

PROCEDURES MANUAL FOR PHYTOSANITARY ACCREDITATION FOR SEED EXPORT



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1- Preface and acknowledgements:

The Seed Science Center within its International Program has led different seed policy and regulations harmonization projects to enhance seed trade within different regions around the world, i.e., South America, Central America, East Central Africa, and Asia Pacific Region. Using process management, ISU has prepared government procedural blueprints for accreditation of seed companies for seed certification that are currently being implemented with local adaptation in many developing countries.

Preparation of this phytosanitary accreditation procedures manual for seed was initiated in late 2004, with the financial assistance of USDA-Foreign Agricultural Service, as part of a grant for the harmonization of phytosanitary regulations for selected countries in the Asia-Pacific region. In addition to USDA-FAS, the other lead organizations in the grant are the Asia Pacific Seed Trade Association (APSA) and the American Seed Trade Association (ASTA). These organizations all contributed in many ways to make this manual possible and our gratitude is extended to them.

Our gratitude is also expressed to the National Seed Health System of USDA/APHIS who gave their permission to utilize several of the NSHS formats in this manual. A special thanks to Ms. Lisa Shephard, Coordinator of the Seed Health Testing Laboratory of the Seed Science Center, ISU, for her assistance in the review of the draft manual. We also thank Melissa Swanson for her contribution.

A special recognition to Dr. John Stevens, Phytosanitary Issues Manager, Pioneer Biotech Affairs & Business Support Dupont Agriculture & Nutrition, for his valuable contribution to the improvement to the manual.

The editing of this manual by Suzanne Schuknecht, Program Assistant Department of Economics ISU, is much appreciated.

2- Introduction:

The Seed Science Center has developed the present Procedures Manual for Phytosanitary Accreditation for Seed Export. This manual has been developed for the National Plant Protection Organizations to enhance their ability to protect plant health resources and facilitate seed trade.

This proposed manual describes the accreditation system for seed export, which means the official recognition by the NPPO to accredited entities to perform specific functions or provide specific services. Accredited entities are any public or private organization or individual that meets the requirements established by NPPO in the accreditation system.

This manual recommends a process management system that can be used as a tool for identifying the critical areas that must be defined, controlled, and maintained during the core process of phytosanitary accreditation for seed export. It is intended as a technical tool for regulatory officials and applicants as a guide and reference source.

This manual has been developed using Process Management as a tool utilized for the control processes, procedures, and activities to streamline operations and achieve proper balance of control processes and ability to perform work. It is a blueprint for the establishment of an ISO-like phytosanitary accreditation system and includes procedures and activities that define the “how”, “what”, “when”, and “where” and describe the sequence that must be followed. The activities are directly linked with the flowcharts that provide a visual representation of each procedure.

The International Plant Protection Convention, IPPC, is an international treaty that is designed to prevent the spread and introduction of pests of plants and plant products throughout the world. It also promotes the establishment of appropriate measures to control plant pests. Under the IPPC, a series of international standards for phytosanitary measures (ISPMs) have been developed, such as Export Certification System ISPM 7. This standard describes the components of the national system for the issuance of phytosanitary certificates. It has also established that non-government personnel may be accredited by the NPPO to carry out specified certification functions. So, NPPO may establish a national accreditation system based on the ISPM 7.

This proposed manual for phytosanitary accreditation is based on the review of IPPC/ ISPM, national and regional systems, such as, the National Seed Health System of the Animal and Plant Health Inspection Service USDA-APHIS CFR 7, Parts 300 and 353 from the United States, the Plant Export Accreditation Requirements MAF Plant Biosecurity from New Zealand, and the North American Plant Protection Organization NAPPO Regional Standards For Phytosanitary Measures.

This phytosanitary accreditation manual describes the procedures of how entities and individuals can be accredited to perform phytosanitary field inspections, seed sampling, seed health testing, and visual inspection of seed shipments.

This manual includes 6 operational procedures:

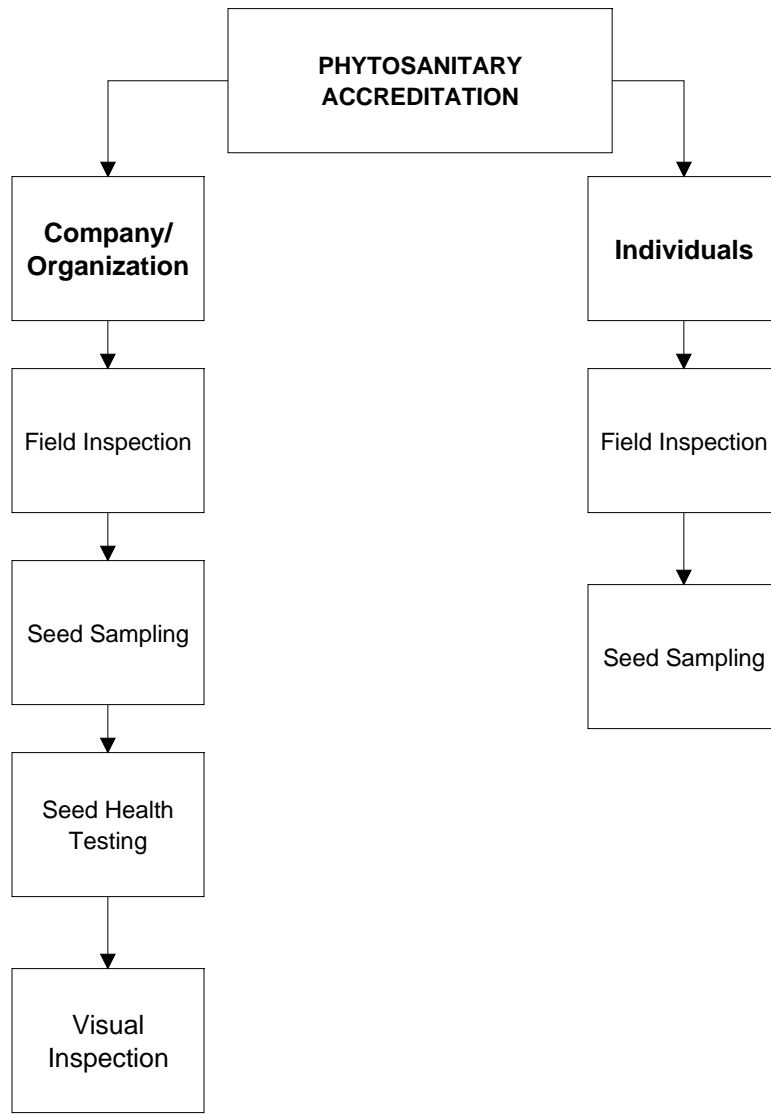
- ✓ Application for Phytosanitary Accreditation
- ✓ Technical Evaluation
- ✓ Initial/ Periodic Audit/Examination
- ✓ Monitoring
- ✓ Appeal
- ✓ Confidential Information

And 3 support procedures:

- ✓ Training
- ✓ Record Control
- ✓ Document Control

In summary the phytosanitary accreditation for seed export should be applied by a company or organization and by individuals for:

- Phytosanitary Field Inspection
- Seed Sampling
- Seed Health Testing
- Visual Inspection of Seed Shipments



3- APPLICATION FOR PHYTOSANITARY ACCREDITATION PROCEDURE

NPPO/ACCREDITATION UNIT

Authorization Date

Effective Date

Created by

Approved by

1. Purpose:

1.1 The objective of this procedure is to define the sequence of events, interfaces and responsibilities involved in the process of applying for phytosanitary accreditation for phytosanitary field inspection and/or sampling and/or laboratory seed health testing and/or visual inspection.

2. Scope:

2.1 From submission of the application for phytosanitary accreditation to the completed review of the application.

3. References:

- 3.1 Phytosanitary Seed Export Regulation.
- 3.2 National Standards for Accreditation.
- 3.3 Criteria for Phytosanitary Accreditation for Entities.
- 3.4 Criteria for Phytosanitary Accreditation for Individual.
- 3.5 Criteria for Seed Health Testing Accreditation.
- 3.6 National Seed Health Testing Methods.
- 3.7 ISTA and ISHI seed health testing methods.
- 3.8 Rules and methods for Seed Sampling (ISTA/ AOSA).
- 3.9 International Standards for Phytosanitary Measures Guidelines for Phytosanitary Certificates, ISPM #12 FAO, 2001.
- 3.10 National Seed Health System USDA/APHIS CFR 7, Part 300 and Part 353
- 3.11 International Standard Organization, ISO 9000/2001.

4. Definitions:

- 4.1 NPPO: National Plant Protection Organization, government agency responsible for Phytosanitary Seed Export.
- 4.2 A.U.: Accreditation Unit, officially responsible for conducting the phytosanitary accreditation.
- 4.3 AE: Applicant Entity/ individual, private or public company or organization as deemed eligible for Phytosanitary accreditation.
- 4.4 AP: Applicant for accreditation entity/individual that apply for the phytosanitary accreditation.
- 4.5 CBI: Confidential Information includes trade secrets, commercial or financial information that must be protected. Includes any information that the entity can claim (within reason) as CBI or Confidential Business Information.)
- 4.6 Phytosanitary Field Inspection: includes inspections of greenhouses or growth chambers or field seed production for disease freedom following the regulations established by NPPO.
- 4.7 Seed Sampling: sampling of seeds following standardized methods approved by NPPO.
- 4.8 Visual Inspection: visual verification for insects, weed seeds, soil, and other contaminants of the seed shipment at the exporter facility. Visual inspection includes other activities at the time of phytosanitary certification, including the above as well as, but not limited to' verifying 'physical data stated on the certificate: i.e. seed species, treatment, number of units, weight...etc.

- 4.9 Seed Health Testing: laboratory based program to test seed for plant pests using standardized methods approved by NPPO.
- 4.10 Quality Manual: document written by the applicant, in which their quality system is described.
- 4.11 ISTA: International Seed Testing Association
- 4.12 ISHI: International Seed Health Initiative
- 4.13 APHIS: Animal and Plant Health Inspection Service.

5. Responsibility and Authority:

- 5.1 The NPPO is responsible for establishing the criteria for accreditation of entities, individual and laboratory (Annexes A, B, and C).
- 5.2 The _____ of NPPO is responsible for receiving and registering the applications.
- 5.3 The _____ of NPPO is responsible for reviewing the applications for completeness and make a preliminary report.
- 5.4 The _____ of NPPO is responsible for notifying to applicant requesting more information.
- 5.5 The _____ of NPPO is responsible for sending the completed application to the Accreditation Unit.

6. Activities:

- 6.1 Receive application.
 - 6.1.1 The _____ of NPPO will receive the application (Annex D, D1, D2, D3, and D4) and record the date of entry. (Annex E)
 - 6.1.2 If the phytosanitary accreditation application contains Confidential Information (CBI) continue with the procedure of handling the CBI.
 - 6.1.3 If the phytosanitary accreditation application is a renewal, continue with 6.2.
 - 6.1.4 If the phytosanitary accreditation application is new continue with 6.3.
- 6.2 Use previously assigned number.
 - 6.2.1 The _____ of NPPO will use assigned number for those phytosanitary accreditation applications that have been approved previously.
- 6.3 Register and assign number.
 - 6.3.1 The _____ of NPPO will register and assign an identification number to the new phytosanitary accreditation applications in a maximum of _____ working days.
- 6.4 Review for completeness/ scrutinization.
 - 6.4.1 The _____ of NPPO will evaluate the completeness of the application following the specific phytosanitary field inspection, sampling, laboratory seed health testing and/or visual inspection criteria established in Annexes A, B, and C in a maximum of _____ working days of receiving the application.
 - 6.4.2 The _____ of NPPO will provide a preliminary report of the revision. (Annex F)
 - 6.4.2.1 If the phytosanitary accreditation application is not completed continue with 6.5.

- 6.4.2.2 If the application is completed and included the fee payment continue with 6.6.
- 6.5 Notify applicant.
 - 6.5.1 The _____ of NPPO will notify the applicants of missing/deficient information through a memorandum (Annex G) in a maximum of _____ working days.
 - 6.5.2 The applicant must provide the information requested in the period of time established in Annex G.
- 6.6 Send application to A.U.
 - 6.6.1 The _____ of NPPO will send the phytosanitary accreditation application to the A.U. for technical evaluation. (Annex H)

7. Records:

- 7.1 Record of application and registration received.
- 7.2 Record of preliminary revision reports.
- 7.3 Record of Memo to applicant for additional information.
- 7.4 Record of Memo of notification to A.U.

8. Flowchart and Annexes:

- 8.1 Flowchart.
- 8.2 Annex A: Criteria for Phytosanitary Accreditation for Entities.
- 8.3 Annex B: Criteria for Phytosanitary Accreditation for individuals.
- 8.4 Annex C: Criteria for Seed Health Testing Accreditation.
- 8.5 Annex D: Phytosanitary Accreditation Application Format.
- 8.6 Annex D1: Request for Crop Inspection Accreditation.
- 8.7 Annex D2: Request for Phytosanitary Seed Sampling.
- 8.8 Annex D3: Request for Laboratory Seed Health Testing Accreditation.
- 8.9 Annex D4: Request for Visual Inspection Accreditation.
- 8.10 Annex E: Format of Record of Application and Registration for Phytosanitary Accreditation Received.
- 8.11 Annex F: Format of Preliminary Revision Report.
- 8.12 Annex G: Format for Memo Requesting Additional Information.
- 8.13 Annex H: Format of Memo of A.U. Notification.
- 8.14 Annex I: Suggested Phytosanitary Inspection Procedures.

ANNEX A

CRITERIA FOR PHYTOSANITARY ACCREDITATION FOR ENTITIES

1. Quality Management System

The accredited entity shall establish, document, implement, and maintain a quality management system which ensures that products conform to the requirements of National Accreditation Standards. The AE must continually improve the effectiveness of the quality system.

The AE should have a documented quality system that describes its regulations, organization, working procedures, and standards. The AE shall establish and maintain a quality manual that includes an organization chart, the scope of the quality system, documented procedures, activities, references, and a description of the interaction between the procedures.

The AE should have procedures to control all documents and data related to quality system, either internal or external. The AE should develop and maintain documented procedures for inspection, sampling and/or testing activities in order to verify the specific requirements for the product are met.

These documents should be: 1) approved and reviewed by authorized personnel, 2) identified in a way that assures their validity, 3) included in the list of references to indicate the latest version is used and who has copies, 4) subject to control modification, 5) replaced when needed, 6) copied and distributed in a controlled manner, and 7) had copies of the phytosanitary regulations and accreditation standards.

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality system.

The required activities for phytosanitary field inspection, visual inspection, sampling and testing, and the way to record shall be described in the quality plan.

Seed samples must be inspected to ensure the requirements for testing are met. The seed testing process must be inspected and tested to ensure that the test is being properly carried out. Field/greenhouse or growth chamber must be inspected to ensure that their conditions are appropriate for the inspection requirements.

Visual inspections of seed shipments at the exporter's facility for insects, weed seeds, soil and other contaminants following the standards.

2. Management Responsibility

The accredited entity (AE) shall designate a representative of the quality system.

The AE shall assure that the regulations are understood and implemented by the entity personnel involved in the accredited process (phytosanitary field inspection, sampling, laboratory seed health testing, and/or visual inspection).

The AE must define and establish the quality policy ensuring that it is appropriate to the purpose of the entity and providing a framework to establish and review the quality objectives.

Top management must ensure that Quality Management System responsibilities and authorities are defined and communicated within the organization.

Top management is responsible for establishing, implementing, maintaining, and improving the quality system and reviewing its effectiveness. Management commitment is demonstrated by communicating to the organization the importance of meeting customer and regulatory requirements.

Top management should ensure the availability of resources, training and capacity building and create and maintain the internal environment to ensure that personnel can become fully involved in achieving the organization quality objectives.

Top management must ensure that customer requirements are determined and met with the main focus of enhancing customer satisfaction.

3. Resource Management

The AE must determine and provide the resources needed to implement, maintain, and improve the quality system.

The AE should develop the quality system involving all the personnel through their directly participation to increase awareness and motivation. The quality system must include the general policy concerning internal and external training, criteria and performance appraisals of the personnel.

Personnel in charge of field inspection, sampling, and seed health testing should be trained. The AE shall establish and maintain documented procedures for identifying training needs and provide a training program of all personnel that covers technical aspects of growing area inspection, sampling, laboratory seed health testing, and visual inspection. Appropriate records of training shall be maintained.

The AE must determine, provide and maintain the infrastructure needed to achieve conformity to the product requirements as well as the appropriate work environment.

4. Product Realization

The AE must identify and define procedures needed for the quality system, their sequences and interaction to obtain/meet a desired product/result.

The AE must comply with the appropriate standards, such as seed health testing methods, phytosanitary field inspection practices, sampling, and visual inspection methodologies and document each process.

The AE should control the processes through developing and maintaining the Quality Manual where standards, seed testing methods, work instructions, and other references come together resulting in quality records and data.

The AE shall establish and maintain documented procedures for contract review. The contracts in question are being those with its customers specifying the requirements of the service or product being supplied and whether the supplier has the capability of meeting those requirements.

The AE shall establish and maintain documented procedures to ensure that purchased products conform to specific requirements. This control is required to assure that substitutions, especially of laboratory supplies, meet the same standard of quality (performance) as those products specified in laboratory procedures/ methodologies.

The AE should establish and document procedures to assure that the seed samples are maintained in good conditions; to control and record seed movements and maintain data reports.

The AE should have a system to assure all seed lots, samples, and seed testing are identified.

The AE should have a system for controlling the product through the entire process of growing area inspection, sampling, laboratory seed health testing and/or visual inspection. The system for tracing the product must be documented and maintained, such as records of all field activities, results of each sampling and inspections, conformities or non-conformities of the product with the standards.

5. Measurement, Analysis and Improvement

The AE must plan and implement the monitoring measurement, analysis and improvement procedure to demonstrate conformity of the product and conformity and improvement of the quality system.

