Reference Manual A (RM-A)

NATIONAL SEED HEALTH SYSTEM

REFERENCE MANUAL FOR ADMINISTRATION, PROCEDURES, AND POLICIES OF THE NATIONAL SEED HEALTH SYSTEM

Version dated
02/25/00

Contents

INTRODUCTION

Seed Health Accreditation

The U.S. Seed Health Accreditation Program has been established by USDA-APHIS to accredit entities to perform laboratory seed heath testing, seed sampling and phytosanitary inspections. Authority for the establishment and operation of the seed health accreditation program are described in 7 CFR Parts 300 and 353.

National Seed Health System

The National Seed Health System (NSHS) has been established in cooperation with 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 and phytosanitary inspection procedures,
2. To develop a process to accredit private entities to carry out the above mentioned activities (see seed health accreditation program),
3. To leverage this initiative as well as other international initiatives to promote international phytosanitary reform and foster fair equitable trade.

SECTION ONE: Administration and Organization of the National Seed Health System

1. OVERVIEW

The National Seed Health System (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 being optimal trade while protecting agriculture, the environment and the economic well being of the interested and affected parties.

1.1 USDA-APHIS

As part of the NSHS, the United States Department of Agriculture/Animal and Plant Health Protection Service (USDA-APHIS) has responsibility for the Seed Health Accreditation Program. (See Section 2; Accreditation of Entities)

The Administrator of APHIS, or his designee, will act as an ex-officio member of the Seed Technical Working Group (STWG) of the NSHS.

1.2. National Plant Board Council/PPQ Strategy Team

The Strategy Team is a long established group of state and USDA plant health officials providing program review of pest management programs within the USA. Their function includes policy recommendations and the identification of issues important to USDA. The Strategy Teams' involvement in the Seed Health Accreditation Program would be to review the program on a regular basis and provide input to the Administrator.

1.3 Seed Technical Working Group (STWG)

The STWG will act as the primary body giving direction to the NSHS. The STWG will contain a 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 Administrative Unit(s) and the Administrator of APHIS (or his designee) will participate as ex-officio members of the STWG.

The STWG will approve a list or "pool" of experts from which volunteers to participate on Technical Panels will be chosen. The STWG will refer test and inspection methodologies to the Technical Panels for evaluation. The STWG shall review the results and recommendations of Technical Panels and forward them to the Administrator for approval. Following APHIS approval, these results will be included in Reference Manual B for official use in phytosanitary certification.

1.4 Technical Panels

Technical Panels shall 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 testing and field inspection methodologies. In addition, the panels will produce checklists of equipment and facilities that can be used to evaluate accreditation candidates. The experts will consist of experts from the private and public sectors and will be open to experts from other countries as well.

The recommendations of the panels will be reviewed by the STWG. In certain cases, where additional research and development are required, financial support may be given to technical experts for specified uses as approved by the STWG.

1.5 Administrative Unit(s) (AU)

The AU(s) shall manage the day-to-day activities of the accredited system on behalf of APHIS as follows:

- **a.** The AU shall receive and process applications from entities wishing to become accredited.
- **b.** The AU will schedule and coordinate the accreditation audits with the applicants.
- **c.** The AU will coordinate and conduct appropriate training sessions and workshops in the appropriate areas of plant health for applicant entities.
- **d.** The AU shall carry out proficiency testing as part of the ongoing audit and surveillance program.
- **e.** The AU shall be the official "record keeper" of the system and shall maintain the controlled versions of all reference materials including the standardized test and inspection methodologies.
- **f.** The AU shall engage in test/inspection standardization and development.
- **g.** The AU shall make provision for the testing of "minor use crops".

The AU shall also collect and organize the relevant body of scientific information for review and consideration by the Technical Panels.

1.6 Accredited Entities (AE's)

Accredited entities are any public or private organization (or individual) that meets the requirements for accreditation as outlined in the Standard. AE's will be allowed to perform only those seed health tests and/or field inspection procedures for which they have been accredited. AE's shall submit to a regular program of surveillance audits and proficiency testing as required by the Administrator.

