## QUALITY MANUAL GUIDELINES <br> FOR A SEED COMPANY



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## 1. Management responsibility

### 1.1 Management commitment:

Describe in this section, in general terms, the organization and how this quality manual relates to the seed company.
For example:
The quality manual of XXX Seed Company describes the procedures, activities and responsibilities that the company carries out in the production of high quality of seeds in rice and maize,

The general manager is responsible to ensure that resources are available to get the required tasks done and on time, in compliance with the quality objectives.
XXX Seed Company was established in year 2005 to provide regional farmers of high quality seeds.
The role of XXX Seed Company is to $\qquad$
The company maintains a system of document control and record control embedded in the quality manual, following procedures 5.21 and 5.22.

### 1.2 Quality Policy

State the seed company's quality policy and whether the entire company from management to all personnel understands the policy.

## Example:

XXX Seed Company is committed to provide/ offer the highest quality of rice and maize seeds, thru a strictest control from the genetic seed to all the production processes.

The quality manager and all the staff of the company are committed with the quality policy.

### 1.3 Quality objectives

Describe the quality objectives and their consistency with the quality policy, and the way forward to measure and improve the quality of the company. Example:
XXX Seed Company has the objective to achieve complete customer satisfaction with the vision of being one of the best seed company in the XXX region.

For the continual improvement of the quality system, the company has selected the qualified staff, and modern equipments that ensure production of highest quality seed, described in Section 3.

### 1.4 Management Review

Describe the process that management follows to review the suitability and effectiveness of the quality system in the seed company and the continual improvement.
This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.
Records from management review shall be maintained.
Example:
The quality manager conducts twice a year the management review meeting, in June and December, following procedure 5.17

## 2. Resource Management

### 2.1 Organization and Resources

Include the list of the personnel, responsibilities, and activities. Draw the organization flowchart of the seed company.
Example:
The company has personnel assigned to perform specific tasks, operations and processes who are qualified on the basis of appropriate skills. Training needs are identified and individuals trained following procedure 5.2

### 2.2 List of personnel and structure of the company:

| Name | Skill | Responsibilities |
| :--- | :--- | :--- |
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Each section has the specific procedures.


Describe the location, infrastructure, work areas with maps of the seed company. Include a list of the equipment per section. Describe the communication system within the company.

### 2.3 Equipment (ownership or access to)

| Section | Number | Equipment |
| :--- | :--- | :--- |
| Processing Plant | 1 | Platform Scales |
|  | 2 | Sampling equipment |
|  | 1 | Sheller/ thresher |
|  | 1 | Scalper |
|  | 1 | Cleaner |
|  | 1 | Drying equipment |
|  | 1 | Seed Treater |
|  |  |  |
|  | 1 | Seed divider |
|  | 1 | Quality Lab |
|  | 1 | Magnifying lamp |
|  | 1 | Purity table |
|  | 1 | Germination Room |
|  | 1 | Moisture meter |

## 3. Product Realization

### 3.1 Seed Production and processing

The seed company has planned and developed the processes needed for product realization (seed production). The seed company has also defined the procedures, documents, records and resources specific to the product.
The seed company has developed the procedures and/or work instructions for seed production based on the seed regulations and customer requirements and company's standards.

## Seed Production:

- Basic seed acquisition
- Field selection and registration
- Seed planting instructions
- Contract with seed growers

- Packaging
- Labeling


### 3.2 Customer Communication

Describe the customer communication system. Example:
The XXX seed company has developed a communication system with our customers as follows

- Post-sale assistance, with field visits after planting seed season.
- Written and verbal communication
- Conducting field days
- Immediate answer to a customer claim to verify and solve the complaint.
- The documents are reports of visits, commercial brochures, records of claims received and actions taken, newsletters, etc.


### 3.3 Purchasing

Describe the purchasing system to ensure that a purchased product conforms to specified requirements. Describe the system of control of suppliers.

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Example:
The seed company shall evaluate and select suppliers based on their ability to supply product in accordance with the company requirements.
The seed company has developed a software system to control and check the materials to purchase under the responsibility of the General Manager.
The company follows procedure 5.5 for purchasing.

### 3.4 Identification and traceability

The seed company shall identify the product (seed) by suitable means throughout product realization.
Describe the manner in which seed is identified and the records and documents that allow and ensure the traceability of the product.
Example:
The seed company identifies the seed thru the elements that are included in the table below. Records are maintained for control at any time.
Each section leader is responsible for registering and maintaining the identification of the seed.


## 4. Measurement, analysis and improvement

The seed company has developed and implemented the monitoring, measurement, analysis and improvement procedures needed to demonstrate conformity of the product, the quality management system and its continuous improvement the effectiveness. Related procedures are 5.6, 5.7 and 5.8

### 4.1 Customer satisfaction

The company monitors information relating to customer perception as to whether the organization has met customer requirements.
The company measures customer satisfaction through the quantity of claims, and growers visits. Information is recorded and maintained in the quality system.

