



KENYA PLANT HEALTH INSPECTORATE SERVICE (KEPHIS)

**GUIDELINES FOR AUTHORIZATION OF SEED CERTIFICATION ACTIVITIES IN
KENYA**

**A DOCUMENT PREPARED TO GUIDE THE PROCESS OF AUTHORIZATION OF
SEED CERTIFICATION ACTIVITIES TO PRIVATE/PUBLIC PERSONS AS
PROVIDED FOR IN SECTION 3B OF THE SEEDS AND PLANT VARIETIES ACT
(CAP 326) OF THE LAWS OF KENYA**

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Better Markets, Better Lives



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List of acronyms

AOSCA	Association of Official Seed Certifying Agencies
AOSA	Association of Official Seed Analysts
ASDS	Agriculture Sector Development Strategy
SRA	Strategy for Revitalizing Agriculture
KCSE	Kenya Certificate of Secondary Education
SRC	Seed Regulations Committee
EU-SMAP	European Union Standards and Market Access Programme
ISTA	International Seed Testing Association
KEPHIS	Kenya plant Health Inspectorate Service
KMT	Kenya Market Trust
MoALF	Ministry of Agriculture, Livestock and Fisheries
OECD	Organization for Economic Cooperation and Development
OPV	Open Pollinated Varieties
PBAK	Plant Breeders Association of Kenya

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1.0 INTERPRETATION OF TERMS

Authorized: Having been formally approved by the SERVICE as competent to perform certain seed certification activities on its behalf.

Authorized seed inspector/sampler/analyst: A person authorized under section 3B (1)(b) of the Seeds and Plant Varieties Act as being competent to carry out inspection/sampling or testing for the purposes of seed certification by the SERVICE.

Applicant for authorization: Person/entity seeking authorization from the SERVICE to undertake seed inspection/sampling/testing.

Audit: Systematic and documented process for obtaining evidence and evaluating it objectively to determine the degree of compliance with documented seed certification procedures/methods and required levels of competence to which audit criteria are fulfilled.

Certificate of authorization: A document issued by the SERVICE, indicating that the named person/entity is authorized to perform seed inspection/sampling/testing.

Check-inspection/Check-sampling/Check-testing: A method of surveillance used by the SERVICE; where authorized and SERVICE inspectors/samplers/analysts independently carry out similar seed inspection/ sampling/testing for comparison.

Confidentiality: State of an inspector/sampler/analyst/entity to keep secret clients' information or any details obtained while performing his/her duties.

Corrective Actions: Action taken to eliminate the causes of a potential non-compliance, defect or other undesirable situation in order to prevent re-occurrence.

Entity: Public or private institutions registered with the government to whom the SERVICE can delegate specified seed certification tasks.

Independent: Able to make decision without undue influence.

Inspection: Examining plant characteristics, seed status or other aspects and comparing the results with the specified requirements in order to establish whether compliance is achieved.

Non-Compliance: Non-fulfillment of a specified requirement.

Proficiency test: Methods of checking laboratory testing performance by means of inter-laboratory tests.

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

SERVICE: Kenya Plant Health Inspectorate Service as established by the Kenya Plant Health Inspectorate Service Act No 54. (2012)

SERVICE Inspector: An inspector appointed under section 3B(1)(a) of the Seeds and Plant Varieties Act

Surveillance: A system of monitoring the competence and adherence of authorized entities/inspectors/samplers/analysts to the conditions of authorization and documented seed inspection/sampling/testing procedures including reporting.

Testing: Examination of a sample of seed with a view to determine its quality

2.0 INTRODUCTION

2.1 Background

The seed industry in Kenya has grown tremendously over the years from a single seed company in the 1950s to the current over 130 companies after the liberalization of the industry in the 1990's. This has resulted in increased seed production hectarage and volumes that require to be certified.

The Seeds and Plant Varieties Act empowers the Kenya Plant Health Inspectorate Service (KEPHIS) hereinafter referred to as the SERVICE to undertake seed certification activities as well as regulate the importation and exportation of seeds. This is undertaken through adoption of international standards and procedures such as the Organization for Economic Cooperation and Development (OECD) Seed Schemes standards for field inspection and the International Seed Testing Association's (ISTA) standards/procedure's for seed sampling and testing.

The global trend currently is geared towards creating an enabling environment for authorization as has been envisaged by international seed institutions like the OECD, International Seed Testing Association (ISTA), Association of Official Seed Analysts (AOSA) and Association of Official Seed Certifying Agencies (AOSCA) amongst others. The Government of Kenya through the Agriculture Sector Development Strategy (ASDS) recognizes the importance of accessibility and affordability of farm inputs, including seed, for sustainable agricultural development. Further, through the Strategy for Revitalizing Agriculture (SRA) under the legal and regulatory reforms, the government provides for growth in agriculture through encouraging authorization of private entities by facilitating capacity building for stakeholders. The Seeds and Plant Varieties Act provides the legal basis for authorization of competent private or public persons to undertake specified certification activities.

The objective of authorization is to complement the SERVICE to enhance efficiency in seed certification process. Authorization is a concept that will create an enabling environment for effective participation of both public and private sectors in the production, inspection and testing of quality planting material and promote sustainable access of affordable seed. It is therefore important that guidelines be developed to guide the process.

The purpose of these guidelines is to define the process of authorization of private or public persons to undertake specified activities under the Seeds and Plant Varieties Act. The authorization process involves training, evaluation, gazettelement, monitoring, suspension, withdrawal of authorization of private and public persons and appeals associated with the same.

The guidelines have been developed as per section 3B of the Seeds and plant varieties Act.

2.2 General Information

2.2.1 The guidelines are a general framework for authorizing competent private/public persons to perform specific seed certification aspects in the Seeds and Plant Varieties Act

2.2.2 The guidelines for authorization will cover aspects and scope as listed in sub sections 3.1 and 3.2.

2.2.3 The SERVICE shall provide access (for information and advice) of its services to all persons seeking to be authorized.