NATIONAL SEED HEALTH SYSTEM

Figure 1
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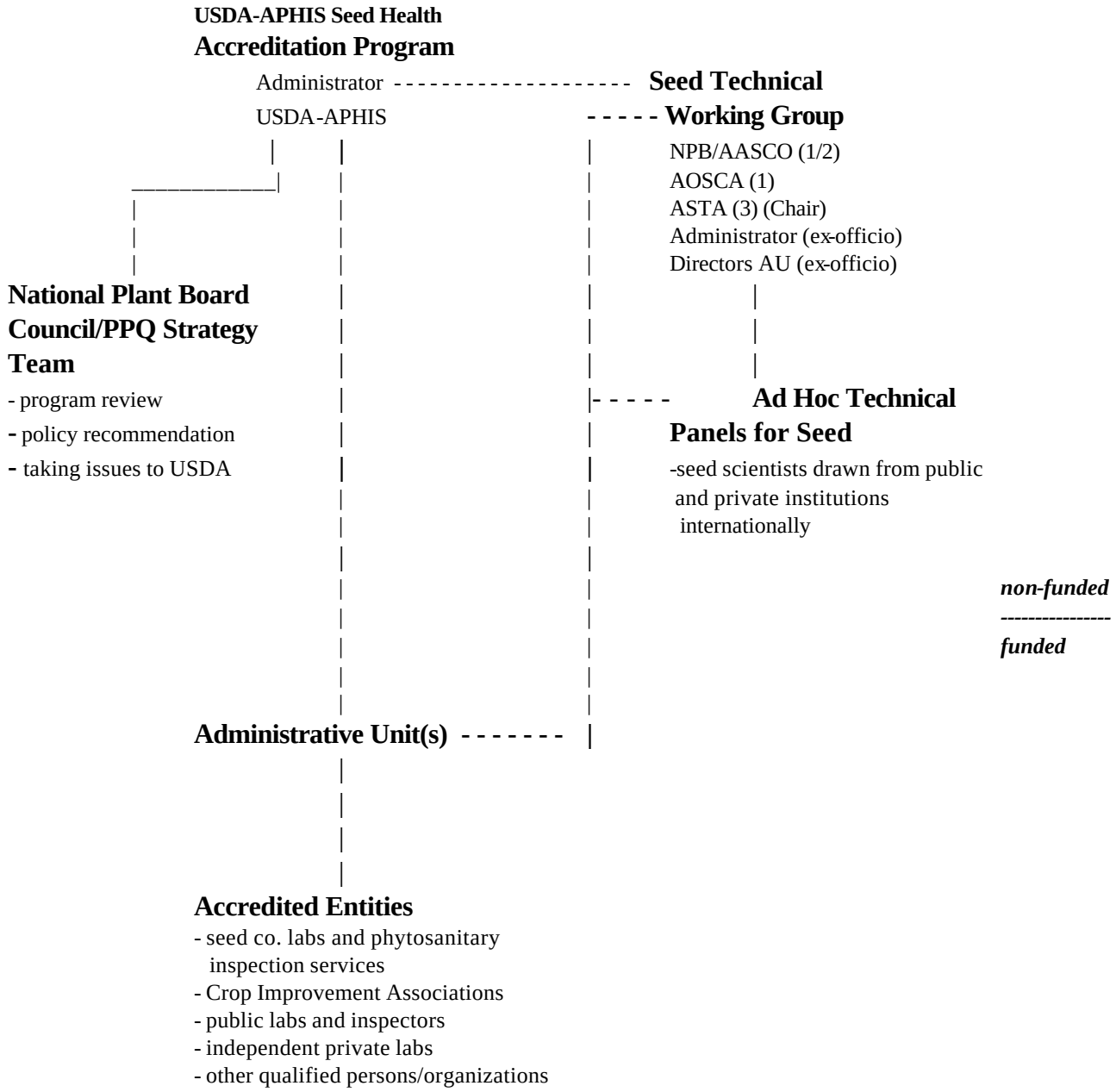

2. ADMINISTRATION OF THE NATIONAL SEED HEALTH SYSTEM

2.1 General provisions

2.1.1 The procedures under which the NSHS operates shall be administered in a nondiscriminatory manner.

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

2.1.2 The competence of an applicant entity to conduct seed health tests and/or plant health inspections shall be assessed according to the accreditation standards established by APHIS and procedures contained within this document.

2.1.3 The NSHS shall be administered in a manner that requires accredited entities (AE), seed health testing laboratories and/or plant health inspection services, to maintain impartiality and integrity.

2.1.4 The administration of the NSHS shall be 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 system in order to maintain the integrity of the international phytosanitary system. USDA-APHIS participates in an ex-officio role as a member of the STWG in the development of standardized laboratory test and phytosanitary inspection methodologies.

2.2 Organizational requirements of the NSHS Administration.

2.2.1 The APHIS Accreditation Manager and the Administration Units (AU) shall:

a. be legally identifiable entities;

b. have rights and responsibilities relevant to its accreditation activities;

c. have adequate arrangements to cover liabilities arising from its 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 it receives its 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 it to give confidence in its ability to operate an accreditation system satisfactorily;

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

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

- policies and procedures for the resolution of complaints and appeals received from AE about the handling of accreditation matters, or from users of services about AE 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 shall be reasonably free from any commercial, financial and other pressures that might influence decisions or shall have a structure where members are chosen to provide impartiality through a balance of interest where no single interest predominates;

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

l. not offer consultant or other services which may compromise the objectivity of its accreditation process and decisions;

m. have arrangements that are consistent with applicable laws, to safeguard, at all levels of its organization (including committees), confidentiality of the information obtained relating to applications, assessment and accreditation of

applicants.

2.2.2 The DA and AU shall have arrangements for either controlling the ownership, use and display of the accreditation documents or controlling the manner in which an AE may refer to its accredited status, or both.

2.3 Administration Structure for the National Seed Health System

2.3.1 Accreditation Manager (APHIS)

a. shall be an appointee of USDA-APHIS and maintain oversight functions of the accredited portion of the National Seed Health System.

b. shall uphold the regulations and rules governing units of the federal government, and be subject to the organizational requirements of section 1.1.

c. shall be an integral part of the accreditation system and work closely with the STWG (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 for applicant entities as a representative of USDA-APHIS according to the provisions of the standards for accreditation.

e. directs the administration units in the activities of accreditation. Including establishing the priorities, criteria and regulations for accreditation of non-government entities.

f. may conduct independent audits of AU.

2.3.2 The Administration Units (AU)

a. shall be designated by a Memorandum of Understanding (MOU) from APHIS;

b. shall be a legally identifiable, public or private entity;

c. shall be an affirmative action, equal opportunity employer;

d. shall confine its requirements, assessment and decision on accreditation to those matters specifically related to the scope of the accreditation being considered;

e. shall be subject to the organizational requirements of section 1.5;

f. shall be responsible for the organization and implementation of the Accreditation;

g. processes outlines in the standards for accreditation;

h. shall train and appoint assessors according to the provisions in section 2 for the NSHS for final approval by the Accreditation Manager;

i. maintain samples for distribution to applicant entities for proficiency testing according to the provisions of section 4.7;

j. maintain procedures and protocols for applicant entities in a manner that assures impartiality and maintains the provisions of the quality system (section 2.4);

k. shall organize and/or hold training workshops to assure that applicant entities can meet the requirements of the Seed Health Accreditation Program.