The AE shall establish and maintain documented procedures for planning internal audit program to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system. The audits should be programmed to function at critical moments of each activity and carried out by person's independent to those tasks. The results of these audits must be recorded and the corrective actions should be implemented.

The AE should establish and maintain documented procedures to detect problems in the products and processes; keep records of the problems; investigate their cause; implement effective solutions; and keep records of actions adopted to prevent reiteration of the problem. The fields, samples and tests status must be identified by suitable means to ensure that only those products, which have got the standards, are dispatched or used.

The AE shall maintain an identification record system that allows a person to know the current status of the sample, field and testing.

ANNEX B **CRITERIA FOR PHYTOSANITARY ACCREDITATION FOR** **INDIVIDUALS**

The individual should demonstrate commitment with quality service and meeting requirements of phytosanitary seed export regulations. At the same time, he/she must have financial resources and materials needed to conduct the crop inspection in a field, greenhouse, or grow-chamber and to take the samples.

The individual should assure the ability to carry out the inspection services. The accredited individual should have current versions of phytosanitary seed export regulations and inspection manuals.

The individual should have knowledge about phytosanitary seed export regulations, and has to attend to technical workshop training and pass a theoretical-practical exam conducted by the Accreditation Unit of NPPO.

The individual should follow the inspection procedures officially approved that contain minimum requirements:

- 1.1 Equipment Requirements (field maps, 10x hand lens, pocket knife/scissors, tape measure, sampling bags, labels, ice chest, hand counter, diagnosis illustrations, report forms)
- 1.2 Field Inspection Strategy:
 - Field overview: verification that the field is correct by comparison between the map and the observed field and identification of special areas or microclimates.
 - Establish the seed field inspection pattern: the pattern should ensure that all parts of the field are adequately and proportionately represented in the plants inspected. (Stagger “X” pattern, equidistant passes pattern, customized field inspection pattern).
 - Disease Diagnosis in the Field: presence or absence of diseases is first determined by visual examination; inspections should be conducted at crop growth stage that allow evidence of symptoms; an appropriate number of plant samples representative of diseases in the field should be taken for laboratory confirmation of visual diagnosis as necessary; all samples should be correctly labeled indicating date, time, locations, crop and plant part.
- 1.3 Disease Diagnosis in the Laboratory: samples should be processed in a laboratory facility with demonstrated proficiency in diagnosing plant diseases.
- 1.4 Reports: inspection reports should be made on a standard form as indicated in Annex I.

The inspector/ individual should have Phytosanitary Growing Season Inspection Report Formats and maintain a file of field inspection reports.

The individual accredited should keep records of complaints related to phytosanitary inspection, and sampling, investigate the reasons and take the corrective actions. The individual accredited shall establish and maintain documented procedures for performing, verifying and reporting that the activities meet the specific requirements.

ANNEX C
CRITERIA FOR PHYTOSANITARY ACCREDITATION FOR SEED
HEALTH TESTING LABORATORY

1. Quality Management System

The laboratory shall establish, document, implement and maintain a quality management system which ensures that products conform to the requirements of National Accreditation Standards. The lab must continually improve the effectiveness of the quality system.

The lab must establish and maintain a quality manual that includes an organization chart listing the personnel and their positions, scope of the quality system, references, documents, procedures and activities with a description of the interaction between them.

The laboratory should have a documented quality system that describes its policy, organization, working procedures and seed health standards.

The accredited lab should have procedures to control the documents related to quality system. The accredited laboratory should have current version of the seed health testing methods from ISTA, ISHI and methods approved by NPPO for testing.

The accredited lab shall maintain records of equipment, their calibration and maintenance records, as well as documentation of procedures, reference materials, etc.

2. Management Responsibility

The head of the lab must define and establish the quality policy ensuring that it is appropriate to the purpose of the lab and providing a framework to establish and review the quality objectives. Quality policy must include the commitment to conform to the requirements of the quality system and the continually improvement of its effectiveness.

The head of the lab, technical manager, quality manager, technicians, and analysts must be organized in a manner to assure proficient performance of seed health testing. All the lab staff should demonstrate commitment with quality service and meet requirements for seed health testing.

The head of the lab should ensure the availability of resources, training, and capacity building and create and maintain the internal environment to ensure that personnel can become fully involved in achieving the organization quality objectives.

The head of the lab must ensure that customer requirements are determined and met with the main focus of enhancing customer satisfaction.

3. Resource Management

The accredited laboratory shall provide a work area dedicated to seed health testing with an adequate protection from excessive conditions as well as comply with the national regulation from chemical handling and disposal and environmental guidelines.

Access to the testing area shall be controlled in an appropriate manner.

All equipment required to correctly carry out the appropriate seed health test must be available and they must be properly maintained, repaired, and calibrated routinely.

The laboratory should have documented procedures to control purchases and maintain a record of suppliers. The suppliers should have the capability to meet the requirements specified by the lab.

Laboratory staff should assure the ability to carry out the seed health testing using the appropriate methodologies.

The accredited laboratory staff should have knowledge about seed health testing and has to attend to technical workshop training and has to pass an exam conducted by the Accreditation Unit of NPPO.

4. Product Realization

The laboratory should have documented procedures to control purchases and maintain a record of suppliers. The suppliers should have the capability to meet the requirements specified by the lab.

The lab must have a documented procedure to identify the product (sample, test report) by suitable ways to ensure the tracking of the product. The accredited lab should identify the samples with appropriate coding information to ensure no confusion regarding identity of the sample through the testing process. The samples shall be clearly marked, stored and labeled with information that is pertinent to testing process, such as treatment, sampling date, crop, variety, and lot number.

5. Measurement, Analysis and Improvement

The lab must monitor information relating customer satisfaction as a performance measurement of the quality system.

The lab shall maintain records of equipment, their calibration and maintenance records, as well as documentation of procedures, reference materials, etc.

- Control of Non-Conformities:

The lab should have documented procedures to indicate how the non-conformity seed health testing is controlled and maintain a record of them, their causes and final destination.

- Corrective Actions:

The lab should establish and maintain documented procedures to detect problems in the product and processes, keep records of them, investigate their causes, implement effective solutions in the period of time established, and keep records of actions adopted to prevent the problem.

- Internal Audits:

The lab should have an internal audit program that covers all stages of the seed health testing procedure. The audits should be programmed to function at critical moments of each activity, and carried out by persons independent of those tasks. The results of these audits must be recorded, and the corrective actions should be implemented.

- Proficiency in Seed Health Testing:

The accredited lab shall participate in a referee test program administrated by the A.U. prior to the accreditation and every ____ years. The A.U. of NPPO shall establish the protocol for conducting the referee tests.

ANNEX D

PHYTOSANITARY ACCREDITATION APPLICATION FORMAT

Applicant Information

New

Renewable

Entity/ Individual to be accredited

| |
|-----------------------|
| Legal Name: |
| Address: |
| City: |
| State/province/region |
| Tel/Fax/E-mail |

Contact Person/ Quality System Representative

| |
|---|
| Name: |
| Position: |
| Address: |
| City |
| State/province/region Tel/Fax/ E-mail: |

Type of Entity

| | |
|------------------------|--|
| Seed Company | |
| Independent Individual | |
| University Laboratory | |
| Private Laboratory | |
| Other (Describe) | |

Accreditation Options

| | |
|---------------------------------|--|
| Phytosanitary Field Inspection: | |
| Sampling | |
| Laboratory Seed Health Testing | |
| Visual Inspection | |

Accreditation Fees

| | |
|------------------------------------|----|
| Phytosanitary Field Inspection Fee | \$ |
| Sampling Fee | \$ |
| Laboratory Seed Health Testing Fee | \$ |
| Visual Inspection | \$ |
| Total Accreditation Fee | \$ |

Signature (Entity representative)

| Name | Title/Position | Signature | Date |
|------|----------------|-----------|------|
| | | | |

ANNEX D1

REQUEST FOR PHYTOSANITARY FIELD INSPECTION
ACCREDITATION

Applicant Entity #: _____

Inspector Information

| | | |
|---|-----|-------|
| Name | | |
| Address | | |
| Telephone | Fax | Email |
| Education | | |
| Phytosanitary Field Inspection Background | | |
| Position | | |
| Quality Manual (if applicable) | | |

| Name | Title/Position | Signature | Date |
|------|----------------|-----------|------|
| | | | |

ANNEX D2

**REQUEST FOR PHYTOSANITARY SEED SAMPLING
ACCREDITATION**

Applicant Entity #: _____
Sampling Inspector Information

| | | |
|--|-----|--------|
| Name | | |
| Address | | |
| Telephone | Fax | E mail |
| Education | | |
| Phytosanitary Seed Sampling Background | | |
| Position | | |
| Quality Manual (if applicable) | | |

| Name | Title/Position | Signature | Date |
|------|----------------|-----------|------|
| | | | |

ANNEX D3

**REQUEST FOR LABORATORY SEED HEALTH TESTING
ACCREDITATION**

Accredited Entity #: _____

Laboratory Manager Information

| |
|-----------------|
| Name |
| Address |
| Tel/Fax/ E-mail |
| |

| |
|--|
| Laboratory Information (Facilities, Personnel) |
| |
| Seed crops |
| |
| Methods Type / Process |
| |
| Equipments (description) |
| |
| Quality Manual |
| |

ANNEX D4

REQUEST FOR VISUAL INSPECTION OF SEED ACCREDITATION

Application Entity #: _____

Inspector Information

| | | |
|--|-----|--------|
| Name | | |
| Address | | |
| Telephone | Fax | E mail |
| Education | | |
| Phytosanitary Visual Inspection Background | | |
| Position | | |
| Quality Manual (if applicable) | | |

| Name | Title/Position | Signature | Date |
|------|----------------|-----------|------|
| | | | |

ANNEX E

**FORMAT OF RECORD OF APPLICATION AND REGISTRATION FOR
PHYTOSANITARY ACCREDITATION RECEIVED**

| Application Number Assigned | Date | Applicant Entity/ Individuals | Accreditation Requested | | | | Crops |
|-----------------------------|------|----------------------------------|--------------------------------|-------------------|----------|---------------------|-------|
| | | | Phytosanitary Field Inspection | Visual Inspection | Sampling | Seed Health Testing | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

ANNEX F

FORMAT OF PRELIMINARY REVISION REPORT

| Accreditation Requested | General Application Completed | | Specific Application Completed | | Quality Manual (not required for individuals) | | Payment of Fees | |
|--------------------------------|-------------------------------|----|--------------------------------|----|---|----|-----------------|----|
| | Yes | No | Yes | No | Yes | No | Yes | No |
| Phytosanitary Field Inspection | | | | | | | | |
| Seed Sampling | | | | | | | | |
| Seed Health Testing | | | | | | | | |
| Visual Inspection | | | | | | | | |

ANNEX G

FORMAT FOR MEMO REQUESTING ADDITIONAL INFORMATION

TO: APPLICANT

FROM: NPPO

DATE:

ACCREDITATION APPLICATION #

After the revision of your application #_____ requesting the accreditation for: phytosanitary field inspection , sampling , laboratory seed health testing , visual inspection , we notify you that the following information has to be submitted _____

That information must be submitted in the next _____ working days, so we would be able to continue with the preliminary completeness revision, otherwise we will cancel the application.

NPPO SIGNATURE

ANNEX H

FORMAT OF MEMO OF A.U. NOTIFICATION

TO: A.U.

FROM: DIRECTOR OF NPPO

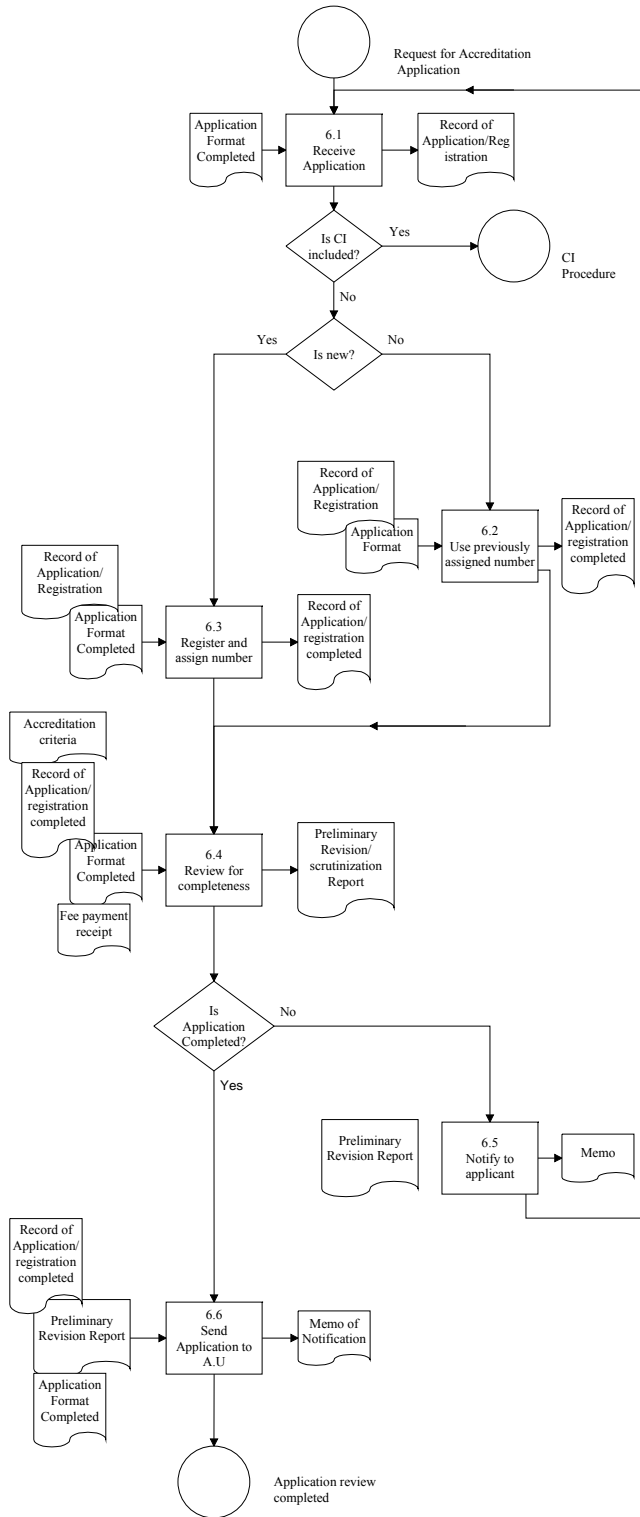
ACCREDITATION APPLICATION #

DATE:

I enclosed the application # _____ requesting accreditation for phytosanitary field inspection ,
sampling , laboratory seed health testing , visual inspection for your technical evaluation.

DIRECTOR OF NPPO SIGNATURE

Application for Phytosanitary Accreditation Procedure Flowchart



ANNEX I
SUGGESTED PHYTOSANITARY FIELD INSPECTION PROCEDURES
EQUIPMENT REQUIREMENTS

1. Field maps
2. 10x hand lens
3. Pocket knife/scissors
4. Tape measure
5. Sampling bags or envelopes
6. Labels
7. Ice chest
8. Hand counter
9. Diagnostic illustrations
10. Report forms

FIELD INSPECTION STRATEGY

Field overview

Find a point near the field that allows the best opportunity to look the field over. This overview enables:

- a. Verification that the field is correct by comparison between the map or information provided and the observed field.
- b. Identification of special areas or microclimates in the field that appears different enough to warrant special attention when inspected. These would include:
 - *Locations in which high moisture levels may be retained such as proximity to:*
 - Rivers and streams
 - Drainage areas
 - Low spots
 - Weedy areas
 - *Areas of the field affected by borders, such as:*
 - Field edges
 - Tree lines in the field
 - Adjacent fields of a similar crop
 - Presence of buildings or bins
 - *Drought stress areas, such as:*
 - High spots
 - Light textured soils
 - Margins or overhead irrigation areas

Establish the seed field inspection pattern

1. The seed field inspection pattern should ensure that all parts of the field are adequately and proportionately represented in the plants inspected within the various usual microclimates of the field.
2. As long as these requirements are met, the pattern of field inspection can vary.
3. Examples of established inspection patterns are as follows. Other formats may, however, be acceptable.

Stagger “X” pattern. (CDFA Phytosanitary Certification Manual, 1985)

This is used for cereal crops and requires examination of plants along one side of the field, then diagonally in a stagger pattern across rows to the far corner, across the far side, and diagonally back to starting corner (Figure 1). Additional examinations may be necessary for field environments not covered by the inspection pattern.

Equidistant passes pattern. (CDFA Phytosanitary Certification Manual, 1985)

This system is used for crops other than cereals. Table 1 lists the minimum number of field passes (Figure 2) in relation to field size to give a minimum of 95% confidence level in detecting an infection level of 0.1%.