### 4.2 Control of non-conformities

The principal product of the seed company is high quality seed production.
The company ensures that seed which does not conform to product requirements is identified and controlled to prevent use or delivery.
In this section the company describes the action, control, responsibilities taken to eliminate any detected non-conformities
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## 5. OPERATIONAL AND ADMINISTRATIVES PROCEDURES

### 5.1 Management Review Procedure

1. Purpose
1.1 The purpose of this procedure is to define the actions, interfaces and responsibilities for scheduling, conducting and recording management reviews of the quality management system.
2. Scope
2.1 From the inputs for management review received to the results of the management review.
3. References
3.1 Management review notes from previous meeting
3.2 Corrective and preventive action reports
3.3 Customer complaints
3.4 Training records
3.5 Schedules and work orders, instructions, samples
3.6 Communications from customers, suppliers
3.7 Internal audit reports
4. Definitions
and
4.3 CA: Corrective Actions
4.4 GM: General Manager

5. Responsibility and authority
5.1 QM is responsible for scheduling the meeting and preparing the management review form (Annex B).
5.2 GM is responsible for chairing the meeting
5.3 A designated member is responsible for recording meeting notes.
6. Activities
6.1 Schedule meeting
6.1.1 $Q M$ will prepare the schedule of the meeting twice a year and communicate to all staff.
6.1.2 Based on special conditions or situation the QM may call for an extra meeting.
6.1.3 QM will prepare the agenda for the meeting (Annex A), and distribute to the staff.
6.2 Conduct meeting
6.2.1 Management review meeting is chaired by the GM and attended by designated staff.
6.2.2 During the meeting, the agenda should cover all items listed as "review input".
6.2.3 A designated employee will record the meeting notes.
6.2.4 A management review form is completed by the QM (Annex B)

### 6.3 Review input

6.3.1 Based on the agenda prepared, management reviews input information.
6.3.2 The quality manager will present:

- Status of action items from last meeting
- Results of audits, including internal and third party.
- Status of corrective and preventive actions
- Customer feedback: communication and satisfaction
- Status of training programs
- Progress on continual improvement goals, and review of current projects.
- Any product, process, capacity or operational changes that could affect the quality management system
6.3.2.1 If any modification is needed continue with 6.4
6.3.2.2 If not, continue with 6.6


### 6.3.3 Other issues related to the quality management system may be presented by other management members.

### 6.4 Review Quality Policy and Objectives

6.4.1 The management reviews include the evaluation of the progress toward fulfilling the quality policy and quality objectives to ensure its continuing relevance.
6.4.2 During the meeting quality objectives will be analyzed with the level of achievement, so that management can decide to drop or change them.
6.4.3 New objectives may be established to improve performance or quality system.

### 6.5 Review output

6.5.1 Management reviews are concluded with actions related to:

- Improvement of effectiveness of the quality system
- Improvement of quality performance
- Improvement of product and/or services to meet customer requirements and satisfaction
- Resource needs
6.5.2 The improvement actions are formulated as quality objectives with measurable targets, due dates, responsibilities and resources for their implementation.


### 6.6 Record of the meeting

6.6.1 Management review output is documented in the minutes of the meeting, action items are placed under special heading to ensure their identification.
6.6.2 QM will distribute the minutes to all the attendees.

## 7 Records

7.1 Record of the agenda
7.2 Records of the management review meeting

8 Flowchart and Annexes
8.1 Flowchart
8.2 Annex A: Management review meeting Agenda
8.3 Annex B: Management review form


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Flowchart: Management Review Procedure


## ANNEX A <br> MANAGEMENT REVIEW AGENDA

$>$ Meeting date and place
$>$ Status of action items from last meeting
$>$ Results of audits, including internal and third party.
$>$ Status of corrective and preventive actions
> Customer feedback: communication and satisfaction
> Status of training programs
> Progress on continual improvement goals, and reviews current projects.
$>$ Any product, process, capacity or operational changes that could affect the quality management system
> Other issues related to the quality management system.


## ANNEX B <br> MANAGEMENT REVIEW FORM



### 5.2 Training Procedure

1. Purpose
1.1 The purpose of this procedure is to define the actions, interfaces and responsibilities for assuming that all staff is trained in the skills expected in their job functions.
2. Scope
2.1 From identifying training needs for each person to personnel trained.

## 3. References

3.1 Training Materials
3.2 Matrix of required training
3.3 Crop production guidelines
3.4 Seed Certification Standards and regulation
4. Definitions
4.1 QM: Quality Manager
4.2 SL: Section leader
5. Responsibility and Authority
5.1 QM and/or SL is responsible for identifying training needs
5.2 Section leader is responsible for establishing specific training programs
6. Activities

### 6.1 Identify training needs

6.1.1 QM and/or SL will evaluate the personnel to determine training needs.
6.1.2 SL will establish specific training programs focused on increasing the level of skills in seed production, processing, rules and regulations, quality system, operating equipment and processes, and internal audit.
6.2 Plan training
6.2.1 QM will ensure that each employee receives training.
6.2.2 QM will designate the type plus location of training.
6.2.3 QM will maintain training matrixes; keep records of all internal and external training.

### 6.3 Evaluate training

6.3.1 SL will evaluate the effectiveness of training provided through observation.
6.3.2 If re-trained is necessary go to 6.1
6.3.3 If retraining is not necessary continue with 6.4

### 6.4 Measure training effectiveness

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6.4.1 QM will evaluate personnel on basis of internal audits, yearly employee evaluations, corrective actions and maintaining of performance data.