2.2.4 Confidentiality of the information obtained in the course of the SERVICE authorized activities, at all levels of its organization shall be maintained.

2.2.5 The authorized personnel shall be free from pressure which might adversely affect the quality of their work, independence of judgment and maintenance of integrity when undertaking authorized activities.

2.2.6 The SERVICE shall provide a system for the control of all documentation relating to the authorization and shall include:

- a) Current issues of the appropriate documents;

- b) A process to ensure that changes or amendments to documents are authorized, processed and implemented in a quick and efficient manner;
- c) An effective process to ensure that authorized inspectors/samplers/analysts are notified of changes.

2.2.7 The SERVICE shall;

- a) Carry out official assessments of competence for authorization of seed inspectors/samplers/analysts/entities.
- b) Provide rules, methods and procedures for inspection, sampling and testing and ensure that they are applied.
- c) Provide seed certification labels to authorized seed entities/ seed inspectors/samplers.

2.2.8 The procedures applicable for authorization are;

- a) Procedure for vetting applications (Annex 1(1));
- b) Procedure for auditing authorized entities (Annex 1(2));
- c) Procedure for monitoring of authorized entities/inspectors/samplers/analysts (Annex1(3));
- d) Procedure for withdrawal of authorization (Annex1(4));
- e) Procedure for appeals (Annex1(5)).

3.0 GENERAL GUIDELINES FOR AUTHORIZATION

3.1 Aspects covered

3.1.1 Seed Field inspection

3.1.2 Seed processing inspection

3.1.3 Seed sampling

3.1.4 Seed testing

3.1.5 Labeling and sealing

3.2 Scope of Authorized activities

3.2.1 Seed Field Inspection

Preliminary inspection, First inspection, Second inspection, Third inspection, Fourth inspection, Stook inspection, Pre-harvest inspection (e.g males separation, machine harvest inspection,) Post-harvest inspection (cob inspection, sampling of soil/plants for disease testing, issuance of transport order) The SERVICE shall provide specific inspection procedures for seed crops. The authorization shall be made for specific crops or groups of crops.

3.2.2 Seed Processing inspection.

- a) Seed intake and handling inspection
- b) Processing facilities inspection
- c) Seed lot examination

3.2.3 Seed Sampling/Re-sampling

- a) Lot identification
- b) Drawing of sample
- c) Sample handling
- d) Sample documentation
- e) Sample storage
- f) Sample dispatch

3.2.4 Seed testing

- a) Seed sample reception
- b) Purity analysis
- c) seed moisture testing
- d) Germination analysis
- e) Vigour testing
- f) Seed health testing
- g) Genetic purity analysis
- h) Issuance of Seed Testing Certificate
- i) Documentation

3.2.5 Labeling and Sealing

- a) Requisition of labels,
- b) Labeling and sealing.

Official seed certification labels shall be provided by the SERVICE.

The SERVICE shall provide specific procedures and methods for handling these components.

Breeder, Pre-basic and Basic seed classes as well as new varieties in their 1st and 2nd season of certification shall only be certified by the SERVICE.

All applications for services shall be submitted to the SERVICE who will forward to the authorized entities. The applicant shall indicate the preferred authorized entity to offer the service.

The authorized entity shall pay an administrative fee to the SERVICE for every application received.

All appeals for re-inspection, re-sampling and retesting shall be done to the SERVICE

4.0 ELIGIBLE ENTITIES

Authorized inspection, sampling, and testing shall be approved only to persons attached to entities registered by the registrar of companies/societies.

Authorized persons may be any of the following;

- a) Persons employed by natural or legal persons whose activities do not involve seed production, seed growing, seed processing or seed trade.
- b) Persons employed by natural or legal persons whose activities involve seed production, seed growing, seed processing or seed trade.

Persons referred to in (a) and (b) shall only undertake authorized activities under their current institutions. In case they change entities they are attached to, Authorized persons shall notify the SERVICE.

Persons referred to in (b) shall only undertake authorized activities on the seed produced by their employer unless it has been otherwise agreed between their employer and the applicant for the certification and the same information provided to the SERVICE.

Persons referred to in (b) shall provide a letter of declaration (as provided in Annex 3), signed by their employer.

5.0 GENERAL REQUIREMENTS FOR AUTHORIZATION

5.1 General

- a. Registration by the registrar of companies/societies.
- b. Demonstrate impartiality, confidentiality and independence.

5.2 Infrastructure and facilities (As applicable)

- a) Reliable means of transport
- b) Inspection/labeling/sealing tools & equipment
- c) seed testing laboratory
- d) Seed testing laboratory tools and equipment
- e) Documentation capacity

5.3 Personnel (As applicable)

- a) Gazetted inspectors/ samplers/analyst.
- b) Gazettement of the entity by the SERVICE.

6.0 CONDITIONS FOR AUTHORIZATION OF PRIVATE INSPECTORS / SAMPLERS / ANALYSTS

6.1 Minimum qualifications

6.1.1 Academic - Kenya Certificate of Secondary Education (KCSE) Grade C- or equivalent.

6.1.2 Technical and professional –

- a) Diploma in General Agriculture or related disciplines from a recognized institution and at least three years' experience in seed industry or related field or one-year internship under a gazetted person. OR

- b) Certificate in Agriculture or related discipline from a recognized institution and ten years' experience in seed Inspection/Sampling/testing

6.1.3 Integrity –Current Certificate of Good Conduct from the National Police Service.

6.2 Training on Seed Inspection/Sampling/Testing

Qualifying applicants for authorization shall only undergo training by the SERVICE appropriate to the activities, which they will be authorized to undertake.

The SERVICE may approve competent third parties to undertake training on its behalf. The training shall be conducted at least once per year. Based on documented experience, applicants may apply to the SERVICE for the option of taking examination without training.