Table 1. Minimum field passes per acre.

| Field size (acres) | Minimum # passes |
|---------------------------|-------------------------|
| 0 - 1 | 6 |
| 1 - 5 | 9 |
| 5 - 10 | 11 |
| 10 - 20 | 13 |
| 20 - 50 | 17 |
| 50 - 100 | 20 |
| 100 - 200 | 24 |
| 200 - 500 | 30 |
| 500 - 1000 | 36 |
| 1000 | + 42 |

Figure 1 “X” Field Inspection Pattern

10 feet

10 feet

Start

Finish

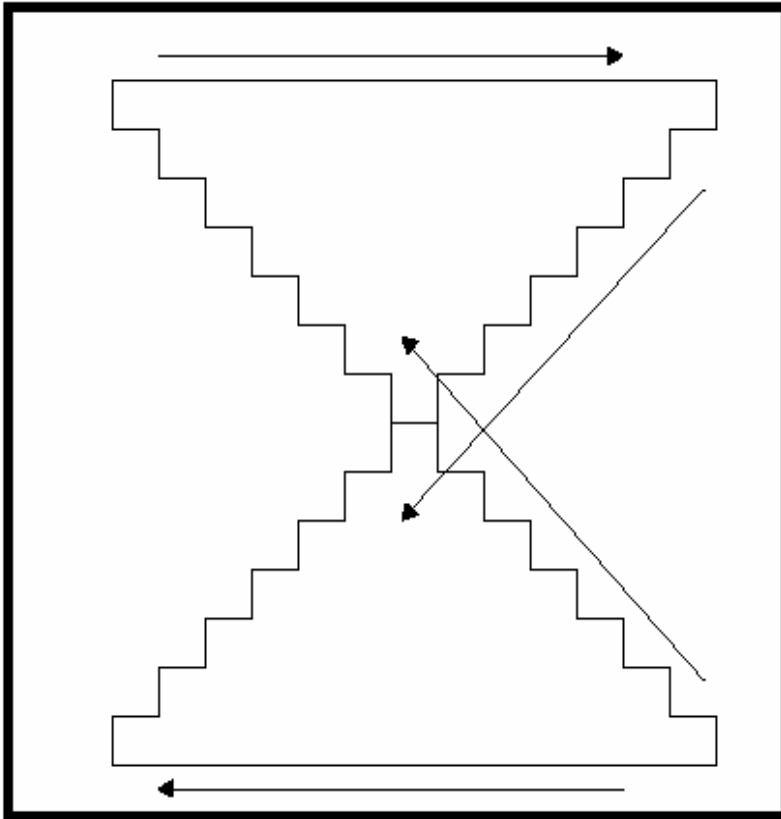


Figure 1 “X” Field Inspection Pattern

Figure 2 - Equidistant Pass Pattern

Customized field inspection pattern.

This system allocates appropriate numbers of plants to be inspected in the various environments in a field. An example is shown in Figure 3.

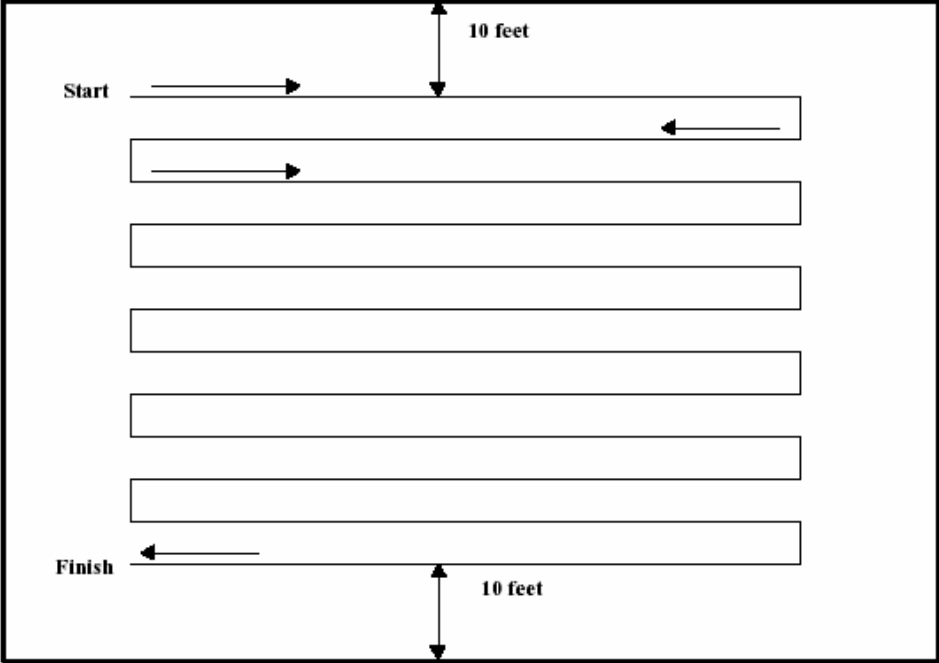
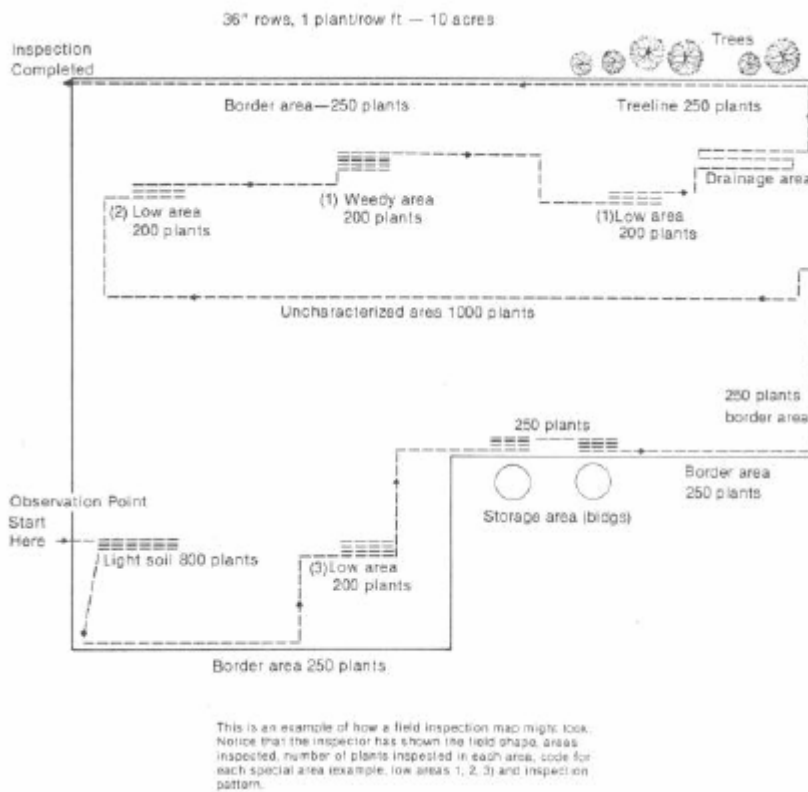


Figure 2 - Equidistant Pass Pattern

Figure 3 - Example of field inspection by customized pattern



Disease Diagnosis in the Field

1. The presence or absence of diseases relevant to the inspection requirements is first determined by visual examination of plants in the field. Descriptions of signs and symptoms are provided in this manual for the individual diseases of the major seed crops. Other established aids to identification may also be used.
2. Inspections have to be made at crop growth stage when signs or symptoms of a disease are evident. Appropriate inspection times for particular pests or diseases are indicated in this manual.
3. An appropriate number of plant samples, representative of diseases in the field, should be taken for laboratory confirmation of the visual diagnosis. More extensive sampling should be carried out when visual symptoms are insufficient to ensure accurate diagnosis. Samples of suspected disease tissue should be kept flat in paper envelopes or towels in a plastic bag in ice chest. All samples should be correctly labeled to indicate date, time, locations, crop, and plant part.

Disease Diagnosis in the Laboratory

1. Samples should be processed systematically in a laboratory facility with demonstrated proficiency in diagnosing plant diseases following the national/ international standards.
2. Information on diagnostic tests for particular diseases is provided in this manual.

Reports

1. Inspection reports should be made on a standard form that is indicated below:

PHYTOSANITARY FIELD INSPECTION REPORT

Applicant Information

| | |
|--------------------------|---------|
| Accredited Entity | |
| Company Name | |
| Company Contact Official | |
| Address | Tel/Fax |
| Contract Grower | Tel/Fax |

Field crop Information

| | | | |
|--|----------------------------|----------------------------|----------------------------|
| Crop | | | |
| Variety | | | |
| Field # | | | |
| Field Size has. | | | |
| Type of Field (increase/production/research) | | | |
| Growth Stage & Date | 1 st Inspection | 2 nd Inspection | 3 rd Inspection |

Inspection Data

| Disease Code | Low, Moderate, High (L, M, H) | Lab Sample Submitted Yes/No | Field Diagnosis Confirmed Yes/No | Additional Pathogens Identified Code | Lab Sample Number |
|--------------|----------------------------------|--------------------------------|-------------------------------------|---|-------------------|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

No Other Diseases Noted

I inspected these fields during active growth and determined the above diseases/pests were found as indicated.

Remarks:

| | | |
|-------------|-----------|------|
| Inspector | ID Number | Date |
| Lab Manager | ID Number | Date |

4- TECHNICAL EVALUATION PROCEDURE

NPPO/ACCREDITATION UNIT

Authorization Date

Effective Date

Created by

Approved by

1. Purpose:

- 1.1 The objective of this procedure is to define the sequence of events, interfaces, and responsibilities involved in the process of technical evaluation for phytosanitary accreditation for phytosanitary field inspection and/or sampling and/or laboratory seed health testing and/or visual inspection applied to entities or individuals.

2. Scope:

- 2.1 From completed revision of the application for phytosanitary accreditation to the approval or not for initial audit.

3. References:

- 3.1 Phytosanitary Seed Export Regulation.
3.2 National Standards for Accreditation.
3.3 Criteria for Phytosanitary Accreditation for Entities.
3.4 Criteria for Phytosanitary Accreditation for individuals.
3.5 Criteria for Seed Health Testing Accreditation.
3.6 National Seed Health Testing Methods.
3.7 ISTA and ISHI seed health testing methods.
3.8 Rules and methods for seed sampling (ISTA/ AOSA).
3.9 National Seed Health System USDA/ APHIS, CFR 7, Part 300 and Part 353.

4. Definitions:

- 4.1 NPPO: National Plant Protection Organization, government agency responsible for Phytosanitary Seed Export.
4.2 A.U.: Accreditation Unit, official responsible for conducting the phytosanitary accreditation.
4.3 A.E.: Accredited Entity, individual, private or public company or organization as deemed eligible for Phytosanitary accreditation.
4.4 AP: Applicant for accreditation entity/individual that apply for the phytosanitary accreditation.
4.5 CBI: Confidential Business Information includes trade secrets, commercial or financial information that must be protected. Includes any information that the entity can claim (within reason) as CBI or Confidential Business Information.)
4.6 Phytosanitary Field Inspection: includes inspections of greenhouses or growth chambers or field seed production for disease freedom following the regulations established by NPPO.
4.7 Seed Sampling: sampling of seeds following standardized methods approved by NPPO.
4.8 Visual Inspection: visual verification for insects, weed seeds, soil, and other contaminants of the seed shipment at the exporter facility. Visual inspection includes other activities at the time of phytosanitary certification, including the above as well as, but not limited to' verifying 'physical data stated on the certificate: i.e. seed species, treatment, number of units, weights, etc.
4.9 Seed Health Testing: laboratory based program to test seed for plant pests using standardized methods approved by NPPO.

- 4.10 Quality Manual: document written by the applicant, in which their quality system is described.
- 4.11 Initial Audit: “in situ” evaluation of the applicant for accreditation to verify if the accreditation criteria have been implemented.
- 4.12 ISTA: International Seed Testing Association
- 4.13 ISHI: International Seed Health Initiative
- 4.14 AOSA: Association of Official Seed Analysts
- 4.15 APHIS: Animal and Plant Health Inspection Service

5 Responsibility and Authority:

- 5.1 The A.U. of NPPO is responsible for receiving the applications and records the reception.
- 5.2 The A.U. of NPPO is responsible for evaluating technically each accreditation application and requesting corrections to the applicant.
- 5.3 The A.U. of NPPO is responsible for notifying the applicant of the rejection or approval for the initial audit.

6 Activities:

- 6.1 Receive application
 - 6.1.1 The A.U. of NPPO will receive the application and record its reception. (Annex A)
 - 6.1.2 If the accreditation is requested by a company, continue with 6.2.
 - 6.1.3 If the accreditation is requested by an individual for crop inspection, continue with 6.6.
- 6.2 Evaluate accreditation for phytosanitary field inspection.
 - 6.2.1 The A.U. of NPPO will conduct the evaluation of the application and the Quality Manual in a maximum of ____ working days and based upon the crop inspection criteria.
 - 6.2.2 The A.U. of NPPO will complete an evaluation report (Annex B), recording dates of reception, revision and results.
 - 6.2.2.1 If the Quality Manual does not meet the requirements but the Manual can be corrected, continue in 6.8.
 - 6.2.2.2 If the application is not approved, continue with 6.9.
 - 6.2.2.3 If the application is approved, continue with 6.10.
- 6.3 Evaluate accreditation for seed sampling
 - 6.3.1 The A.U. of NPPO will conduct the evaluation of the application and the Quality Manual in a maximum of ____ working days, based on seed sampling accreditation criteria.
 - 6.3.2 The A.U. of NPPO will complete an evaluation report (Annex B) recording dates of reception, revision and results.
 - 6.3.2.1 If the Quality Manual does not meet the requirements but the Manual can be corrected, continue in 6.8.
 - 6.3.2.2 If the application is not approved, continue with 6.9.
 - 6.3.2.3 If the application is approved, continue with 6.10.

- 6.4 Evaluate accreditation for visual inspection
 - 6.4.1 The A.U. of NPPO will conduct the evaluation of the application and the documents in a maximum of ___ working days, based on the requirements for the visual inspection accreditation.
 - 6.4.2 The A.U. of NPPO will complete an evaluation report (Annex B) recording dates of reception, revision and results.
 - 6.4.2.1 If some of the documents can be corrected, continue with 6.8.
 - 6.4.2.2 If the application is not approved, continue with 6.9.
 - 6.4.2.3 If the application is approved, continue with 6.10.
- 6.5 Evaluate accreditation for laboratory seed health testing
 - 6.5.1 The A.U. of NPPO will conduct the evaluation of the application and the Quality Manual in a maximum of _____ working days, based on the health testing criteria.
 - 6.5.2 The A.U. of NPPO will complete an evaluation report (Annex B) recording dates of reception, revision and results.
 - 6.5.2.1 If the Quality Manual does not meet the requirements, but the Manual can be corrected, continue in 6.8.
 - 6.5.2.2 If the application is not approved, continue with 6.9.
 - 6.5.2.3 If the application is approved, continue with 6.10.
- 6.6 Evaluate individual for phytosanitary field inspection.
 - 6.6.1 The A.U. of NPPO will evaluate the individual's credentials and documentation, based on the phytosanitary field inspection criteria for individuals.
 - 6.6.2 The A.U. will complete an evaluation report (Annex C)
 - 6.6.2.1 If the requirements are not satisfied, but corrections are possible continue with 6.8.
 - 6.6.2.2 If the technical evaluation is not satisfactory continue with 6.9.
 - 6.6.2.3 If the technical evaluation is satisfactory continue with 6.10.
- 6.7 Evaluate individual for seed sampling.
 - 6.7.1 The A.U. of NPPO will evaluate the individual's credentials and documentation, based on the seed sampling criteria for individuals.
 - 6.7.2 The A.U. will complete an evaluation report. (Annex C)
 - 6.7.2.1 If the requirements are not satisfied, but corrections are possible continue with 6.8.
 - 6.7.2.2 If the technical evaluation is not satisfactory continue with 6.9.
 - 6.7.2.3 If the technical evaluation is satisfactory continue with 6.10.
- 6.8 Request corrections
 - 6.8.1 The A.U. of NPPO will request corrections based on the evaluation reports in a maximum of _____ working days. (Annex D)
- 6.9 Notify rejection.
 - 6.9.1 The A.U. of NPPO will send a written notification of disapproval. (Annex E)
 - 6.9.2 The applicant may appeal the decision following the appeal procedure.
- 6.10 Notify for initial audit.
 - 6.10.1 The A.U. of NPPO will notify the applicant the approval for an initial audit in a maximum of _____ working days. (Annex F)

7 Records:

- 7.1 Record of application received.
- 7.2 Record of evaluation report for crop inspection accreditation for entity/individual.
- 7.3 Record of evaluation report for sampling accreditation for entity/individual.
- 7.4 Record of Evaluation report for visual inspection accreditation.
- 7.5 Record of evaluation report for seed health testing accreditation for entity.
- 7.6 Record of notification of corrections.
- 7.7 Record of notification of application not-approved.
- 7.8 Record of notification of application approved.

8 Flowchart and Annexes:

- 8.1 Flowchart.
- 8.2 Annex A: Format of Record of Application Reception.
- 8.3 Annex B: Technical Evaluation Record.
- 8.4 Annex C: Report of Technical Evaluation for Entities.
- 8.5 Annex D: Annex E: Report of Technical Evaluation for Seed Health Testing.
- 8.6 Annex E: Report of Technical Evaluation for Individuals.
- 8.7 Annex F: Format Memo of Notification for Corrections.
- 8.8 Annex G: Format Memo of Non-approval Notification.
- 8.9 Annex H: Format Memo of Approval Notification.