2.3.3 The STWG shall consist of six (6) members:

- one member of the National Plant Board (NPB);
- one member from AASCO;
- one member of AOSCA;
- three members from ASTA

Ex-officio members shall be the Accreditation Manager and the directors of the AU(s).

The STWG shall:

a. Develop policy and panels for the Accreditation Manager of the NSHS;

b. Provide technical expertise and information that is deemed necessary for the Accreditation Manager to effectively administer the system;

c. Develop technical subcommittees of public and private experts to provide sound scientific support and integrity of procedures, protocols for the accreditation system;

2.3.4 The National Plant Board/PPQ Strategy Team is made up of the NPB and APHIS members. This team shall:

a. Provide the Accreditation Manager with policy coordination, reviews and recommendations;

b. Review provisions of the accreditation system on behalf of the Accreditation Manager and;

c. Resolve issues of regulatory procedures to assure the integrity of the accreditation system.

2.4 Quality system

2.4.1 The AU shall operate a quality system appropriate to the type, range and volume of work performed. This system shall be documented and the documentation shall be available for use by the AU staff. The AU shall designate a person having direct access to the Accreditation Manager, to take responsibility for the quality system and the maintenance of the quality documentation.

2.4.2 The quality system shall be documented in a quality manual and associated quality procedures. The quality manual shall contain or refer to at least the following:

a. A quality policy statement;

b. The organizational structure of the accreditation body;

c. The operational and functional duties and services pertaining to quality, so that each person concerned will know the extent and the limits of their responsibility;

d. Administrative procedures including document control;

e. Policies and procedures to implement the accreditation process;

f. Arrangements for feedback and corrective actions whenever discrepancies are detected;

g. The policy and procedures for dealing with appeals, complaints and disputes;

h. The policy and procedures for conducting internal audits;

i. The policy and the procedures for conducting quality system reviews;

j. The policy and the procedures for the recruitment and training of assessors and monitoring their performance.

2.4.3 The AU shall audit its activities at least annually to verify that they comply with the

requirements of the quality system. The quality system shall also be reviewed to ensure its continued effectiveness. Audits and reviews shall be carried out systematically and periodically and recorded together with details of any corrective actions taken.

2.4.4 The AU shall maintain records to demonstrate that accreditation procedures have been effectively fulfilled, particularly with respect to application forms, assessment reports, and reports relating to granting, maintaining, extending, suspending or withdrawing accreditation. These accreditation documents shall form part of the record.

2.4.5 The AU body shall have a policy and procedures for retaining records for a period consistent with its contractual and legal obligations. The AU body shall have a policy and procedures concerning access to these records consistent with section 2.2 of this document.

2.5 Granting, maintaining, extending, suspending, and withdrawing accreditation

2.5.1 The Accreditation Manager, through technical advice from its committees, shall specify the conditions for granting, maintaining and extending accreditation and the conditions under which accreditation may be suspended or withdrawn, partially or in total for all or part of the AE's scope of accreditation.

2.5.2 The Accreditation Manager shall have arrangements to grant, maintain, suspend or withdraw accreditation, increase or reduce the scope of accreditation or require reassessment, in the event of changes affecting the AE's activity and operation, such as changes in personnel or equipment, or if analysis of a complaint or any other information indicates that the AE no longer complies with the requirements of the DA.

2.5.3 The Accreditation Manager shall review the accreditation status relating to the transfer of accreditation when the legal status (*e.g.*, ownership) of the AE changes.

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

2.6 To maintain accreditation, the entity must:

i. Perform all work for which it is accredited in conformance with approved protocols, methods or procedures.
ii. Be assessed and evaluated on a bi-yearly basis by means of proficiency testing or

check samples. Audits of the entity will be performed on a yearly basis. Proficiency testing, check samples and audit procedures are determined by APHIS and listed in Reference Manual B. The AE is responsible for arranging the proficiency testing and audit schedule with the AU.

iii. Demonstrate on request that it is able to perform the laboratory seed health test or inspection services for which it is accredited.

iv. If at any time, an entity is determined by the Administrator to be unable to perform the laboratory seed health test or inspection services for which it is accredited, that entity shall immediately cease to perform those activities until it can demonstrate to the Administrators satisfaction that corrective action has been implemented.

v. Notify the Administrator immediately (within two business days) of any changes in key management personnel or staff accountable for the testing or phytosanitary inspection services for which the entity is accredited.

vi. Notify the Administrator within five business days, of any changes involving the location, ownership, physical facilities, equipment on other conditions that existed at the facility at the time accreditation was granted and are material to the accreditation.

vii. Pay all fees billed by the Administrator to cover costs associated with audits, proficiency tests or other work performed by the Administrative Unit.

2.7 **Refusal, Suspension or Cancellation and Notification**

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

2.7.2 Accreditation shall be refused if the administrative unit determines that the accreditation candidate does not met the requirements, has falsified any information provided on the application or to the administrative unit or fails to pay any fees billed by the Administrator. The accreditation candidate shall be notified of refusal within 15 days of determination by the administrative unit.

2.7.3 Accreditation shall be re-evaluated within 90 days of change of ownership of the accredited entity. Based upon this evaluation the administrator may require an audit of the entity.

2.7.4 Incidences of non compliance are defined as either Critical, Major or Minor depending on how severely they effect the systems ability to continue to provide confidence that the results obtained meet the conditions established in this standard.

2.7.4.1 Critical Non Compliance is defined as:

Audit findings that reveal that the integrity of the program is in jeopardy. The results being those test or inspection findings could not be utilized as supporting documentation for the issuance of the phytosanitary certificate.

