisational 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	-
Blaska	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

Training

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

A. Basic training for new analysts

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 groups 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	Initial

Example 12:
 Training Guide

Document name, file reference, version, date

page No

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

PURITY	Date Training Initiated	Date Signed Off	
		Trainer	Trainee
Noxious weeds			
Cultivated crops			
Sow thistles - comparison of			
Small mustards - comparison of			
Brassicac - comparison of rapeseed and wild mustards			
Agropyrons - comparison of Couchgrass, slender wheatgrass, western 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			

Document name, file reference, version, date

page No

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	03.05.2010	Within
2	Species SX – sample 158662	10.05.2010	Within
3	Species SX – sample 158701	11.05.2010	Within

REFERENCE			Document No.		
Department:		Title: Equipment Register.	Purpose: Each item of laboratory equipment is registered for ease of reference.		
Seed Testing Station:		Page 1 of 2 Authorised by:(Signature).....	Scope: All items of laboratory equipment.		
LABORATORY No.	ITEM & MODEL No.	MANUFACTURER & SERIAL No.	DATE OF PURCHASE	Maintenance interval and calibration	COMMENTS
INC 01 (20°C)	Incubator	Labmaster No. 3137			
INC 03 (as req'd)	Incubator	Labmaster No. 2327			
INC 07 (15-25°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			
GRIN01	Grinder	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 National Certificates and for ISTA Certificates, monitoring of sampler, as well as conditions for withdrawal of authorisation.

2. Related documents

ISTA Rules current edition
 ISTA Seed Testing Laboratory Accreditation Standard, 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)

Document code:
Version: 1.0
Date of Approval:
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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.
- 3.2.2. The Head of Laboratory 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:
 - introduction to ISTA Rules for seed sampling, as well as national rules (Rules for basic requirements for quality, packaging and certification of agricultural seed (Reference)
 - 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
- 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 the Official Sampler of the Seed Testing Laboratory (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 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 the Official Sampler at official sampling. During sampling, the trainer shows and explains to the trainee all the elements of sampling procedure.

Document code:
Version: 1.0
Date of Approval:
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- 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 on the basis of '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 informs the relevant office at the Ministry of Agriculture and Forestry that the trainee has successfully completed training and exam for seed sampling. The new sampler is registered into the Register of Authorised Seed Samplers, held by the Ministry.
- 4.2. The State Institute for Seed and Seedlings, on behalf of the Ministry, 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 National Certificates.
- 4.3. If the new sampler is a member of staff of the Seed Testing Laboratory, her/his 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 photo-copy of sampler's Certificate of proficiency is filed into her/his personal file.
- 4.4. Authorised sampler has to be subjected to monitoring and control, performed by the Seed Testing Laboratory of the State Institute for Seed and Seedlings (see Point 5).
- 4.5. After the new sampler has successfully performed seed sampling for National Certificates for at least one year and providing that no major non-conformities have been recorded in her/his work, the sampler may be formally authorised to draw ISTA samples.
- 4.6. The decision to authorise the sampler for drawing ISTA samples is made by the Head of the Seed Testing Laboratory of the State Institute for Seed and Seedlings. The Head of Laboratory formally recommends to the Ministry to authorise the sampler.
- 4.7. The Ministry of Agriculture and Forestry records the authorisation in sampler's file in the Register of Authorised Seed Samplers. The State Institute for Seed and Seedlings, on behalf of the Ministry, issues the formal Certificate of proficiency in seed sampling for ISTA Certificates.