ANNEX A

FORMAT OF RECORD OF APPLICATION RECEPTION

| Date | Application # | Accredited Entity/ Individual | Accreditation for: | | | |
|------|---------------|-------------------------------------|--------------------------------------|----------|----------------------|-----------------------------------|
| | | | Phytosanitary Field Inspection | Sampling | Visual inspection | Laboratory seed health testing |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

ANNEX B

TECHNICAL EVALUATION RECORD

Applicant # _____

Accreditation for phytosanitary field inspection, seed sampling, laboratory seed health testing visual inspection

| Manual received date | Version and date of Manual | Code of Review Status | Review date | Receive by | Review by | Accepted | | Rejected | | Notification date |
|----------------------|----------------------------|-----------------------|-------------|------------|-----------|----------|----|----------|----|-------------------|
| | | | | | | Date | By | Date | By | |
| | | | | | | | | | | |
| | | | | | | | | | | |
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| | | | | | | | | | | |

Indicate the code of review status: 1st Rev. Second Review; 2nd Rev. First Review

*** Use one of this report for each accreditation: phytosanitary field inspection, sampling, laboratory seed health testing, visual inspection.**

ANNEX C
REPORT OF TECHNICAL EVALUATION FOR ENTITIES

| | | | |
|---|-----|----|--------------|
| Application # _____ | | | |
| Name of Entity _____ | | | |
| | Yes | No | Observations |
| Quality Management System | | | |
| Quality Manual | | | |
| Documents and Records | | | |
| Quality Policy and Quality Objectives | | | |
| Resources, Personnel, Training Program | | | |
| Infrastructure, Work Environment | | | |
| Identification and traceability of the product | | | |
| Procedures | | | |
| Control of inspection, measuring and equipment | | | |
| Internal Quality Audit | | | |
| Control of non-conformities | | | |
| Corrective actions | | | |
| Handling, storage, packaging, preservation and delivery | | | |
| Customer complaints/satisfaction | | | |
| Other comments | | | |

ANNEX D
REPORT OF TECHNICAL EVALUATION FOR
LABORATORY SEED HEALTH TESTING

| | | | |
|--|-----|----|--------------|
| Application # _____ | | | |
| Name of Laboratory: _____ | | | |
| | Yes | No | Observations |
| Quality Management System | | | |
| Documents and Records control | | | |
| Management Responsibility Quality Policy and objectives | | | |
| Personnel, competence, training plan | | | |
| Resources, facility and environment | | | |
| Equipments and machinery | | | |
| Samples and documentation | | | |
| Quality Manual | | | |
| Monitoring and measurements | | | |
| Internal Audit | | | |
| Control of non-conformities | | | |
| Corrective Actions | | | |
| Proficiency in Seed health testing | | | |
| Other comments | | | |

ANNEX E
REPORT OF TECHNICAL EVALUATION FOR
INDIVIDUALS

| | | | |
|---|-----|----|--------------|
| Application # _____ Name of individual: _____ | | | |
| Accreditation for <input type="checkbox"/> phytosanitary field inspection, <input type="checkbox"/> seed sampling | | | |
| | Yes | No | Observations |
| Demonstrate credentials and responsibility | | | |
| Documents and record control | | | |
| Identifying / interpreting the requirements of standards | | | |
| Training | | | |
| Adequate records and reports | | | |
| Availability of equipment | | | |
| Control of Quality Records | | | |
| Other comments | | | |

ANNEX F

FORMAT OF MEMO NOTIFICATION FOR CORRECTIONS

TO: APPLICANT

FROM: A.U.

DATE:

ACCREDITATION APPLICATION # _____

After the technical evaluation of your accreditation application for phytosanitary field inspection, seed sampling, laboratory seed health testing, visual inspection, please see the attached report.

The corrections required must be submitted in the next _____ working days, otherwise the application for accreditation will be denied.

A.U. SIGNATURE

ANNEX G

MEMO OF A.U. NON-APPROVAL NOTIFICATION FORMAT

TO: APPLICANT

FROM: A.U.

DATE:

ACCREDITATION APPLICATION #

I inform you that your application for accreditation of phytosanitary field inspection, seed sampling, laboratory seed health testing, visual inspection has not been approved. Please see attached report. You may appeal this decision in accordance with the regulation and appeal procedure.

A.U. SIGNATURE

ANNEX H

MEMO OF A.U. APPROVAL NOTIFICATION FORMAT

TO: APPLICANT

FROM: A.U.

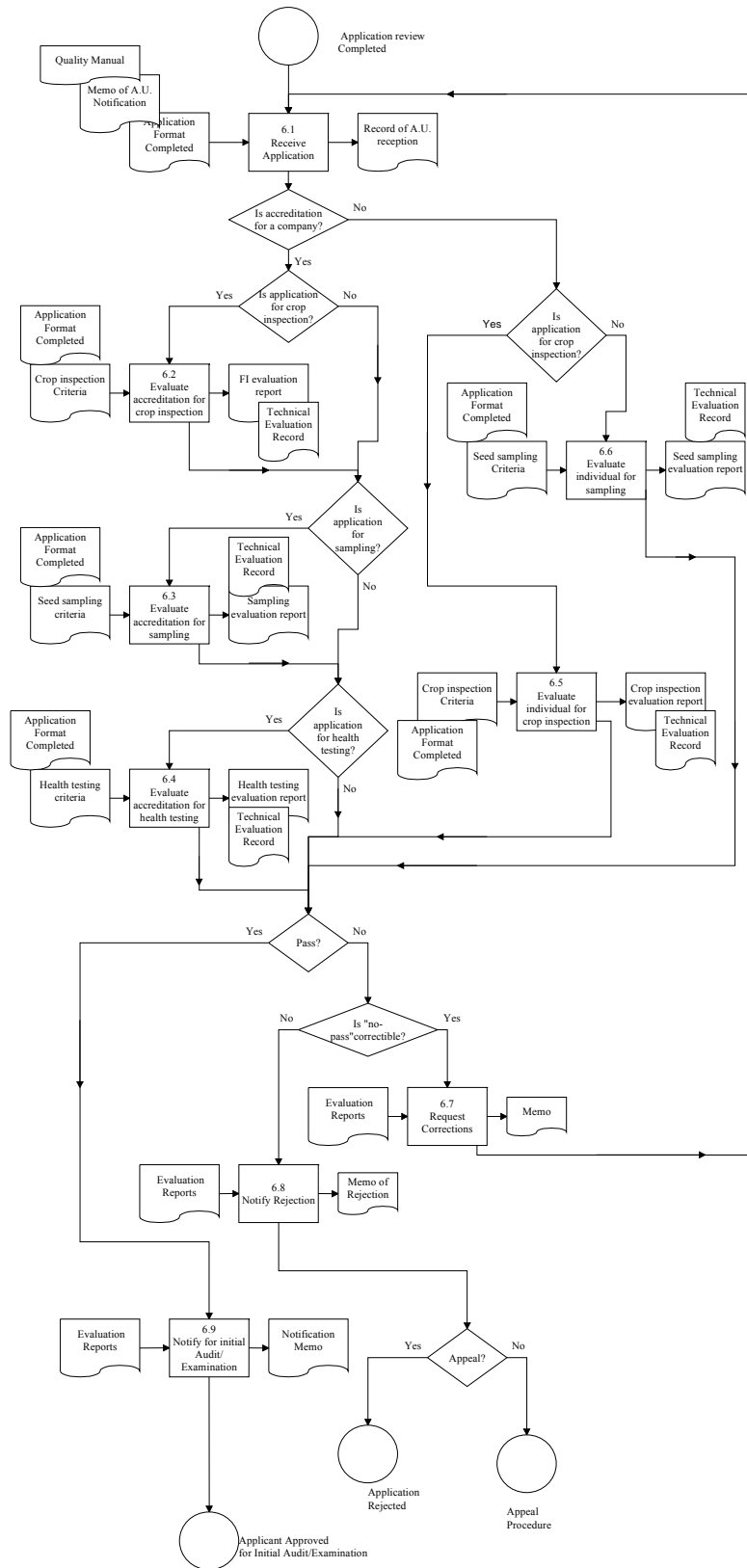
DATE:

ACCREDITATION APPLICATION #

I am informing you that your application for accreditation of phytosanitary field inspection, seed sampling, laboratory seed health testing, visual inspection, has been approved for the initial audit. Please see attached report.

A.U. SIGNATURE

Technical Evaluation Procedure Flowchart



5- INITIAL/ PERIODIC AUDIT/EXAMINATION FOR ACCREDITATION PROCEDURE

NPPO/ACCREDITATION UNIT

| | |
|---------------------------|----------------------|
| Authorization Date | <input type="text"/> |
| Effective Date | <input type="text"/> |
| Created by | <input type="text"/> |
| Approved by | <input type="text"/> |

1. **Purpose:**
 - 1.1 The objective of this procedure is to define the sequence of events, interfaces, and responsibilities involved in the process of initial audit/periodic/examination for entities and individuals to perform phytosanitary field inspection, and/or seed sampling, and/or laboratory seed health testing tasks and/or visual inspection.

2. **Scope:**
 - 2.1 From identification of applicant for initial/ periodic audit/examination to approved/ renewed or canceled/rejected for accreditation.

3. **References:**
 - 3.1 Phytosanitary Seed Export Regulation.
 - 3.2 Criteria for Phytosanitary Accreditation for Entities.
 - 3.3 Criteria for Phytosanitary Accreditation for individuals.
 - 3.4 Criteria for Seed Health Testing Accreditation.
 - 3.5 Phytosanitary inspection, Sampling and Laboratory Seed Health Testing Reports.
 - 3.6 Audit Documents.
 - 3.7 ISO 9000/2001.

4. **Definitions:**
 - 4.1 NPPO: National Plant Protection Organization, government agency responsible for Phytosanitary Seed Export.
 - 4.2 A.U.: Accreditation Unit, official responsible for conducting the phytosanitary accreditation.
 - 4.3 AP: Applicant for accreditation entity/individual that apply for the phytosanitary accreditation.
 - 4.4 A.E.: Accredited Entity, individual, private or public company or organization as deemed eligible for Phytosanitary accreditation.
 - 4.5 CBI: Confidential Business Information includes trade secrets, commercial or financial information that must be protected. Includes any information that the entity can claim (within reason) as CBI or Confidential Business Information.
 - 4.6 Phytosanitary Field Inspection: includes inspections of greenhouses or growth chambers or field seed production for disease freedom following the regulations established by NPPO.
 - 4.7 Quality Manual: document written by the applicant, in which their quality system is described.
 - 4.8 Visual Inspection: visual verification for insects, weed seeds, soil, and other contaminants of the seed shipment at the exporter facility. Visual inspection includes other activities at the time of phytosanitary certification, including the above as well as, but not limited to' verifying 'physical data stated on the certificate: i.e. seed species, treatment, number of units, weight, etc.

- 4.9 Seed Health Testing: laboratory based program to test seed for plant pathogens using standardized methods established by NPPO.
- 4.10 Non-Conformity: any situation different from standards.
- 4.11 Initial Audit: assessment in situ, of the entities for accreditation to verify if the accreditation criteria have been implemented.
- 4.12 Periodical Audits: assessment in situ, of entities, after accreditation status has been granted to verify the accreditation criteria are being followed.
- 4.13 Examination: evaluation of individuals to verify if the accreditation criteria have been implemented.
- 4.14 C.A.: Corrective Actions, action taken to eliminate the causes of an existing non-conformity, defect or other undesirable situation in order to prevent recurrence.
- 4.15 Audit Team: The person/s with knowledge about audit techniques, accreditation criteria and phytosanitary seed export regulations authorized by the A.U./NPPO to conduct audits/examinations.

5. Responsibility and Authority:

- 5.1 The A.U. of NPPO is responsible for notifying applicant of planned audit/examination.
- 5.2 The A.U. of NPPO is responsible for designating the audit team.
- 5.3 The Audit Team is responsible for preparing and conducting the audits/examination, preparing reports, generating the corrective actions and verifying completed corrective actions.
- 5.4 The A.U. of NPPO is responsible for notifying applicant of approved/renewed/ canceled/ rejected accredited status.

6. Activities:

- 6.1 Contact applicant.
 - 6.1.1 The A.U. of NPPO will contact the applicant to organize an “in situ” evaluation where an operational audit/examination will be conducted.
- 6.2 Prepare Audit/examination.
 - 6.2.1 The A.U. of NPPO will designate the audit team
 - 6.2.2 The A.T. will collect previous information, prepare and send an audit/examination agenda to the applicant (Annex A), in a maximum of ____ working days.
 - 6.2.3 The A.T. will prepare the audit checklist (Annex B, C, D, and E) following the accreditation criteria and phytosanitary seed export regulations.
 - 6.2.4 The A.T. will verify fee payment for accreditation.
- 6.3 Conduct Audit/examination.

- 6.3.1 The leader of A.T. will conduct the opening meeting, review the agenda and explain the methodology to be followed to conduct the audit/examination.
- 6.3.2 The A.T. will utilize the checklist for taking notes on compliance and comments.
- 6.3.3 The leader of A.T. will interview the personnel of the entity or individuals and review records, procedures and documents.
- 6.3.4 The leader of A.T. will meet to prepare the closing meeting in the case of entities.
- 6.3.5 The leader of A.T. will conduct the closing meeting to present the audit summary, observations of non-conforming activities, and inform the date of the audit report submission.
 - 6.3.5.1 If there are non-conformities continue with 6.4.
 - 6.3.5.2 If there are not non-conformities continue with 6.5.
- 6.4 Request corrective actions.
 - 6.4.1 The A.T. will present the corrective actions requests to non-conformities detected during the audit/examination; these will be given to AP/A.E. in the closing meeting. (Annex G)
 - 6.4.2 The AP/A.E. will provide a date to implement corrective actions.
- 6.5 Prepare audit report.
 - 6.5.1 The leader of A.T. will prepare the audit/ examination report that includes: area/ audited activity, participants, objective and scope, reviewed documents, summary of activities, non-conformities and requests for corrective action.
 - 6.5.2 The leader of A.T. will provide the report to the audited during the closing meeting, and will send a copy to the A.U. of NPPO.
- 6.6 Follow up corrective actions.
 - 6.6.1 The leader of A.T. will verify the implementation and efficacy of corrective actions through either documentation or “in situ” verification.
 - 6.6.2 The leader of A.T. will close the report of corrective actions if the corrections have been made and will submit a follow up report to the A.U.
 - 6.6.2.1 If the required corrective actions are not satisfactory continue with 6.7.
 - 6.6.2.2 If the corrective actions are satisfactory continue with 6.8.
- 6.7 Notify disapproval/ cancellation.
 - 6.7.1 The A.U. of NPPO will send a written notification to the AP/AE of the disapproval/ cancellation for accreditation (crop inspection, sampling and/or laboratory seed health testing and/or visual inspection) in a maximum of ____ working days. (Annex H)
 - 6.7.2 The AP/ A.E. may appeal the decision following the appeal procedure.
- 6.8 Notify approval/ renewal.

- 6.8.1 The A.U. of NPPO will notify the applicant the approval/ renewal for accreditation in a maximum of _____ working days. (Annex I)
- 6.8.2 The A.U. will add or renew the A.E/AP to the master-list of A.E.

7. Records:

- 7.1 Record of audit reports.
- 7.2 Record of audit/ examination agenda.
- 7.3 Record of Checklists Completed.
- 7.4 Record of Corrective Actions.
- 7.5 Record of notification of disapproval/ cancellation and approval/ renewal.
- 7.6 Record of List of Accredited Entities/ Individuals.

8. Flowchart and Annexes:

- 8.1 Flowchart.
- 8.2 Annex A: Audit/ Examination Agenda Format.
- 8.3 Annex B: Accreditation Auditor Checklist for Phytosanitary Field Inspection for Entities.
- 8.4 Annex C: Accreditation Auditor Checklist for Seed Sampling for Entities.
- 8.5 Annex D: Accreditation Auditor Checklist for Laboratory Seed Health Testing for Entities.
- 8.6 Annex E: Accreditation Auditor Checklist for Visual Inspection for Entities .
- 8.7 Annex F: Accreditation Examination Checklist for Phytosanitary Inspection and/or Sampling for Individuals.
- 8.8 Annex G: Request for Corrective Actions Format.
- 8.9 Annex H: Format Notification of Disapproval/Cancellation Memo.
- 8.10 Annex I: Format Notification of Approval/ Renewal Memo.

ANNEX A

AUDIT/ EXAMINATION AGENDA FORMAT

| Objective: | | | |
|-------------|------|------------|------------|
| Scope: | | | |
| Date: | | | |
| Audit Team: | | | |
| SCHEDULE | | | |
| Date | Hour | Audit Team | Activities |
| | | | |
| | | | |
| | | | |
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ANNEX B

ACCREDITATION AUDITOR CHECKLIST FOR PHYTOSANITARY FIELD INSPECTION FOR ENTITIES

| | | |
|-------------------------|----------------|----------|
| Entity to be Accredited | | |
| Legal Name | | |
| Address | | |
| City | State/Province | Zip Code |
| Tel. | Fax | E-mail |
| Contact Person | | |

AUDITOR TEAM INSTRUCTIONS:

Completion of checklist:

- 1- This checklist has been designed as an aid to auditors to ensure that the essential elements of the National Accreditation System Standards as outlined in regulations for “Phytosanitary Field Inspection” are revised.
- 2- The A.T. may modify the questions on the checklist with additions and/ or deletions as appropriate. It is requested that the additions be included in the additional pages and deletions be marked with “Not applicable” N/A.