6.2.1 Examinations/Assessment.

Applicants shall satisfy the SERVICE of their competence to become authorized through examinations. The following parts of examination shall be used:

- a) A written examination to test knowledge on principles and procedures.
- b) A practical examination to test field inspection/sampling/seed testing skills.

The overall pass mark shall be 60% subject to obtaining 50% in both theory and practicals. In the case of entities, an assessment shall be done to confirm if the general requirements are fulfilled as per the guidelines and criteria in annex 6.

6.2.2 Attachment

Where applicable candidates for authorization shall undergo attachment under an experienced SERVICE inspector/sampler/analyst. The attachment shall be undertaken within 9 months after successful completion of the examination

7.0 AUTHORIZATION

Entities/inspectors/samplers/analysts who meet the requirement shall be authorized through gazettelement by the SERVICE which shall be done within a period of not more than 60 days after successful completion of the attachment.

Authorized Entities/Inspectors/Samplers/Analysts shall be issued with a Certificate of authorization, which shall specify the scope and aspects of authorized activities and accompanying conditions. The certificate shall have a validity period and a provision for renewal.

8.0 MAINTENANCE OF KNOWLEDGE AND SKILLS

Authorized personnel shall maintain their knowledge and skills by:

- a) Undertaking regular(not more than one year break) inspection/sampling/testing,
- b) Participating in periodic refresher training and keeping up to date with applicable seed inspection/Sampling/testing standards, rules, regulations and procedures.

9.0 SURVEILLANCE AND AUDIT PROCEDURES

9.1 Documentation check

The SERVICE shall require submission of copies of official documents used during authorized inspections/sampling/testing and other relevant reports for monitoring purposes within 48 hours of the certification exercise.

The SERVICE shall track proper use and trail of official documents.

9.2 Check inspections

A proportion of crops inspected by authorized inspectors shall be check-inspected by official inspectors. The exact method used shall be as per 14.1.6(a).

9.3 Check Sampling

- a) Check-sampling shall be done as provided sub-section 14.2.7(b).

- b) In the case of automatic seed sampling, check-sampling shall be replaced by audits, process monitoring and other relevant tests as approved by the SERVICE.

9.4 Check testing

Check testing shall be done as provided in sub-section 14.3.6(a).

9.5 Proficiency laboratory test

Proficiency test is meant to test the competence of the authorized seed testing laboratory. This shall be done three times per year to every authorized seed testing laboratory. The SERVICE shall administer the proficiency tests.

9.6 Pre and Post control

The SERVICE shall use the results of pre and post control plot assessment as an indicator of performance of authorized inspectors.

9.7 Audits

Audit procedure shall include checks on documentation and adherence to documented procedures and standards.

Authorized entities/ inspectors/samplers/analysts shall be audited annually by the service during inspection/sampling and testing following the procedure in Annex 1(2).

10.0 RE-EXAMINATION

The SERVICE shall require authorized inspectors/samplers/analysts to undertake examinations after 3 years or after recommendation following audit or check-inspection/sampling/testing.

11.0 SUSPENSION/WITHDRAWAL OF AUTHORIZATION

The SERVICE shall withdraw authorization on the following reasons;

- a) If false or misleading information has been provided in the application for authorization
- b) If the authorized inspector/sampler/analyst fails to meet the requirements as stated during the application for authorization.
- c) In case of sheer negligence
- d) If false or misleading information has been provided in a report
- e) If there is evidence from surveillance activities that the entity/inspector/sampler/analyst does not meet the required standard of competence.
- f) If the authorized inspector/sampler/analyst/ has not followed procedures during inspection/sampling/analysis.
- g) If there is evidence from surveillance and / or audit activities that authorized seed persons and / or laboratories have yielded to pressures that have adversely affected the quality of their work, independence of judgment and maintenance of integrity when undertaking activities for which they are authorized.
- h) Failure to renew Certificate of authorization.
- i) In case of voluntary withdrawal
- j) In case of morbidity or de-registration
- k) On recommendation by the Seed Regulations Committee

The authorized persons/entity may be given a maximum of two warnings after which the authorization will be withdrawn. For violations (a), (b) and (c) no warnings shall be given. In case of (e) and or (f) the authorized person shall be suspended and required to undergo refresher training.

12.0 APPEALS

The SERVICE shall operate an appeals procedure to enable a review of decision not to authorize, suspend, or to withdraw authorization.

Any person aggrieved by the decision of the SERVICE may appeal to the SERVICE, the Seed Regulations Committee or the Seeds and Plants Tribunal. Appeals procedure is as detailed in Annex 1(5).

13.0 ABSOLUTION FROM LIABILITY

The SERVICE shall not take liability for injuries, claims, suits, loss, or damages arising from the actions of authorized persons. Applicants for authorization shall be required to indemnify the SERVICE on this aspect.

14.0 SPECIFIC GUIDELINES

14.1 Criteria for Authorizing Seed Inspectors

14.1.1 Training.

Applicants for authorization shall undergo training appropriate to the crops which they would be authorized to inspect. Based on documented experience, applicants may apply to the service for the option of taking examination without training.

14.1.2 Knowledge and skills required

Applicants shall have the following knowledge and skills;

- a) Seed industry in Kenya
- b) The Seed and Plant Varieties Act (CAP 326)
- c) Plant protection act (CAP 324)
- d) Other Seed related policies and laws
- e) Seed Regulations of Regional Economic Blocks where Kenya has membership
- f) International Varietal Certification Schemes applied by the service
- g) The methods of seed field inspection and field standards for the crops for which authorization is sought
- h) The varietal characteristics of the relevant crops.
- i) Use of varietal characteristics and variety descriptors to confirm varietal identity of seed crops.
- j) Identification of noxious weeds, pests and seed borne diseases
- k) Detection, characterization and quantification of varietal impurities in seed crops.

