



OFFICIAL SEED TESTING STATION
KEPHIS SEED TESTING LABORATORY, KEDL0100

QUALITY ASSURANCE MANUAL

PART 1

ISTA SEED TESTING LABORATORY ACCREDITATION STANDARD
KENYA PLANT HEALTH INSPECTORATE SERVICE

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ISTA MEMBER LABORATORY KEDL0100

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APPENDIX1

Layout of the seed testing laboratory

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MANAGEMENT COMMITMENT

The Board of Directors of KEPHIS, the management and the entire staff of KEPHIS Seed Testing Laboratory are committed to the implementation and adherence to ISTA Seed Testing Accreditation Standards. This will contribute to the achievement of the set vision, mission and the goals of the Seed Testing Laboratory and the overall objective of KEPHIS.

It is the policy and mission of KEPHIS to assure plant health, quality of agricultural inputs and produce towards a food secure nation and safe trade

Kenya Plant Health Inspectorate Service (KEPHIS) management will therefore offer unreserved support to the KEPHIS Seed Testing Laboratory (KEDL0100) by availing all the necessary resources i.e. facilities, finance, human resource and moral support to enable the Seed Testing Laboratory comply with ISTA accreditation requirements and realise the set goals.

SIGNED:

Date.....

Managing Director

Laboratory Quality Policy Statement

KEPHIS Seed Testing Laboratory is committed to providing accurate information on the quality of seed to the agricultural and business community in a timely manner.

To achieve this, the Laboratory is accredited to the International Seed Testing Association (ISTA). The objectives of this accreditation are:

1. To operate a seed testing system that meets clients' needs through timely provision of accurate test results.
2. To demonstrate technical competence in seed sampling and testing
3. To facilitate international seed trade through issuance of ISTA Certificates

Further, the laboratory shall:-

- i. be committed to good professional practice
- ii. be committed to ensuring quality during testing and servicing clients thereby meeting customer satisfaction.
- iii. provide an independent and accurate seed testing service to the Kenyan seed industry, thereby maintaining and promoting the country's sustainable agriculture and economic growth
- iv. Comply with ISTA Seed Testing Laboratory accreditation Standards and ISTA Rules.
- v. ensure that all staff in seed testing and sampling activities familiarize themselves with and understand the quality documentation, and implement the policies and procedures in their work
- vi. ensure that tests for the purpose of ISTA Certificates are always carried out in accordance with the ISTA Rules
- vii. ensure that only proven competent personnel will be responsible for all the tests and results reported by the Laboratory.
- viii. ensure that Laboratory personnel are not subjected to undue pressures either internally or externally.
- ix. be committed to the development and implementation of the management system and continually improving its effectiveness to the satisfaction of its clients.

Signed:

Date:

**Quality Assurance Manager,
KEPHIS Seed Testing Laboratory**

Signed:

Date:

Managing Director

HISTORICAL BACKGROUND

Kenya being an agricultural economy, the government felt the need for a Seed Testing Laboratory and established one in 1944 at the National Agricultural Laboratory (NAL) Kabete, Nairobi. The Seed Laboratory was then serving mostly the European large-scale farmers who wanted to determine the quality of cereals and grass seeds before exporting.

The first ISTA meeting in Nairobi, Kenya was held in 1964 on seed testing. The Kenyan Seed Testing Laboratory was then accredited to ISTA. In 1979, the Seed Testing Laboratory was moved to Lanet in Nakuru and was renamed National Seed Quality Control Service. The Seed Testing Laboratory was then modernized and joined with the expanded field Seed Certification Program.

In 1980, the Seed Testing Laboratory was further expanded to include seed pathology tests (viz. virus, bacterial and fungal tests). The seed pathology tests were intended to support seed inspectorate in identifying seed borne diseases and to safeguard against importation of seed borne diseases and pests. The establishment of the sub-section within the Seed Testing Laboratory has gone a long way in enhancing the quality of seeds being accessed by the farming community.

In 1996 KEPHIS was established to vigilate for agricultural community on the quality of agricultural inputs and produce. The Seed Testing Laboratory was brought under KEPHIS and the location remained at Lanet, Nakuru.

1.0 PURPOSE AND SCOPE

- 1.1 The purpose of this Quality Assurance Manual is to ensure that the Seed Testing Laboratory meets the specific needs of ISTA Laboratory Accreditation standard so as to facilitate seed trade.
- 1.2 The Laboratory adheres to current ISTA International Rules for seed testing for issuance of ISTA certificates
- 1.3 This Quality Assurance Manual ensures that the laboratory is comparable with other ISTA member laboratories and that test results are reliable
- 1.4 The language to be used in this quality manual is English.
- 1.5 The laboratory carries out its work according to ISTA requirements.