Submission of Report:

- 1- The A.T. should complete the report form for each accreditation option.
- 2- This checklist should be submitted with the audit report to:
(Accreditation Unit Chief)
(Address)
(Tel/ Fax/ E-mail)

| Requirement | Compliance (Yes/ No/ NA) | Comments |
|---|-----------------------------|----------|
| Section A- Physical Conditions | | |
| 1- Office space enclosed in such way to prevent unauthorized entry. | | |
| 2a- The facility conforms to and has documentation of all national and local requirements. | | |
| 2b- Personnel know about and have access to these documents. | | |
| 3a- A work area that is dedicated to the function of crop inspection has appropriate space for its operation. | | |
| 3b- The work space is designed and designated to avoid contaminations from other sources in the facility. | | |
| 3c- Procedures are in place to prevent contamination of the work space. | | |
| 4-The entity has space and equipment to administer crop inspection | | |
| a- Filling | | |
| b- Reporting | | |
| c- Office and equipment | | |
| d- Computers | | |
| Section B- Methods of Inspection | | |
| 1a- The entity has copies of the accreditation criteria/standards. | | |
| 1b- These documents are accessible by personnel. | | |
| 1c- Personnel are familiar with the sections relevant to phytosanitary inspection. | | |
| 2a- The entity has a Quality Manual for crop inspection. | | |
| 2b- This manual is readily accessible to personnel. | | |
| 2c- The Quality Manual is appropriately: - Identified - Indexed - Filed - Maintained | | |
| 3-The entity can demonstrate conformance to the manual and effective operation on quality system by: | | |
| - Internal Audits | | |
| - Accessible records of audits | | |
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| Section C- Personnel | | |
| 1- Job descriptions exist for inspectors, supervisors. | | |
| 2- Education, technical knowledge and experience of personnel are defined in the Quality Manual. | | |
| 3-Personnel training system to ensure competence and knowledge such as: | | |
| - Internal and/or external training | | |
| - Attendance to approved official workshops | | |
| - Documented training records for each staff | | |
| Section D- Equipment and Procedures | | |
| 1-Seed crop phytosanitary equipment | | |
| - Field maps/diagrams of area to be inspected | | |
| - Hand lens | | |
| - Secure containers for collection, storage and transportation of samples | | |
| - Pocket knife/scissors | | |
| - Sampling bags/envelopes (paper) | | |
| - Labels | | |
| - Ice chest | | |
| - Hand counter | | |
| - Diagnosis aids | | |
| - Tape measure | | |
| 2-Plant sample handling | | |
| - Refrigeration and storage facilities to hold plant samples before submission to diagnostic lab | | |
| -Means of transport of samples to diagnostic lab | | |
| -Provision to ensure that sample quality will be maintained during transport | | |
| 3-Evaluation of performance procedure | | |
| -Inspection of seed production fields | | |
| -Monitoring of inspection performance by supervisors staff | | |

ADDITIONAL PAGES

| Requirement | Compliance (Yes/ No/ NA) | Comments |
|--------------------|-------------------------------------|-----------------|
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ANNEX C

ACCREDITATION AUDITOR CHECKLIST FOR SEED SAMPLING FOR ENTITIES

| | | |
|-------------------------|----------------|----------|
| Entity to be Accredited | | |
| Legal Name | | |
| Address | | |
| City | State/Province | Zip Code |
| Tel. | Fax | E-mail |
| Contact Person | | |

AUDITOR TEAM INSTRUCTIONS:

Completion of checklist:

- 1- This checklist has been designed as an aid to auditors to ensure that the essential elements of the National Accreditation System Standards as outlined in regulations for “Seed Sampling” are reviewed.
- 2- The A.T. may modify the questions on the checklist with additions and/ or deletions as appropriate. It is requested that the additions be included in the additional pages and deletions be marked with “Not applicable” N/A.

Submission of Report:

- 1- The A.T. should complete the report form for each accreditation option.
- 2- This checklist should be submitted with the audit report to:
(Accreditation Unit Chief)
(Address)
(Tel/ Fax/ E-mail)

| Requirement | Compliance (Yes/ No/ NA) | Comments | |
|--|-----------------------------|----------|--|
| Section A- Physical Conditions | | | |
| 1- Office space enclosed in such way to prevent unauthorized entry. | | | |
| 2a- The facility conforms to and has documentation of all national and local requirements. | | | |
| 2b- Personnel know about and have access to these documents. | | | |
| 3a- A work area that is dedicated to the function of seed sampling has appropriate space for its operation. | | | |
| 3b- The work space is designated to avoid sampling mixing or contamination from other sources in the facility. | | | |
| 3c- Procedures are in place to prevent contamination of the work space. | | | |
| 4-The entity has space and equipment to administer seed sampling including: a. Receiving b. Sorting c. Filling d. Reporting e. Office and equipment f. Computers | | | |
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| Section B- Methods of Sampling | | | |
| 1a- The entity has copies of the accreditation criteria/standards. | | | |
| 1b- These documents are accessible by personnel. | | | |
| 1c- Personnel are familiar with the sections relevant to seed sampling. | | | |
| 2a- The entity has a Quality Manual or equivalent documentation for seed sampling. | | | |
| 2b- This manual is readily accessible to personnel. | | | |
| 2c- The Quality Manual is appropriately: | | | |
| - Identified | | | |
| - Indexed | | | |
| - Filed | | | |
| - Maintained | | | |
| 3-The entity can demonstrate conformance to the manual and effective operation on quality system | | | |
| by: - Internal Audits | | | |
| - Accessible records of audits | | | |

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| Section C- Personnel | | |
| 1- Job descriptions exist for sampling staff. | | |
| 2- Education, technical knowledge and experience of personnel are defined in the Quality Manual. | | |
| 3-Personnel training system to ensure competence and knowledge such as: | | |
| - Internal and/or external training | | |
| - Attendance and approved to official workshops | | |
| - Documented training records for each staff | | |
| Section D- Equipment and Procedures | | |
| 1-Equipment and Supplies: | | |
| - Triers, probes and other sampling devices | | |
| - Sampling bags, pail or cloth | | |
| - Seals and pressure sensitive tape | | |
| - Stapling pliers and sewing needle | | |
| - Flashlight | | |
| - Magnifying glass | | |
| - Clipboard | | |
| - Quart and pint container | | |
| - Seed envelopes or bags of various sizes | | |
| - Sampling report forms | | |
| - Appropriate marking equipment (pens) | | |
| - Replacement labels | | |
| 2-Evaluation of performance procedure. | | |

ADDITIONAL PAGES

| Requirement | Compliance (Yes/ No/ NA) | Comments |
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ANNEX D

ACCREDITATION AUDITOR CHECKLIST FOR LABORATORY SEED HEALTH TESTING

| | | |
|-------------------------|----------------|----------|
| Entity to be Accredited | | |
| Legal Name | | |
| Address | | |
| City | State/Province | Zip Code |
| Tel. | Fax | E-mail |
| Contact Person | | |

AUDITOR TEAM INSTRUCTIONS:

Completion of checklist:

- 1- This checklist has been designed as an aid to auditors to ensure that the essential elements of the National Accreditation System Standards as outlined in regulations for “Laboratory Seed Health Testing” are reviewed.
- 2- The A.T. may modify the questions on the checklist with additions and/ or deletions as appropriate. It is requested that the additions be included in the additional pages and deletions be marked with “Not applicable” N/A.

Submission of Report:

- 1- The A.T. should complete the report form for each accreditation option.
- 2- This checklist should be submitted with the audit report to:
(Accreditation Unit Chief)
(Address)
(Tel/ Fax/ E-mail)

| Requirement | Compliance (Yes/ No/ NA) | Comments |
|--|-----------------------------|----------|
| Section A- Physical Conditions | | |
| 1- Laboratory and office space enclosed in such way to prevent unauthorized entry. | | |
| 2a- The facility conforms to and has documentation of all national and local requirements. | | |
| 2b- Personnel know about and have access to these documents. | | |
| 3a- A work area that is dedicated to the function of seed health testing has appropriate space for its operation. | | |
| 3b- The work space is designed and designated to avoid contamination of seed health tests from other sources in the facility. | | |
| 3c- Procedures are in place to prevent contamination of the work space. | | |
| 4-The entity has space and equipment to administer seed health testing including: a. Filling b. Reporting c. Office and equipment d. Computers | | |
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| Section B- Methods of Testing | | |
| 1a- The entity has copies of the accreditation criteria/standards. | | |
| 1b- These documents are accessible by personnel. | | |
| 1c- Personnel are familiar with the sections relevant to seed health testing. | | |
| 2a- The entity has a Quality Manual or equivalent documentation for seed health testing. | | |
| 2b- This manual is readily accessible to personnel. | | |
| 2c- The Quality Manual is appropriately: | | |
| - Identified | | |
| - Indexed | | |
| - Filed | | |
| - Maintained | | |
| 3-The entity can demonstrate conformance to the manual and effective operation on quality system | | |
| by: - Internal Audits | | |
| - Accessible records of audits | | |

| Requirement | Compliance (Yes/ No/ NA) | Comments | | |
|---|-----------------------------|-------------------------|--|--|
| Section C- Personnel | | | | |
| 1- Job descriptions exist for seed health testing staff. | | | | |
| 2- Education, technical knowledge, and experience of personnel are defined in the Quality Manual. | | | | |
| 3-Personnel training system to ensure competence and knowledge such as: | | | | |
| - Internal and/or external training | | | | |
| - Attendance and approved to official workshops | | | | |
| - Documented training records for each staff | | | | |
| Section D- Equipment and Procedures | | | | |
| <u>Direct Visual Examination</u> | | | | |
| <u>General equipment</u> | | | | |
| - Common Lab glassware and equipment | | | | |
| - Scales | | | | |
| - PH meter | | | | |
| - Distilled and sterile water | | | | |
| - Gas burners | | | | |
| <u>Specialized Equipment</u> | | | | |
| <i>Method</i> | <i>Process</i> | <i>Equipment</i> | | |
| 1- Dry | Microscopy | Stereoscopic microscope | | |
| 2- Internal Tissue | Seed preparation | Mortar and pestle | | |
| | Microscopy | Compound microscope | | |
| 3-Accompanying structures | Seed preparation | Centrifuge | | |
| | | Shaker | | |
| | Microscopy | Compound microscope | | |
| Evaluation of performance procedure | | | | |

| Requirement | | | Compliance (Yes/ No/ NA) | Comments |
|--|-----------------------------|--|-----------------------------|----------|
| Incubation | | | | |
| <u>General equipment</u> | | | | |
| -Common laboratory glassware and instruments | | | | |
| -Scales | | | | |
| -Ph meter | | | | |
| -Distilled and sterile water | | | | |
| -Gas burners | | | | |
| -Autoclave | | | | |
| -Laminar flow hoods | | | | |
| -Incubation chambers | | | | |
| -Stereoscopic microscope | | | | |
| -Compound microscope | | | | |
| <u>Specialized equipment</u> | | | | |
| <i>Method type</i> | <i>Process</i> | <i>Equipment</i> | | |
| 1-Blotter | Incubation | Transparent containers | | |
| | | Blotters | | |
| 2-Culture plate | Seed preparation | Tissue grinder | | |
| | | Extraction equipment specific to the test(s) | | |
| | Incubation | Media & reagents specific to the test(s) | | |
| | Seedling pathogenicity test | Growth chamber or greenhouse | | |
| | Biochemical analysis | -Reagent strip kits | | |
| | | -Membranes (DNA tests) | | |
| | Serological analysis | Specific antiserum | | |
| | | ELISA kits | | |
| | | ELISA plate reader | | |
| | | Fluorescence microscope | | |
| | Nucleic Acid analysis | Spectrophotometer | | |
| DNA extraction | | | | |
| Thermocycler | | | | |
| | | Electrophoresis | | |
| Evaluation of performance procedure | | | | |

| Requirement | | Compliance (Yes/ No/ NA) | Comments |
|--|----------------------|-----------------------------|------------------------|
| Grow out tests | | | |
| 1-Greenhouse, growth chambers or outdoor quarantine facility | | | |
| 2-Designated diagnostic lab to verify phytosanitary inspection | | | |
| -Name, address, telephone/fax & e-mail of the laboratory | | | |
| -Name of the responsible individual at the laboratory | | | |
| -Certification/documents that the lab is qualified to perform diagnostic work | | | |
| -Written acknowledgement that the lab is prepared to perform tests | | | |
| 3-Sampling handling | | | |
| -Refrigeration and storage facilities to hold samples before submission to a designated diagnostic lab | | | |
| -Means of transport of samples to diagnostic lab | | | |
| -Provisions to ensure that quality of sample will be maintained during transport | | | |
| Evaluation of performance of procedure | | | go to additional pages |
| Serological tests - General equipment | | | |
| -Common lab glassware and instruments | | | |
| -Scales | | | |
| -pH meter | | | |
| -Distilled and sterile water | | | |
| -Gas burners | | | |
| -Autoclave | | | |
| -Laminar flow hoods | | | |
| -Refrigerator 4 C | | | |
| -Incubation Chamber | | | |
| Serological tests - Specialized equipment | | | |
| Method | Process | Equipment & materials | |
| 1-Aglutination | Seed preparation | Tissue grinder | |
| | Microscopy | Stereoscopic microscope | |
| | Serological analysis | Specific antiserum | |
| 2-Immuno-Fluorescence | Seed preparation | Tissue grinder | |
| | Microscopy | Fluorescent microscope | |
| | Serological analysis | Specific antiserum | |
| 3-ELISA | Seed preparation | Tissue grinder | |
| | Microscopy | Stereoscopic microscope | |
| | Serological analysis | Specific antiserum | |
| | | ELISA kits | |
| | | ELISA plate reader | |
| Multi-channel pipettes | | | |
| Evaluation of performance of procedure | | | |

| Requirement | | Compliance (Yes/ No/ NA) | Comments |
|--|-----------------------|--|----------|
| Nucleic acid analysis | | | |
| <i>General equipment</i> | | | |
| -Common laboratory glassware and instruments | | | |
| -Scales | | | |
| -pH meter | | | |
| -Distilled and sterile water | | | |
| -Gas burners | | | |
| -Autoclave | | | |
| -Laminar flow hoods | | | |
| -Incubation chambers | | | |
| -Stereoscopic microscope | | | |
| -Compound microscope | | | |
| -Freezer to -20C | | | |
| -Refrigerator 4C | | | |
| -Vortex | | | |
| -Pipettes | | | |
| <i>Specialized equipment</i> | | | |
| Method | Process | Equipment & materials | |
| Dot-blot | Seed preparation | Tissue grinder | |
| | | DNA extraction equipment | |
| | Hybridization | Membranes | |
| | | DNA probes | |
| PCR | Seed preparation | Tissue grinder DNA extraction equipment | |
| | Nucleic acid analysis | Primers | |
| | | DNA Polymerase | |
| | | Thermocycler | |
| | Nucleic Acid analysis | Electrophoresis | |
| | | Centrifuge | |
| | | Microcentrifuge | |
| | | Water bath | |
| | | Gel reader | |
| | | Waste disposal for ethidium chloride | |
| Evaluation of performance of procedure | | | |

ADDITIONAL PAGES

| Requirement | Compliance (Yes/ No/ NA) | Comments |
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ANNEX E

ACCREDITATION AUDITOR CHECKLIST FOR VISUAL INSPECTION FOR ENTITIES

| | | |
|-------------------------|----------------|----------|
| Entity to be Accredited | | |
| Legal Name | | |
| Address | | |
| City | State/Province | Zip Code |
| Tel. | Fax | E-mail |
| Contact Person | | |

AUDITOR TEAM INSTRUCTIONS:

Completion of checklist:

- 1- This checklist has been designed as an aid to auditors to ensure that the essential elements of the National Accreditation System Standards as outlined in regulations for “Visual Inspection” are reviewed.
- 2- The A.T. may modify the questions on the checklist with additions and/ or deletions as appropriate. It is requested that the additions be included in the additional pages and deletions be marked with “Not applicable” N/A.

Submission of Report:

- 1- The A.T. should complete the report form for each accreditation option.
- 2- This checklist should be submitted with the audit report to:
(Accreditation Unit Chief)
(Address)
(Tel/ Fax/ E-mail)

| Requirement | Compliance (Yes/ No/ NA) | Comments | |
|--|-----------------------------|----------|--|
| Section A- Physical Conditions | | | |
| 1- Office space enclosed in such way to prevent unauthorized entry. | | | |
| 2a- The facility conforms to and has documentation of all national and local requirements. | | | |
| 2b- Personnel know about and have access to these documents. | | | |
| 3a- A work area that is dedicated to the function of visual inspection has appropriate space for its operation. | | | |
| 3b- The work space is designated to avoid sampling mixing or contamination from other sources in the facility. | | | |
| 3c- Procedures are in place to prevent contamination of the work space. | | | |
| 4-The entity has space and equipment to administer seed sampling including: a. Receiving b. Sorting c. Filling d. Reporting e. Office and equipment f. Computers | | | |
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| Section B- Methods of Visual Inspection | | | |
| 1a- The entity has copies of the accreditation criteria/standards. | | | |
| 1b- These documents are accessible by personnel. | | | |
| 1c- Personnel are familiar with the sections relevant to visual inspection. | | | |
| 2a- The entity has a Quality Manual or equivalent documentation for visual inspection. | | | |
| 2b- This manual/ documentation is readily accessible to personnel. | | | |
| 2c- The Quality Manual/ documentation is appropriately: | | | |
| - Identified | | | |
| - Indexed | | | |
| - Filed | | | |
| - Maintained | | | |

| Requirement | Compliance (Yes/ No/ NA) | Comments |
|--|-----------------------------|----------|
| 3-The entity can demonstrate conformance to the manual/documentation and effective operation on quality system by: - Internal Audits - Accessible records of audits | | |
| Section C- Personnel | | |
| 1- Job descriptions exist for sampling staff. | | |
| 2- Education, technical knowledge and experience of personnel are defined in the Quality Manual/ equivalent documentation. | | |
| 3-Personnel training system to ensure competence and knowledge such as: - Internal and/or external training - Attendance and approved to official workshops - Documented training records for each staff | | |
| Section D- Equipment and Procedures | | |
| 1-Equipment and Supplies - Triers, probes and other sampling devices - Sampling bags, pail or cloth - Seals and pressure sensitive tape - Stapling pliers and sewing needle - Flashlight - Magnifying glass - Clipboard - Quart and pint container - Seed envelopes or bags of various sizes - Sampling report forms - Appropriate marking equipment (pens) - Replacement labels | | |
| 2-Designated laboratory to verify visual seed inspection: - Name, address, TEL/Fax, e-mail - Name of the responsible individual Certification of qualification to perform diagnostic work | | |
| 3-Seed Sampling Handling: - Storage facilities to hold seed samples - Means of transport of samples to the laboratory - Provisions to ensure that sample quality will be maintained during transport | | |
| 4-Evaluation of performance procedure | | |

ADDITIONAL PAGES

| Requirement | Compliance (Yes/ No/ NA) | Comments |
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ANNEX F

**ACCREDITATION CHECKLIST FOR PHYTOSANITARY FIELD
INSPECTION AND SEED SAMPLING FOR INDIVIDUALS**

| | | |
|-----------------------------|----------------|----------|
| Individual to be Accredited | | |
| Legal Name | | |
| Address | | |
| City | State/Province | Zip Code |
| Tel. | Fax | E-mail |
| Contact Person | | |

| Requirement | Compliance (Yes/ No/ NA) | Comments |
|---|-----------------------------|----------|
| Section A- Methods of Inspection and Sampling | | |
| 1a- The individual has copies of the accreditation criteria/standards | | |
| 1b- These documents are accessible | | |
| 1c- Individuals are familiar with the sections relevant to crop inspection/sampling | | |
| Section B- Personnel | | |
| 1- Job description exist for inspectors | | |
| 2- Education, technical knowledge and experience of individuals | | |
| 3-Individual training system to ensure competence and knowledge such as: - Internal training - Attendance to approved official workshops - Documented training records | | |
| | | |
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| | | |
| Section C- Equipment and Procedures | | |
| 1-Seed crop inspection/sampling equipment - Field maps/diagrams of area to be inspected - Hand lens - Secure containers for collection, storage and transportation of samples - Pocket knife/scissors - Sampling bags/envelopes (paper) - Labels - Ice chest - Hand counter - Diagnosis aids - Tape measure - Tools for taking samples | | |
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| 3-Plant sample handling - Refrigeration and storage facilities to hold plant samples before submission to diagnostic lab - Means of transport of samples to diagnostic lab - Provision to ensure that sample quality will be maintained during transport | | |
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| 4-Evaluation of performance procedure - Inspection of seed production fields | | |
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ADDITIONAL PAGES

| Requirement | Compliance (Yes/ No/ NA) | Comments |
|--------------------|-------------------------------------|-----------------|
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ANNEX G

REQUEST FOR CORRECTIVE ACTIONS FORMAT

| | | |
|----------|---|------------------------------------|
| | Entity: | Date: |
| | Accredited Register # | |
| | Area/ Activity: | |
| | Description of Non-Conformity: | |
| A | Non-Conformity with (standards/ regulation): | |
| | Date to conduct corrective action: | |
| | Audit Team Leader Name: Signature: | Auditee Name: Signature: |
| B | Adopted action to correct non-conformity and prevent repetition | |
| | Auditee Signature: | Date: |
| C | Verification of adopted corrective action: | |
| | Audit Team Leader Signature: | Date: |

ANNEX H

**FORMAT: NOTIFICATION OF DISAPPROVAL/
CANCELLATION MEMO**

TO: APPLICANT

FROM: A.U.