## 7. Records

7.1 Matrix of Personnel Training Needs
7.2 Records of Training

## 8. Flowchart and Annexes

### 8.1 Flowchart

8.2 Annex A: Matrix needs for training
8.3 Annex B: Training Record Format


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FLOWCHART: TRAINING PROCEDURE


## Annex A <br> Matrix Needs for Training

| NAME | SKILL | Position | Training Request | Recommendation |
| :--- | :--- | :--- | :--- | :--- |
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### 5.3 Staff Recruitment procedure

## STAFF RECRUITMENT PROCEDURE FLOWCHART



### 5.4 Determining foundation seed production for five years



### 5.5 Basic seed acquisition



### 5.6 Field Production Procedure

## 1. Purpose

1.1 The purpose of this procedure is to define the sequence of events, interfaces and responsibilities involved in the process of seed production for maize and rice.

## 2. Scope

2.1 From maize and rice seed production planning to the seed harvested.

## 3. References

3.1 Seed production manual
3.2 Seed certification Standards and regulations
3.3 Model of seed production contracts with growers

## 4. Definitions

4.1 Contract Grower: qualified farmer that produces seed under contract for the seed company
4.2 Contract: legal document that establishes the agreement of production between the contract grower and Seed Company.
4.3 GM: General Manager
4.4 QPM: Quality and Production Manager
$\xrightarrow{2}$

### 4.5 MM: Monitoring Manager

5. Responsibility and Authority
5.1 The GM is responsible of signing the contracts
5.2 The QPM is responsible of planning the seed production, selecting the growers, reviewing the field reports and coordinating the reception from the field.
5.3 The field technician is responsible of controlling the production, preparing field reports, and documents of harvested seed.
6. Activities
6.1 Plan seed production
6.1.1 QPM plans the production twice a year based on the potential market and the storage inventory established by the MM completing Annex A.
6.1.2 MM will adjust the seed production based on the market and government policies.
6.1.3 QM will contract parent seed for basic seed from authorized providers 6 month earlier.
6.1.4 QPM will maintain a stock of the parent and basic seeds.

### 6.2 Select fields for planting

6.2.1 QPM will select the best areas/ fields based on the list of contract growers with experience.
6.2.2 QPM will prepare the contracts for the contract growers that will be signed by the general manager. (Annex B).

### 6.3 Register fields

6.3.1 The QPM will register the fields at the government certification agency with the official formats.

### 6.4 Plant fields

6.4.1 Dates for planting will be established by the QPM in coordination with the field personnel and the growers.
6.4.2 QPM will provide the basic seed to growers one week in advance.
6.4.3 The growers will plant the fields following the agreement of the contracts administration of the seed company.

### 6.5 Inspect fields

6.5.1 QPM or his designated will conduct at least $x x$ field inspections based on the seed company guidelines for field inspection.
6.5.2 After each inspection, field technicians will prepare a report using the format developed by Seed Company. (Annex C)
6.5.3 The field technicians will give inspection report to the grower and a copy to QPM.
6.5.4 The field technician will decide the approval or not of the field, during the
flowering inspection or last inspection depending on the crop.
6.5.4.1 If the field is rejected continue with discard procedure.
6.5.5 The field technician will approve the field and authorize the harvest, signing the last field inspection format (Annex C).

### 6.6 Harvest fields

6.6.1 The field technician will verify the cleanliness and calibration of the harvesting machinery.
6.6.2 The harvesting will be carried out based on the production guidelines from the Seed Company.

## 7 Records

7.1 Signed Contracts
7.2 Field selections
7.3 Report of inspections, field approvals/ rejections
7.4 Discard report

## 8 Flowchart and Annexes

8.1 Flowchart Field Production Procedure
8.2 Annex A: Production Plan Format
8.3 Annex B: Seed Growers Contract Format
8.4 Annex C: Field Inspection Report Format


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Field Production Procedure



#### Abstract

ANNEX A PRODUCTION PLAN FORMAT | Cariety |  |  |  |  |  | Tons Required | Area Required | Date Required |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  |  |
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Discussed
with:
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Approved by:
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ANNEX B
SEED GROWERS CONTRACT FORMAT

## SEED COMPANY

| Name of Grower | Address | Crop \& Variety |
| :--- | :--- | :--- |
| Generation or Class | Total Area |  |

XXX Seed company under takes to supply the grower with the required quantities of parent seed, the technical advice, inspection services, and the packaging material for the raw seed at harvesting

The GROWER will plant the seed at the prescribed population and will return all excess seed within one week after the panting to XXX Seed Company. The farmer will retain all the labels and the packaging material of all the planted foundation seed until the seed has been delivered to XXX Seed Company.