14.1.3 Examinations

Applicants shall demonstrate their competence to become authorized inspectors through examinations. The following examinations shall be used in assessing competence;

- a) A written examination to test knowledge of principles and procedures.
- b) A practical examination to test seed field inspection skills.

14.1.4 Field attachment

Candidates for authorization shall undergo field attachment under an experienced inspector for six weeks.

14.1.5 Maintenance of Knowledge and Skills

Authorized inspectors shall maintain their knowledge and skills by:

- a) Undertaking regular (not more than one year break) inspection of crops,
- b) Participating in periodic retraining and,
- c) Keeping up-to-date copies of Seed Laws, certification schemes and crop inspection procedures and being familiar with any changes.

14.1.6 Surveillance and Audit Procedures

a) Check Inspections

A proportion of seed crops inspected by authorized inspectors shall be check-inspected by SERVICE inspectors. The exact method will follow the following options on a case by case basis. The SERVICE shall;

- i. Check inspect a proportion of crops for each authorized inspector;
- ii. Check inspect a proportion of crops selected randomly from all crops which are inspected by authorized inspectors;
- iii. Check inspect a proportion of crops selected randomly from all authorized inspectors and additionally, monitor inspectors with a higher risk of non-compliance at a higher frequency than normal.

The sample size for check inspections shall be determined as provided in Table 1.

Table 1: Check Inspection tolerance

Initial Sample size	Rate of Conformity	New Sample size
30%	>95	10%
30%	90 - 95	20%
20%	80-90%	30%
30%	80-90%	30%

Any authorized Inspector achieving 80-90% conformity for more than three subsequent checks shall be suspended and required to undergo retraining and re-examination. Any Inspector achieving less than 80% conformity shall have their authorization withdrawn.

b) Inspection Audits

Authorized inspectors shall be audited by SERVICE Inspectors during field inspections as provided in sub section 9.7

c) Re-examination

The SERVICE shall require authorized inspectors to be re-examined every 3 years.

d) Documentation Checks

The SERVICE shall examine inspection records to monitor the status of completion of documentation.

e) Laboratory tests, pre- and post-control plots

The results of laboratory tests and control plots shall be compared with authorized inspectors' field reports and shall be used as an indicator of performance.

14.1.7 Withdrawal of authorization

The SERVICE shall withdraw authorization as provided in sub section 11.0.

14.2 Authorization of Seed Samplers (including sealing and labeling)

14.2.1 Training

The SERVICE must be satisfied that applicants have been sufficiently trained and are competent.

14.2.2 Knowledge and skill requirements

Applicants shall;

- a) Be trained and competent in taking seed samples for seed certification purposes;
- b)
- c) Have knowledge of and work according to current methods approved by the SERVICE;
- d) Have sufficient knowledge of seed certification (e.g. relevant to sampling, testing and labeling)
- e) Have access to appropriate tools and equipment;
- f) Maintain their expertise by regularly undertaking seed sampling work (not more than one year break)

14.2.3 Sampling equipment

Any equipment which is used for seed sampling must fulfill the requirements of the rules and methods as approved by the SERVICE.

14.2.4 Competence assessment

The competence of applicants shall be assessed by;

- a) A written examination to test the knowledge of National Laws and International Seed Certification Schemes and principles and procedures of seed sampling, sealing and labeling;
- b) A practical examination of the application of seed sampling methods
- c) A re-examination in case of recognized deficiencies of the authorized seed sampler.

14.2.5 Attachment

Candidates for authorization shall undergo attachment under an experienced seed sampler for two weeks.

14.2.6 Maintenance of knowledge and skills

Authorized seed samplers need to maintain their knowledge and skills by;

- a) Undertaking regular seed sampling work (not more than one year break)
- b) Keeping up-to-date the documentation and being familiar with the appropriate operating procedures and methods based on the seed sampling rules and methods as provided by the SERVICE.
- c) Participating in re-training if required.

14.2.7 Surveillance and audit procedures

a) Audits

- i. Examining adherence to sampling procedures and methods including checks and documentations as well as examination of company records on label and seal usage.
- ii. Availability, use and condition of appropriate tools and sampling equipment
- iii. Traceability and use of the labels issued shall be assessed

b) Check-Sampling

- i. Check sampling involves taking a duplicate sample from the same seed lot by an experienced sampler from the SERVICE.
- ii. Newly authorized samplers are to be check sampled at least three times a year. If within tolerance, check sampling may be done twice a year.

Check sampling tolerances are as provided in Table 2.

Table 2: Check sampling tolerances

Sampling frequency per year	Rate of conformity (%)	New sampling frequency per year
3	≥ 90	2
3	80 -89	4
3	<80	Withdrawal

Any authorized institution/sampler achieving 80-89%conformity for more than three subsequent checks shall be suspended and be retrained and re-examined. Any institution/sampler achieving less than 80% conformity shall have their authorization withdrawn.

14.2.8 Withdrawal of Authorization

The SERVICE shall withdraw authorization as provided in sub section 11.0

14.3 Criteria for Authorizing Seed Testing Laboratories

14.3.1 Training

The SERVICE shall be satisfied that staff of the applicant laboratory have been sufficiently trained and are competent.

14.3.2 Knowledge and skill requirements

Seed testing laboratories shall;

- a) have a qualified laboratory manager (analyst in charge);
- b) have enough qualified seed analysts in relation to the volume of tests carried out, with the appropriate technical qualifications in accordance with the rules and methods as provided by the SERVICE and confirmed by official examinations;
- c) be situated in appropriate premises and have appropriate calibrated and well maintained equipment which fulfill the requirements of the methods and rules for the tests the lab is authorized to conduct.
- d) test according to methods and rules for seed testing approved by the SERVICE

The staff working in the laboratory shall have the following knowledge and skills;

- a) Seed testing
- b) Application of seed testing methods and procedures approved by the SERVICE
- c) Seed industry in Kenya
- d) Seeds and Plant Varieties Act (CAP 326)
- e) Other seed related policies and laws

- f) Apply the seed testing methods and procedures approved by the SERVICE

14.3.3 Competence assessment

The following methods shall be used to assess the competence of applicants:

- a) The laboratory Manager/Analyst In-charge will be assessed on laboratory management and technical skills particularly control of testing conditions and documentation as per annex 6.
- b) Seed testing examination for all seed analysts on all the methods the laboratory is seeking authorization including process flow and documentation

The examination shall be in two parts; theory and practical

14.3.4 Attachment

Candidates for authorization shall undergo attachment under an experienced seed analyst for four weeks.