2.0 DEFINITIONS AND ACRONYMS

The following terms are used in this manual:

Accreditation:	Formal recognition of technical competence to carry out specific tasks.
Audit:	Periodical and systematic on-site assessment of all policies and procedures to ensure that practice in accordance with written policies and procedures.
Certificate:	A document that presents test results and other information relevant to a test.
Compliance:	The affirmative indication or judgement that the supplier of a product or service has met the requirements of the relevant specifications, contract, or regulation.
Document:	Information and its supporting medium, eg Policy statement, procedures, specifications, calibration tables, charts, records, books notices, work instructions, plans, drawings, etc; in electronic, photographic, handwritten, analogue, digital or print media etc.
General Manager	Quality Assurance and Standards: Means the head of Quality Assurance and Standards Department at KEPHIS, under which the Seed Testing Laboratory falls under. The person is responsible for the co-ordination of management reviews, staff appraisal and training.
Inspection:	The activities, such as measuring, examining, testing, gauging one or more characteristics of a product or service, and comparing these with specified requirements to determine conformity.
ISTA Rules:	International Rules for Seed Testing published by the International Seed Testing Association; includes standardised definitions and methods to be used in evaluating seeds for transactions in international trade.
ISTA:	International Seed Testing Association. It is the body that accredits the Seed Testing Laboratory
Kenya Bureau of Standards (KEBS):	National body that carries out calibration of equipments.
KEPHIS:	Means the Kenya Plant Health Inspectorate Service. It is a state corporation under the Ministry of Agriculture formed by an act of parliament, through the state corporations act Cap. 446 and gazette notice no. 305
Laboratory:	Entity performing seed sampling and testing.
Laboratory management:	Composed of the Managing Director, General Managers, Laboratory Quality Assurance Manager, Laboratory Technical Manager and Heads of Seed Samplers
Management review:	The continual review of the quality system by management to make sure the quality system remains suitable and effective.

Managing Director (MD): Means the Managing Director of the Kenya Plant Health Inspectorate Service.

OECD: Means Organization of Economic Cooperation and Development

Official Seed Tester: Means the Quality Assurance Manager and an ISTA accredited laboratory member.

Plant Protection Act, Chapter 324, laws of Kenya: This is the substantive chapter in the laws of the Republic of Kenya dealing with protection of plants and plant products in the course of exchange/movement

Proficiency testing (Inter-laboratory tests): Methods for checking laboratory testing performance by means of inter-laboratory tests i.e. ISTA proficiency test program.

Quality Inspection: means to confirm adherence to the set quality requirements.

Quality management system(QAM): a method for ensuring that all the activities necessary to design, develop and implement a product or service are effective and efficient with respect to the system and its performance

Quality Manual: A collection of documents which describes quality policy, quality system and quality practices in the laboratory.

Quality policy: The overall intention and direction of an organisation in regards to quality as formally expressed by top management

Reference material: Materials which provide essential traceability and are used to demonstrate the accuracy of results, calibration of equipment and methods, monitoring of laboratory performance, validation of methods, and which enable comparison of methods by use as transfer standards.

Scope of Accreditation: defines the activities of a laboratory for which it has demonstrated its competence and that are covered in a system providing confidence in the laboratory's ability to meet established criteria. The scope of accreditation is a summary of the laboratory's work but detailed enough to make the distinction between its different elements. It is based on individual methods and species or groups of species, as applicable.

Secrets Act, Chapter 187, laws of Kenya: This is the substantive chapter in the laws of the Republic of Kenya guiding public officers on handling with official secrets of the Government of Kenya

Seed sampler: A person trained and experienced in seed sampling and who is authorised by the Official Seed Tester (Quality Assurance Manager) to obtain seed samples for submission to the Seed Testing Laboratory.

Seed sampling: A defined procedure whereby a representative part of a seed lot is taken for submission to a seed testing station.

Seeds and Plant Varieties Act, Chapter 326, Laws of Kenya. This is the substantive chapter in the laws of the Republic of Kenya where matters relating to regulation of the seed industry are found. KEPHIS implements this Act.

Standard Operating Procedures (SOPs): These are documented practices defining the who, what and when of quality activities.

Supplier: Is an organization that provides a product or service to the customer

Suppression of Noxious Weeds, Chapter 325, laws of Kenya: This is the substantive chapter in the laws of the Republic of Kenya dealing with regulation of noxious weeds in Kenya

Technical Manager: Means the person who has the overall responsibility for the technical operations of the laboratory.