DATE:

ACCREDITATION APPLICATION #

Your accreditation application # _____ requesting accreditation of phytosanitary field inspection, seed sampling, laboratory seed health testing, visual inspection was disapproved/ cancelled. Attached is the respective technical report which provides the reasons for disapproval/cancellation.

You may appeal this decision in accordance with the regulations.

A.U. SIGNATURE

ANNEX I

FORMAT: NOTIFICATION OF APPROVAL/ RENEWAL
MEMO

TO: APPLICANT

FROM: A.U.

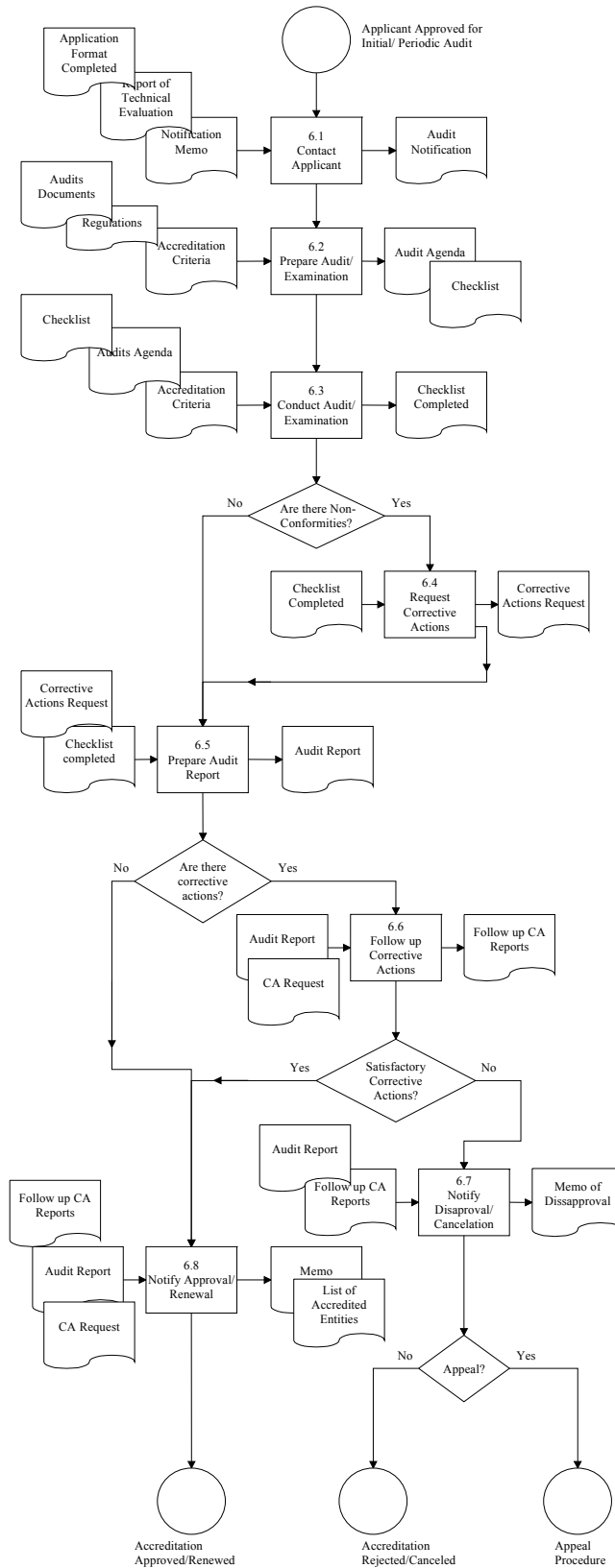
DATE:

ACCREDITATION APPLICATION #

Your accreditation application # _____ requesting accreditation of phytosanitary field inspection, seed sampling, laboratory seed health testing, visual inspection was approved/renewed. Attached is the respective technical report which may include conditions of approval.

A.U. SIGNATURE

Initial/ Periodic Audit/Examination for Accreditation Procedure Flowchart



6- MONITORING OF PHYTOSANITARY FIELD INSPECTION PROCEDURE

NPPO /ACCREDITATION UNIT

Authorization Date

Effective Date

Created by

Approved by

1. **Purpose:**
 - 1.1 The objective of this procedure is to define the sequence of events, actions, interfaces, and responsibilities involved in monitoring the field sites where a phytosanitary accreditation field inspection has been conducted.

2. **Scope:**
 - 2.1 From each field site approved for a phytosanitary field inspection to the phytosanitary seed lot approved.

3. **References:**
 - 3.1 Phytosanitary Seed Export Regulations.
 - 3.2 Criteria for Phytosanitary Inspection Accreditation.
 - 3.3 Phytosanitary Field Inspection application approved.
 - 3.4 Importing Country Requirements.
 - 3.5 Rules and Methods for seed sampling (ISTA/AOSA).
 - 3.6 Phytosanitary Field Inspection Guidelines.

4. **Definitions:**
 - 4.1 NPPO: National Plant Protection Organization, government agency responsible for Phytosanitary Seed Export.
 - 4.2 A.U.: Accreditation Unit, official responsible for conducting the phytosanitary accreditation.
 - 4.3 AP: Applicant Entity, individual, private or public company or organization as deemed eligible for Phytosanitary accreditation.
 - 4.4 A.E.: Accredited Entity, individual, private or public company or organization as deemed eligible for Phytosanitary accreditation.
 - 4.5 Phytosanitary Field Inspection: includes inspections of greenhouses or growth chambers or field seed production for disease freedom following the regulations established by NPPO.
 - 4.6 Quality Manual: document written by the applicant, in which their quality system is described.
 - 4.7 ISTA: International Seed Testing Association.
 - 4.8 AOSA: Association of Official Seed Analysts.

5. **Responsibility and Authority:**
 - 5.1 The _____ of NPPO is responsible for receiving and registering the fields
 - 5.2 The _____ of NPPO is responsible for planning the schedule of the plots to be monitored.
 - 5.3 The _____ of NPPO is responsible for conducting the monitoring of the plots and reporting the results.
 - 5.4 The _____ of NPPO is responsible to compare the results of the monitoring reports and the accredited entity inspection report.

6. Activities:

- 6.1 Receive and register fields.
 - 6.1.1 The _____ of NPPO will receive and register the applications approved for the phytosanitary inspection under the accreditation scheme. (Annex A)
 - 6.1.2 The _____ of NPPO will determine the percentage of fields to be monitored following the national standards. (15% for seed certification)
 - 6.1.3 The _____ of NPPO will maintain a record of the sites to be inspected/monitored
- 6.2 Plan schedule of monitoring.
 - 6.2.1 The _____ of NPPO, in coordination with the accredited entity/individual, will plan a schedule for conducting the monitoring inspection dates and visits of each field site based on the list of plots recorded and the applications completed. (Annex B)
- 6.3 Conduct monitoring.
 - 6.3.1 The _____ of NPPO shall conduct the monitoring inspection following the schedule plan and prepare monitoring report ___ days after finishing each monitoring inspection. (Annex C)
 - 6.3.2 The _____ of NPPO should reject the fields because of the non-conformities during the monitoring.
- 6.4 Compare results.
 - 6.3.1 The _____ of NPPO will compare the results of the monitoring inspection with the inspection report issued by the accredited entity/individual and prepare a final report (Annex D).
 - 6.3.2 If the percentage of non-conformities is less than __ % the results of the accredited entity inspections will be accepted.
 - 6.3.3 If the non-conformities are over __ %, the result of the accredited entity inspections will be not accepted and the percentage of monitoring will be increased to ___ %.
 - 6.3.4 In the case of rejection of the field inspection, the accredited inspector may appeal the decision following the appeal procedure.

7. Records:

- 7.1 Monitoring Inspection Report.
- 7.2 Monitoring Schedule.
- 7.3 Monitoring Report
- 7.4 Final report of comparison of the monitoring and inspection reports.

8. Flowchart and Annexes:

- 8.1 Flowchart.
- 8.2 Annex A: List of Field Record Format.
- 8.3 Annex B: Monitoring Schedule Format.
- 8.4 Annex C: Monitoring Report Format.
- 8.5 Annex D: Final Monitoring Report Format.

ANNEX A
LIST OF FIELD RECORD FORMAT

ACCREDITED ENTITY:

| Field # | Crop | Variety | Location | Size | Map Attached |
|---------|------|---------|----------|------|--------------|
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ANNEX B

MONITORING SCHEDULE FORMAT

| | Accredited Entity | Field # | Monitoring Date (DD/MM/YY) |
|-----|-------------------|---------|-------------------------------|
| 1. | | | |
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ANNEX C

MONITORING REPORT FORMAT

- Accredited Entity Name Tel/Fax/Address
- Accreditation
- Contact Person Tel/Fax/Address
- Crop Variety
- Location of Site (if more than one list separately)
- Purpose of the Inspection
- Requirements of Importer Country, if pre-determined country is identified.
- Growth Stage and date of monitoring
- Other Observations

OBSERVATIONS OF MONITORING INSPECTION

| Disease Name | Low, Moderate, High (L, M, H) | Lab Sample Submitted (Yes/No) | Field Diagnosis Confirmed (Yes/No) | Additional Pathogens Identified Code | Lab Sample Number |
|--------------|----------------------------------|----------------------------------|---------------------------------------|---|-------------------|
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| Inspector Accredited | ID Number | Date |
| Lab Manager | ID Number | Date |

ANNEX D

FINAL MONITORING REPORT FORMAT

Accredited Entity (Elaborate one table per each accredited entity)

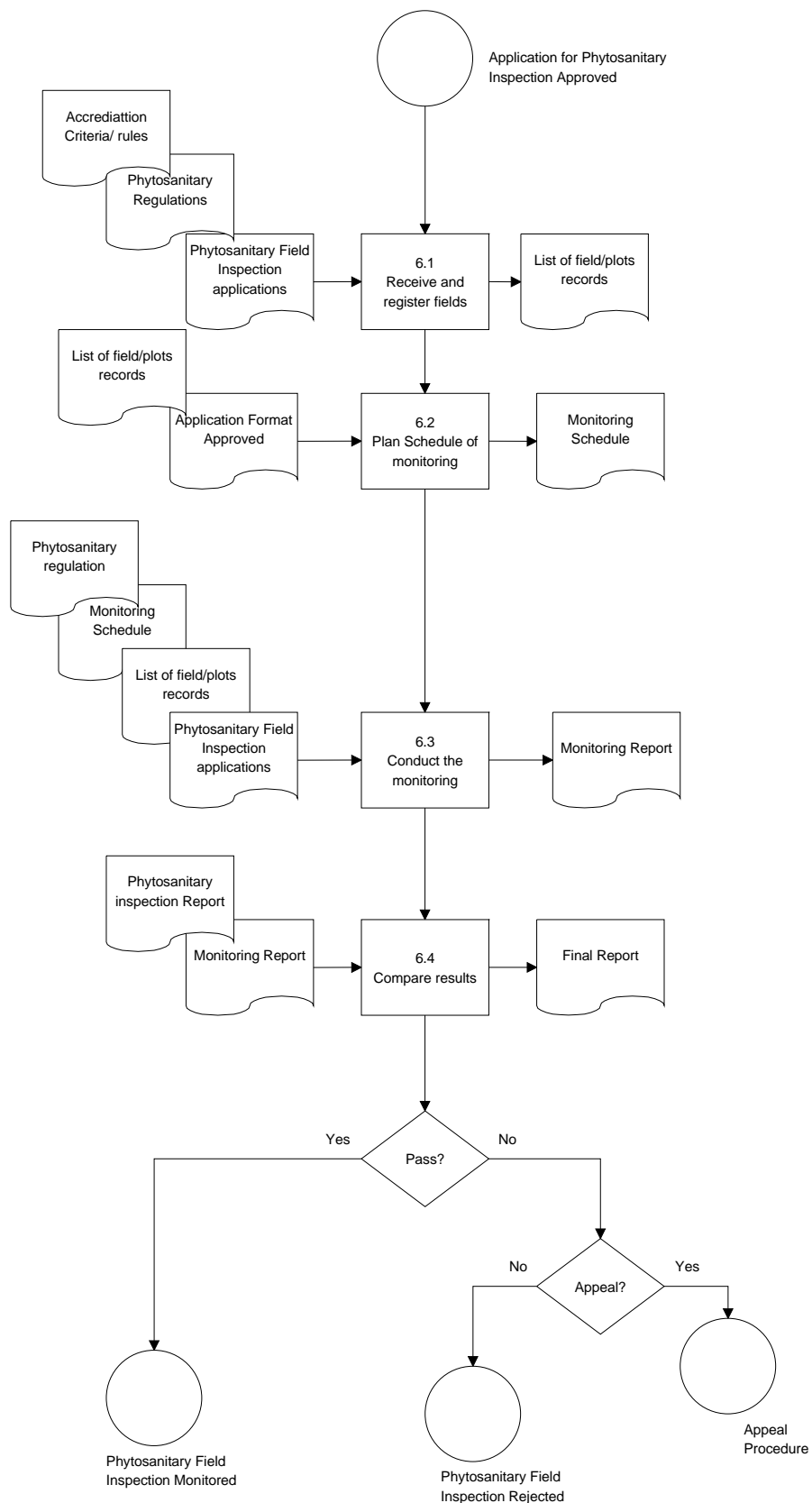
| Field # | Growth Stage & Date | Field Approved by Accredited Entity | | Field Approved by NPPO | |
|---------|---------------------|-------------------------------------|----|------------------------|----|
| | | Yes | No | Yes | No |
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Analysis of Comparison of Field Inspections:

Field Inspection comparison results satisfactory Yes _____ No _____

Signed by _____ of NPPO

MONITORING OF PHYTOSANITARY INSPECTION PROCEDURE



7- CONFIDENTIAL BUSINESS INFORMATION

HANDLING PROCEDURE

NPPO / ACCREDITATION UNIT

Authorization Date

Effective Date

Created by

Approved by

1. **Purpose:**
 - 1.1 The objective of this procedure is to define the sequences of events, interfaces, and responsibilities involved in the procedure of handling Confidential Business Information with an application of accreditation for crop inspection, seed sampling, laboratory seed health testing, and/or visual inspection.

2. **Scope:**
 - 2.1 From receipt of an application containing Confidential Business Information (CBI) to file maintenance of application.

3. **References:**
 - 3.1 National Regulations on the Protection of CBI.
 - 3.2 List of authorized experts to receive CBI.

4. **Definitions:**
 - 4.1 NPPO: National Plant Protection Organization, government agency responsible for Phytosanitary Seed Export.
 - 4.2 A.U.: Accreditation Unit, official responsible for conducting the phytosanitary accreditation.
 - 4.3 AP: Applicant for accreditation entity/individual that apply for the phytosanitary accreditation.
 - 4.4 A.E.: Accredited Entity, individual, private or public company or organization as deemed eligible for Phytosanitary accreditation.
 - 4.5 CBI: Confidential Business Information: includes trade secrets, commercial or financial information that must be protected. Includes any information that the entity can claim (within reason) as CBI or Confidential Business Information.

5. **Responsibility and Authority:**
 - 5.1 The _____ of NPPO is responsible for receiving the CBI and implementing a secure a document tracking system and storage system.
 - 5.2 The _____ of NPPO is responsible for designating the experts who will be given access to CBI.
 - 5.3 The designated technical experts are individually responsible for maintaining the confidentiality of the information throughout the revision of the application.

6. **Activities:**
 - 6.1 Receive and evaluate CBI.
 - 6.1.1 The _____ of NPPO will receive in a double envelope an application containing information the applicant claims to be CBI.
 - 6.1.2 The _____ of NPPO will assess applicant's justification for claiming CBI.

