

Reference Manual A **(RM-A)**

**NATIONAL SEED HEALTH
SYSTEM (NSHS)**

***REFERENCE MANUAL FOR
ADMINISTRATION, PROCEDURES,
AND POLICIES OF THE NSHS***

Version dated
10/20/09

INTRODUCTION

Seed Health Accreditation Program

The U.S. Seed Health Accreditation Program, in the form of the NSHS has been established by the U. S. Department of Agriculture-Animal and Plant Health Inspection Service (USDA-APHIS) to accredit entities to perform laboratory seed health testing, seed sampling, visual inspections, and phytosanitary field inspections. Authority for the establishment and operation of the seed health accreditation program are described in Title 7 Code of Federal Regulations (7 CFR) Parts 300 and 353.

NSHS

The NSHS has been established in cooperation with the USDA-APHIS, the National Plant Board (NPB), the Association of American Seed Control Officials (AASCO), the Association of Official Seed Certifying Agencies (AOSCA), and the American Seed Trade Association (ASTA).

The three main objectives of the NSHS are as follows:

1. To develop standardized seed health laboratory test procedures, seed sampling procedures for laboratory seed health testing, visual inspections procedures, and phytosanitary field inspection procedures;
2. To develop a process to accredit private and public entities to carry out the above mentioned activities (see seed health accreditation program); and
3. To leverage this initiative as well as other international initiatives to promote international phytosanitary reform and foster fair equitable trade.

SECTION ONE: Administration, Organization, and Structure of the NSHS

1.1 OVERVIEW

1.1.1 NSHS

The NSHS is a cooperative government and industry consortium formed to address seed health and trade problems in an orderly, scientific, and systematic manner. The goals are promoting trade while protecting agriculture, the environment, and the economic well being of the interested and affected parties.

1.1.2 USDA-APHIS

The USDA-APHIS has responsibility for the Seed Health Accreditation Program in the form of the NSHS. (See Section 2; Administration of the NSHS)

The Administrator¹ of APHIS, or his designee (the USDA-APHIS Accreditation Manager (AM)), acts as an ex-officio member of the Policy and Procedures Advisory Board (PPAB) of the NSHS. The AM responsibilities are outlined in Section 2.3.1. This person is responsible for maintaining oversight functions of the NSHS.

1.1.3 NPB Council/ Plant Protection and Quarantine (PPQ) Strategy Team

The Strategy Team is a group of state and USDA plant health officials that provides program review of pest management programs within the U.S. Their function is to provide policy recommendations and identify issues important to the USDA and the states. The Strategy Teams' involvement in the Seed Health Accreditation Program is to review the program and provide input to the Administrator.

1.1.4 PPAB

The PPAB acts as the primary body giving direction to the NSHS. The PPAB contains one member each from the National Plant Board (NPB), the American Association of Seed Control Officials (AASCO), the Association of Official Seed Certifying Agencies (AOSCA), and three members from the American Seed Trade Association (ASTA). The director(s) of the Administration Units (AU) and the Administrator of APHIS (or his designee) participate as ex-officio members of the PPAB.

The PPAB determines specific host/pathogen combinations for which test methods are developed, with recommendations from groups such as the ASTA Veg-Tech Subcommittee, etc. They assist in setting the agenda for the Administration Unit's (AU) activities and priorities. The PPAB reviews the results and recommendations of the

¹ The Administrator delegates this authority to the AM on his or her behalf as listed at 7 CFR 301.38-1.

Technical Panels, makes any recommendations based on their review, and forwards them to the Administrator for approval. Following USDA-APHIS approval, these results are included in Reference Manual B for official use in phytosanitary certification. The PPAB also approves checklists of equipment and facilities that can be used to evaluate accreditation candidates.

1.1.5 Technical Panels

Technical Panels are chosen from a pool of ‘qualified experts’ based on their area of expertise to serve as volunteers to review existing and propose new: seed health laboratory test procedures, seed sampling procedures for laboratory seed health testing, visual inspections procedures, and phytosanitary field inspection methodologies. The panels may consist of experts from the private and public sectors and are open to experts from other countries as well.

Methods that have not been reviewed by a Technical Panel for host/pathogen combinations and have already been reviewed by ISHI or ISTA may be published in Reference Manual B as “B” rated methods until passed by a Technical Panel. These laboratory testing ISHI/ISTA methods that are non-Technical Panel reviewed are approved for publication by the PPAB.

The recommendations of the panels are reviewed by the PPAB. In certain cases, where additional research and development are required, financial support is provided to technical experts or the AU for specified uses as approved by the PPAB.

1.1.6 AUs

The AU(s) manages the day-to-day activities of the NSHS on behalf of the USDA-APHIS as follows:

- 1.1.6.1 The AU receives and processes applications from entities wishing to become accredited;
- 1.1.6.2 The AU schedules and coordinates the accreditation and recertification audits with the applicants and accredited entities;
- 1.1.6.3 The AU coordinates and conducts appropriate training sessions and workshops in the appropriate areas of plant health for applicant entities, as needed;
- 1.1.6.4 The AU assists in performing proficiency testing, if deemed necessary by USDA-APHIS, as part of resolving any phytosanitary issues;
- 1.1.6.5 The AU is the official “record keeper” of the system and maintains the controlled versions of all reference materials including the standardized test and inspection methodologies;

1.1.6.6 The AU engages in test/inspection standardization and development;

1.1.6.7 The AU makes provisions for the testing of “minor use crops;”

1.1.6.8 The AU develops lists of experts from which volunteers are selected to serve on Technical Panels. The selection process is under the guidance of the PPAB and the AM; and

1.1.6.9 The AU collects and organizes the relevant body of scientific information for review and consideration by the Technical Panels.

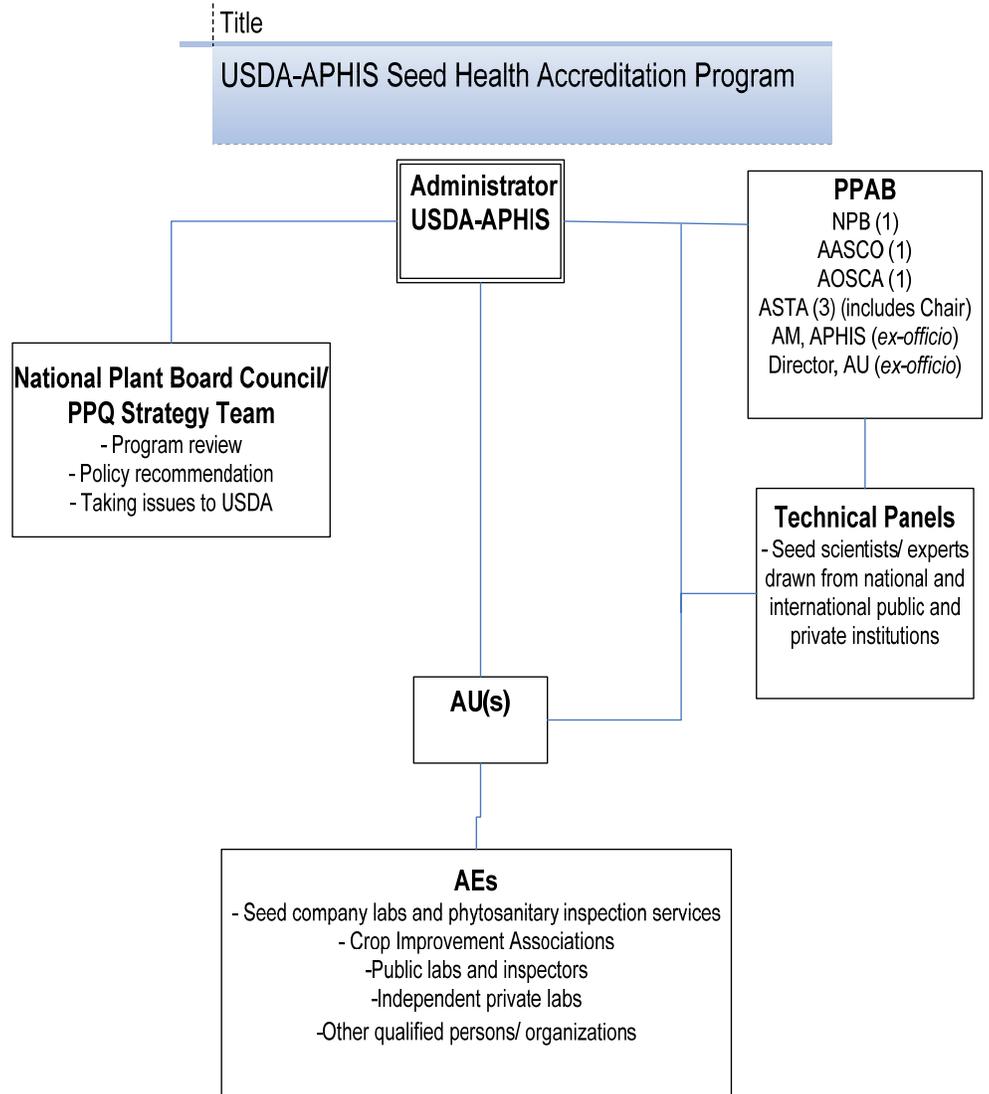
1.1.7 Accredited Entities (AE’s)