14.3.5 Maintenance of knowledge and skills

- a) Authorized seed testing laboratories shall ensure that their staff maintain knowledge and skills by;
 - i. Undertaking regular (not more than one year break) seed testing work
 - ii. Keeping up-to-date the documentation and being familiar with the seed testing rules and methods as approved by the SERVICE.
 - iii. Participating in retraining as need arises.
- b) Premises and equipment used for seed testing shall meet the specifications of the rules and methods approved by the SERVICE
 - iv. Authorized analysts shall take an examination after every three years

14.3.6 Surveillance and audit procedures

a) Check-testing

Check testing involves taking the reference sample from the authorized laboratory and testing at the SERVICE Seed Testing Laboratory.

- i. Newly authorized laboratories shall be check tested 3 times a year.
- ii. Check testing tolerances are as provided in Table 3.

- iii. Authorized laboratories achieving 80-89% conformity for more than three subsequent checks shall be suspended and required to be retrained and re-examined.
- iv. Authorized laboratories achieving less than 80% conformity shall have their authorization withdrawn.

Table 3 Check testing tolerances

Testing frequency per year	Rate of conformity (%)	New testing frequency per year
3	≥ 90	2
3	80 -89	3
3	<80	Withdrawal

b) Proficiency Laboratory Test

Authorized laboratories shall participate in proficiency tests three times in a year

c) Audits of seed test laboratories

Audits shall examine adherence to laboratory management principles and the appropriate testing procedures and methods and shall include checks on documentation, tools and equipment as well as the examination of laboratory records.

14.3.7 Withdrawal of Authorization

The SERVICE shall withdraw authorization as provided in sub section 11.0

14.4 Criteria for authorization of Entities

14.4.1 Independence

The SERVICE must be satisfied that authorized entities have independence in their operations.

14.4.2 Personnel

The SERVICE shall be satisfied that the authorized entities have competent staff to undertake the authorized activities.

14.4.3 Knowledge and skill requirements

Authorized entities shall;

Have a qualified manager who is technically competent in seed certification requirements;

- a) Have enough qualified field inspectors, samplers and/or analysts in relation to the volume of inspections, sampling and/or tests carried out, with the appropriate technical qualifications in accordance with the procedures and methods as approved by the SERVICE and confirmed by official examinations;
- b) Be situated in a physical location and shall have appropriate premises, tools and equipment which fulfill the requirements provided by the SERVICE.
- c) Work according to the procedures and methods provided by the SERVICE.
- d) Have an internal system of quality control and audit.

14.4.4 Competence assessment

The following methods may be used to assess the competence of applicants;

- a) The entity manager(s) shall be assessed on management and technical skills particularly control of seed certification activities, and associated documentation.
- b) Technical staff shall be assessed on the relevant rules and procedures including process flow and documentation

14.4.5 Maintenance of knowledge and skills

- a) Authorized entities shall ensure that the staff maintain their knowledge and skills

14.4.6 Surveillance and Audit procedures

The SERVICE shall ensure the requirements of authorization guidelines are fulfilled through audits as per the audit procedure in Annex 1(2)

14.4.7 Withdrawal of authorization

The SERVICE shall withdraw authorization as provided for in sub section 11.0 following the procedure in Annex 1(4).

15.0 ANNEX 1: PROCEDURES FOR AUTHORIZATION ACTIVITIES

1. Procedure for vetting applications

- i. Potential applicants shall make an application for authorization in form AG 1.
- ii. The duly filled form with appropriate fee will be forwarded to the managing director KEPHIS who shall acknowledge receipt.
- iii. All applications shall be entered in the register for authorization.
- iv. In case of incomplete applications, applicants shall be informed and advised appropriately to take corrective measures, otherwise the application shall be rejected.
- v. Complete applications shall be vetted against the requirements in the guidelines.
- vi. All applicants shall be notified on the outcome of the application.
- vii. Successful individual applicants shall be invited for training and advised on training requirements including payment of fees. In case of entities they shall be notified of assessment upon payment of appropriate fees.
- viii. Successful individual applicants will undergo training followed by examination as provided for in the guidelines to assess their competence. Entities shall be assessed and a decision made on their suitability for authorization.
- ix. Individuals and entities meeting the examination and assessment requirements shall be granted a Certificate of authorization in form AG 2 and gazetted.
- x. Authorized individuals or entities shall be entered into the authorization register and issued with identification documents.

2. Procedure for audit of authorized entities

i. Tools, equipment and environment;

The audit will cover all tools, equipment and their calibration status as well as the operating environment of authorized entities/inspectors/samplers/analysts.

ii. Staff competence;

The audit will assess the competence and ability of the staff in the authorized entities and inspectors/samplers/analysts to carry out their duties efficiently and to determine their weaknesses that may call for training/withdrawal of authorization.

iii. Organization;

To determine appropriateness of the entity's organizational structure and /or staff responsibilities

iv. Inspection;

To check whether there is independence and integrity in field inspection, whether inspection is done as per the procedures and standards provided by the SERVICE

v. Sampling;

To check whether there is independence and integrity in seed sampling, whether sampling is done as per the methods and procedures as provided by the SERVICE and the adequateness of the sampling equipment.

vi. Testing;

The audit will examine the competence of the laboratory and analysts to apply authorized methods and whether the tests are done according to the methods and procedures as provided by the SERVICE.

vii. Frequency;

The auditing of entities/inspectors/samplers/analysts shall be done annually.

viii. Audit Report;

The audit findings shall be communicated immediately and the full report within two weeks.

ix. Corrective Actions;

Corrective Actions shall NOT exceed three months except in special circumstances as agreed with the auditors and shall be commenced immediately

after receiving the audit report to address the Non-conformances raised. The audit shall be closed within three months. The final audit report with recommendations and decisions shall be shared with entities/inspectors/samplers/analysts.