- 6.1.2.1 If the _____ of NPPO does not uphold the applicant's justification continue with 6.2.
- 6.1.2.2 If the _____ of NPPO has justified the CBI documents continue with 6.3.
- 6.1.3 The _____ of NPPO will record date of receipt and give each CBI document a record identity. (Annex A)
- 6.1.4 The _____ of NPPO will authorize and train personnel who will be responsible for handling CBI documents.
- 6.2 Notify denied CBI.
 - 6.2.1 The _____ of NPPO will notify to applicant the non-justification for claiming CBI. (Annex B).
 - 6.2.2 The applicant may appeal the decision following the appeal procedure.
- 6.3 Store CBI.
 - 6.3.1 The authorized personnel of the NPPO will store the CBI in a secure area when it is not in use.
- 6.4 Authorize access to CBI.
 - 6.4.1 The NPPO will designate and list the technical experts who will be allowed to review the CBI.
 - 6.4.1.1 Authorized personnel of the NPPO will only provide CBI documents to technical experts whom the NPPO has designated and are listed. (Annex C)
 - 6.4.2 The authorized personnel will record date when technical experts receive and return CBI documents. (Annex D)
 - 6.4.2.1 The authorized officers are individually responsible for maintaining confidentiality of the CBI.

7. Records:

- 7.1 Date of receipt of application containing CBI.
- 7.2 List of authorized technical officers.
- 7.3 Registry of CBI utilization.
- 7.4 List of authorized officers.

8. Flowchart and Annexes:

- 8.1 Flowchart.
- 8.2 Annex A: CBI Entry Record Format.
- 8.3 Annex B: Letter for denying CBI justification format.
- 8.4 Annex C: CBI Utilization Registry Format.
- 8.5 Annex D: List of Designated Officers Format.

ANNEX A

CONFIDENTIAL BUSINESS INFORMATION ENTRY RECORD
FORMAT

| APPLICATION # CBI | DATE OF RECEIPT | OFFICER NAME | SIGNATURE |
|-------------------|-----------------|--------------|-----------|
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ANNEX B

LETTER FOR DENYING CBI JUSTIFICATION FORMAT

TO: APPLICANT

FROM: NPPO

APPLICATION # CBI

DATE:

I am informing you that the application # _____ requesting accreditation for _____ which contains CBI documents has not been justified as a CBI. You may appeal the decision following the appeal procedure.

NPPO AUTHORITY

ANNEX C

CONFIDENTIAL BUSINESS INFORMATION UTILIZATION
REGISTRY

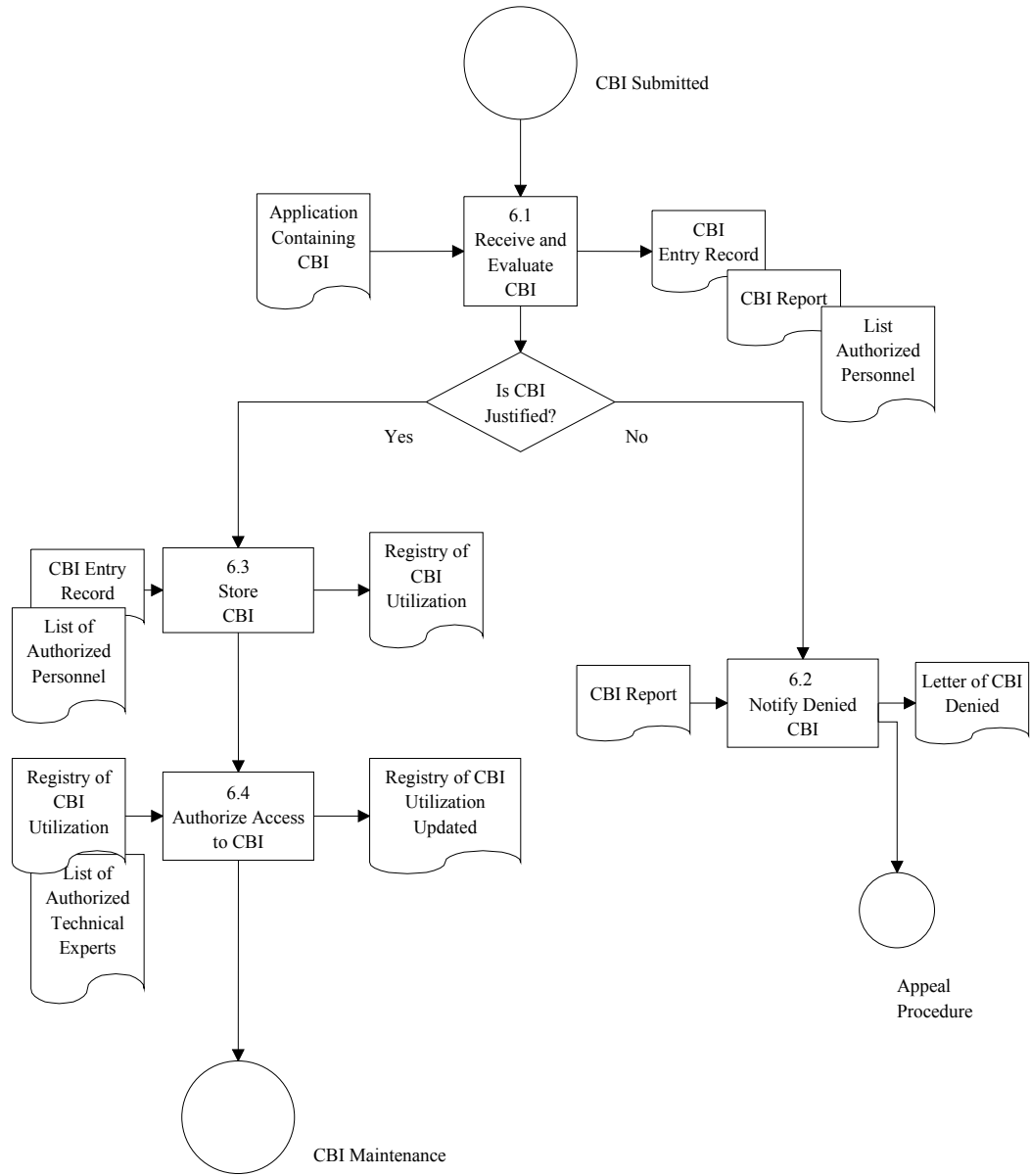
| APPLICATION # CBI/ ID | DATE OUT | DATE IN | NPPO OFFICERS |
|--------------------------|----------|---------|---------------|
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ANNEX D

LIST OF AUTHORIZED NPPO OFFICERS

| NAME | ID | ADDRESS | INSTITUTION | DATE AUTHORIZED | SIGNATURE |
|------|----|---------|-------------|--------------------|-----------|
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CONFIDENTIAL BUSINESS INFORMATION HANDLING FLOWCHART



8- APPEALS PROCEDURE

NPPO / ACCREDITATION UNIT

Authorization Date

Effective Date

Created by

Approved by

1. **Purpose:**
 - 1.1 The objective of this procedure is to define the procedures to be followed to appeal against a decision taken by the NPPO in regard to phytosanitary accreditation.

2. **Scope:**
 - 2.1. From the reception of the appeal to the report of the final decision.

3. **References:**
 - 3.1. Phytosanitary Seed Export Regulations
 - 3.2. National Standards for Accreditation
 - 3.3. National Regulations of Appeal

4. **Definitions:**
 - 4.1. NPPO: National Plant Protection Organization, government agency responsible for Phytosanitary Seed Export.
 - 4.2. A.U.: Accreditation Unit, official responsible for conducting the phytosanitary accreditation.
 - 4.3. AP: Applicant for accreditation entity/individual that apply for the phytosanitary accreditation.
 - 4.4. A.E.: Accredited Entity, individual, private or public company or organization as deemed eligible for Phytosanitary accreditation.
 - 4.5. Appeal Panel: group of experts that will review the decision taken.

5. **Responsibility and Authority:**
 - 5.1. The NPPO is responsible of receiving the appeal, establishing the date to meet with the A.U., and obtaining reports and previous documents.
 - 5.2. The A.U. is responsible of publishing a report of the meeting's discussion and findings.
 - 5.3. The appeal panel is responsible for reviewing the decision and making a recommendation.
 - 5.4. The NPPO is responsible for making a decision, which will be considered definitive.

6. **Activities:**
 - 6.1. Receive appeal.
 - 6.1.1. The _____ of NPPO will receive and record the appeal request within 30 days after the notification. (Annex A)
 - 6.1.1.1 In the case of suspension or cancellation the AP/AE is not allow to conduct activities which is accredited until the final decision is taken.
 - 6.1.2. The _____ of NPPO will send the appeal to A.U.
 - 6.2. Review appeal.
 - 6.2.1. The A.U. will review the appeal request and make a preliminary report in _____ working days.
 - 6.3. Meeting with the appellant.

- 6.3.1. The director of NPPO will schedule a date to have a meeting with A.U., the appellant, and appeal panel. (Annex B)
 - 6.3.1.1. The appeal panel will be comprised of: Director of NPPO, Legal expert, Plant Seed Science, representative of National Seed Association.
- 6.3.2. The appellant will present the case including new reasons directly or indirectly related with the case.
- 6.3.3. The appeal panel will prepare a recommendation to the director of NPPO.
- 6.4. Review Decision.
 - 6.4.1. The director of NPPO will make a decision within the legal period established by the country and will publish the final decision.
 - 6.4.2. A favorable decision to the appeal may contain conditions that the entity must consider. The director of NPPO will notify the appeal entity of the decision.

7. Records:

- 7.1. Record of appeal request.
- 7.2. Preliminary report.
- 7.3. Meeting report.
- 7.4. Decision report.
- 7.5. Notification report.

8. Flowchart and Annexes:

- 8.1. Flowchart.
- 8.2. Annex A: Format Memo for Appeal request.
- 8.3. Annex B: Format Memo for Appeal Meeting.

ANNEX A

FORMAT MEMO FOR APPEAL REQUEST

TO: NPPO

FROM: APPLICANT

APPLICATION/ ACCREDITATION #:

DATE:

I have been notified about the non-approval of my application/ accreditation # _____ for the accreditation for _____. I wish to exercise my right to appeal the decision. In accordance with your procedures, I am filing this appeal within the established time limits and annexing the grounds for appeal and pertinent additional information.

APPLICANT/ACCREDITED SIGNATURE

ANNEX B

FORMAT MEMO FOR APPEAL MEETING

TO: APPEAL PANEL

FROM: Director of NPPO

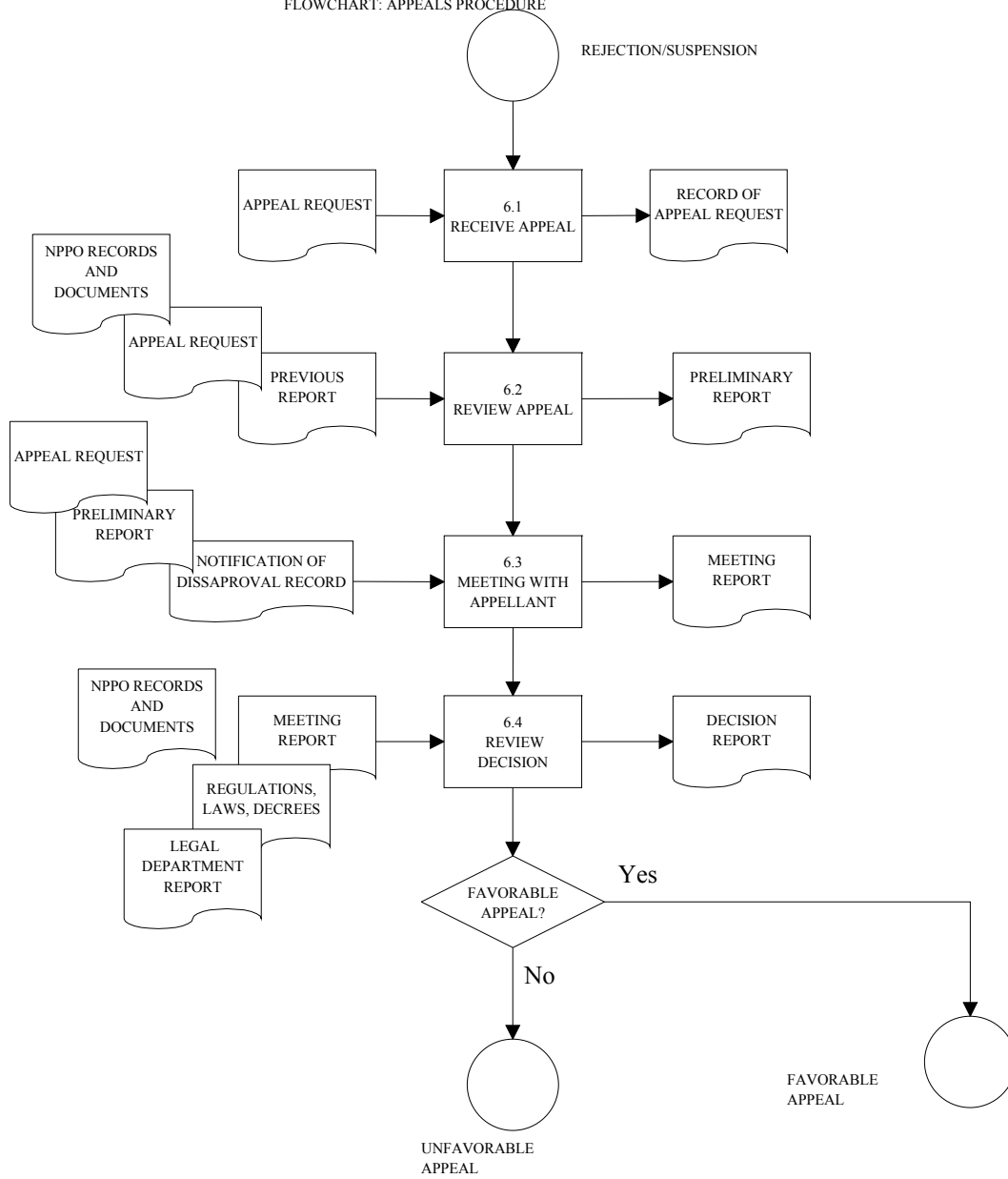
APPLICATION/ ACCREDITATION #:

DATE:

I hereby notify you to participate in the appeal meeting that will be held on _____ (DD/MM/YY), in _____ (address), at _____ (time) to conduct the appeal meeting referred to us by _____. During the meeting we will discuss the technical aspects presented in the applicant's appeal, meet with the appellant, and make a decision on the appeal. I am attaching the records related to the case for your study prior to the meeting. I thank you in advance for your cooperation in this matter.

Director of NPPO SIGNATURE

FLOWCHART: APPEALS PROCEDURE



9- TRAINING PROCEDURE

NPPO/ACCREDITATION UNIT

Authorization Date

Effective Date

Created by

Approved by

1. **Purpose:**
 - 1.1 The objective of this procedure is to define the sequence of events, interfaces, and responsibilities involved in the process of training internal personnel and entities/individuals to be accredited, for quality management, accreditation, phytosanitary field inspection, seed sampling, laboratory seed health testing and/or visual inspection.

2. **Scope:**
 - 2.2 From the identification of internal/external training needs to the internal/external personnel trained.

3. **References:**
 - 3.1 Phytosanitary Seed Export Regulation.
 - 3.2 Criteria for Phytosanitary Accreditation for Entities.
 - 3.3 Criteria for Phytosanitary Accreditation for individuals.
 - 3.4 Criteria for Seed Health Testing Accreditation.
 - 3.5 Phytosanitary field inspection, Sampling, Visual inspection and Laboratory Seed Health Testing Reports.
 - 3.6 Laboratory Seed Health Testing Standards.
 - 3.7 ISTA and ISHI seed health testing methods.
 - 3.8 ISO 9000/2001.

4. **Definitions:**
 - 4.1 NPPO: National Plant Protection Organization, government agency responsible for Phytosanitary Seed Export.
 - 4.2 A.U.: Accreditation Unit, official responsible for conducting the phytosanitary accreditation.
 - 4.3 AP: Applicant for phytosanitary accreditation
 - 4.4 A.E.: Accredited Entity, individual, private or public company or organization as deemed eligible for Phytosanitary accreditation.
 - 4.5 ISTA: International Seed Testing Association
 - 4.6 ISHI: International Seed Health Initiative

5. **Responsibility and Authority:**
 - 5.1 The _____ of NPPO is responsible for determine the internal/external training needs.
 - 5.2 The _____ is responsible for preparing the budget, planning, conducting and evaluating the training program according to guidelines defined by A.U.
 - 5.3 The _____ is responsible for planning the workshops for each crop and test.
 - 5.4 The A.U. of NPPO is responsible for providing the training certificates.