AEs are any public or private organization (or individual) that meet the requirements for accreditation as outlined in this manual and the regulations at 7 CFR 353.9. Private AE’s are allowed to perform only those seed health laboratory test procedures, seed sampling procedures for laboratory seed health testing, visual inspections procedures, and phytosanitary field inspection procedures for which they have been accredited. AE’s will adhere to a regular program of surveillance audits and proficiency testing as required by the Administrator and/or as outlined in this manual and the regulations at 7 CFR 353.9.

9/9/2009

National Seed Health System

Figure 1



1.2 ADMINISTRATION OF THE NATIONAL SEED HEALTH SYSTEM

1.2.1 General Provisions

1.2.1.1 The procedures under which the NSHS operates are administered in a nondiscriminatory manner.

Access to the NSHS is not conditional upon the size of the operation, laboratory or membership of any association or group, nor are there any undue financial conditions restricting participation.

1.2.1.2 The competence of an applicant entity to conduct seed health laboratory test procedures, seed sampling procedures for laboratory seed health testing, visual inspections procedures, and/or phytosanitary field inspection procedures is assessed according to the accreditation standards established by the USDA-APHIS and the procedures contained within this document.

1.2.1.3 The NSHS is administered in a manner that requires AEs to maintain impartiality and integrity.

1.2.1.4 The administration of the NSHS is organized as outlined in **Figure 1**. The NSHS is organized in a manner that gives the USDA-APHIS oversight responsibility for the accredited portion of the NSHS in order to maintain the integrity of the international phytosanitary system. The USDA-APHIS participates as an ex-officio member of the PPAB in the approval of standardized seed health laboratory test procedures, seed sampling procedures for laboratory seed health testing, visual inspections procedures, and phytosanitary field inspection procedures.

1.2.2 Organizational Requirements of the NSHS Administration

1.2.2.1 The USDA-APHIS AM and the AU:

- a. Are legally identifiable entities;
- b. Have rights and responsibilities relevant to NSHS accreditation activities;
- c. Have adequate arrangements to cover liabilities arising from operations and/or activities;
- d. Have the financial stability and resources required for the operation of an accreditation system;
- e. Have and make available on request a description of the means by

which each receives financial support;

f. Employ a sufficient number of personnel having the necessary education, training, technical knowledge, and experience for handling the type, range, and volume of work performed, under a senior executive who is responsible to the organization, body, or board to which it reports;

g. Have a quality system including an organizational structure, that enables each to give confidence in their ability to operate an accreditation system satisfactorily;

h. Have documented policies and procedures for the operation of the quality system that include:

i. Policies and decision-making procedures that distinguish between accreditation and any other activities in which the body is engaged; and

ii. Policies and procedures for the resolution of complaints and appeals received from AEs about the handling of accreditation matters, or from users of services about AEs or any other matters;

i. Together with its senior executive, and staff, be reasonably free from any commercial, financial, and other pressures which might influence the results of the accreditation process;

j. Have formal rules and structures for the appointment and operation of committees involved in the accreditation process; such committees are reasonably free from any commercial, financial, and other pressures that might influence decisions, or they have a structure where members are chosen to provide impartiality through a balance of interests where no one interest predominates;

k. Establish one or more technical committees or panels, each responsible within their scope, for advising the AM and AU on the technical matters relating to the operation of their accreditation system;

l. Will not offer consultant or other services potentially compromising the objectivity of their accreditation process and decisions; and

m. Have arrangements that are consistent with applicable laws, to safeguard, at all levels of their organization (including committees), confidentiality of all information obtained relating to applications, assessments, and accreditation of applicants.

1.2.2.2 The AM and AU have written procedures for controlling the ownership,

use, or display of accreditation documents. Both also have procedures the AE utilizes to refer to their accredited status.

1.2.3 Administration Structure for the NSHS

1.2.3.1 The AM (USDA-APHIS):

- a. Is an appointee of the USDA-APHIS and maintains oversight functions of the accredited portion of the National Seed Health System;
- b. Upholds the regulations and rules governing units of the Federal government, and is subject to the organizational requirements of Section 1.1;
- c. Is an integral part of the accreditation system and works closely with the PPAB (Section 1.3.3) and the National Plant Board/PPQ Strategy Team (Section 1.3.4) to set and maintain policy and priorities of the accreditation system;
- d. Grants official accreditation to applicant entities as a representative of the USDA-APHIS according to the provisions of the standards for accreditation;
- e. Directs the AU(s) in the activities of accreditation. This includes establishing the priorities, criteria, and regulations for accreditation of non-government entities; and
- f. May conduct independent audits of the AUs.

1.2.3.2 The AUs:

- a. Are designated by a Memorandum of Understanding (MOU) from the USDA-APHIS;
- b. Are a legally identifiable, public or private, entity;
- c. Are an affirmative action, equal opportunity employer;
- d. Confine their requirements, assessments, and decisions on accreditation to those matters specifically related to the scope of the accreditation being considered;
- e. Are subject to the organizational requirements of Section 1.5;
- f. Are responsible for the organization and implementation of the accreditation processes outlined in the standards for accreditation;

- g. Train and appoint auditors according to the provisions in Section 2 and for final approval by the AM;
- h. Maintain procedures and protocols for applicant entities in a manner that assures impartiality and maintains the provisions of the quality system (Section 2.4); and
- i. Organize and/or hold training workshops, as needed, to assure that applicant entities can meet the requirements of the Seed Health Accreditation Program.

1.2.3.3 The PPAB shall consist of six (6) members:

- a. One member of the NPB (National Plant Board);
- b. One member from AASCO (Association of American Seed Control Officials);
- c. One member of AOSCA (Association of Official Seed Certifying Agencies); and
- d. Three members from ASTA (American Seed Trade Association).

1.2.3.4 Ex-officio members of the PPAB are the AM and the director(s) of the AU(s).

1.2.3.5 The PPAB develops policies and procedures for the AM, provides technical expertise and information deemed necessary for the AM to effectively administer the system, and performs other duties as outlined in Section 1.1.4.

1.2.3.6 The NPB/PPQ Strategy Team consists of members from the NPB and the USDA-APHIS. This team:

- a. Provides the AM with policy coordination, reviews, and recommendations;
- b. Reviews the provisions of the accreditation system on behalf of the AM; and
- c. Resolves issues of regulatory procedures to assure accreditation system integrity.