3.0 MANAGEMENT REQUIREMENTS

- 3.1. Kenya Plant Health Inspectorate Service (KEPHIS), which is a government body charged with the responsibility of ensuring the quality agricultural inputs and agricultural produce in Kenya. The Laboratory is a legal entity charged with the responsibility of testing seed quality. It is legally responsible for its seed testing activities as per Seeds and Plant Varieties Act (Cap.326 of the Laws of Kenya).
- 3.2. The Seed Testing Laboratory has clearly defined the involvement and responsibilities of key personnel so as to avoid conflict of interest (ref. Organisation and Management Structure)
- 3.3. The laboratory carries out testing work at its permanent facility in Lanet, Kenya and coordinates seed sampling at various production and entry/border points.
- 3.4. The laboratory has defined the organisation management structure of the laboratory including its place in the parent organisation (ref. Organisation and Management Structure) and KEPHIS Strategic Corporate Business Plan, 2017/18 – 2021/22)
- 3.5. The parent organisation under which the laboratory falls is a government regulatory body whose main mandate is to facilitate trade and does not engage in any profit making business (ref. KEPHIS Strategic Corporate Business Plan, 2017/18 – 2021/22).
- 3.6. The laboratory has ensured that seed analysts and samplers are not subjected to undue pressure or inducements that might influence their judgement or results of their work by:-
 - 3.6.1. Limiting access to the Seed Laboratory to staff members of the laboratory. Entry into the Seed Testing Laboratory by non-staff (such as service technicians, students etc) requires an official approval by the Official Seed Tester (Form. FRM/STL/01).
 - 3.6.2. Declaration of interest by analysts and samplers, if any is mandatory.
 - 3.6.3. Billing for the sampling and testing services done centrally at technical administration.
 - 3.6.4. Coding of samples and ensuring that samples are tested on the basis first in first out
 - 3.6.5 Ensuring that official communications to the Seed Testing Laboratory shall be directed to the Official Seed Tester. This is expected to

prevent undue pressure on samplers and analysts. It will also reduce direct contact between the seed samplers/analysts and the clients.

3.7. The laboratory ensures that staff members remuneration and condition of employment do not depend on the results of accredited work through:-

3.7.1. Permanent and pensionable terms of employment for staff

3.7.2. Annual appraisals/interviews for staff progression.

3.7.3. Salary scales are determined by board of directors hence not dependent on volume of accredited work (ref. Human Resource Manuals).

3.8. The laboratory excludes any commercial, financial or other undue influence on the results of examination and tests as per clause 3.6 above.

3.9. The laboratory ensures that access to and use of all laboratory test areas is controlled as per clause 3.6.1 above.

3.10. Scope of Accreditation

Elements of the seed Testing Laboratory Scope of Accreditation

Test object	Test Principle	Reference chapter	Field of application	Accredited test defined to the level of
Sampling⁽¹⁾: Obtain a representative sample				
	Sampling from the lot: Manual	2	All species of table 2C	Appendix R3 of SOP/MET/02
Purity and determination of other seeds⁽¹⁾: Determine percent composition and identity of species, determine the number of species of other seeds				
	Separation, weighing of fractions and identifying other seeds. Other seed determination	2, 3, 4, 1	All species of table 2C	Appendix R3 of SOP/MET/02
Germination⁽¹⁾: Determine maximum germination potential				
	Germination on 400 seeds	2, 3, 5, 6, 1	All species of table 5A	Appendix G10 of SOP/MET/04
	Germination by weighed replicates	2, 3, 5, 6, 13, 1	All species of Table 13B	<i>Chloris gayana</i>
Moisture content⁽¹⁾: Determine moisture content				
	Low and high constant temperature oven method : fine grinding	2, 9, 1	Species in table 9A Part 1	Appendix M4 of SOP/MET/07
	Low and high constant temperature oven method : coarse grinding	2, 9, 1	Species in table 9A Part 1 and 2	Appendix M4 of SOP/MET/07
	Low and high constant temperature oven method : cutting	2, 9, 1	Species in table 9A Part 1 and 2	Appendix M4 of SOP/MET/07
	Low and high constant	2, 9, 1	Species in table 9A	Appendix M4 of



Test object	Test Principle	Reference chapter	Field of application	Accredited test defined to the level of
	temperature oven method : no grinding		Part 1 and 2	SOP/MET/07

NB: ⁽¹⁾ Already accredited

- 3.11. The law governing the seed industry (CAP. 326, Laws of Kenya) does not allow the seed testing laboratory to sub-contract.
- 3.12. The laboratory has policies and procedures that ensure the protection of its clients confidential information and proprietary rights through:-
 - 3.12.1. Computer passwords
 - 3.12.2. Official secret Act and Civil service Ethics Act binding seed analysts and samplers to comply with the requirement.
 - 3.12.3. The Orange ISTA certificates shall be kept in the Official Seed Tester's office. Copies of issued ISTA certificates are retained by the Seed Testing Laboratory in a file (ref. FL/STL/02).
 - 3.12.4. The Official Seed Tester is responsible for storage, issue and signing of all the test result certificates.
- 3.13. The laboratory has specified responsibilities, authorities, and interrelationships of the personnel who manage, perform or verify work affecting quality of tests (ref. Organisation and Management)
- 3.14. The Technical Manager is responsible for technical operations of the Seed Testing Laboratory.
- 3.15. The Quality Assurance Manager is the Official Seed Tester. He is responsible and has authority to ensure that the quality system is implemented according to the requirements of the accreditation standard and ISTA. He has access to the highest level of management at which decisions are made on laboratory policy and resources. The Quality Assurance Manager is also the Regional Manager, KEPHIS Nakuru Regional office.
- 3.16. The laboratory has appointed suitable deputies to take responsibilities in the absence of staff (ref. Organisation and Management).
- 3.17. The laboratory has formulated policies, goals and procedures with respect to the education, training and skills of seed samplers and analysts. (ref. Human resource policies and procedures manual, career progression guidelines, training manual, Training, Authorisation and monitoring of samplers(SOP/GEN/07) and blind test results (SOP/GEN/03), identification of training needs(SOP/GEN/12)). As determined by training needs assessment, staff members attend internal/external training courses, technical or scientific seminars or workshops depending on the relevance of the course to the individual in enhancing his/her performance.
- 3.18. The laboratory has appointed specific personnel to perform particular types of work and to issue ISTA certificates (ref. personnel files, organisation and Management, list of samplers/analysts –(FL/STL/31)
- 3.19. The laboratory provides any additional documentation/information requested by ISTA secretariat.