Critical Non Compliance incidences include:

- No inspection or test conducted;
- Failure to follow inspection/testing methods in accordance with this standard;
- Deliberate attempt to provide incorrect results of inspection/testing;
- Three or more Major Non Compliance items detected in any one audit;
- Any reoccurrence of the same Major Non Compliance detected in the two previous consecutive audits.

Action

The Accredited Entity will be notified of their violation of the Standard. The Accredited Entity will be removed from the approved list until:

- An agreed corrective strategy has been identified by the Administrative Unit, the Accreditation Manager, and the Entity.
- Another audit is completed on the area that covers Critical Non Compliance.

2.7.4.2 Major Non Compliance is defined as:

Audit findings that reveal an isolated incident(s) that results in decreased confidence of the Entity's inspection or testing results, but having no direct impact on the integrity of the program. Corrective action needs to be implemented promptly in order to retain confidence that the conditions of the Standard are being met. Immediate corrective action is required.

Major Non Compliance events include:

- Significant difference between Auditor's and Entity's inspection/test findings;
- Entity fails to identify, classify or record problems correctly;
- No inspection facilities and/or equipment;
- Internal audits not conducted or properly documented;

- Actions taken following audits not recorded;
- Documentation not available to auditors;
- Corrective action for Minor Non Compliance not implemented within the agreed time frame;
- Three or more Minor Non Compliance incidents in any one audit.

Action

Where one or more Major Non Compliance incidents are identified during an initial audit, the entity will not be accredited.

Where one or two Major Non Compliance incidents are identified during a surveillance audit, then corrective action needs to be implemented as soon as possible. An additional audit may need to be conducted to confirm that the corrective actions have been made.

A Critical Non Compliance is to be recorded for every three Major Non Compliance incidents identified during a single visit.

2.7.4.3 Minor Non Compliance

Minor Non Compliance is defined as:
Audit findings that reveal a non-conformance that does not immediately and/or significantly affect 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:

- Any amendment to procedural details not documented;
- Incomplete inspection/testing/audit records, e.g.
- Not recording critical test steps
- Not signing records and recording dates
- Improper Grower Identification
- Improper Sample Identification
- Incomplete inspection and testing facilities or equipment
- Any other deviations from the Entity's Quality Manual

Action

A Major Non Compliance is to be recorded for every three (3) Minor Non Compliance incidents identified during a single audit.

2.7.5 Where Non Compliance not covered by the above examples and definitions are identified, They are to be classified as Major Non Compliance incidents until clarified by

the Accreditation Manager.

2.8 Corrective Action

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

2.8.2 The Auditor will provide the entity with a list of all agree on corrective actions to be taken to correct identify system non-compliance. Corrective actions shall outline:

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

2.9 Contingencies for Non Compliance

Where agreed corrective actions for Major or Critical Non Compliance are not implemented, then the entity is subject to suspension of accreditation.

2.10 When accreditation is suspended or cancelled, the accredited entity and all certifying officials shall be notified within 48 hours by telephone, Electronic mail, facsimile, overnight mail or courier service. The accredited entity shall immediately cease all suspended or cancelled sampling, testing or inspection activities.

2.11 The Administrator shall apprise the accredited entity of **a;** the reason(s) for the suspension or cancellation, **b;** the corrective action(s) required, and **c;** the process for re-accreditation.

2.12 The accredited entity shall be responsible for notifying the Administrator of corrective measures taken and for requesting re-accreditation. Accreditation may be granted when the corrective measures have been verified to the satisfaction of the Administrator.

2.13 Appeal of refusal, suspension or cancellation of accreditation by the Accreditation Officer may be made to the Administrator within 5 working days of notification. The Administrator shall make a determination and notify the appellant within 15 working days. The Administrators decision shall be final.

2.14 **Dispute Resolution**

2.14.1 Disputes relative to testing or inspections results shall be resolved by a mediator or trained arbitrators, as the Administrator deems appropriate. The mediation or arbitration panel shall consist of testing or inspection professionals with expertise in the testing or inspection protocol(s) or procedure(s) in dispute.

2.15 **Documentation**

2.15.1 The AU shall provide (through publications, electronic media or other means), updates at adequate intervals, and make available on request

a. information about the authority under which accreditation systems operated by the DA body were established and specifying whether they are mandatory or voluntary;

b. a document containing its requirements for accreditation in accordance with this document;

c. the Standard for Accreditation stating the arrangements for granting, maintaining, extending, suspending and withdrawing accreditation;

d. information about the assessment and accreditation process;

e. general information on the fees charged to applicant and AE;

f. a description of the rights and duties of 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.

3. ACCREDITATION ASSESSORS

3.1 **Requirements for assessors**

The assessor or assessment team appointed to assess an applicant shall:

a. be familiar with the relevant legal regulations, accreditation procedures and accreditation requirements;

b. have a thorough knowledge of the relevant assessment method and

assessment documents;

c. have appropriate technical knowledge of the specific seed health tests and/or the plant health inspection protocols for which accreditation is sought and the associated sampling procedures;

d. be able to communicate effectively, both in writing and orally;

e. be reasonably free of any commercial, financial or other pressures or conflicts of interest that might cause assessor(s) to act in other than an impartial or non-discriminatory manner;

f. not have offered consultant services to the applicant which might compromise their impartiality in the accreditation process and decisions.

3.2 Qualification procedures for assessors

The AU shall have an adequate procedure for:

a. Qualifying assessors, comprising an assessment of their competence and training, and attendance at one or more actual assessments with a qualified assessor;

b. Monitoring the performance of assessors.