1.2.4 AU Quality System

1.2.4.1 The AU operates a quality system according to the type, range, and

volume of the work performed. This system is documented and the documentation is available for use by the AU staffs. The AUs designate a specific person to communicate directly with the AM, to be responsible for the quality system, and to maintain the quality documentation.

1.2.4.2 The quality system is documented with a quality manual or equivalent documentation and relevant quality procedures. The quality manual contains or refers to, at a minimum:

- a. A quality policy statement;
- b. The organizational structure of the accreditation body;
- c. The operational and functional duties and services pertaining to quality; each person involved is able to refer to this information to ascertain the extent and the limits of their responsibility;
- d. Administrative procedures including document control;
- e. Policies and procedures to implement the accreditation process;
- f. Procedures for feedback and corrective actions to address discrepancies after detection;
- g. The policies and procedures for responding to appeals, complaints, and disputes;
- h. The policies and procedures for conducting internal audits;
- i. The policies and procedures for conducting quality system reviews;
- j. The policies and procedures for the recruitment and training of auditors and for monitoring their performance.

1.2.4.3 The AUs audit their activities at a minimum of once a year to verify compliance with the requirements of the quality system. The quality system is also reviewed to ensure its effectiveness. Audits and reviews are performed systematically and periodically and also include details of any corrective actions performed.

1.2.4.4 The AUs maintain records to document accreditation procedures have been effectively performed, including but not limited to, application forms, regular audit reports, and reports related to granting, maintaining, extending, suspending, or withdrawing accreditation. These documents form part of the official record.

1.2.4.5 The AUs have policies and procedures for retaining records for a period consistent with their contractual and legal obligations. The AUs also have policies and procedures for accessing these records consistent with Section 2.2 of this document.

1.2.5 Granting, Maintaining, Extending, Suspending, and Withdrawing Accreditation

1.2.5.1 The AM, through technical advice from its committees, specifies the conditions for granting, maintaining, and extending accreditation and the conditions under which accreditation will be suspended or withdrawn, partially or in full for all or part of the AE's scope of accreditation.

1.2.5.2 The AM has procedures to grant, maintain, suspend, or withdraw accreditation, and also to increase or reduce the scope of accreditation or to require reassessment, due to changes affecting the AE's activity and operation. This includes changes, such as personnel or equipment, or if the investigation of a complaint or any other information indicates that the AE no longer complies with the requirements of their quality system.

1.2.5.3 The AM reviews the accreditation status relating to the transfer of accreditation when the legal status (*e.g.*, ownership) of the AE changes.

1.2.5.4 These responsibilities are detailed in: 7 CFR 353: Accreditation Standards for Laboratory Seed Health Testing and Seed Crop Phytosanitary Inspection

1.2.6 In Order to Maintain Accreditation, the AE Must:

1.2.6.1 Perform all work for which it is accredited in conformance with their approved protocols, methods, or procedures;

1.2.6.2 Be re-assessed (via a re-certification audit) and evaluated on a three year schedule by providing a report of activities (positive and negative issues and suggestions), send an updated Quality Manual to the AU, which would include any new methods, and undergo an external audit. An option of referee (proficiency) testing may be required of the AE under circumstances as deemed necessary by the AM and/or another USDA-APHIS official. The AU is responsible for scheduling the audit and any necessary proficiency testing;

1.2.6.3 Demonstrate on request that it is able to perform the procedures for which it is accredited;

1.2.6.4 Be able to perform the laboratory seed health tests or inspection services for which it is accredited. If at any time, an AE is determined by the AM to be unable to perform accredited duties, they will immediately cease those activities until they can demonstrate to the AM's satisfaction that corrective action has been

identified and implemented;

1.2.6.5 Notify the AM immediately (within two business days) of any changes in key management personnel or staff responsible for the testing or phytosanitary inspection services for which the entity is accredited;

1.2.6.6 Notify the AM within five business days, of any changes in the location, ownership, physical facilities, equipment, or other pertinent conditions that existed at the facility at the time of accreditation and are critical to the performance of the accreditation functions; and

1.2.6.7 Pay all fees required to cover costs associated with audits, proficiency tests, or other work performed by the AU.

1.2.7 Refusal, Suspension or Cancellation, and Notification

1.2.7.1 Applications that are incomplete, unsigned, or signed by an unauthorized person or not on the USDA-APHIS approved forms will be refused. Notice of any refusal shall be provided within 15 working days of receipt, not including the time for mail or other delivery delay. Re-application may not be made for 90 days after a notice of refusal. A new application fee is required with any reapplication.

1.2.7.2 Accreditation is refused if the AM determines that the applicant does not meet the requirements, has falsified any information provided on the application or to the AU, or fails to pay any fees. The applicant shall be notified of refusal within 15 days of a determination by the AM.

1.2.7.3 Accreditation is re-evaluated within 90 days of any change of ownership. Based upon this evaluation, the AM may also require an audit.

1.2.7.4 Incidences of non-compliance are defined as either Critical, Major, or Minor. This depends on the extent to which they effect the AE's ability to continue to provide confidence that the performance of the AE meets the conditions established in this standard.

a. A Critical Non-Compliance is defined as:

An audit finding that reveals that the integrity of the program is jeopardized. The result of this finding indicates the tests or inspection findings could not be utilized as supporting documentation for the issuance of the phytosanitary certificate.

Critical Non-Compliance incidences include, but are not limited to:

i. No inspection or test conducted;

ii. Failure to follow inspection/testing methods in accordance with this standard;

iii. A deliberate attempt to provide incorrect results of an inspection or testing;

iv. Three or more Major Non-Compliance items detected in any one audit; and

v. Any reoccurrence of the same Major Non-Compliance detected in the two previous consecutive audits.

Action taken for Critical Non-Compliance: The AE is notified of their violation of the Standard. The AE is removed from the approved list until:

i. An agreed corrective strategy has been identified by the AU, the AM, and the AE; and

ii. An audit is completed of all areas found not to be in compliance, if designated as required by the corrective strategy.

b. A Major Non-Compliance is defined as:

An audit finding that reveals an isolated incident(s) that results in decreased confidence of the AE's inspection, sampling, or testing results; however, it does not have a direct impact on the integrity of the program. Corrective action is required immediately so that implementation is in place to retain confidence that the conditions of the Standard are being fulfilled.

Major Non-Compliance incidences include, but are not limited to:

i. A significant difference between the Auditor's and AE's inspection and/ or test findings;

ii. The AE fails to identify, classify, or record problems correctly;

iii. Lack of inspection facilities and/or equipment;

iv. Internal audits are not conducted or properly documented;

v. Actions taken following audits are not recorded;

vi. Documentation is unavailable for auditors;

vii. Corrective action for a Minor Non-Compliance(s) is not implemented within the agreed time-frame; and

viii. Three or more Minor Non-Compliance incidents result from any one audit.

Action taken for a Major Non-Compliance:

i. When one or more Major Non-Compliance incidents are identified during the initial accreditation audit, the entity will not be accredited.

ii. When one or two Major Non-Compliance incidents are identified during a surveillance audit, corrective action is required for implementation as soon as possible. An additional audit may be conducted to confirm that the corrective actions have been made.

iii. A Critical Non-Compliance will be recorded for every three Major Non-Compliance incidents identified during a single visit.

c. A Minor Non-Compliance is defined as:

An audit finding that reveals a non-conformance that does not immediately and/ or significantly affect the integrity of the program. Corrective actions must be undertaken no later than the next audit, or within a time-frame agreed to by the Auditor and Entity.