3. Procedure for Monitoring of authorized entities/inspectors/samplers/analysts

- i. The SERVICE shall regularly monitor authorized persons by undertaking documentation checks, check inspections, check sampling, check testing proficiency laboratory tests and pre/post control tests as provided in the guidelines.
- ii. The results of check inspection, sampling and testing shall be recorded in such a way that trends are detectable.
- iii. The monitoring records of entities/inspectors/samplers/analysts shall be maintained by the SERVICE.
- iv. The entities/inspectors/samplers/analysts shall take part in regular (every three years) refresher trainings and maintain records on the same.
- v. Monitoring findings/decisions shall be shared with entities/inspectors/samplers/analysts.

4. Procedure for withdrawal of authorization

a) Voluntary withdrawal;

- i. The SERVICE receives a written notification for voluntary withdrawal from the entity/inspector/sampler/analyst.
- ii. The SERVICE acknowledges and verifies the notification.
- iii. The SERVICE withdraws the authorization and notifies the public through a gazette notice.

b) Withdrawal due to Non-compliance;

For non-compliance where corrective action is applicable

- i. The SERVICE notifies the entities/inspectors/samplers/analysts in writing of non-compliance/violation finding(s) and demands corrective action.

- ii. If the entities/inspectors/samplers/analysts are unable to satisfactorily address the non-compliance within three months, the SERVICE shall withdraw authorization as provided in the guidelines and notify the public through a gazette notice.

For violations where corrective actions do not apply, the SERVICE shall withdraw authorization and inform the entity/Inspector/sampler/analyst in writing within seven working days and notify the public through a gazette notice.

For cases requiring investigation the authorized entity/inspector/sampler/analyst shall be suspended for a period not exceeding six months during which all official documents shall be surrendered to the SERVICE, while awaiting findings of the investigation

5. Procedure for appeal

- i. The applicant writes an appeal letter to the SERVICE, detailing the basis for the appeal and provides any supporting documents. The letter should be accompanied by an appropriate fee. The appeal letter should reach the SERVICE within 14 working days following the decision on authorization.
- ii. The SERVICE acknowledges receipt of the appeal letter, within 7 working days.
- iii. The SERVICE invites the applicant for a hearing within 21 working days after receipt of the appeal and if necessary sends an appeal team to review the application and file a report with recommendations.
- iv. The SERVICE considers the report of the review team, makes a decision and communicates to the applicant within 14 working days after the hearing.
- v. If the applicant is not satisfied with the decision of the SERVICE, he/she may appeal to the Seed Regulations Committee.
- vi. The Seed Regulations Committee evaluates the appeal and makes a decision, which is communicated to the applicant.
- vii. If the applicant is still not satisfied with the decision of the SRC, they may appeal to the Seeds and Plants Tribunal.

16.0 ANNEX 2: FORMS FOR AUTHORIZATION ACTIVITIES

Form AG 1

APPLICATION FOR AUTHORIZATION

To
The Managing Director
Kenya Plant Health Inspectorate Service
P.O Box 49592 - 00100

NAIROBI

1. Applicant's Information

Name : _____

Postal Address: _____

Physical Address -----

Telephone: _____

email: _____

For Entities:

Registration certificate number (attach copy)

Number of technical staff _____ (provide list separately with qualifications and copies of certificates).

For Individuals:

Education level(s)

_____ (attach copies of certificates)

Number of years of relevant experience

_____ (attach documentary evidence)

Staff of seed companies/growers should attach a letter of declaration of independence signed by their employer. See template in Annex 3

Indemnity declaration.....(dully complete template) Annex 4

2. Aspects of authorization being sought (tick where appropriate)

- i. Seed field inspection
- ii. Seed processing inspection
- iii. Seed sampling
- iv. Seed testing
- v. Labeling and sealing

I/We wish to deal in the following crop(s) or groups of crops (Tick appropriately)

- i. Maize and sorghum (Both Hybrids & OPV)
- ii. Small cereals (wheat, barley, oats, Millets, rice etc.)
- iii. Pulses (beans, broad bean, chickpea, cowpea, pea, Dolichos, pigeon peas, green grams etc.)
- iv. Oil crops (sunflower, soya beans, sesame, oilseed, linseed, groundnuts etc.)
- v. Root and tuber crops (Irish potato, cassava, sweet potato, etc.)
- vi. Herbage grasses (Rhodes, setaria, sudan, guinea grass, etc.)
- vii. Pasture legumes
- viii. Vegetables.
- ix. Fiber crops (cotton)
- x. Sugarcane
- xi. Flowers (pyrethrum, etc.)
- xii. Other crops (Specify)

For laboratories:

I/We wish to apply for the following tests and methods (tick appropriately)

Test	Method(s) specify
Purity (compulsory)	
Germination (compulsory)	
Moisture	
Seed health (Specify)	
Seed vigor	
Seed viability	
Genetic purity	
Other relevant tests (Specify)	

3. Infrastructural capacity

Do you have adequate facilities, tools and equipment? _____(Yes/No)

If yes list as per guidelines requirement.

- i.
- ii.
- iii.
- iv.
- v.

I enclose payment of KShs. ----- for this application.

In signing this application, I/We declare that I/We are conversant with the various articles and requirements and the guidelines and also applicable clauses in the Seeds and Plant Varieties Act (Cap 326.)