3.3 Contracting of assessors

The Accreditation Manager, through the AU, shall require the assessors to sign a contract or other document by which they commit themselves to comply with the rules defined by the NSHS, including those relating to confidentiality and those relating to independence from commercial and other interests, and any prior association with the applicant to be assessed.

3.4 Assessor records

The AU shall possess and maintain up-to-date records on assessors consisting of:

a. name and address;

b. organization affiliation and position held;

c. educational qualification and professional status;

d. work experience;

e. training in seed health testing and/or plant inspections

f. experience in laboratory seed health testing and/or plant inspections

g. date of most recent revision of record.

3.5 **Procedures for assessors**

Assessors shall be provided with an up-to-date set of procedures giving assessment instructions and all relevant information on accreditation arrangements.

4. ACCREDITATION PROCESS

4.1 Application for accreditation

4.1.1 A detailed description of the assessment and accreditation procedure, the documents containing the requirements for accreditation and documents describing the rights and duties of the AE (including fees to be paid by AA and AE) shall be maintained up-to-date and given to AA's.

4.1.2 Additional relevant information shall be provided to applicant laboratories on request.

4.1.3 The Administrator shall develop an application form that provides for the collection of all but not limited to the following information and authorization.

i. Legal name and full address (mail and business address) of the entity;
ii. Name, address, telephone and fax numbers and E-mail address (if available) of the responsible individual or his/her authorized representative;
iii. A description of the entity, including its physical facilities, primary function, scope of operation and relationship to a larger corporate entity;
iv. A description of the specific laboratory testing or phytosanitary inspection services for which the entity is seeking accreditation;
v. Authorization for Administrative Unit representatives to access, during normal business hours, the applicants facilities and relevant records;
vi. Agreement to provide all relevant information requested by the Administrative Unit representatives;
vii. Agreement to pay all accreditation fees as billed to the applicant to cover costs

incurred in conducting accreditation audits including travel costs for the Administrative Units representatives.

To become an Accreditation Candidate, the senior most authorized representative of an interested entity shall obtain, complete, sign and submit to the Administrator an application together with the required fees. Applications that are incomplete or unsigned or not on USDA-APHIS approved forms shall be rejected. A notice of rejection shall be issued within 15 working days not including mail service.

Confidential Business Information shall not be disclosed by the Administrator, Accreditation Officer or the Administrative Unit or independent auditors to any person not authorized by the applying entity or the accredited candidates.

4.1.4 A duly authorized representative of the AA shall be required to sign an official application form, in which or attached to which:

a. the scope of the desired accreditation is clearly defined;
b. the AA's representative agrees to fulfill the accreditation procedure, especially to receive the assessment team, to pay the fees charged to the applicant whatever the result of the assessment may be, and to accept the charges of subsequent maintenance of the accreditation;
c. the AA agrees to comply with the requirements for accreditation and to supply any information needed for the evaluation.

4.1.5 The following minimum information shall be provided by the AA prior to the on-site assessment:

a. the general features of the applicant (corporate entity: name address, legal status, human and technical resources);

b. general information concerning the AA covered by the application, such as primary function, relationship in a larger corporate entity and, if applicable, physical location of the facilities involved;

c. a descriptive list of the laboratory seed health tests and/or phytosanitary inspections the methods for which accreditation is sought;

d. a copy of the AA's quality manual and, where required, the associated documentation.

The information gathered shall be used for the preparation of on-site assessment and shall be treated with complete confidentiality.

4.1.6 Upon receipt of an application, the Administrator will review the application for completeness and to determine the scope of the assessment that will be required to adequately review the entity's fitness to conduct the laboratory seed health testing or phytosanitary inspection services for which the applicant is seeking accreditation. This review shall be completed within 30 days. The information shall then be entered into the APHIS accreditation database.

4.1.7 Before assessment of the facility begins, the applicant must agree in writing to fulfill the accreditation procedure, especially to receive the assessment team, to supply any information needed for the evaluation of the facility, and to pay in advance the fees charged to the applicant. Such fees will cover the costs incurred in conducting the accreditation audits including travel costs for the assessors.

4.1.8 Once an application has been approved, the Accreditation Officer shall contact the nearest or appropriate Administrative Unit and request that it perform an Accreditation Candidate Assessment within 30 working days after it is notified. The Accreditation Candidate shall be notified of the name and means of contact for the accreditation unit. If the accreditation assessment cannot be performed within 30 days, the candidate shall be notified and another date determined.

4.2 Assessment

4.2.1 The AU shall appoint qualified assessor(s) to evaluate all material collected from the AA and to conduct the assessment on its behalf at the AA's location and any other sites where activities to be covered by the accreditation are performed.

4.2.2 To ensure that a comprehensive and correct assessment is carried out, each assessor shall be provided with the appropriate working documents.

4.2.3 The date of assessment shall be mutually agreed with the AA's laboratory. The latter shall be informed of the name(s) of the qualified assessor(s) nominated to carry out the assessment, with sufficient notice so that the applicant is given an opportunity to appeal against the appointment of any particular assessor.

4.2.4 The assessor(s) shall be formally appointed by the Accreditation Manager. A lead assessor shall be designated, if relevant. The mandate given to the assessor(s) shall be clearly defined by the Accreditation Manager and made known to the applicant.

4.3 Sub-contracting of assessment

4.3.1 If the AU, with approval from the Accreditation Manager, decides to delegate fully

or partially the assessment of a applicant to another body, then the AU shall take full responsibility for such an assessment made on its behalf.

4.3.2 The AU shall ensure that any body to which assessment has been delegated is competent and complies with the applicable provisions of this document.