Minor Non-Compliance incidents include, but are not limited to:

i. Any amendment to procedural details that is not documented;

ii. An incomplete inspection, testing, or audit record, such as:

(1) No recording of critical test steps;

(2) No signing of records and recording of dates;

(3) Improper grower identification;

(4) Improper sample identification;

(5) Incomplete inspection and testing facilities or equipment; or

(6) Any other deviations from the Entity's Quality Manual.

Action taken for Minor Non-Compliances: A Major Non Compliance will be recorded for every three (3) Minor Non Compliance incidents identified during an audit.

1.2.7.5 If a Non Compliance not covered by the above examples and definitions is identified, it will be classified as a Major Non Compliance incident until clarified by the AM.

1.2.8 Corrective Action Implementation

1.2.8.1 A corrective action and a time frame for implementation will be agreed between the Auditor and the Entity for each non-compliance. The auditor verifies that the corrective action has been implemented and is operating effectively within the agreed time frame. Any non-compliance incident will be accompanied by an action plan. Failure to follow the action plan may result in cancellation of accreditation.

1.2.8.2 The Auditor provides the entity with a list of all corrective actions to be taken to identify and correct system non-compliances. Corrective actions will outline:

- a. What will be done;
- b. By whom it will be done;
- c. The time frame for implementation of the corrective action; and
- d. The verification activities to be undertaken to ensure that corrective actions have been successfully implemented.

1.2.9 Corrective Action Non-Implementation

When agreed-upon corrective actions for Major or Critical Non Compliances are not implemented, the entity is subject to suspension of accreditation.

1.2.10 Suspension or Cancellation

When accreditation is suspended or cancelled, the AE and all certifying officials will be notified within 48 hours by telephone, electronic mail, facsimile, overnight mail, or courier service. The AE will immediately cease activities for which a major or critical non-compliance has been recorded.

1.2.11 AM Suspension or Cancellation Responsibilities

The AM apprises the AE of the reason(s) for suspension or cancellation, the corrective action(s) required, and the process for re-accreditation.

1.2.12 AE Corrective Measures Requirements and Re-accreditation

The AE is responsible for notifying the AM of corrective measures taken and for requesting re-accreditation. Re-accreditation may be granted when the corrective measures have been verified to the satisfaction of the AM.

1.2.13 Appeals

Appeal of any refusal, suspension, or cancellation of accreditation by the AM may be made within 5 working days of notification. The AM then makes a determination and notifies the appellant within 15 working days. The AM's decision is final.

1.2.14 Dispute Resolution

Disputes relating to testing or inspections results will be resolved by a mediator or trained arbitrator, according to the AM's discretion. The mediation or arbitration panel will consist of testing or inspection professionals with expertise in the disputed testing or inspection protocol(s) or procedure(s)

1.2.15 Documentation

1.2.15.1 The AU will provide updates at adequate intervals and make available upon request through publications, electronic media, or other means. These will include the following:

- a. Information on the authority under which accreditation systems operated by the AM are established. This will also specify whether they are mandatory or voluntary;
- b. A document containing the requirements for accreditation in accordance with this document;
- c. The Standards for Accreditation identifying the requirements for granting, maintaining, extending, suspending, and withdrawing accreditation;
- d. Information about the assessment and accreditation processes;
- e. General information on the fees charged to the applicant and the AE; and
- f. A description of the rights and duties of the AE as specified in Clauses 4.1, 4.2, and 4.3 of this document, including requirements, restrictions, or limitations on the use of the NSHS logo and on the ways of referring to the accreditation granted.

1.3 AUDITORS

1.3.1 Requirements for Auditors

The auditor or auditor team appointed to assess an applicant:

- 1.3.1.1 Is familiar with the relevant legal regulations, accreditation procedures, and accreditation requirements;
- 1.3.1.2 Has a thorough knowledge of the relevant audit method and documents;
- 1.3.1.3 Has appropriate technical knowledge of the identified seed health tests, plant health inspection protocols, or the visual and sampling procedures relevant to the accreditation;
- 1.3.1.4 Is able to communicate effectively, both orally and in writing;
- 1.3.1.5 Is reasonably free of any commercial, financial, or other pressures or conflicts of interest leading the auditor(s) to act in an unfair or discriminatory manner; and
- 1.3.1.6 Has not have offered consultant services to the applicant potentially compromising their impartiality in the accreditation process and decisions.

1.3.2 Qualification Procedures for Auditors

The AM has an adequate procedure for:

- 1.3.2.1 Qualifying auditors, through an assessment of their competence and training, and by attending one or more actual training sessions with a qualified auditing program;
- 1.3.2.2 Monitoring the performance of auditors.

1.3.3 Contracting of Auditors

The AU requires the auditors to sign a contract or other document by which they commit themselves to comply with the rules defined by the NSHS. These include rules pertaining to confidentiality as well as those relating to independence from commercial and other interests, and to any prior association with the applicant undergoing auditing.

1.3.4 Auditor Records

The AU shall possess and maintain up-to-date records of all auditors consisting of their:

- 1.3.4.1 Name and address;

1.3.4.2 Organization affiliation and position held;

1.3.4.3 Educational qualification and professional status;

1.3.4.4 Work experience;

1.3.4.5 Training in procedures involving seed health laboratory testing, seed sampling for laboratory seed health testing, visual inspections, and phytosanitary field inspection;

1.3.4.6 Experience in procedures involving seed health laboratory testing, seed sampling for laboratory seed health testing, visual inspections, and phytosanitary field inspection; and

1.3.4.7 Date of most recent record revision.

1.3.5 Procedures for Auditors

Auditors are provided with an up-to-date set of procedures outlining auditing instructions and all other relevant information required to perform an audit.

1.4 ACCREDITATION PROCESS

1.4.1 Application for Accreditation

1.4.1.1 A detailed description of the audit and accreditation procedure, documents containing the requirements for accreditation, and documents describing the rights and duties of the applicant (including fees to be paid by the applicant) are current and are provided to the applicants by the AU.

1.4.1.2 Additional relevant information is provided to applicants on request.

1.4.1.3 The AU supplies an application form that provides for the collection of all, but not limited to, the applicant's following information, authorization, and agreements:

- a. Legal name and full address (mail and business);
- b. Name, address, telephone and fax numbers, and e-mail address (if available) of the responsible individual or his/her authorized representative;
- c. A description of the entity, including its physical facilities, primary function, scope of operation, and relationship to its larger corporate entity;

- d. A description of the laboratory testing or phytosanitary inspection services for which the entity is seeking accreditation;
- e. Authorization for auditors to access the applicant's facilities and review relevant records during normal business hours;
- f. Agreement to provide all relevant information requested by the auditor; and
- g. Agreement to pay all accreditation fees as billed in order to cover costs incurred while conducting accreditation audits. This includes travel costs for the auditor.

1.4.1.4 To apply for accreditation, the applicant obtains, completes, signs, and submits an application to the AM along with the required fees. Applications that are incomplete or unsigned, or not on the USDA-APHIS/NSHS approved forms will be rejected. A notice of rejection will be issued within 15 working days (not including the normal time for delivery by mail).

1.4.1.5 Confidential Business Information (CBI) will not be disclosed by the AM, the AU, or independent auditors, to any unauthorized persons according to the applicant or the AE.

1.4.1.6 A duly authorized representative of the applicant is required to sign an official application form, which includes (and/ or may be attached):

- a. The clearly defined scope of the desired accreditation;
- b. The applicant's representative's agreement to fulfill the accreditation procedure which includes receiving the assessment team, paying the fees charged to the applicant regardless of the result of the assessment, and accepting the charges of subsequent maintenance of the accreditation; and
- c. The applicant's agreement to comply with the requirements for accreditation and to supply any information needed for the evaluation.