6. Activities:

- 6.1 Determine training needs.
 - 6.1.1 The _____ of NPPO will identify internal and external needs for training.
 - 6.1.2 The _____ of NPPO will record the training needs.
 - 6.1.3 If the training needs are for NPPO internal personnel continue with 6.3.
 - 6.1.4 If the training needs are external for applicants of phytosanitary accreditation continue with 6.2.
- 6.2 Establish external training program.
 - 6.2.1 The _____ of NPPO will establish a program for the external training based on the identification of training needs.
- 6.3 Establish internal training program.
 - 6.3.1 The _____ of NPPO will establish a program for the internal training.
 - 6.3.2 If the resources are not available continue with 6.4.
 - 6.3.3 If the resources are available continue with 6.5.
- 6.4 Identify resources.
 - 6.4.1 The _____ of NPPO will identify the resources to develop the training program.
 - 6.4.2 The _____ of NPPO will maintain an updated list of human resources base on the training program that is required.
- 6.5 Organize training workshop.
 - 6.5.1 The _____ of NPPO will prepare the training schedules for groups of plant pathogens, field crops, quality manual, accreditation system/scheme (Annex A).
 - 6.5.2 The _____ of NPPO will develop a budget plan for the workshops.
 - 6.5.3 The _____ of NPPO will establish the locations and facilities where the workshops will be carried out and select the instructors.
- 6.6 Prepare workshop.
 - 6.6.1 The _____ of NPPO will establish a field location to ensure that necessary disease symptoms will be evident during the workshop.
 - 6.6.2 The _____ of NPPO will define the place/ warehouse where seed is stored for the sampling and visual inspection training workshop to be held.
 - 6.6.3 The _____ of NPPO will obtain seeds with appropriate levels of infection for the seed health test methods to be studied during the workshop.
 - 6.6.4 The _____ of NPPO will ensure that the selected facilities have the necessary equipment and space to carry out the workshop.
 - 6.6.5 The _____ of NPPO will prepare a program for each workshop

- 6.6.5.1 If the field conditions are not appropriate continue with 6.7.
- 6.6.5.2 If the field conditions are available continue with 6.8.
- 6.7 Re-schedule workshops.
 - 6.7.1 The _____ of NPPO will re-schedule the workshops for the time of field lot availability.
 - 6.7.2 The _____ of NPPO will inform to A.U. the new schedule.
- 6.8 Conduct workshops.
 - 6.8.1 The instructor will carry out the workshops according to the program.
 - 6.8.2 The instructor will prepare and provide the participants with guidelines on methods and procedures.
 - 6.8.3 The instructor will prepare an evaluation form to be completed by the workshops participants at the end of the training period.
- 6.9 Evaluate and submit result.
 - 6.9.1 The _____ of NPPO will evaluate the results of each individual participant.
 - 6.9.2 The _____ of NPPO will submit the result of evaluation to the A.U.
 - 6.9.3 The A.U. will maintain an official record of individuals who attended to the workshops.
 - 6.9.3.1 If the results are not satisfactory a re-training will be necessary.
 - 6.9.3.2 The A.U. will issue certificates of satisfactory completion of workshops, if the results are satisfactory
- 6.10 Approve trainee.
 - 6.10.1 The A.U. will notify the approval of the training workshops.
 - 6.10.2 The A.E. has to participate in the actualization workshops each _____ years.

7. Records:

- 7.1 Program of internal and external training needs.
- 7.2 Record of workshop schedules.
- 7.3 Record of workshops programs.
- 7.4 List of human resources.
- 7.5 Record of list of participants.
- 7.6 Record of evaluation/ certificates.

8. Flowchart and Annexes:

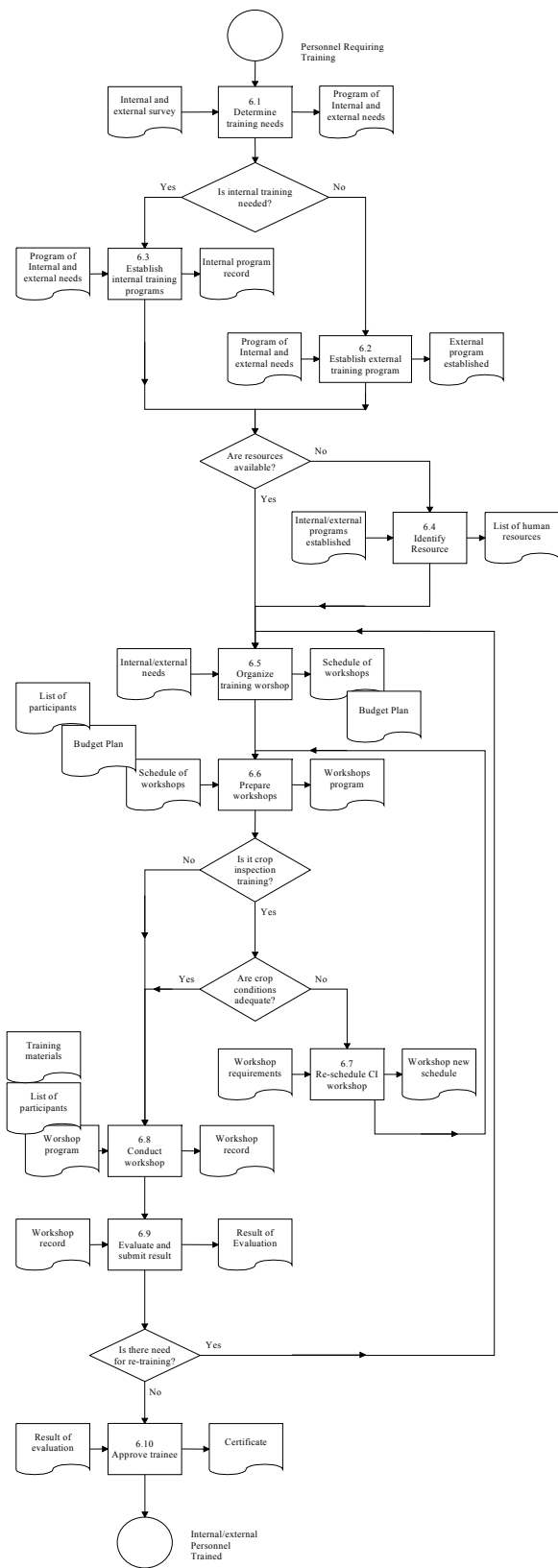
- 8.1 Flowchart.
- 8.2 Annex A: Schedule of Internal/External Workshops.

ANNEX A

SCHEDULE OF INTERNAL/EXTERNAL WORKSHOPS

| Workshop of: | Place | Date/Time | Instructor |
|--------------|-------|-----------|------------|
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TRAINING PROCEDURE FLOWCHART



10- RECORD CONTROL PROCEDURE

NPPO / ACCREDITATION UNIT

Authorization Date

Effective Date

Created by

Approved by

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 through the procedures of accreditation application, technical evaluation, initial/ periodic audit, confidential business information, appeal and training to their control.

3. **References:**
 - 3.1 Administrative, Operational and Support Procedures.
 - 3.2 Regulations of Public Administration.
 - 3.3 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 being keeping and maintaining under safeguard for future reference in an audit and/or for traceability of a result.

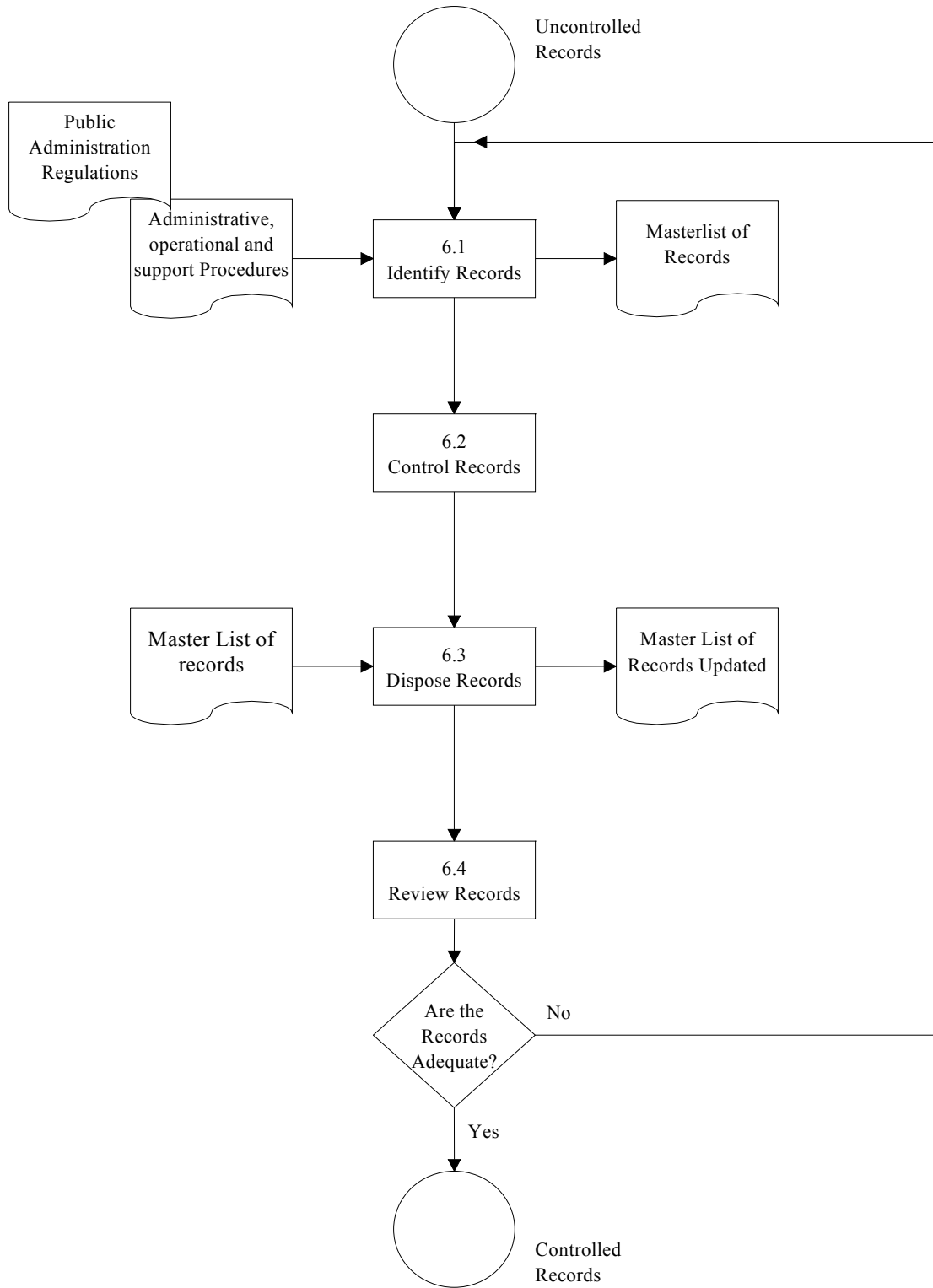
5. **Responsibility and Authority:**
 - 5.1 The A.U. of NPPO is responsible to identify, collect, file, store, discharge and review records.

6. **Activities:**
 - 6.1 Identify Records.
 - 6.1.1 The NPPO will identify the records to be controlled, as indicated by the Administrative, Operational and Support Procedures, and the Public Administration Regulation and will be included in the Master List of Records.
 - 6.2 Control Records.
 - 6.2.1 The A.U. of NPPO will collect, file, and keep the records.
 - 6.2.2 The A.U. of NPPO will control the access to the records.
 - 6.3 Dispose Records.
 - 6.3.1 The NPPO will periodically evaluate the Master List of Records and will dispose of obsolete and unnecessary records.
 - 6.4 Review Records.
 - 6.4.1 The NPPO 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



11- DOCUMENT CONTROL PROCEDURE

NPPO/ACCREDITATION UNIT

Authorization Date

Effective Date

Created by

Approved by

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

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 accreditation application, technical evaluation, initial/periodic audit/examination, appeal, training, confidential business information handling procedures.

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.

5. **Responsibility and Authority:**
 - 5.1 The A.U. of the NPPO will assure that the control of documents is conducted following this procedure.

6. **Activities:**
 - 6.1 Identify Documents.
 - 6.1.1 Any representative of the A.U. of NPPO that needs a new controlled document will inform the NPPO, which will determine whether or not to proceed with the request
 - 6.1.2 Create the Master List of Controlled Documents related to phytosanitary accreditation.

- 6.2 Create Documents.
 - 6.2.1 If the Document does not exist, the A.U. of the NPPO will assure that this Document is created. The procedures and work instruction will be prepared following the model approved by NPPO.
- 6.3 Review Document.
 - 6.3.1 If the document already exists, the A.U. of the NPPO 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, the A.U. of the NPPO will modify the internal document according the activity 6.5
 - 6.3.2 The new documents will be reviewed by the NPPO 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 The NPPO will review and approve the new document to verify its precision.
- 6.5 Request Document Change.
 - 6.5.1 Any representative of the A.U. of the NPPO can request any change to the documents through the Document Change Application. The NPPO 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.
 - 6.6.1 The A.U. of NPPO will assure that:
 - 6.6.1.1 The Master List of Controlled Documents is kept in both 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 The A.U. of the NPPO 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 The A.U. of the NPPO will determine a date for the document to become valid.
 - 6.7.2 The A.U. of the NPPO will distribute the new document.
- 6.8 Inform the concerned personnel and institutions.
 - 6.8.1 The A.U. of the NPPO will assure that the concerned personnel understand the content of the new document or any change made to the original documents.
 - 6.8.2 The A.U. of the NPPO will provide the training to the personnel when necessary to achieve the new requirements.
- 6.9 Ensure the access.
 - 6.9.1 The A.U. of the NPPO will ensure that documents of reference are available.

7. Records:

- 7.1 Master List of Controlled Documents.

8. Flowchart and Annexes:

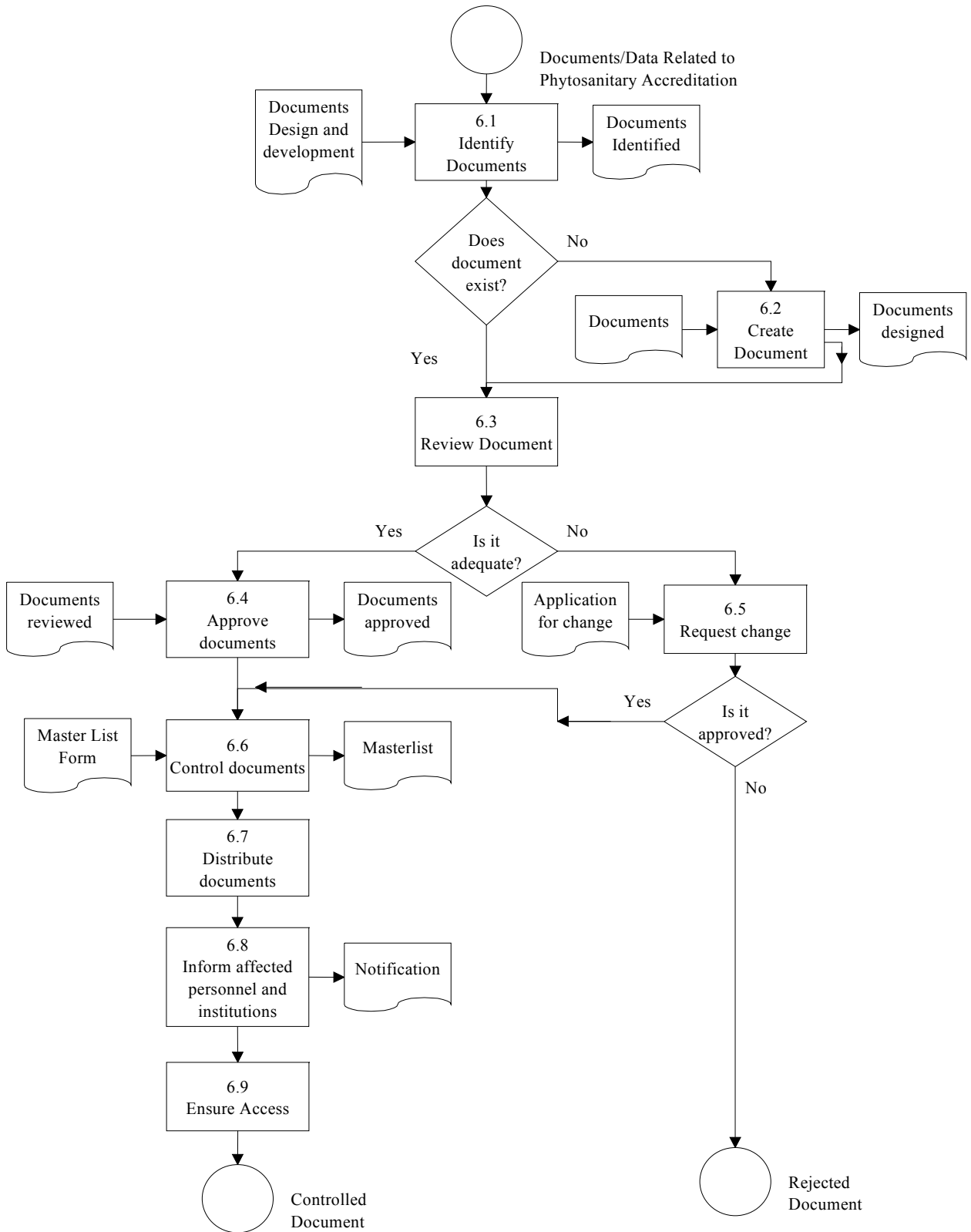
- 8.1 Flowchart.
- 8.2 Annex A: Controlled Documents Master List.
- 8.3 Annex B: Document Change Application.

ANNEX B

DOCUMENT CHANGE APPLICATION

| | | | |
|---|--|--------------------------|--------------------|
| CHANGE REQUESTED BY | | APPLICATION DATE: | |
| DOCUMENT TITLE | | | |
| CHANGE REQUESTED | | | |
| REASON | | | |
| RECOMMENDATION (SELECT ONE) | | | |
| <input type="checkbox"/> REJECT (reason) | | | |
| <input type="checkbox"/> ACCEPT WITH CHANGES (explain) | | | |
| <input type="checkbox"/> ACCEPT | | | |
| IF ACCEPTED | | SUGGESTED DATE | VALID SINCE |
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DOCUMENT CONTROL PROCEDURE FLOWCHART



12- References:

- Code of Federal Regulations Title 7 Chapter III, Part 353 Export Certification, APHIS, USDA January 2003.
- Reference Manual A, Administration, Procedures and Policies of the NSHS, National Seed Health System, USDA APHIS, Version 2000.
- Reference Manual B Seed Health Testing and Phytosanitary Field Inspection Methods, National Seed Health System, USDA APHIS, Version 2001.
- North American Plant Protection Organization, NAPPO, Regional Standards for Phytosanitary Measures RSPM #8, Ottawa, Canada October 2004.
- International Standards for Phytosanitary Measures ISPM #7, Export Certification System, International Plant Protection Convention, FAO 1997.
- International Standards for Phytosanitary Measures, Guidelines for Phytosanitary Certificates ISPM # 12, FAO 2001.
- International Standards for Phytosanitary Measures, Glossary of Phytosanitary Terms, ISPM # 5, FAO 2003.
- ISO 9000/1994 Quality Management and Quality Assurance Standards.
- ISO 9000/2001 Quality Management System.