Name _____ sign _____ Date: _____

Name _____ sign _____ Date: _____

Name _____ sign _____ Date: _____

Official stamp

Attach any other relevant document as required by the guidelines.

FOR OFFICIAL USE ONLY

Application received on

Verification and verdict (Approved/Rejected)

KENYA PLANT HEALTH INSPECTORATE SERVICE

Form AG 2.

CERTIFICATE OF AUTHORIZATION

Authorization No. _____

Name _____

Postal Address: _____

Physical address _____

Telephone: _____ email:

Authorized Aspect(s)

- i.
- ii.
- iii.
- iv.

Scope of authorization

- i.
- ii.
- iii.
- iv.

Date _____ Managing Director

This authorization is valid for 3 years, subject to the following conditions:

1. Adherence to rules and procedures of aspects and scope of activities authorized
2. Maintaining of authorization requirements
3. Avoidance of conflict of interest
4. Demonstration of integrity
5. That the authorization will be withdrawn in case of violations as listed in the guidelines.
6. Payment of annual fees.

17.0 ANNEX 3; LETTER OF DECLARATION OF INDIPENDENCE

We the management of (Company)-----Registration No.-----
--with its headquarters in..... of P.O Box.....

Having our staff member name.....ID No..... authorized as an
Inspector/sampler/analyst under the Seeds and Plant Varieties Act , do hereby to state
as follows:

- We allow the said officer having met the required approval for authorization to perform the authorized duties as per the authorization instruments.
- We commit to facilitate the officer to undertake his/ her duties as required in the certificate of authorization and the Seeds and Plant Varieties Act.
- The management commits that it shall not in any way influence, induce or coerce the said officer in the course of his/her duty.

This is our declaration

Managing Director/Chief Executive Officer: Name:

Signature:

Date:

Company seal;

Commissioner of Oath; Name:.....

Signature:.....

Date:.....

18.0 ANNEX 4: INDEMNITY DECLARATIONS

1. INDEMNITY DECLARATION FOR ENTITIES

I/We of (Company)-----Registration No.-----with its headquarters in..... of P. O Box.....having been authorized by KEPHIS to undertake seed inspection/sampling/testing on its behalf, declare as follows;

- i. I/We undertake to maintain professionalism and integrity, while following the laid down processes and procedures.
- ii. I/We shall not bind KEPHIS to any personal liability, claim, suit, loss or damage that may arise in the course of performing authorized activities.
- iii. I/We commit to maintain confidentiality of any information that I/We may be privy to in the course of performing authorized activities.
- iv. I/We do acknowledge that any liabilities arising from negligence on our part shall be borne by us and not by KEPHIS.

This is our declaration

Managing Director: NameSignature.....

Date.....

WITNESSED BY:

Commissioner of Oaths; Name..... Signature.....

Date.....

2. INDEMNITY DECLARATION FOR INDIVIDUALS

I,..... ID No.----- of P.O
Box.....having been authorized by KEPHIS to undertake seed
inspection/sampling/testing on its behalf, declare as follows;

- i. I undertake to maintain professionalism and integrity, while following the laid down processes and procedures.
- ii. I shall not bind KEPHIS to any personal liability, claim, suit, loss or damage that may arise in the course of performing authorized activities.
- iii. I commit to maintain confidentiality of any information that I may be privy to in the course of performing authorized activities.
- iv. I do acknowledge that any liabilities arising from negligence on our part shall be borne by us and not by KEPHIS.

This is my declaration.

Name:.....

Signature:.....

Date:.....

Commissioner of Oaths:

Name:.....

Signature:.....

Date:.....

19.0 ANNEX 5: FEES FOR AUTHORIZATION ACTIVITIES

Description	Amount in Kshs
Application Fees	
Individuals	2,000
Entities	5,000
Assessment fees (Entities)	10,000 per day
Registration Fees	
Individuals	10,000
Entities	50,000
Training fees- to cover tuition for two weeks (including exams), training materials, lunch and teas.	100,000
Examination fees when training is exempted (theory and practical)	5,000
Attachment fees	7,500 per week
Gazettement fees	1,000
Audit fees(Entities)	10,000 per day
Administrative fees	10% of Gazettement fees of the particular service
Check inspection fees	Gazetted inspection fees for the specific crop.
Check sampling fees	Gazetted sampling fees for the specific crop.
Check testing fees	Gazetted seed testing fees
Appeals fees	
Individuals	1,000
Entities	5,000
Annual renewal fees	
Individuals	10,000
Institutional	20,000
Proficiency test fees	3,000
Post and pre control fees	1,000 per sample

- Mileage – at gazetted rates
- Applicants shall pay subsistence for SERVICE staff where applicable.
- Appeals fees (applies only when appealing to the SERVICE, to be refunded if the appeal is successful).

**20.0 ANNEX 6(A1): CHECKLIST FOR ASSESSING SEED TESTING
LABORATORIES**

Seed testing laboratories				
Criteria	Number (Where applicable)	Conforming (C)	Non- conforming (NC)	REMARKS
Training				
Staff are sufficiently trained and are competent.				
Knowledge and skill requirements				
Laboratory manager/analyst in charge has necessary qualification?				
Laboratory has Personnel with;				
a) Appropriate technical qualifications and/or experience?				
b) Apply seed testing methods and procedures approved by the SERVICE?				
c) Understand the Seed industry in Kenya				
d) Understand the Seeds and Plant Varieties Act (CAP 326) and other seed regulations				
e) Sufficient number of seed analysts in relation to the Volume of tests carried out				
Equipment				
Laboratory has appropriate calibrated and well maintained equipments?				
Check Testing				
Laboratory participates in check testing as per the schedule provided by the service.				
Proficiency Test				
Laboratory participates in all proficiency tests required by the service.				