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

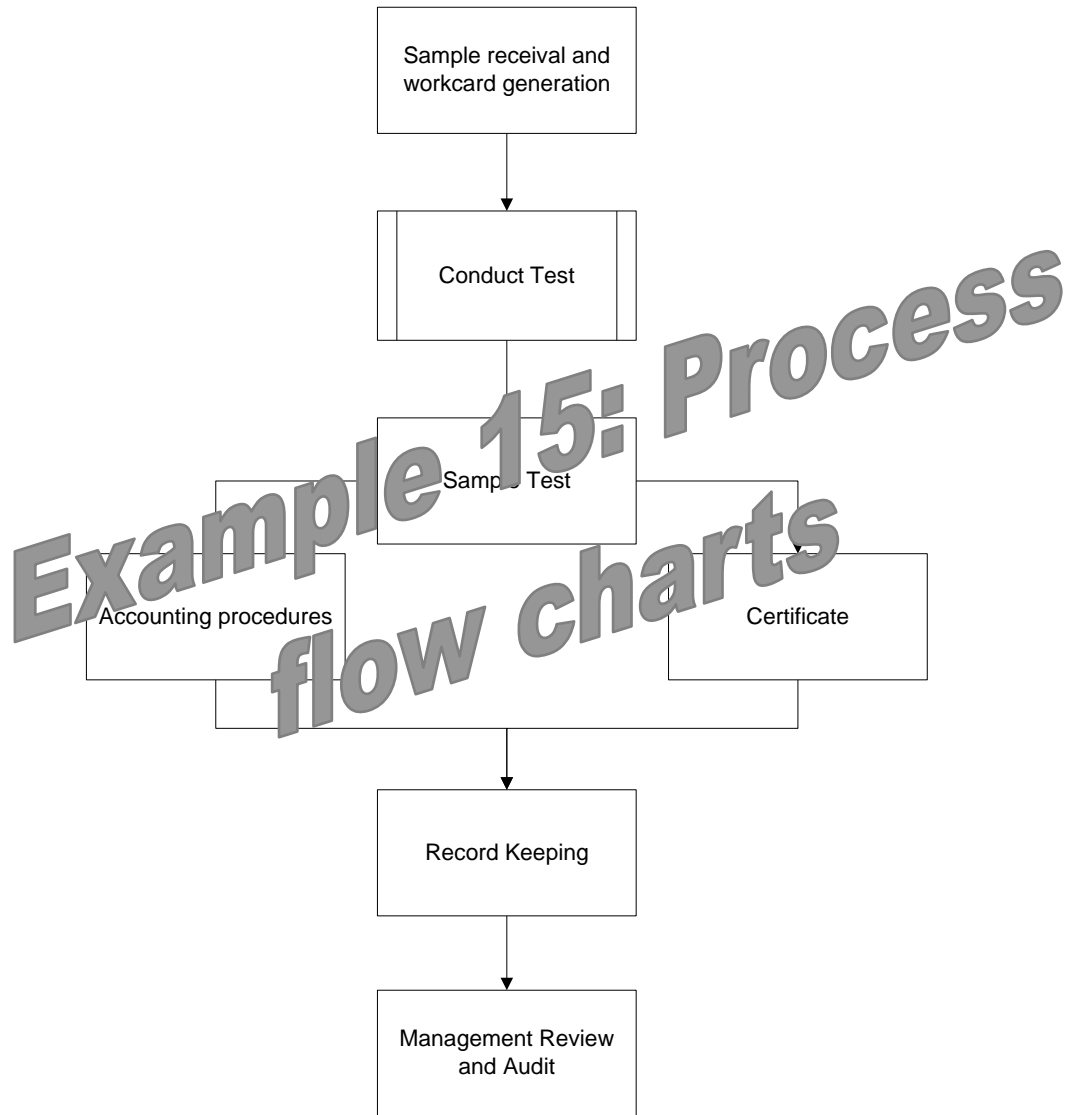
5. Monitoring of seed sampler

- 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 has to be check sampled 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 refresher trainings are recommended.