The GROWER will make sure that the land to planted to the seed crop had not been planted to another cereals during the past season, so as to ensure that the high quality seed is produced

The GROWER will ensure that proper cultural practices are followed in time, such as weeding, rouging, proper fertilizer application and irrigation at their cost
Weeding: The field should be kept weed free at all times and the GROWER should use all the possible measures including herbicides to control weeds
Rouging: All the off-types should be removed from the crop and there should be less than $0.05 \%$ off-types at any one inspection
Fertilizer Application: The farmer will fertilizer the crop at the rates that enable him to get the maximum yield possible e.g. 150 KG of Nitrogen, 80 kg of Phosphorus and 120 Kg of potassium per hectare
Planting Pattern: The crop will be planted at a ratio of 6 female rows to 2 male rows on the same day.
Planting Population: The crop will be planted at the population of ----- to ----- plants per hectare using ---- kgs of foundation seed per hectare
Irrigation: The GROWER will ensure that the field is kept at field capacity at all times through irrigation
The GROWER will implement a follow all the instruction given to them by the seed inspector. If the GROWER does not follow the instruction and this leads to the rejection of the crop. XXX Seed Company will be entitled to recover the cost of the foundation seed and $10 \%$ of the gross value of the grain.
$\qquad$

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## ANNEX C <br> FIELD INSPECTION REPORT FORMAT



### 5.7 DISCARD PROCEDURE

## 1. Purpose

1.1 The purpose of this procedure is to define the sequence of events, interfaces and responsibilities involved in the process of discarding rejected seed crops.

## 2. Scope

2.1 From rejection of the field/ seed to final disposal of plant material.

## 3. References

3.1 Seed production manual
3.2 Seed certification Standards and regulations
3.3 Grower Contracts
3.4 Inspection report

## 4. Definitions

4.1 Contract Grower: qualified farmer that produces seed under contract with the seed company.
4.2 Contract: legal document that establishes the agreement of production between the grower and Seed Company.
4.3 Discard seed: Any seed that does not meet the quality standards as laid out in the certification scheme or company standards and has been rejected
4.4 QPM: Quality Production Manager

## 5. Responsibility and Authority

5.1 The field technician is responsible for writing the rejection report.
5.2 QPM is responsible for signing the rejection and the disposal for of the grain.

## 6. Activities

### 6.1 Determine the source of the discard

6.1.1 QPM will use the rejection report to determine the source of the discard
6.1.2 If the source of the discard is the field continue with 6.4.
6.1.3. If the source of seed is from the warehouse go to 6.2

### 6.2 Isolate the affected seed lot

6.2.1 The QPM will have the seed lot taken to a designated area in the warehouse
6.2.2 Indicate the lot with a clear label of not for seed sale/ distribution and red tape around the lot.
6.2.2.1 If the seed has not been treated, go to 6.3.
6.2.2.2 If the seed has been treated, destroy in presence of seed certification official and obtain signed record of destruction.

### 6.3 Contact the grain buyer

6.3.1 Write a letter giving information of the grain quantities involved.
6.3.2 Enter into an agreement with the grain buying company detailing the purchase price and delivery dates and keep sales receipt records.

### 6.4 Notify the grower

6.4.1 Notify the contract grower informing him/her of the rejection of the field lot according to the inspection report.
6.4.2 Inform the contract grower of the obligation to provide the company with proof of sale to a non-seed entity.

### 6.5 Control harvest

6.5.1

### 6.6 Deliver to grain buyer

6.6.1 QPM of Seed Company will organize the delivery of the discarded seed lot to industry based on the agreement document and obtain sales receipt.

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7.1 Rejection report
7.7. Filed obsactid feaid ersity of Nairobi
7.3 Seed Lot Discard document
7.4 Sale Agreement document
7.5 Sale receipt

## 8. Flowcharts and Annexes

8.1 Flowchart
8.2 Annex

## Discard Procedure Flowchart



### 5.8 Seed Processing and certification Procedure

1. Purpose
1.1 The objective of this procedure is to define the sequence of events, interfaces and responsibilities involved in the process of seed processing/ labeling and storage.
2. Scope
2.1 From the harvest of seed crop to certify seed ready for marketing.
3. References
3.1 Seed Company Production Standards
3.2 Seed Certification Standards and Regulation
4. Definitions
4.1 Contract Grower: qualified farmer that produces seed under contract with the seed company.
4.2 NSCA: National Seed Certification Agency
4.3 QPM: Quality and Production Manager
5. Responsibilities and Authority
5.1 The head of processing plant is responsible for receiving seed at the plant.
5.2 The head of processing plant is responsible for taking a sample and sending it to the quality control Haboratory
5.3 QPM is responsible for obtaining testing results.
5.4 Personnel of processing plant are responsible for seed drying, conditioning, processing, treating and packaging.
5.5 QPM is responsible for supervising the labeling of the processed seed.
6. Activities
6.1 Take sample
6.1.1 As the seed is received into the processing plant, staff will take a representative sample from the seed lot and send to the laboratory/ QPM with a sampling card (Annex A).

### 6.2 Test quality of pre-processed seed

6.5.1 The head of seed quality control lab will conduct the seed testing following the ISTA Rules and the company seed standards.
6.5.2 The head of seed quality control lab will issue a quality report of the seed received following Annex B.
6.5.3 If the results of the quality test are out of standards established by the company, continue with the procedure of Discard Seed.
6.5.4 If the results are within the standards established by the company, the seed is accepted and continue with 6.3.