1.4.1.7 The following minimum information is provided by the applicant prior to the on-site assessment (as listed in the application form):

- a. The general features of the applicant (corporate entity: name, address, legal status, and human and technical resources);
- b. General information concerning the applicant covered by the application (such as the primary function), relationship to/ in a larger corporate entity, and, if applicable, physical location of all facilities

involved;

c. A descriptive list of the procedures for: seed health laboratory testing, sampling, and visual inspections, and phytosanitary field inspections for which accreditation is sought; and

d. A copy of the applicant's quality manual and associated documentation.

1.4.1.8 This information used for the preparation of the on-site assessment will be treated as confidential.

1.4.1.9 Fees for accreditation are described in the official NSHS application form.

1.4.1.10 Upon receipt of an application, the AM will review the application for completeness and in order to determine the scope of the audit that will be required to adequately review the entity's fitness to conduct accredited seed health laboratory test procedures, seed sampling procedures for laboratory seed health testing, visual inspections procedures, and phytosanitary field inspection procedures.. This review will be completed within 30 days. The information is then entered into the USDA-APHIS accreditation database.

1.4.1.11 By submitting a signed application form, the applicant agrees to fulfill the accreditation procedure, specifically to receive the auditor team, to supply any information needed for the audit of the facility, and to pay in advance the fees charged to the applicant. These fees will cover the costs incurred in conducting the accreditation audits and include travel costs for the auditors.

1.4.1.12 Once an application has been approved, the AM contacts the AU and requests that it arrange an audit within 30 working days after notification. If the audit cannot be performed within 30 days, the applicant is notified and another date is determined.

1.4.2 Audit

1.4.2.1 The AU appoints a qualified auditor(s) to evaluate all material collected from the applicant and to conduct the audit on its behalf at the applicant's location and any other sites where accreditation activities are to be performed.

1.4.2.2 To ensure that a comprehensive and correct audit is completed, each auditor is provided with the appropriate working documents; auditor checklist templates are available from the AU.

1.4.2.3 The date of audit is mutually agreed upon with the applicant. The latter is informed of the name(s) of the qualified auditor(s) nominated to perform the audit, with sufficient notice so that the applicant has an opportunity to appeal against the appointment of any particular auditor.

1.4.2.4 The auditor(s) is formally appointed by the AM. A lead auditor is designated, if appropriate. The mandate given to the auditor(s) is clearly defined by the AM and forwarded to the applicant.

1.4.3 Sub-contracting of Auditors

1.4.3.1 If the AU, with approval from the AM, decides to fully or partially delegate the audit of an applicant to another body, the AU takes full responsibility for such an audit made on its behalf.

1.4.3.2 The AU ensures that any body to which an audit has been delegated is competent and complies with the applicable provisions of this document.

1.4.4 Audit Report

1.4.4.1 The AU may adopt reporting procedures that suit its needs but at a minimum these procedures ensure that:

- a. A meeting takes place between the auditor(s) and the applicant prior to leaving the facilities; the auditor provides a written or oral report on the results of the audit;
- b. The auditor(s) team provides the AU with a detailed report containing all relevant information concerning the ability of the applicant to comply with all of the accreditation requirements; and
- c. A report on the outcome of the audit is promptly brought to the applicant's notice by the AM, identifying any non-compliance that must be corrected in order to comply with all of the accreditation requirements. The applicant is invited to present its comments on this report and to describe the specific actions taken, or planned to be conducted (within a time frame as specified by the AM), in order to remedy any non-compliance with the accreditation requirements.

1.4.4.2 The final report is authorized by the AU and then submitted to the applicant, if different, and includes, at a minimum:

- a. The date(s) of the audit(s);
- b. The names of the auditor(s) that completed the report;
- c. The names and addresses of all the facilities audited;
- d. The scope of the audit of accreditation or reference thereto; and

e. The comments of the auditor(s) about the compliance of the applicant with the accreditation requirements.

1.4.4.3 The audit reports take the following into consideration:

a. The technical qualification, experience, education, and authority of the staff encountered, particularly the persons responsible for the technical validity of the laboratory seed health test reports. Technical qualifications should also be noted for all staff preparing seed sampling reports and field inspection reports, and for those reviewing seed reports;

b. The competency of the internal organization and the applicant's adopted procedures adequacy to give confidence to the quality of its services, and physical facilities;

c. Proficiency testing of all accredited activities or other inter-laboratory comparisons performed by the applicant, the results of the testing or comparison, and the use of the results by the applicant; and

d. The actions taken to correct any non-compliance identified during previous audits.

1.4.5 Decision on Accreditation

1.4.5.1 The decision whether or not to accredit an applicant is made by the AM on the basis of the information gathered during the accreditation process (this includes information received by all credible sources) and by the AU.

1.4.5.2 The AM does not delegate its responsibility for granting, maintaining, extending, suspending, or withdrawing accreditation.

1.4.6 Documentation Granting Accreditation

1.4.6.1 The AM transmits to each applicant formal accreditation documents such as a letter or a certificate signed by an officer who has been assigned this responsibility. These formal accreditation documents permit the identification of:

a. The name and address of the accredited applicant;

b. The scope of the accreditation including:

i. The type of accreditation granted (seed health testing, phytosanitary field inspections, sampling for phytosanitary testing, visual inspections);

ii. The crop species on which these test and inspections may be

carried out.

c. The persons recognized by the AM responsible for: supervising or conducting the seed health laboratory tests, seed sampling procedures for laboratory seed health testing, visual inspection procedures, and phytosanitary field inspection procedures and that these persons have met the appropriate qualifications and training requirements.

d. The effective date of accreditation, and the corresponding term, if applicable.

1.4.7 Re-Accreditation of AEs

1.4.7.1 The AU has a program for carrying out re-accreditation audits and is performed every three years to ensure that the AE continues to comply with the accreditation requirements.

1.4.7.2 The re-accreditation audit of the AE includes:

a. A report of activities and any internal audits (positive and negative issues and suggestions) for the AU;

b. An updated Quality Manual for the AU, which would include any new methods; and

c. An external audit.

1.4.8 Certificates or Reports Issued by AE

1.4.8.1 The AM normally allows an AE to refer to its accreditation in seed health test for reports that contain only the tests for which the AE is accredited. The AE refers to NSHS accreditation for use on certificates and documentation referencing accredited procedures only; specific language used may be referenced in the AE's Quality Manual. Specific information regarding accredited services for each AE is also listed on the USDA-APHIS NSHS website. The AE will not use NSHS attribution on any non-accredited services. Failure to comply with this requirement may result in the AE's suspension of accreditation or indefinite expulsion from the NSHS program.

SECTION TWO: Process of Accreditation.

2.1 PURPOSE OF ACCREDITATION:

2.1.1 Issuing Phytosanitary Certificates

Provide a program where non-government entities and public entities are accredited to perform seed health laboratory test procedures, seed sampling procedures for laboratory seed health testing, visual inspection procedures, and phytosanitary field inspection procedures of seed crops for use in issuing phytosanitary certificates.

2.1.2 Ensure Quality

Provide quality data for phytosanitary certifications through accreditation and quality assurance processes.

2.1.3 Ensure High Performance Standards

Maintain high standards of performance for testing and inspecting, ensuring movement of healthy seed within the U.S. and internationally.

2.2 ACCREDITATION PROCEDURES

2.2.1. Facility; Documentation and Staff Requirements

2.2.1.1 The applicant:

- a. Is organized in a manner to assure proficient: performance of seed health laboratory test procedures, seed sampling procedures for laboratory seed health testing, visual inspection procedures, and phytosanitary field inspection procedures;
- b. Has a Quality Manual or equivalent documentation to describe the Quality System;
- c. Is organized in a manner that avoids undue pressure or inducement possibly influencing judgment or results;
- d. Makes staff aware of specific job duties, including the extent and limitations of responsibilities; and
- e. Requires the technical manager to be sufficiently trained for tests and inspections.