- 3.20. The laboratory advise ISTA secretariat in advance whenever there are changes in the laboratory's ownership, affiliation, organisation, location and any relevant matter.
- 3.21. The laboratory discontinues the use of ISTA certificates and returns any unused certificates and the certificate of accreditation to the ISTA secretariat in the event of withdrawal or termination of accreditation.

4.0. STAFF

- 4.1. The laboratory has ensured that seed analysts and seed samplers have and maintain the necessary education, training, technical knowledge, skills and experience for the assigned duties (ref. training log books, personal files (Qualifications/Job descriptions), Human Resource Policies and Procedures Manual and the Career Progression and Guidelines, training SOPs – SOP/GEN/07, SOP/GEN/10, SOP/GEN/12., approval/authorisation of seed samplers and analysts)
- 4.2. The recruitment of staff to duties in the Seed Testing Laboratory is based on specific academic qualification and experience. This is stipulated in the staff recruitment policy of KEPHIS outlined in the Human Resource Policies and Procedures Manual and the Career Progression and Guidelines. The laboratory ensures that seed analysts and samplers are supervised to work in accordance with the laboratory's quality management system. The laboratory currently does not engage analysts and samplers on contract.
- 4.3. The job description for seed samplers and analysts are also outlined in the Human Resource Policies and Procedures Manual and the Career Progression and Guidelines. Seed samplers are authorised by the Official Seed Tester.
- 4.4. New seed analyst and samplers undergo training and supervision by experienced staff. (Ref. training SOPs – SOP/GEN/07, SOP/GEN/10)

5.0. ENVIRONMENT, EQUIPMENT AND CALIBRATION

5.1 Environment

- 5.1.1 The laboratory has ensured that the test environment is conducive so that it does not invalidate the test results or adversely affect the accuracy of measurements. The laboratory has adequate equipment and energy sources needed for the tests.
- 5.1.2. The laboratory has ensured that test activities with potential for incompatibility are adequately separated
- 5.1.3. The laboratory has ensured that there is good housekeeping (ref SOP/GEN/08 – environment and safety)
- 5.1.4. The samplers ensure that the environment of the premises where sampling is carried out meets the requirements of the sampling procedure, and does not affect the validity of the sampling or subsequent test results (Sampling SOP- SOP/MET/01).

5.2. Provision and maintenance of equipment

- 5.2.1. Seed samplers and analysts have adequate equipment for correct performance of sampling and testing for which the laboratory is accredited.
- 5.2.2. The laboratory ensures that equipment are **appropriately** run by authorised staff. Up-to-date instructions on use and maintenance of equipment are available to appropriate staff.
- 5.2.3. The laboratory ensures that equipment and its software used for testing and sampling are capable of achieving the accuracy required and comply with specifications relevant to the tests concerned
- 5.2.4. There are documented procedures for operating, maintaining, calibrating and monitoring of sampling and testing equipment (Ref. SOP/GEN/13, SOP/MET/01, SOP/MET/02, SOP/MET/03, SOP/MET/04 and SOP/MET/06.)
- 5.2.5. The laboratory ensures that all equipment are properly maintained to ensure protection from corrosion and other causes of deterioration.
- 5.2.6. The laboratory ensures that any equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by calibration or otherwise to be defective, is clearly labeled until it has been repaired and then shown by test or calibration to be performing its function again (SOP/GEN/13)
- 5.2.7. The laboratory ensures that each equipment and the software used for testing and significant to the result must, when practicable, be uniquely identified. Records are maintained include:-
 - a) Name and identification of equipment.
 - b) Details of maintenance and monitoring.
 - c) the current location
 - d) manufacturer's manual
 - e) Details of repair/maintenance
 - f) Dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and date due for next calibration.
 - g) Checks that equipment complies with the specification