4.4 **Assessment report**

4.4.1 The AU may adopt reporting procedures that suit its needs but as a minimum these procedures shall ensure that:

a. a meeting takes place between the assessor or assessment team and the AA's management prior to leaving the facilities at which the assessment team provides a written or oral report on the compliance of the applicant with the accreditation requirements;

b. the assessor or assessment team provides the accreditation body with a detailed assessment report containing all relevant information concerning the ability of the AA to comply with all of the accreditation requirements, including any which may come about from the results of proficiency testing;

c. a report on the outcome of the assessment is promptly brought to the applicant's notice by the accreditation body, identifying any non-compliance that must be corrected in order to comply with all of the accreditation requirements. The AA shall be 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 Accreditation Manager**, to remedy any non-compliance with the accreditation requirements identified during the assessment.

4.4.2 The final report authorized by the AU and submitted to the applicant, if it is different, shall include as a minimum:

a. date(s) of assessment(s);

b. the names of the assessor(s) responsible for the report;

c. the names and addresses of all the facilities assessed;

d. the assessed scope of accreditation or reference thereto;

e. comments of the assessor(s) or assessment team on the compliance of the

applicant with the accreditation requirements.

4.4.3 The reports should take into consideration:

a. the technical qualification, experience and authority of the staff encountered especially the persons responsible for the technical validity of seed health test reports;

b. the adequacy of the internal organization and procedures adopted by the applicant to give confidence in the quality of its services, the physical facilities, *i.e.,* the environment and the seed health testing equipment of the laboratory including maintenance and calibration having regard to the volume of work undertaken;

c. proficiency testing or other inter-laboratory comparison performed by the AA, the results of this proficiency testing, and the use of these results by the applicant;

d. the actions taken to correct any non compliance identified at previous assessments.

4.5 **Decision on accreditation**

4.5.1 The decision whether or not to accredit an applicant shall be taken by the Accreditation Manager on the basis of the information gathered during the accreditation process and by the AU according to clause 2.1.

4.5.2 The Accreditation Manager shall not delegate its responsibility for granting, maintaining, extending, suspending or withdrawing accreditation.

4.6 **Granting accreditation**

4.6.1 The Accreditation Manager shall transmit to each AE formal accreditation documents such as a letter or a certificate signed by an officer who has been assigned such responsibility. These formal accreditation documents shall permit identification of:

a. the name and address of the applicant that has been accredited;

b. the scope of the accreditation including:

1. the seed health tests and field plant health inspections for which

accreditation has been granted;

2. the seed and plant types on which these test and inspections may be carried out;

3. methods used as defined by written standards or reference documents that have been approved by a technical committee of the DA.

c. the persons recognized by the DA as being responsible for supervising or the conducting the seed health tests, that have met staff qualifications and training as defined in LABORATORY ACCREDITATION PROCEDURES, defined in section 4, or PHYTOSANATARY FIELD INSPECTION ACCREDITATION PROCEDURES, defined in section 4.

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

e. the AE by a unique number.

4.7 **Surveillance Audit and Proficiency Testing of AE**

4.7.1 The AU shall have an established documented program consistent with the accreditation granted for carrying out annual surveillance audits and proficiency testing to ensure that the AE's continue to comply with the accreditation requirements.

4.7.2 The annual surveillance audits and biannual proficiency testing by the accreditation body shall include:

a. comparison of standardized tests and inspection procedures between the AU and the AE;

b. Reports of the performance of AE in the surveillance and proficiency tests;

c. Notification to AE of test results which are out of tolerance according to standards defined by the AU, indicating its status regarding suspension or withdrawal of accreditation.

4.7.3 Surveillance and proficiency testing procedures shall be consistent with those concerning the assessment of the AE as described in this document.

4.8 **Certificates or reports issued by AE**

4.8.1 The Accreditation Manager shall normally allow an AE to refer to its accreditation in seed health test reports that contain only the tests for which accreditation is held.

SECTION TWO: Accreditation of Entities

1. **PURPOSE OF ACCREDITATION:**

1.1 To provide a program where non-government entities and public entities can be accredited to perform seed health testing and plant health inspections of seed crops for use in gaining phytosanitary certificates.

1.2 Assure testing and inspecting capability to provide quality data for phytosanitary certification through accreditation and quality assurance.

1.3 Assure quality training and education for seed health testing and plant health inspections for phytosanitary certification.

1.4 Assure uniform, consistent, reliable and repeatable data by approving and "standardizing" test methods and inspection protocols.

1.5 Reduce multiple testing for pathogens.

1.6 Maintain high standards of performance for testing and inspecting which will assure movement of healthy seed:

a. within the United States and
b. internationally.

1.7 Lower liability concerns of seed-borne disease by documenting and researching seed health tests and plant inspection protocols.

1.8 To leverage this infrastructure with other international infrastructures to promote international phytosanitary reform.

2. ACCREDITATION PROCEDURES

2.1. **Pre-accreditation procedures: facility; documentation and staff requirements.**

2.1.1 Applicant shall:

a. Be organized in a manner to assure proficient performance of function

(laboratory seed health testing and/or phytosanitary inspections);

b. Have a quality assurance program and manual;

c. Be organized in a manner that avoids undue pressure or inducement that might influence judgment or results.

d. Make staff aware of specific job duties, extent and limitations of responsibilities;

e. Require technical manager sufficiently trained for tests and inspections.

2.1.2 Facility and Environment should:

a. Conform to all local zoning and ordinances.

b. Provide a work area that is dedicated to laboratory function and sufficiently removed (physical barriers) from residence(s) and food preparation areas.

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

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

e. Provide adequate protection from excessive conditions (dust, contamination, temperature extremes, moisture extremes, etc.).

f. Be maintained to ensure “good housekeeping”.