### 6.3 Seed processing

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6.3.1 Staff of processing plant will start with the pre-cleaning and drying of the seed to remove contaminants and reduce moisture content as necessary.
6.3.2 Staff will record all operations procedures in the processing line (Annex C).
6.3.3 Staff will continue with the cleaning and finally with drying, treating and bagging.
6.3.4 QPM will determine the seed lot to be processed following a processing schedule.
6.3.5 Staff will record the following
6.3.3.1 Volume of harvested seed before pre-cleaning (Annex D)
6.3.3.2 Volume of chaff and good seed after cleaning (Annex D)

### 6.4 Test cleaned seed

6.4.1 Staff of processing plant will take a sample of cleaned and send to the lab for testing.
6.4.2 The head of seed quality control lab will conduct a test to verify the quality and the compliance with company and official standards.
6.4.3 If the quality of seed is within standards, continue with 6.5
6.4.4 If the quality of seed is not within standards, but may be re-processed, continue with 6.3.
6.4.5 If the quality of seed is within standards, and cannot be re-processed, continue with the Discard Procedure.
6.5 Treat seed
6.5.1 Staff of processing plant will treat the seed, thru disinfection and protection to prevent plant diseases.
6.5.2 The treatment will be done following the Seed Company standards using the chemicals and doses established.

### 6.6 Apply labels

6.6.1 QPM will apply to NSCA for the labels, based on the seed testing and field inspection reports (Annex E).

### 6.7 Weigh, pack and label

6.7.1 After processing and treatment are completed, seed are packaged into containers of specific net weight.
6.7.2 Staff will pack and sew the bags. At the time the seed is placed in the bags, the official labels must be sewn on each bag to maintain the identity of certified seed.

### 6.8 Store seed

6.8.1 Staff will stack the bags in the storage facility in such a way as to prevent the bags from touching the floor and record (Annex F).

## 7. Records

7.1 Sampling reports
7.2 Seed Testing reports
7.3 Record of processing
8. Flowchart and Annexes
8.1 Flowchart
8.2 Annex A: Sampling card format
8.3 Annex B: Seed Testing Report Format
8.4 Annex C: Seed Processing Operation Format
8.5 Annex D: Volume of Harvested and Cleaned Seed Format
8.6 Annex E: Certification Label Requeste Format (To be developed)
8.7 Annex F: Certified Seed Storage Record Format (To be developed)


Seed Processing and Certification Procedure Flowchart


ANNEX A
SAMPLING CARD FORMAT


Sampler's Signature
Date

ANNEX B
SEED TESTING REPORT FORMAT

| Crop <br> Sample Number <br> Lot \# <br> Variety <br> Test Requested <br> Contract Grower Information <br> Date Sample Received <br> Signature <br> Test Result: <br> Purity test: <br> Germination test: <br> Moisture test: <br> Tetrazolium Test: <br> Seed Health Test: Date tests concluded |
| :--- |
| Remarks |

Signature and date

## ANNEX C <br> SEED PROCESSING OPERATIONS FORMAT



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## ANNEX D <br> VOLUMES OF HARVESTED AND CLEANED SEED FORMAT

| Contract <br> grower | Crop <br> Variety | Volume <br> harvested | Date | Volume <br> cleaned | Date |
| :--- | :--- | :--- | :--- | :--- | :--- |
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### 5.9 SEED TREATMENT



### 5.10 TRACEABILITY PROCEDURE



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### 5.11 SEED VOLUME DETERMINATION PROCEDURE



### 5.12 SEED STORAGE PROCEDURE



### 5.13 PRICE DETERMINATION PROCEDURE



### 5.14 SALES AND DISTRIBUTION PROCEDURES




### 5.15 IMPORT/EXPORT PROCEDURES



## SEED EXPORT PROCEDURE



### 5.16 CUSTOMER COMPLAINT PROCEDURE

CUSTOMER COMPLAINT PROCEDURE


### 5.17 PURCHASING PROCEDURE

## 1. Purpose

1.1 The purpose of this procedure is to define the sequence of events, actions, interfaces and responsibilities to ensure that critical products purchased and received comply with specific requirements.

## 2. Scope

2.1. From product ordered to purchase of supplies received and approved.

## 3. References

3.1 Product requirements
3.2 Quality Standards
3.3 National and international Suppliers

## 4. Definitions

4.1 List of Suppliers: Suppliers registered with Seed Company.
4.2 QPM: Quality and Production Manager

## 5. Responsibility and Authority

5.1 QPM is responsible to obtain the list of suppliers registered.

5.2 QPM is responsible to evaluate and select suppliers.
5.3 QPM is responsible to document the supplies required and the specifications and requirements.
5.4 QPM is responsible to review and approve the purchasing.
5.5 QPM is responsible to verify the product received.

## 6. Activities

### 6.1 Evaluate and select suppliers

6.1.1 QPM will evaluate and select suppliers based on their ability to supply products that conform to the specific requirements established by the company.
6.1.2 QPM will prepare a list of suppliers per product. (Annex A)

### 6.2 Review purchase

6.2.1 Section leader will document the description of the product requested with an identification, quality and quantity requirements.
6.2.2 Purchasing documents will be presented to the QPM, who will review the purchasing so that an order form can be prepared.

### 6.3 Order purchase

6.3.1 Administrative assistant will prepare and order the purchasing and notify supplier.(Annex B)
6.3.2 $\mathrm{He} /$ she will inform to QPM and section leader the date of reception.