5.3. Calibration, references, and testing materials

- 5.3.1. The laboratory ensures that all sampling, measuring and testing equipment, for which this is possible, are adequately calibrated before being placed into service and regularly afterwards, according to a calibration programme (SOP/GEN/13).
- 5.3.2. Calibration of equipment ensures that, where applicable, measurements made in the laboratory are traceable to national and international standards of measurement. This is done annually by an external calibration firm, Kenya Bureau of Standards (KEBS). Internal calibration of equipment shall be done in accordance with instructions provided in their manufacturer's operation manuals and/or laboratory prepared instructions in the respective SOPs (SOP/GEN/13, SOP/MET/01, SOP/MET/02, SOP/MET/03, SOP/MET/04 and SOP/MET/06,).
- 5.3.3. The lab ensures that there are appropriate calibration samples, reference materials and reference standards of measurement must

be held by the laboratory, and used for calibration and reference purpose only. They are, where possible traceable to SI units of measurement, or to certified reference materials. There are calibration samples for seed blower (SOP/MET/03), buffer solutions for pH meters (SOP/MET/04), calibration weights for balances and reference collections for seed (SOP/MET/03).

- 5.3.4. The laboratory ensures that reference materials are, if necessary, verified by an authority nominated by the ISTA secretariat.
- 5.3.5. The laboratory ensures that calibration samples for the blower are provided by arrangement with the ISTA Secretariat
- 5.3.6. The laboratory examines the effect of defective equipment on any previous tests, and withdraws and re-issues certificates where faulty results are suspected.
- 5.3.7. The laboratory has procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and protect their integrity.

5.4. Purchasing services and supplies

- 5.4.1. The laboratory has policies and procedures for selection and purchasing of services and supplies it uses that affect the quality of the tests (SOP/GEN/11). The procedure provides guidance for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests. The procurement of services and supplies is carried out according to the Kenya Government procurement procedures and rules (Purchasing and Supplies Guidelines Manual).
- 5.4.2. The laboratory ensures that purchased supplies, reagents and consumable materials that affect the quality of test are NOT used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for tests concerned.(ref. SOP/GEN/11, SOP/GEN/13, SOP/MET/04)
- 5.4.3. The laboratory ensures that purchasing documents for items affecting quality of testing and sampling contain data describing the services and supplies ordered. The documents are reviewed and approved for technical content prior to release. (SOP/GEN/11)
- 5.4.4. The laboratory evaluates suppliers of critical consumables, maintains records of evaluations, and list of those approved.

6. Lot identification, sampling, and handling of samples

6.1 Lot identification and sampling.

The laboratory has:-

- 6.1.1. a system for the approval of lot identification (SOP/MET/01)
- 6.1.2. procedures and practices to monitor uniformity of seed lots and to refuse sampling and testing where doubt exists concerning uniformity (SOP/MET/01)
- 6.1.3. a system of authorisation of samplers, including approval and/or provision of sampler training programs, and arrangements for

maintaining and distributing up-to-date lists of samplers (file FL/STL/31, SOP/GEN/07, SOP/GEN/12).

- 6.1.4. Adequate procedures and practices to monitor the performance of individual samplers with respect to adherence to the ISTA Rules as well as provisions to cancel the authorisation of individual samplers who for any reason fail to meet the requirements of the standard. These are found in SOP/GEN/07.

6.2. Handling of samples

- 6.2.1. The laboratory has a system of identifying samples to be tested, through marking and documentation, to ensure there is no confusion regarding the identity of samples and the results of tests (ref. SOP/MET/01, SOP/MET/02).
- 6.2.2. The laboratory ensures that at all stages of obtaining, dispatching, transporting, storing, handling, sub-sampling and testing of samples, precautions are taken to prevent contamination, damage or deterioration, which would invalidate test results. Samples in storage are monitored (ref. SOP/MET/02). There are arrangements for storage and security to protect the condition and integrity of samples. Entry is restricted to the laboratory and sample store.
- 6.2.3. The laboratory ensures that appropriate information relating to sampling of a seed lot is included in the documentation sent to the laboratory. This includes:-
 - 6.2.3.1. Name/signature of sampler
 - 6.2.3.2. Name and address of client/merchant
 - 6.2.3.3. Date of sampling
 - 6.2.3.4. Seed lot/reference number
 - 6.2.3.5. Crop species and cultivar
 - 6.2.3.6. Lot weight
 - 6.2.3.7. Number of containers
 - 6.2.3.8. Tests required
 - 6.2.3.9. Details of any environmental or other conditions during sampling which may affect the interpretation of the results
 - 6.2.3.10. Any other information as requested by the client.
 - 6.2.3.11. Any other information relevant to the laboratory.
- 6.2.4. The laboratory has clear rules for the receipt, retention and disposal of samples. Samples are retained for not less than one year after receipt of the sample. Exceptions of this retention time is defined in the current version of the ISTA Rules.
- 6.2.5. The laboratory maintains records of any unusual conditions of the sample at the sample receipt at the laboratory. When there is doubt as to the suitability of a sample for testing, or when a sample does not conform to the description provided, or the test required is not specified in sufficient detail, the laboratory consults the client for further instructions before proceeding. Any discussions are recorded. (ref. SOP/MET/02, R/STL/04)