2.2.1.2 The facility and environment:

- a. Conform to all local zoning and ordinances;
- b. Provide a work area that is dedicated to laboratory function and is

sufficiently removed (by physical barriers) from all residence(s) and food preparation areas;

c. Comply with all Federal and local regulations for chemical handling and disposal;

d. Provide a facility that does not invalidate the test results or adversely affect the accuracy of data;

e. Provide adequate protection from adverse environmental conditions (such as dust, contamination, temperature extremes, moisture extremes, etc.);

f. Are maintained to ensure "good housekeeping"; and

g. Comply with all USDA-APHIS-PPQ requirements for the movement of regulated articles.

2.2.1.3 Data reporting, records, and documents:

a. Clearly state the results of the: seed health laboratory test procedures, seed sampling procedures for laboratory seed health testing, visual inspection procedures, and phytosanitary field inspection procedures, methodology, and other information pertinent to the results;

b. Are maintained for a period that corresponds to the inventory of the product, and no less than three years and a statutory maximum;

c. Are kept secure and are considered confidential, unless otherwise stipulated.

2.2.1.4 Other records and documents include:

a. Records of equipment calibration and maintenance repair; and

b. All procedures, tests methods, and inspection methods.

2.2.1.5 Samples and sampling records:

a. Sampling is according to NSHS sampling procedures in order to assure the sample is representative as listed in the reference manual.

b. Sampling is the responsibility of those authorized under state and Federal seed laws, or official sampling agents, and must be done in a manner suitable to assure adequate representation of the seed lot or plants.

2.2.2. Facility Inspection Prior to Accreditation

2.2.2.1 A registration audit is:

- a. Performed by a an approved NSHS auditor; and
- b. Verifies that resources (such as equipment and trained staff) are present and/ or in functioning order.

2.2.2.2 Additional laboratory requirements:

a. The laboratory utilizes Good Laboratory Practices (GLP) including, but not limited to:

- i. Aseptic techniques;
- ii. Identification of contamination potential and relevant containment procedures;
- iii. Sterilization and disinfestation of microbiological agents; and
- iv. Safe chemical handling and disposal procedures in accordance with Federal, State, and local laws and regulations as well as manufacturer guidelines.

b. Equipment and machinery:

- i. Is required to correctly carry out the designated test;
- ii. Is properly maintained and repaired;
- iii. Is re-calibrated routinely or as necessary to correct erroneous results;
- iv. Contain calibration information that is logged as necessary or appropriate (pH meters, incubators, etc.); and
- v. Contatin records of maintenance requirements, if relevant and they are current and accessible.

c. Test methods and inspection protocols use approved methods and inspection protocols as listed in Reference Manual B.

d. Other facility requirements include:

- i. Control of access to the testing area; and
- ii. Access only by persons subject to the rules of the testing and inspecting

protocols.

2.2.2.3 Staff and training requirements include:

- a. Appropriate education, training, technical knowledge, and experience for assigned functions is documented and clearly defined; and
- b. Evaluation of seed health tests and inspections are performed: by a University trained plant pathologist, under the supervision of a plant pathologist, or by a person with a related degree and with training approved by the AM.

2.2.2.4 The Quality Manual or equivalent documentation outlines how the AE will:

- a. Ensure the accuracy and precision of all tests and data, document control, and sample control;
- b. Define the policy, purpose, and obligation of the AE;
- c. Document the quality for staff review;
- d. Document the structure/ facility;
- e. Document the operational staff and functional duties and responsibilities;
- f. Document all test procedures;
- g. Document all feedback and corrective actions;
- h. Define all customer complaint procedures;
- i. Document all procedures for new testing, including the assignment, as well as facility requirements prior to initiation; and
- j. Document the internal periodic audits of quality procedures.

2.2.2.5 Documentation requirements for samples are outlined in Reference Manual B.

2.2.3 Accreditation Review and Post-accreditation Inspection

2.2.3.1 The AE, after accreditation, provides periodic reports to the accrediting organization or an appointee of the organization.

2.2.3.2 The AE faces the possibility of periodic accreditation review, in which all

or part of the above documentation is reviewed by the AU and/or AM.

2.2.3.3 Accreditation review is mandatory and/or the AE reports to the AU when:

- a. Significant staff changes occur in technical or evaluating personnel; and
- b. Significant errors occur in any referee sample tests.

2.3 RELATIONSHIP BETWEEN THE NSHS AND THE APPLICANT OR ACCREDITED ENTITY

2.3.1 General Provisions

The administrators of the NSHS have arrangements to ensure that the applicant and its representatives afford such accommodation and cooperation as is necessary, to enable the accreditation body to verify compliance with the requirements for accreditation. These arrangements include provisions for examination of documentation and access to all testing areas, records, and personnel for the purpose of assessment, surveillance, proficiency testing, and complaints resolution.

2.3.2 Specific Provisions

The AM shall require that an AE:

2.3.2.1 Maintains compliance with the relevant provisions of this document at all times;

2.3.2.2 Make claims to be accredited only in terms of the services for which it has been granted accreditation and which are carried out in accordance with these conditions;

2.3.2.3 Pays all fees determined by the AM;

2.3.2.4 Abstains from using its accreditation in such a manner as to bring the NSHS into disrepute and does not make any statement relevant to its accreditation which the AM may consider misleading or otherwise unauthorized;

2.3.2.5 Discontinues its use of all advertising matter that contain any reference thereto and return any certificates of accreditation to the AU upon suspension or withdrawal of its accreditation;

2.3.2.6 Does not use its accreditation to imply product approval by the NSHS;

2.3.2.7 Attempts to ensure that no certificate or report nor any part thereof is used in a misleading manner; and

2.3.2.8 Complies with the requirements of the NSHS when making reference to its accreditation status in communication media such as advertising, brochures, or other documents.

2.3.3 Notification of Changes

2.3.3.1 The AU makes arrangements to ensure that an AE provides notification immediately for any change in any aspect of the AE's status or operation affecting the AE's:

- a. Legal, commercial, or organizational status;
- b. Organization and management (*e.g.*, key managerial staff);
- c. Policies or procedures, where appropriate;
- d. Facilities (any premises involved in accredited activities);
- e. Personnel, equipment, facilities, working environment, or other resources, where significant; and
- f. Authorized signatories; or
- g. Other issues affecting the laboratory's capability, scope of accredited activities, or compliance with the requirements in this document; or any other relevant competence criteria specified by the AM.

2.3.3.2 Upon receipt of a notice of any intended changes relating to the requirements of this document, the relevant competence criteria, and any other requirements specified by the AM, the AU shall ensure that the AE carries out any necessary procedural changes within a timeframe designated by the AM. The AE will notify the AU when such adjustments have been made.

2.3.4 Directory of AEs

The AM produces an annual directory of AEs describing any accreditation granted.

SECTION THREE: Evaluation and screening of laboratory seed health testing, seed sampling, visual inspections, and phytosanitary field inspections methodologies

3.1 CRITERIA FOR THE EVALUATION OF LABORATORY SEED HEALTH TESTING METHODOLOGIES; EVALUATION PROCEDURES

3.1.1 A Review of Test Methods is Conducted by the AU and Includes:

3.1.1.1 A literature review of the host/pathogen interactions and a compilation of the published interactions and detection methods;

3.1.1.2 A compilation of unpublished laboratory seed health tests currently in use; and

3.1.1.3 A compilation of proprietary methodologies, if so offered for evaluation by the owner. The evaluation of proprietary methodologies is governed by a confidentiality agreement.

A list is made of all methods found with a brief description of each method (*i.e.* cultural, serological, etc.), and the literature citation, if available. Proprietary methods are noted.

3.1.2 Elimination of Methodologies

The AU eliminates those laboratory methodologies it judges to be unfit, irrelevant, or out of date.