2.1.3 Data Reporting, Records and Documents:

a. must clearly state the results of the test or inspection methodology and any other information that are pertinent to the results;

b. are to be maintained for a period that corresponds with the inventory of the product, but not less than three years and a maximum of five years;

c. are to be held secure and in confidence to the client, unless otherwise stipulated.

2.1.4 Other Records and Documents should include:

a. Records of equipment calibration and maintenance repair.

b. Documentation of procedures, tests methods, and inspection methods.

c. Records and rules for shelf-life for buffers, media or other chemical or equipment that may adversely affect the results of the test or inspection.

2.1.5 Samples and Sampling Records.

a. Sampling will be according to AOSCA, AOSA, and ISTA guidelines to assure the sample is representative as documented in reference manual.

b. Sampling is the responsibility of the AU, AE, or those authorized under state and federal seed laws, or official sampling agent, unless otherwise negotiated, but must be in a suitable manner to assure representation of the seed lot or plants.

2.2. **Facility inspection prior to accreditation**

2.2.1 Pre-accreditation inspection:

a. shall be done by a member of the AU or an appointed person(s) deemed qualified by the AU;

b. the facility inspection shall be used to insure that the requirements in pre-accreditation procedures are met;

c. the facility inspection shall be used to insure that resources (equipment and trained staff) are present and in functioning order.

2.2.2 Additional laboratory requirements:

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

1. Aseptic technique.

2. Identification of contamination potential and containment procedures.

3. Sterilization and disinfestation of microbiologicals.

4. Chemical handling and disposal is safe and in accordance to federal,

local and manufacturers environmental guidelines.

b. Equipment and Machinery:

1. All equipment is required to correctly carry out the appropriate test.

2. Equipment must be properly maintained and repaired.

3. Equipment shall be re-calibrated routinely or as necessary to correct suspect results.

4. Calibration information needs to be logged as necessary (pH meters, incubators, etc.).

5. Records of equipment and maintenance requirements must be kept and accessible to staff or appointed staff.

c. Test Methods and Inspection Protocols

1. The test method shall use approved methods and inspection protocols.

2. New methods need to be tested and approved by the Accreditation Manager.

d. Other Facility Requirements

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

2. Persons entering the facility shall be subject to the rules of the testing and inspecting protocols.

2.2.3 Staff and Training Requirements.

a. Appropriate education, training, technical knowledge and experience for assigned functions should be documented and clearly defined.

b. Evaluation of seed health tests must be undertaken by a university trained plant pathologist or under the supervision of a plant pathologist, or a person with a related degree and trained at the accreditation organization approved laboratory or training program.

2.2.4 Internal Quality Assurance and Quality Assurance Manual must be able:

a. To ensure accuracy and precision of tests and data, document control, sample control.

b. To define policy, purpose and obligation of the AE.

c. To document quality for staff review.

d. To document structure/facility.

e. To document operational staff and functional duties and responsibilities.

f. To document test procedures.

g. To document feedback and corrective action.

h. To define customer complaint procedures.

i. To document procedures for new testing, including the assignment, and facility requirement prior to initiation.

j. To document internal periodic audits of quality procedures.

2.2.5 Documentation of samples should include but not limited to:

a. Thorough identification of sample number, crop, field location to ensure no confusion regarding identity of the sample through the testing process

b. Clear marking and labeling with information that is pertinent to testing process (such as treatment, size of seed, condition, shortages, plant material, sampling date, etc.).

c. Working sheets maintained with the samples must be marked and labeled with any pertinent information that may influence the results of the test during processing (such as damaged seed, protocol errors, further tests and pathogenicity tests, etc.).

2.3 **Test procedure reviews and referee samples testing**

2.3.1 All AA's that have met the pre-accreditation requirements are to demonstrate proficiency in testing by participation in a referee testing program, administered by the AU or an appointee of the organization as a condition of accreditation.

2.3.2 The AE shall participate every two years in the referee samples testing program for all procedures the AE is to be accredited to perform.

2.3.3 The AE shall follow the standard method for the referee test.

2.3.4 The AE must report the final results to the AU or the appointee of the organization within 60 days of receiving the sample for testing. The results of the test will be evaluated by the AU.

2.3.4 Referee samples shall be sent to the AE for each specific protocol or procedure on at least a biennial basis.

2.3.5 A new procedure for a seed health test shall require referee sample testing by the AA and administered by the AU. For new proprietary procedures, these referee sample tests can utilize materials supplied by the AE if necessary. The AU or its representatives will maintain complete confidentiality regarding these materials and protocols. New procedures that are proprietary and accepted as standards will be incorporated into Reference Manual B. Confidentiality will be maintained in the reference manual for the critical steps in the procedure.

2.4 Accreditation review and post-accreditation inspection

2.4.1 The AE, after accreditation, will provide periodic reports to the accrediting organization or an appointee of the organization.

2.4.2 The AE may face periodic accreditation review, in which all or part of the above documentation may be reviewed by the AU and/or Accreditation Manager.

2.4.3 Accreditation review is mandatory and/or the AE must report to the AU when:

a. Significant staff changes occur in technical or evaluating personnel.

b. Significant errors occur in referee sample tests.

3. RELATIONSHIP BETWEEN THE NSHS ADMINISTRATORS AND THE APPLICANT OR ACCREDITED ENTITY

3.1 General provisions

The administrators of the NSHS shall 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 shall include provision for examination of documentation and access to all testing areas, records and personnel for the purposes of assessment, surveillance, proficiency testing, and resolution of complaints.