7. Methods and procedures



- 7.1. The laboratory only apply the current ISTA Rules in issuance of ISTA certificates.
- 7.2. Seed analysts and samplers adhere to the methods and procedures of sampling and testing, as published in the current version of the ISTA Rules
- 7.3. The laboratory ensures that all rules, handbooks, manuals, instructions and reference data relevant to the work of the laboratory are current, up-to-date and readily available to staff. Documents will be written as detailed as necessary to allow staff to perform their tasks.
- 7.4. The laboratory ensures that all calculations and data transfers are subjected to appropriate checks in a systematic manner (ref. SOP/MET/05).
- 7.5. When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data, the laboratory ensures that:-
 - 7.5.1. There are procedures for protecting data to ensure integrity and confidentiality of data management (SOP/GEN/14)
 - 7.5.2. Computers and automated equipment are maintained to ensure proper functioning.

8. Test reports and certificates.

- 8.1. The laboratory ensures that results of each test carried out are reported accurately, clearly unambiguously and objectively, and in accordance with ISTA Rules (ref. SOP/MET/05).
- 8.2. The laboratory ensures that test results for which ISTA certificate is sought are reported on an ISTA certificate, obtainable from the ISTA secretariat, in accordance with procedures prescribed in the ISTA Rules.
- 8.3. The laboratory ensures that ISTA certificates are only issued on species which are listed in the ISTA Rules, and which the laboratory has been accredited (Ref. Scope of accreditation – clause 3.10).
- 8.4. The laboratory does not sub-contract any test work (ref. clause 3.11 and 10.7.2)
- 8.5. The laboratory ensures that ISTA certificate contains a signature and title or equivalent designation of the Official Seed Tester who has the responsibility of the test report and date of issue (Ref. SOP/MET/05).
- 8.6. The laboratory ensures that the results reported on any ISTA Certificate, , is kept confidential.

9. Documents and records

- 9.1. The laboratory maintains an up-to-date record of seed samplers and analysts together with records of their training (FL/STL/31)
- 9.2. The laboratory maintains a document and record system for all its operations. The laboratory retains records of initial testing equipment and method verification. The laboratory has procedures to retain records

of original observations, derived data and sufficient information to establish an audit trail, calibration records and test reports issued for at least six years.

- 9.3. The laboratory ensures that all documents and records are legible, properly stored and retained in such a way that they are readily retrievable.
- 9.4. The laboratory ensures that all records and test reports are held securely and in confidence to the client
- 9.5. The laboratory has procedures for protection and backup of records stored electronically to prevent unauthorised access to or amendment to the records (SOP/GEN/14).
- 9.6. The laboratory ensures that when a mistake occurs in records, each mistake is crossed out, not erased, made illegible or deleted and the correct value entered alongside, then initialled by the person making the correction. All alterations to records are dated, signed or initialled by the person making the correction. This includes electronic records. To avoid loss of original data.
- 9.7. The laboratory ensures that notes or inscriptions are made using inerasable pen.

10. Quality assurance System.

10.1. Operation of the quality assurance system

- 10.1.1. The laboratory has designed and is operating a quality assurance system appropriate to the type, range and volume of seed sampling and testing work. The quality assurance system ensures that the required degree of accuracy and precision is achieved, deficiencies are detected and appropriate corrective actions taken.
- 10.1.2. The laboratory's quality assurance system is documented in a quality assurance manual, which is available to the seed analysts and samplers. The Quality assurance manual is updated regularly. The overall objectives are stated in the quality policy statement (ref. page 5)
- 10.1.3. The Quality Manual describes the overall scope of operation for which the laboratory seeks accreditation/re-accreditation and defines the procedures devised to ensure that the set quality standards are met.
 - 10.1.3.1. Organisation and Management Structure is an extension of the Quality Assurance Manual. It gives various organo-structures and responsibility matrices.
 - 10.1.3.2. Other quality documents are the Standard Operating Procedures (SOPs) which shall be documented separately from this Quality Assurance Manual. There shall be two categories of SOPs namely:-

1. Standard Method SOPs

SOP Name	Code
Standard operating procedure for Seed Sampling	SOP/MET/01
Sample reception, storage and Disposal standard operating procedure	SOP/MET/02
Seed Purity analysis standard operating procedure	SOP/MET/03
Standard operating procedure for Germination tests	SOP/MET/04