3.1.3 AU Communication to Panel Members

The AU forwards to each panel member a description of all laboratory seed health tests. Included in this description are all relevant scientific documentation on the test development and record of use (if any) as routine tests.

3.1.3.1 Panel Responsibilities

It is the responsibility of panel members to evaluate the information provided based upon the following criteria:

a. Criterion 1. Empirical Test Data

These are suggested parameters for establishment of a laboratory seed health test from published information. New techniques will have the following parameters included in the development process:

i. Sensitivity. Determine how sensitive the assay is in terms of either percent-infected seed or target pathogen quantification, such as CFU, number of conidia, etc. Panel members may need to make an arbitrary determination about whether the methodology in question is sensitive enough, or they will make a recommendation that the test requires further work. The panel members should also make recommendations on sample size if this is not clearly spelled out in the existing procedures for that test.

ii. Specificity. Determine whether the assay is capable of detecting a range of isolates of the pathogen from different geographical regions, races, etc. Determine whether other closely related organisms are separated with the technique.

iii. Repeatability and Reliability. Replicate experiments of 1 and 2 help determine these parameters. Additional experimentation including varying types of seed samples (varieties, production areas, etc.) will further refine these parameters.

b. Criterion 2. Internal Comparative Data

Comparisons with already established techniques will yield useful information regarding new techniques. If a new technique performs as well or better than an established technique then it should be accepted. This information is generated internally through the developmental process or through group comparative testing. These criteria may be of limited applicability to panel members evaluating existing test methodologies.

c. Criterion 3. Historical Data

If a technique has been used in industry or academia there may be some indication or record of the number of uses of that technique. In commercial use there may also be a record of the number of complaints associated with a particular assay. These records may be a good indicator of the effectiveness of the assay, and if available will be reviewed.

3.1.3.2 Other Criteria

Panel members will consider any other criteria that might have significant impact on the recommendation for use of a test. These include the cost of the test, facilities required to perform it, time to perform test, and other factors.

3.1.4 Panel Report

The Technical Panel prepares a report rating each of the various methodologies evaluated by these criteria listed above and states the reason(s) for their rating. The report also includes panel recommendations on any improvements that should be made to any aspect

of the process.

The panel members use the following guidelines for rating the methodology(s):

3.1.4.1 Class A. The test or method acceptable as a standard test;

3.1.4.2 Class B. The test or method needs further research before acceptance as a standard test. This could be for improvement to the method itself or a recommendation for a comparative test with a known method; or

3.1.4.2 Class C. The test should not be accepted as a standard test.

3.2 CRITERIA FOR THE EVALUATION OF PHYTOSANITARY FIELD INSPECTION METHODOLOGIES

A review of new seed crop field inspection methodologies will be conducted by the PPAB and may be referred to a Technical Panel if the proposed method differs from the procedure for Seed Crop Field Inspection listed in Reference Manual B.

See Reference Manual B for the Seed Crop Field Inspection procedure. This includes a detailed strategy for inspecting fields and diagnosing diseases (both in the field and in the laboratory).

3.3 CRITERIA FOR THE EVALUATION OF SAMPLING PROCEDURES

The PPAB has voted to use the AASCO Handbook on Seed Sampling (http://www.seedcontrol.org/seed_sampling_handbook.html) for its seed sampling methodology for phytosanitary seed health testing for the NSHS. This is in accordance with current State and Federal visual inspection policy.

3.4 CRITERIA FOR THE EVALUATION OF VISUAL INSPECTION METHODOLOGIES

The PPAB has voted to use the “General Procedures: Inspecting Commodities” section from the USDA Export Program Manual (XPM) (http://www.aphis.usda.gov/import_export/plants/manuals/domestic/downloads/xpm_pdf/3_5genproc_inspecting_commods.pdf) for its visual inspection methodology for the NSHS. This is in accordance with current State and Federal visual inspection policy.

GLOSSARY OF TERMS

Accredited Entity (AE): An entity, which has been accredited by the USDA-APHIS to perform laboratory seed health tests or phytosanitary inspections in support of phytosanitary certification.

Accreditation Candidate (or Applicant): An entity from which an application form and appropriate fees has been accepted by the USDA-APHIS.

Accreditation Manager (AM): An officer of the USDA-APHIS appointed by the Administrator of APHIS to administer and direct the accreditation of entities to perform seed health laboratory test procedures, seed sampling procedures for laboratory seed health testing, visual inspections procedures, and phytosanitary field inspection procedures.

Administration Unit (AU): An organization authorized by the USDA-APHIS to perform specific functions involving the evaluation of applicants for accreditation as well as managing the administrative, technical, and scientific aspects of the NSHS. Iowa State University Seed Science Center was designated as the AU at the inception of the NSHS in 2001. Other AU will be designated as well, if needed.

American Seed Trade Association (ASTA): A trade organization with membership consisting of about 850 companies involved in seed production and distribution, plant breeding, and related industries in North America. This group has three members on the PPAB, one of which is the Chair. <http://www.amseed.com/>

Association of American Seed Control Officials (AASCO): An organization of seed regulatory officials from the United States and Canada that works to achieve uniformity of seed legislation between member states and Federal agencies. This group has one member on the PPAB. <http://www.seedcontrol.org/index.html>

Association of Official Seed Certifying Agencies (AOSCA): A group of seed certifying agencies and foundation seed organizations that work on production, identification, distribution, and promotion of certified classes of seed and other crop propagation materials. This group has one member on the PPAB. <http://www.aosca.org/>

Authorized Certification Official (ACO): Any Federal, state, or local government official authorized by the USDA-APHIS to issue Federal phytosanitary certificates.

Entity: Any organization, company, limited partnership, corporation, association, individual, or any other legally constituted entity, whether in the private or public sector who wishes to provide services to the seed industry in support of phytosanitary certification.

International Seed Health Initiative (ISHI): An initiative that works on seed health issues under the International Seed Federation.

http://www.worldseed.org/en-us/international_seed/seed_health_testing.html

International Seed Testing Association (ISTA): An international seed organization that works on developing, adopting, and publishing standard procedures for sampling and testing seeds, and promoting uniform application of these procedures for evaluation of seeds moving in international trade.

<http://www.seedtest.org/en/home.html>

Minor Use Crops: Host/pathogen combinations that are tested for so infrequently that forming Technical Panels to approve methods is not reasonable.

National Plant Board (NPB): A non-profit organization of the plant pest regulatory agencies of each of the states and Commonwealth of Puerto Rico. Membership of the NPB is made up of the principal plant pest regulatory officials of each state. They inspect plants and commodities for export so that required phytosanitary certification can be provided. This group has one member on the PPAB.

National Seed Health System (NSHS): A cooperative government and industry consortium formed to address seed health and trade problems in an orderly, scientific and systematic manner. The goal is optimal trade while protecting agriculture, the environment, and the economic well being of the interested and affected parties. The consortium is composed of participants from NPB, AASCO, AOSCA, ASTA, and with ex-officio membership of the Administrator of APHIS and the director of the AU.

The Policy and Procedures Advisory Board (PPAB): The primary body giving direction to the NSHS. The PPAB will contain one member each from NPB, AASCO, AOSCA, and three members from ASTA. The director(s) of the AU(s) and the Administrator of APHIS (or his designee) will participate as ex-officio members of the PPAB.

Quality Manual: A document that includes or makes reference to the quality system procedures and outlines the structure of the documentation used in the quality system. The Quality Manual is only a general outline. Specific procedures are reserved for detailed work instructions and reference materials such as laboratory procedures, manuals, etc.