Laboratory Manager-Competence assessment			
Criteria	Conforming (C)	Non conforming (NC)	REMARKS
Laboratory test conditions are controlled so as not to invalidate tests.			
Purchased services and supplies are controlled so as to meet specified requirements.			
Laboratory maintains defined roles for personnel performing tests.			
Staff training records are maintained			
Laboratory maintains all records of tests			
Laboratory maintains records of all equipments			
Existing knowledge and skills			
Personnel performing tests maintain knowledge and skills by; Undertaking regular seed testing work			
Participating in proficiency tests approved by the service.			
Re-examination after every three years			

Recommendation.....
.....
.....

Inspector name..... Sign..... Date.....

21.0 ANNEX 6(A2) SAMPLING AND TESTING LABORATORY EQUIPMENT

CHECKLIST

SECTION/UNIT	Functional EQUIPMENT	Number	REMARKS
Sampling	Sample dividers – e.g Soil/Riffle, conical		
	Sample Triers; e.g Sleeve type, Nobbe triers		
	Weighing balances; Capacity - 15000g, Readability - 0.1g, Capacity - 5000g. Readability – 0.01g		
	Samples bags (paper bags, cloth bags and seals), Moisture sample bags		
Sample Reception	Weighing balance Capacity - 5000g, readability - 0.01g		
	Computer (Desktop/Laptop)		
Purity	Weighing balances a. Readability of 0.01g b. Readability of 0.001g c. Readability of 0.0001g		
	Soil divider		
	Lenses		
	Dissecting microscope (Stereo binocular)		
	Reference collections		
	Dissecting kit		
	Overhead lamps		
	Purity boards/work tops and spatula		
	Separation Sieves		
	Calibration weights(masses)		
	Containers for remnant samples		
	Impurity containers		
	Trolleys		
	Temperature controlled Sample store		
	General seed blower		
	Diaphanoscope		
	Fume chamber		
Germination	Media –Sand, Germination paper		
	vacuum counter		
	Counting boards,		
	Germination dishes		
	Water dripper		
	Foceps		
	Evaluation sieves		
	Trays		
	Trolleys-Germination room, sample movement		

SECTION/UNIT	Functional EQUIPMENT	Number	REMARKS
	Temperature Monitors; e.g Data loggers, Digital Thermometers, Mercury thermometers		
	Water Distiller		
	Water heaters		
	pH meters		
	Aspirators (graduated)		
	Glassware (Beakers/Test Tubes)		
	Autoclave (60 litres and above)		
	Dissection kits		
	Calculators		
	Computer		
	Walk in germination rooms/cabinet (20°C↔30°C, 20°C)		
Pre-chilling (5°C to 10°C) growth rooms/ cabinet			
Moisture	Hot Air Oven		
	Grinding mill		
	Weighing balance		
	Desiccators		
	Drying containers-Metal aluminum containers (5-8 cm diameter)		
	Pair of Tongs		
	Calibration sieve (0.8mm and 0.05mm)		
	Temperature Monitors e.g Data loggers, Digital Thermometers, Mercury thermometers		
	Heat resistance gloves		
Ground sample container			
Documentation Section	Computer with relevant software		
	Printer		
	Certificate templates		
	Backup(UPS)		
	Files and folders		

Recommendation.....
.....
.....

Inspector name..... Sign..... Date.....

22.0 ANNEX 6(B1): CHECKLIST FOR ASSESSING INSPECTION ENTITIES

	Number (where applicable)	Conforming	Non- conformity	Remarks
General				
a) Registration by the registrar of companies/societies.				
b) Demonstrate impartiality				
c) Demonstrate Confidentiality				
d) Demonstrate Independence of Entity, Inspector, Sampler				
Infrastructure and facilities				
Reliable means of transport				
Inspection tools and equipment (appropriateness & calibration)				
Labeling tools and equipment (appropriateness & calibration)				
sealing tools and equipment (appropriateness & calibration)				
Records of equipment, tools and their identification marks				
Documentation capacity				
Documentation system				
Premise/Office space/work station suitability				
Personnel				
Gazetted inspectors				
Gazetted samplers				
Knowledge and skills				
i. Manager(s)				
Qualification evidence				
Experience evidence				
Competence tests				
ii. Inspectors				
Inspectors application of relevant procedure and methods				
Inspectors use of documents and tools				
Inspectors overall performance				
iii. samplers				
Samplers application of				

procedure and methods				
samplers use of documents and tools				
Samplers overall performance				
Manager(s)				
Does the entity manager(s) have management skills on control of seed certification activities? Planning..... Coordination..... Monitoring..... Supervision.....				
Does the entity manager(s) have technical skills particularly control of seed certification activities? Experience in seed industry & Agriculture..... Knowledge in seed production.....				
Does the entity manager(s) have knowledge on documentation of seed certification activities? Correct document..... Accuracy..... Data retrieval capacity..... Data Analysis.....				
Maintenance of knowledge and skills				
Evidence of Training programs?				
Evidence of training records				
Inspection reference materials and documents				
Surveillance and Audit procedures				
Does the entity have qualified Internal Auditors?				
Does the entity apply Inspection Audit systems?				
Does the entity implement audit recommendations?				
Quality control systems				

Implementation of inspection Quality controls system				
Check off quality control record				

Recommendation.....
.....
.....

Inspector name..... Sign..... Date.....

23.0 ANNEX 6(B2) FIELD INSPECTION TOOLS AND EQUIPMENT CHECKLIST

Tools and Equipment	Number	Remarks
One meter rule		
Tape measure		
Hand lens (X10 and X20)		
Tally counter		
Inspection kit (eg. Knife, gloves, blade, poly- bags, Appropriate disinfectant, forceps)		
Sampling bags and cooler boxes where applicable		
Quick diagnostic test kits for pathogens		
Moisture meter		

Recommendation.....
.....
.....

Inspector name..... Sign..... Date.....