### 6.4 Verify purchased supplies

6.4.1 Upon product reception, the section leader will verify the compliance of the requirements by checking the products.
6.4.2 If supplies are Ok continue with 6.6
6.4.3 If supplies are not Ok continue with 6.5

### 6.5 Reject supplies

6.5.1 Section leader will check the supplies received and in consultation with QPM will reject the product if non compliance with requirements is found. (Annex C)
6.5.2 Supplier will be notified of the rejection by the QPM.

### 6.6 Approve and receive supplies

6.6.1 Section leader, after checking the supplies will approve the purchase
6.6.2 Section leader will prepare a record of supplies received and notify the approval and reception. (Annex D)

## 7. Records <br> 7.1 Record of list of suppliers <br> 7.2 Record of purchase orders <br> 7.3 Record of notification of rejection of supplies <br> 7.4 Record of supplies received

8.1 Flowchart
8.2 Annex A: Format of list of suppliers
of Nairobi
8.3 Annex B: Format of purchase order
8.4 Annex C: Format of notification of rejection of supplier
8.5 Annex D: Format of supplies received

Purchasing Procedure Flowvchart


### 5.18 Internal Audit Procedure

## 1. Purpose

1.1 The purpose of this procedure is to define the sequence of events, actions, interfaces and responsibilities in internal quality audit implementation to determine the quality system is working correctly.
2. Scope
2.1 From requirements of an internal quality audit to audit completed.
3. References
3.1 Approved list of potential internal auditors
3.2 Internal audit checklist
3.3 Quality Manual
4. Definitions
4.1 Internal Audit: independent activity to verify, through an exam and evaluation of objective evidence, if the processes and elements applicable to the quality system have been developed, documented and implemented.
4.2 Internal auditors: independent and trained person/s that conduct internal quality audit
4.3 Non-Conformity: any situation that differs from standards
4.4 Objective evidence: data supporting the existence or verify something
4.5 Corrective action: action to eliminate the cause of a detected non-conformity.
4.6 Corrective action follow-up: effective evidence to verify that the corrective action has been implemented.
4.7 QPM: Quality and Production Manager
5. Responsibility and Authority
5.1 The QPM must:

- Ensure that internal quality audits are programmed, planned, and recorded according to the procedure.
- Designate the internal auditor/s
- Be responsible of giving access to auditors, to documentation, working place and company staff involved in the audit.
- Ensure that the documentation of corrective actions is filed with their audit record.
- Ensure that the audit reports and any other corrective actions are reviewed and followed up.
5.3 The auditor/s shall:
- Conduct internal quality audit
- Change the audit program as necessary
- Publish audit report
- Notify the staff of the audit date


## 6. Activities

### 6.1 Establish an audit plan

6.1.1 QPM will establish an audit plan and schedule for areas where the quality system is implemented at least once a year.

### 6.2 Designate internal auditor/s

6.2.1 QPM will designate the auditor/s that will carry out internal audits.
6.2.2 Personnel assigned are independent of those having direct responsibility for the audited activity.
6.2.3 Internal auditor/s is trained by quality manager.

### 6.3 Prepare internal audit

6.3.1 Internal Auditor/s will prepare the checklist and the internal audit agenda.
6.3.2 Internal Auditor/s must be familiarized with quality manual and relevant procedures to prepare the questions for the audit.

### 6.4 Inform the auditee

6.4.1 Internal Auditor/s should inform the audited about the internal audit at least five days before the audit is conducted.

### 6.5 Conduct internal audit

6.5.1 Internal Auditor/s will conduct the initial meeting, introducing the agenda to audit.
6.5.2 Internal Auditor/s conducts the audit looking for objective evidence that demonstrate the audited activities conform with requirements of documented quality system and whether it is effectively implemented and maintained.
6.5.3 If a non-conformity is noted it is discussed and documented.
6.5.4 Auditor will conduct the closing meeting.

### 6.6 Publish corrective action follow up

6.6.1 The internal auditor will publish the corrective action needed for nonconformity that has been detected during the audit.
6.6.2 Upon receiving the report the section investigates the cause of the problem noted as non-conformity, proposes a corrective action to be taken and reports the date by which the corrective action will be fully implemented.
6.6.3 Internal Auditor/s review and approve the action proposed.

### 6.7 Prepare internal audit report

6.7.1 Internal Auditor/s will prepare the final audit report with the following content: area/activities audited participants, objective, and scope of the audit, written documents, summary of activities, and non-conformities.
6.7.2 Internal Auditor/s will verify the implementation and efficacy of the corrective actions and submit a follow up report.
6.7.3 All non-conformities are compiled and presented at the management review meeting.

### 6.8 Follow-up of corrective action

6.8.1 Internal Auditor/s will verify the implementation and efficacy of the corrective actions during the stipulated time through either document verification or in situ.
6.8.2 Internal Auditor/s will close the corrective action follow-up and submit the report to the quality manager.