Reference Manual A (RM-A): Reference Manual for Procedures and Policies of the National Seed Health System. RM-A describes the structure, administration, procedures, policies, and working practices of both the Seed Health Accreditation Program and the NSHS. The manual also contains the relevant documentation, forms and references for the NSHS. *(RM-A will be accessible on the USDA-APHIS web site.)*

Reference Manual B (RM-B): Reference Manual for Laboratory Test and Phytosanitary Inspection Methodologies of the National Seed Health System. RM-B contains the detailed seed health testing, seed sampling, and phytosanitary inspection procedures for

the NSHS. (*RM-B will be publicly accessible on the USDA-APHIS web site.*)

REFERENCES:

ANSI/ASQC Q9001-1994:

American National Standard: Quality Systems-Model for Quality Assurance in Design, Development, Production, Installation and Servicing. American Society for Quality Control, 1994.

IPPC, 2001

International Standards for Phytosanitary Measures 12: Guidelines for phytosanitary certificates.

https://www.ippc.int/servlet/BinaryDownloaderServlet/16199_ISPM_12_E.pdf?filename=1146658528409_ISPM12.pdf&refID=16199

NAPPO, 2004

Regional Standards for Phytosanitary Measures No. 9: The Accreditation of Laboratories for Phytosanitary Testing. <http://www.nappo.org/Standards/REVIEW/RSPM%20No9-e.pdf>

NAPPO, 2009

Regional Standards for Phytosanitary Measures No. 5: NAPPO Glossary of Phytosanitary Terms. <http://www.nappo.org/Standards/REVIEW/2009/RSPMNo.5Rev-02-02-09-e.pdf>

APPENDIX A: **Quality System and the Quality Manual**

The Requirement for a Quality Manual is stated in: 7 CFR Part 353.8 Accreditation of non-government facilities.

(b)(3)(iii) Methods of testing or inspection. The facility must have a quality manual or equivalent documentation that describes the system in place at the facility for the conduct of laboratory testing or phytosanitary inspection services for which the facility seeks accreditation. The manual must be available to, and in use by, the facility personnel who perform the services. The methods and procedures used by the facility to conduct the laboratory testing or phytosanitary inspection services for which it seeks accreditation must be commensurate with those identified in the accreditation standards and must be consistent with or equivalent to recognized international standards for such testing or inspection.

The key requirement listed here is: **“...a quality manual or equivalent documentation that describes the system...”**

For the purposes of assessment and accreditation the NSHS requires that an applicant satisfy the appropriate elements in order to receive accreditation. These 20 elements for consideration are listed below. Only those elements relevant to the applicant’s registration need to be addressed in the Quality Manual or equivalent documentation describing the system. The applicant may be asked to show why certain elements are not relevant during the registration audit.

1. Management responsibility
2. Quality system
3. Contract review
4. Design control
5. Document and data control
6. Purchasing
7. Control of customer supplied product
8. Product identification and traceability
9. Process control
10. Inspection and testing
11. Control of inspection, measuring, and test equipment
12. Inspection and test status
13. Control of non-conforming product
14. Corrective and preventative action
15. Handling, storage, packaging, preservation, and delivery
16. Control of quality records
17. Internal quality audits
18. Training
19. Servicing
20. Statistical techniques

1. Management Responsibility

The AE designates managers responsible for the system and defines and documents the quality policy of the system.

2. Quality System

The AE establishes, documents, and maintains a quality system as a means of ensuring that a product (or service) conforms to specified requirements. The AE maintains a quality manual or equivalent documentation that includes or makes reference to the quality-system procedures and also outlines the structure and documentation used in the system.

3. Contract Review

The AE establishes and maintains documented procedures for contract review. The contracts are those with customers specifying the requirements of the service or product being supplied and indicating the supplier has the capability of meeting those requirements.

4. Design Control

The AE establishes and maintains documented procedures to control and verify the design of the product or service to ensure that all specified requirements are met.

5. Document and Data Control

The AE establishes and maintains documented procedures to control all documents and data relating to the requirements of the NSHS, including where applicable, external documents such as standards and other customer-supplied documents and drawings (*i.e.*, field maps).

6. Purchasing

The AE establishes and maintains documented procedures to ensure that all purchased products conform to specified requirements. This control is required to assure that substitutions, especially of laboratory supplies, meet the same standards of quality (performance) as those products specified in the lab procedures or methodologies.

7. Control of Customer Supplied Product

The AE establishes and maintains documented procedures for the control of verification, storage, and maintenance of all customer-supplied products incorporated into supplies (either supplied products or services) or for related activities. Verification of the AE does not release the customer of the responsibility to provide an acceptable product.

For the most part, this would refer to the maintenance of samples. It also requires the customer (the AE contracted for testing/inspection service) to provide a proper sample and/ or appropriate field documentation/ maps for inspection purposes.

8. Product Identification and Traceability

The AE's product is also data. The AE has a system for controlling that product (data) throughout the entire process of production and development. The system for tracing the product is documented and maintained.

9. Process Control

The supplier identifies and plans production, installation, and servicing processes that directly affect quality and ensures that these processes are carried out under controlled conditions.

In other words, the AE abides by the appropriate standards, whether Good Laboratory Practices (GLP), lab methodologies, field inspection practices, or other and also documents this process. This is the portion of the Quality Manual where standards, lab methodologies, work instructions, and other references are assembled and result in quality records or data.

10. Inspection and Testing

The supplier establishes and maintains documented procedures for inspection and testing activities in order to verify that the specific requirements for the product are met. The required inspection and testing, and the record to be established, are detailed in the quality plan or other documented procedures.

Seed samples are inspected to ensure they meet the requirements for testing. The testing process itself is subject to inspection and testing to ensure that the test is being properly performed. Similarly, fields must be "inspected prior to seed inspection" to ensure that they are in the proper condition (i.e., stage of development) for the requested seed inspection. If access to a field is not possible for any reason (i.e., flood, tornado, chemical application, etc.) it should not be inspected.

11. Control of Inspection, Measuring, and Test Equipment

The supplier establishes and maintains documented procedures to control, calibrate, and maintain inspection, measuring, and test equipment.

12. Inspection and Test Status

The product's inspection and test status is identified by suitable methods to ensure that only a product which has passed the required inspections and tests is dispatched, used, or

installed.

Test results are not issued until the relevant verification (i.e., inspection or test of the data) has been made and the data is determined to be correct. Similarly, field inspection reports are not issued until samples have been evaluated.

13. Control of Non-Conforming Product

The supplier establishes a maintained and documented procedure to ensure that product that does not conform to specified requirements is prevented from unintended use or installation.

Data from improperly performed tests or field inspections may not be issued to the customer.

14. Corrective and Preventive Action

The AE establishes and maintains documented procedures for implementing corrective and preventive action. If the testing or inspection process cannot be performed as outlined, the AE must document the process required to overcome any problem. If this requires a revision of testing and inspection methodologies, these processes may be subject to review by a technical panel prior to incorporation into the accepted methodologies and procedures.

15. Handling, Storage, Packaging, Preservation, and Delivery

There is an established and documented procedure for delivering data to customers.

16. Control of Quality Records

The supplier maintains documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records. Quality records are maintained to demonstrate conformance to specified requirements and effective operation of the quality system.

17. Internal Quality Audits

The supplier establishes and maintains documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

18. Training

The AE establishes and maintains documented procedures for identifying training needs and provides for the training of all personnel performing activities affecting quality.

Personnel performing specific assigned tasks are qualified on the basis of appropriate education, training, and/ or experience, as required. Appropriate records of training are maintained.

19. Servicing

When servicing is a specified requirement, the AE establishes and maintains documented procedures for performing, verifying, and reporting that the servicing meets the specified requirements.

20. Statistical Techniques

The supplier identifies the need for statistical techniques required for establishing, controlling, and verifying process capability and product characteristics, and also establishes and maintains documented procedures to implement and control the application of the statistical technique identified.

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