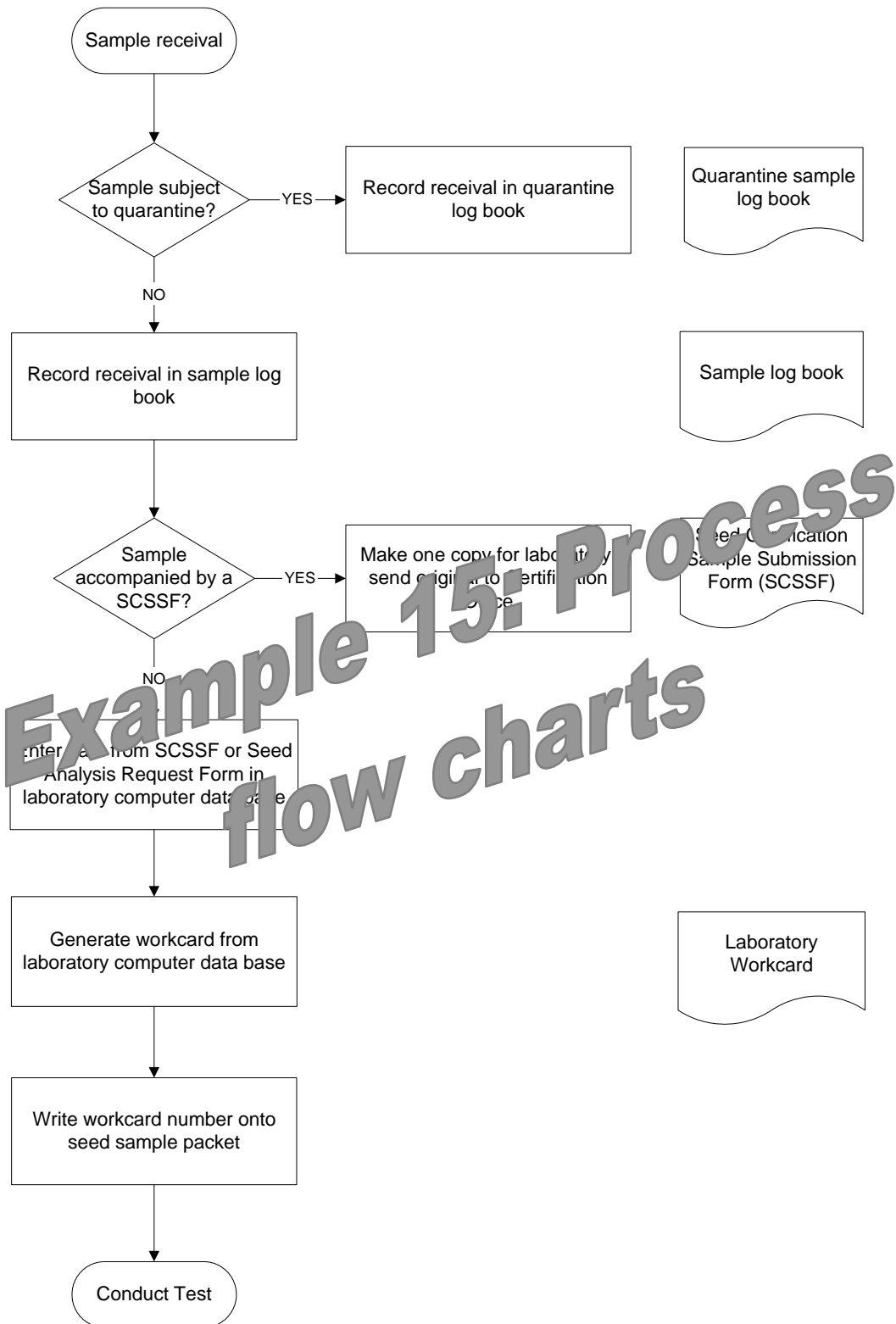
6. Conditions for suspension or withdrawal of authorisation

- 6.1. In the following cases the Institute 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 serious trends are visible
 - if the sampler makes repeated unintentional mistakes in marking the samples and filling the Sampling Report
 - if it is obvious that the sampler does not follow strictly the prescribed methods 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 year 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 evidences 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 receipt and workcard generation



H. _____ INSTITUTE	
Title: Continuous Improvement Procedure	Document No: xxx 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 organisation", to identify and implement solutions and report on their effectiveness and appropriateness. The aim is to respond quickly to feedback and to give appropriate recognition when positive feedback is received.

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 (Yrs)	
					Location	Archive
Feedback form	xyz	Feedback file	#	Manager, Lab Ops	2	6
Feedback Register	zzz	Feedback Register - Approach	#	Manager, Lab Ops	3	6
Feedback Investigation Report	xxx	Feedback Investigation Report - Approach	#	Manager, Lab Ops	3	6

<i>I. _____ INSTITUTE</i>	
Title: Continuous Improvement Procedure	Document No: xxx Page x of y Approved by: _____ <div style="text-align: right;">Supervisor</div>

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 feed back 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 feed back are to be copied to the 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 the feedback provider with a proposed short term and long term fix to 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 Manager, Laboratory Operations and send a copy to the provider.

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

J. _____ <i>INSTITUTE</i>	
Title: Continuous Improvement Procedure	Document No: xxx Page x of y Approved by: _____ Supervisor

5.3 Responsibility of the 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 feed backs to the Management team on a monthly basis.

Example 16:
Corrective Action Procedure

Sources:

<input type="checkbox"/>	Customer	<input type="checkbox"/>	Staff	<input type="checkbox"/>	Audit	<input type="checkbox"/>	Other
<input type="checkbox"/>	Equipment	<input type="checkbox"/>	Supplier	<input type="checkbox"/>	Test	<input type="checkbox"/>	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: _____

<i>Investigator Use only</i>	<input type="checkbox"/>	Supplier	<input type="checkbox"/>	Discipline	<input type="checkbox"/>	Training	<input type="checkbox"/>	Breakdown
	<input type="checkbox"/>	Capability	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	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 ...

Title: **ISTA Proficiency Samples**

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. This procedure deals with the registration, analysis and reporting of these samples.

Seed Testing Station

Page 1 of 2

Authorised by: (Signature).....

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 workcard.	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 workcard.	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 issue corrective action	Quality Manager and Technical Manager		