### 6.9 File and distribute report

6.9.1 QPM will file and distribute the internal audit final report.

## 7 Records

7.6 Internal Audit Program/ agenda
7.7 Internal Audit final report
7.8 Record of corrective actions and follow up report

## Flowchart and Annexes

8.6 Flowchart
8.7 Annex A: Audit Agenda
8.8 Annex B: Verification List
8.9 Annex C: Corrective Action requested
University of Nairobi

Internal Audit Procedure Flowchart


ANNEX A

## AUDIT AGENDA



ANNEX B

## VERIFICATION LIST



Approved by
Version July2010

## ANNEX C

REQUEST FOR CORRECTIVE ACTIONS FORMAT


### 5.19 Calibration of Critical equipments Procedure

## 1. Purpose

1.1 The purpose of this procedure is to define the sequence of events, actions, interfaces and responsibilities involved in the process of identification, calibration and maintenance of measuring and monitoring critical equipment.

## 2. Scope

2.1 From the critical equipment without maintenance to equipment calibrated and maintained.
3. References
3.1 Calibration Standards
3.2 Test requirements

## 4. Definitions

4.1 Critical equipment: equipment that is critical for product realization (processing, testing).
4.2 QPM: Quality and Production Manager

## 5. Responsibility and Authority

5.1 QPM is responsible for verification of conformance of measuring and monitoring

## S 1 equipments.

5.2 Section leader is responsible for calibration of equipments.
5.3 Section leader is responsible for keeping and maintaining calibration records of critical equipment in the logbook.

## 6. Activities

### 6.1 Identify equipment

6.1.1 Section leader and QPM will identify and document all critical equipment.
6.1.2 Section leader will identify and record each critical equipment using a serial number, number/code and or model number and register in a logbook.

### 6.2 Calibrate equipment

6.2.1 Section leader will calibrate equipment in accordance with written instructions and tolerances.
6.2.2 Records of calibrated equipment are maintained with the information of frequency, conditions, tolerances, method and current status (Annex A).
6.2.3 Calibrated equipment is labeled with a sticker indicating the status and maintains a calibration record for equipment (Annex B).
6.2.4 When equipment requires calibration from outside the company, a certificate of proof of calibration is keeping in the file.

### 6.3 Maintain and store equipments

6.3.1 QPM will maintain a list of all equipment with location, item name, manufacturer, model number, serial number, calibration, frequency, calibration standard and tolerance if applicable.
6.3.2 The list is verified and updated at least annually.
6.3.3 Equipment is maintained, stored and handled to preserve their accuracy and protect from damage and deterioration.
7. Records
7.1 Record of Calibrated equipment
7.2 List of inventory equipment
8. Flowchart and Annexes
8.1 Flowchart
8.2 Annex A: Record of Calibrated Equipment
8.3 Annex B: Calibration Record Format


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## Equipment Calibration Procedure Flowchart



## ANNEX A <br> RECORD OF CALIBRATED EQUIPMENT

| EQUIPMENT | I.D NUMBER | TOLERANCE | FREQUENCY | LOCATION | COMMENTS |
| :--- | :--- | :--- | :--- | :--- | :--- |
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ANNEX B
CALIBRATION RECORD FORMAT


### 5.20 Control of non-conformities procedure

## 1. Purpose

1.1 The purpose of this procedure is to define the sequence of events, actions, interfaces and responsibilities to ensure the identification of the nonconformities, and the corrective and preventive actions have been taken in order to prevent recurrence.
2. Scope
2.1 From non-conformity detected to correction and implementation.

## 3. References

3.1 Certification Standard
3.2 Quality Standards of the seed company

## 4 Definitions

4.1 Non-conformity: non-fulfillment of a requirement
4.2 Corrective action: action to eliminate the cause of a potential non-conformity or other undesirable potential situation.
4.3 QPM: Quality and Production Manager

5 Responsibility and Authority
5.1 All personnel are responsible to identify record and report non-conformity.
5.2 QPM is responsible to detect the cause of non-conformity and implement corrective actions.
5.3 Each section leader shall complete the corrective action form and maintain a record.

## 6 Activities

6.1 Identify non-conformity
6.1.1 All personnel should report identified non-conformities to their supervisor.
6.1.2 Whenever non-conformity is identified, it is documented in a form (Annex A).
6.2 Define and implement corrective action
6.2.1 The section leader and the quality manager will define and implement the corrective action (Annex B) in a maximum of --- working days.

### 6.3 Notify result

6.3.1 Section leader will communicate to quality manager the result of the corrective action.
6.3.1.1 If the corrective action is satisfactory, include in the procedure.
6.3.1.2 If the corrective action is not appropriate continue with 6.2

## 7 Records

7.1 Record of non-conformities
7.2 Record of corrective actions

8 Flowcharts and Annexes
8.1 Flowchart
8.2 Annex A: Non-conformity identification Format
8.3 Annex B: Corrective Action Format


## Control of Non-Conformities Procedure Flowchart



### 5.21 DOCUMENT CONTROL PROCEDURE

1. Purpose:
1.1 Identify events, actions, activities and responsibilities involved in the creation, identification, approval, distribution, and storage of controlled documents of the seed company

## 2. Scope:

2.1 From the document and data identification to the implementation of their control.

This will be applied to documents and data related to the seed company quality manual.
3. References:
3.1 Model for Document Generation.
4. Definitions:
4.1 Document: Procedures, work instructions, references, specifications or regulatory material for the administration of the system.
4.2 Data: Quantified information in documents.
4.3 Controlled document: Documents formally identified. These documents are registered, maintained and their change, as well as, their implementation is regulated.
4.4 Procedure: Document that describes, "Who does the job", "when", "where", and "why".
4.5 Work instructions: Document that identifies the procedures to perform a task or activity.
4.6 Internal document: Document generated outside the limits of the administrative system for example: a regulatory document that is referred to a procedure or work instruction.
4.7 Master List: List that contains information related to documents and includes information such as documents titles, revision number and document codes.
4.8 QPM: Quality and Production Manager
5. Responsibility and Authority:
5.1 QPM will assure that the control of documents is conducted following this procedure.