Standard operating procedure for Handling Test results	SOP/MET/05
Standard operating procedure for Tetrazolium test (Non Accredited method)	SOP/MET/06
Standard operating procedure for Moisture test	SOP/MET/07
Standard operating procedure for Weight Determination (Non Accredited method)	SOP/MET/08
Standard operating procedure for Detection of <i>Ustilago nuda</i> in <i>Hordeum vulgare</i> (Non Accredited method)	SOP/MET/9a
Standard operating procedure for Detection of <i>Colletotrichum lindemuthianum</i> on <i>Phaseolus vulgaris</i> (Non Accredited method)	SOP/MET/9b
Standard operating procedure for Mycology tests (Non Accredited method)	SOP/MET/9c
Standard operating procedure for Detection of <i>Ralstonia solanacearum</i> (Bacterial Wilt) in Potatoes (Non Accredited method)	SOP/MET/9d
Standard operating procedure for Detection of <i>Drechslera oryzae</i> on <i>oryza sativa</i> (Non Accredited method)	SOP/MET/9e
Standard operating procedure for Detection of <i>Pyricularia oryzae</i> on <i>oryza sativa</i> (Non Accredited method)	SOP/MET/9f
Standard operating procedure for Vigour Testing by Conductivity method (Non Accredited method)	SOP/MET/10

2. General SOPs

SOP Name	Code
Standard operating procedure for Overview of seed testing laboratory	SOP/GEN/01
Standard operating procedure for Document control	SOP/GEN/02
Standard operating procedure for Blind test	SOP/GEN/03
Standard operating procedure for Corrective and preventive actions	SOP/GEN/04
Standard operating procedure for Internal audit	SOP/GEN/05
Standard operating procedure for Management review	SOP/GEN/06
Standard operating procedure for Training, Authorization and Monitoring of seed samplers	SOP/GEN/07
Standard operating procedure for Environment and safety	SOP/GEN/08
Standard operating procedure for Training seed analysts	SOP/GEN/10
Standard operating procedure for Requisition, Purchases and supplies	SOP/GEN/11
Standard operating procedure for Identification of training needs	SOP/GEN/12
Standard operating procedure for Equipment calibration and maintenance	SOP/GEN/13
Standard operating procedure for Handling electronic data	SOP/GEN/14
Standard operating procedure for Quality Control	SOP/GEN/15
Standard operating procedure for Continuous improvement	SOP/GEN/16
Standard operating procedure for Actions to Address Risks And Opportunities	SOP/GEN/17

3. Forms

Any form generated by procedures of SOPs will be controlled by the said procedure or SOP.

The overall structure of all quality documentation is given in Document Control SOP (SOP/GEN/02)

10.2. Document control

- 10.2.1. The laboratory has established and maintained procedures to control all documents that form part of the quality system. (ref. SOP/GEN/02).
- 10.2.2. The laboratory ensures that all documents issued to the seed samplers and analysts are controlled (ref. SOP/GEN/02).
- 10.2.3. The laboratory ensures that appropriate documents are available at their point of use, and are periodically reviewed for continued suitability and prompt removal of invalid/obsolete documents.
- 10.2.4. The laboratory's quality system documents are uniquely identified and maintained.
- 10.2.5. Changes to documents are reviewed and approved by the same function that performed the original review. Procedures have been established to describe how changes in documents are made and controlled.

10.3. Quality control procedures

- 10.3.1. The laboratory has defined and documented quality control procedures specific to seed lot identification and sampling arrangements and testing (SOP/GEN/15). These may include but not limited to the following:-
 - 10.3.1.1. Regular use of certified reference materials and/or internal quality control using secondary reference materials.
 - 10.3.1.2. Participation in the ISTA Proficiency Test Programme.
 - 10.3.1.3. Replicate tests using the same or different methods
 - 10.3.1.4. Re-testing of retained samples.
 - 10.3.1.5. Participation in interlaboratory comparative tests

10.4. Control of non-conforming testing and sampling work.

- 10.4.1. The laboratory has policy and procedures that are implemented when any aspects of its testing work and sampling work, or the results of this work, do not conform to its own procedures or the agreed requirements of the client. (ref. to SOP/GEN/04)

10.5. Proficiency testing

- 10.5.1. The laboratory participates actively in ISTA Proficiency test program and demonstrates that any inconsistencies are investigated and any corrective action taken (ref. SOP/MET/05)
- 10.5.2. The laboratory ensures that when machine is used to replace the human Analyst, the machine is validated by participation internal and ISTA proficiency tests.

10.6. Corrective actions and complaints (ref. SOP/GEN/04)

- 10.6.1. The laboratory has policies and procedures to address nonconforming work and implementation of corrective actions.



- 10.6.2. The procedure for corrective actions starts with an investigation to determine the roots cause(s) of the problem
- 10.6.3. Where corrective actions are needed the laboratory identifies potential corrective actions and documents and implements any required changes resulting from corrective actions investigations.
- 10.6.4. The laboratory monitors the results to ensure the corrective actions taken are effective
- 10.6.5. The laboratory has defined and documented arrangements for dealing with complaints and taking corrective actions whenever discrepancies are identified.

10.7. Review of requests tenders and contracts

- 10.7.1. The laboratory has established and maintains procedures for the review of requests, tenders and contracts (ref. SOP/MET/02)
- 10.7.2. The Seed Testing Laboratory currently does not sub-contract its activities (seed sampling and testing). This may be possible in future when the National Seed Laws (CAP 326) are amended. However, when sub contracting; only a laboratory which adheres with ISTA Accreditation Standard and holds ISTA accreditation for the method in question shall be used.