## 6. Activities:

### 6.1 Identify Documents.

6.1.1 Any representative of Seed company that needs a new controlled document will inform the QPM, which will determine whether or not to proceed with the request
6.1.2 Create the Master List of Controlled Documents.

### 6.2 Create Documents.

6.2.1 If the document does not exist, QPM will assure that this Document is created. The procedures and work instruction will be prepared following the model approved by QPM.

### 6.3 Review Document.

6.3.1 If the document already exists, QPM will review it to assure that the information is current and achieves the needs of the system, and that it is on the Document Master List. If the document is not adequate, QPM will modify the internal document according the activity 6.5
6.3.2 The new documents will be reviewed by the QPM before their approval.

### 6.4 Approve Document.

6.4.1 Changes in the procedures won't be allowed, except for those related to work instructions and identification of responsibilities.
6.4.2 QPM will review and approve the new document to verify its precision.
6.5 Request Document Change.
6.5.1 Any seed company staff member can request any change to the documents through the Document Change Application. QPM will evaluate the application as well as its consequences and will either authorize it or not.
6.5.2 The modified document will be controlled through the activity 6.6

### 6.6 Control Documents.

 hardcopy and electronically.6.6.1.2 The controlled documents are available and identified in the Master List.
6.6.1.3 These documents are stamped as "controlled document".
6.6.1.4 In the case that the elements of the system are kept electronically (in red), the obsolete documents will be identified and removed to prevent use.
6.6.1.5 Confidential documents will be identified with the stamp and will handle by authorized personnel who will be identified in the work instructions.
6.6.2 Obsolete Documents:
6.6.2.1 QPM will discard either the obsolete documents or file them. The word "OBSOLETE" will be stamped on the cover page or diskette, and they will be filed in the section of obsolete documents
6.6.3 Photocopies:
6.6.3.1 Photocopies and printouts of controlled documents will be made just for internal training and revisions. Photocopies of
confidential documents are not allowed under any circumstance.
6.7 Distribute Documents.
6.7.1 QPM will determine a date for the document to become valid.
6.7.2 QPM will distribute the new document.
6.8 Inform the concerned personnel and institutions.
6.8.1 QPM will assure that the concerned personnel understand the content of the new document or any change made to the original documents.
6.8.2 QPM will provide the training to the personnel when necessary to achieve the new requirements.
6.9 Ensure the access.
6.9.1 QPM will ensure that documents of reference are available.
7. Records:
7.1 Master List of Controlled Documents.
8. Flowchart and Annexes:
8.1 Flowchart.
8.2 Annex A: Controlled Documents Master List.
8.3 Annex B: Document Change Application.

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## DOCUMENT CONTROL PROCEDURE FLOWCHART



Document approved date

ANNEX A

## CONTROLLED DOCUMENTS MASTER LIST



## ANNEX B

## DOCUMENT CHANGE APPLICATION



### 5.22 record control procedure

## 1. Purpose

1.1. The objective of this procedure is to define the events, actions, interfaces and responsibilities involved in the identification, collection, file, access, storage, maintenance and discharge of records.
2. Scope
2.1. From records that have been generated by Seed Company quality manual to their control.

## 3. References

3.1. Administrative, Operational and Support Procedures.
3.2. Master List of Records
4. Definitions
4.1. Record: Document (electronic or print), product or sample statement, which will confirm that a procedure (or part of the procedure) has been carried out.
4.2. Controlled Record: is a record that requires be keeping and maintaining under safeguard for future references
4.3. QPM: Quality and Production Manager
5. Responsibility and Authority
5.1. QPM is responsible for identifying, collecting, filing, storing, discharging and reviewing records.

## 6. Activities

### 6.1. Identify Records

6.1.1. QPM will identify the records to be controlled, as indicated by the administrative, operational and support procedures of the seed company and will be included in the Master List of Records.
6.2. Control Records
6.2.1. QPM will collect, file and keep the records.
6.2.2. QPM will control the access to the records.

### 6.3. Dispose Records

6.3.1. QPM will periodically evaluate the Master List of Records and will dispose of obsolete and unnecessary records.

### 6.4. Review Records

6.4.1. QPM will prepare a record review schedule with the purpose of verifying if the records are created and maintained in an adequate manner.

## 7. Records

7.1. Master List of Records
8. Flowchart and Annexes
8.1. Flowchart
8.2. Annex A: Master List of Records


RECORD CONTROL PROCEDURE FLOWCHART


## ANNEX A

## FORMAT: MASTER LIST OF RECORDS

| RECORD TITLE | CODE NUMBER | DATE OF DISPOSAL | DISPOSAL AUTHORIZED BY | DISPOSAL MADE BY | PERIOD OF RETENTION | METHOD OF DISPOSAL | COMMENTS |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
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