10.8. Audits

- 10.8.1. The laboratory undergoes internal audit at least once a year so as to verify the laboratory's continuous compliance with the standard and its quality system (ref.SOP/GEN/05)
- 10.8.2 The laboratory cooperates in pre- or post-accreditation audit or assessment as required by ISTA Executive committee and permits access to documents and records as required.
- 10.8.3 The laboratory affords the representatives and auditors of accreditation body access to the laboratory and to all the documents needed for an assessment.
- 10.8.4 The laboratory will afford representatives and auditors of the accreditation body access to the laboratory, laboratory staff, equipments and to all documents needed for an assessment

10.9 Reviews by management

- 10.9.1 The laboratory executive management periodically (at least once a year) conducts a review of the laboratory's quality system, testing and sampling activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvement.(ref. SOP/GEN/06)

10.10 Continuous improvement

- 10.10.1 The laboratory strives for continuous improvement and for improvements of efficiency by implementing the outcomes of activities like but not limited to internal quality audits, management reviews,

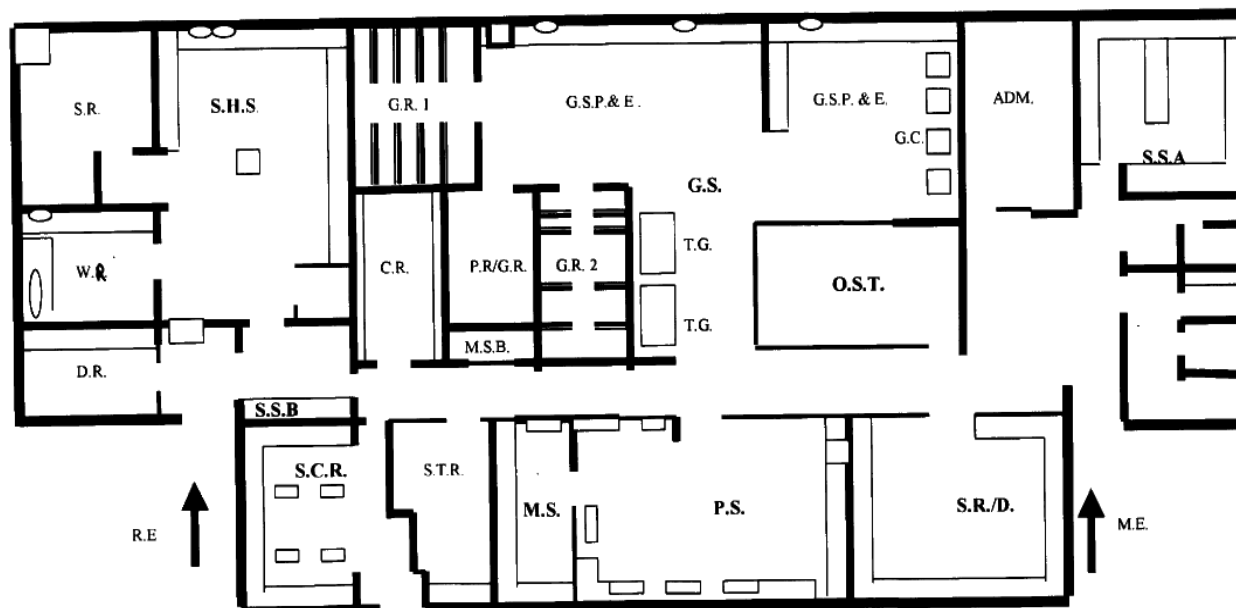
corrective and preventive actions, regular review of quality documents, analysis of data and customer feedbacks(SOP/GEN/16).

10.11 The laboratory has a procedure (SOP/GEN/17) on actions to address risks and opportunities.



APPENDIX 1. LAYOUT OF THE SEED TESTING LABORATORY

FIGURE 3: LAYOUT OF THE SEED TESTING LABORATORY



KEY:

S.S.A: Sample Store A
 ADM: Administration
 G.S: Germination Section
 G.S.P&E: Germination Sample Preparation & evaluation
 G.R.2: Germination Room : 20°C
 G.R.1: Germination Room : 20°C - 30°C
 T.G: Table Germinator
 G.C: Germination Cabinets

P.R./G.R.: Pre-chilling/Germination Room : 10°C
 O.S.T.: Official Seed Tester
 S.R./D.: Sample Reception/Distribution
 P.S.: Purity Section
 M.S.: Moisture Section G.R.2
 S.H.S: Seed Health Section
 S.R.: Sterile Room : 6°C
 W.R.: Washing Room

C.R.: Climate Room
 S.T.R.: Special Tests Room
 D.R.: Dark Room
 S.S.B: Sample Store B
 S.C.R.: Seed Clearing Room
 M.S.B.: Main Switch Board
 M.E.: Main Entrance
 R.E.: Rear Entrance