3.2 **Specific provisions**

The Accreditation Manager shall require that an AE:

a. at all times complies with the relevant provisions of this document;

b. claims that it is accredited only in respect of services for which it has been granted accreditation and which are carried out in accordance with these conditions;

c. pays such fees as shall be determined by the Accreditation Manager;

d. does not use 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 Accreditation Manager may consider misleading or unauthorized;

e. upon suspension or withdrawal of its accreditation (however determined) forthwith discontinues its use of all advertising matter that contains any reference thereto and return any certificates of accreditation to the AU;

f. does not use its accreditation to imply product approval by the NSHS;

g. endeavors to ensure that no certificate or report nor any part thereof is used in a misleading manner;

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

3.3 **Notification of change**

3.3.1 The AU shall have arrangements to ensure that an AE informs it without delay of changes in any aspect of the AE's status or operation that affects 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. premises involved in accredited activities;

e. personnel, equipment, facilities, working environment or other resources, where significant;

f. authorized signatories;

or other such matters that may affect the laboratory's capability, or scope of accredited activities, or compliance with the requirements in this document, or any other relevant criteria of competence specified by the DA.

3.3.2 Upon receipt of due notice of any intended changes relating to the requirements of this document, the relevant criteria of competence and any other requirements prescribed by the DA, the AU shall ensure that the AE carries out the necessary adjustments to its procedures within such time, as in the opinion of the DA is reasonable. The AE shall notify the AU when such adjustments have been made.

3.4 **Directory of AEs and Phytosanitary Inspectors.**

The AU shall produce annually a directory of AE describing the accreditation granted.

SECTION THREE: 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.

(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 words here are: **"…a quality manual or equivalent documentation that describes the system…"**

A Quality Manual is a document that includes or makes reference to the quality-system procedures and outline the structure of the documentation used in the quality system (ANSI/ASQC Q9001-1994). 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.

The definition above is taken from the American National Standard for Quality Systems. While the references within the standard are to "Quality Systems" the (Proposed) Rule specifies only that a 'system' be in place.

For purposes of assessment and accreditation the NSHS will require that an applicant satisfy the appropriate elements of the National Standard in order to receive accreditation. These 20 elements are outlined below:

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 accredited entity (AE) shall designate managers responsible for the system and define and document the quality policy of that system.

2. Quality System

The AE shall establish, document and maintain a quality system as a means of ensuring that a product (or service) conforms to specified requirements. The entity shall prepare a quality manual and include or make reference to the quality-system procedures and outline the structure and documentation used in the quality system.

3. Contract Review

The AE shall establish and maintain documented procedures for contact review. The contracts in question 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.

4. Design Control

The entity shall establish and maintain documented procedures to control and verify the design of the product/service in order to ensure that the specified requirements are met.

(This section applies primarily to those organizations conducting research or "inventing

something" as part of their system. With the exception of the Administrative Unit(s) this section will not likely be applicable to most applicants seeking accreditation in the NSHS.)

5. Document and Data Control

The entity shall establish and maintain documented procedures to control all documents and data that relate to the requirements of the system (NSHS) including to the extent applicable, documents of external origin such as standards and customer supplied documents and drawings, i.e. field maps.

6. Purchasing

The entity shall establish and maintain documented procedures to ensure that purchased product conforms to specified 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 lab procedures/methodologies.

7. Control of Customer Supplied Product

The entity shall establish and maintain documented procedures for the control of verification, storage, and maintenance of customer supplied product for incorporation into the supplies (supplied product or service) or for related activities. Verification of the entity does not absolve the customer of the responsibility to provide acceptable product.

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

8. Product Identification and Traceability

The product of the AE's is data. The AE must have a system for controlling that product (data) throughout the entire process of its production/development. The system for tracing the product must be documented and maintained.

9. Process Control

The supplier shall identify and plan production, installation and servicing processes that

directly affect quality and shall ensure that these processes are carried out under controlled conditions.

In other words, the AE must abide by the appropriate standards, whether they by GLP's, lab methodologies, field inspection practices…etc. and to document this process. This is the portion of the Quality Manual where standards, lab methodologies, work instruction and other references come together resulting in quality records or data.

10. Inspection and Testing

The supplier shall establish and maintain documented procedures for inspection and testing activities in order to verify hat the specific requirements for the product are met. The required inspection and testing, and the record to be established shall be detailed in the quality plan or documented procedures.

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

11. Control of Inspection, Measuring and Test Equipment

The supplier shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment.

12. Inspection and Test Status

The inspection and test status of product shall be identified by suitable means to ensure that only product which has passed the required inspections and tests is dispatched, used or installed.

Test results shall not be issued until the relevant verification (inspection/test of the data itself) has been made, *i.e.* is the data correct. Likewise with field inspections, the report cannot be issued until any samples have been evaluated.

13. Control of Non-Conforming Product

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

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

14. Corrective and Preventive Action

The AE shall establish and maintain 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 the problem. If this requires a revision of testing and inspection methodologies, these actions may be subject to review by a technical panel for incorporation into the accepted methodologies and procedures.

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

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

16. Control of Quality Records

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

17. Internal Quality Audits

The supplier shall establish and maintain 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 shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate

education, training and/or experience, as required. Appropriate records of training shall be maintained.

19. Servicing

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

20. Statistical Techniques

The supplier shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics, and shall establish and maintain documented procedures to implement and control the application of the statistical technique identified.

SECTION FOUR: Evaluation and Screening of Seed Health Testing and Field Inspection Methodologies

1. Criteria for the Evaluation of Laboratory Seed Health Testing Methodologies

Introduction

As in many areas of science, researchers in plant and seed pathology have derived various test methodologies in the course of their research. Many of these published methodologies find their way into the commercial and regulatory environment as the tests required to gain phytosanitary certification for export. The use of many of these methodologies for such purposes may not be appropriate. To date, there has been no systematic attempt to evaluate the large number of test procedures for their appropriateness, whether in terms of cost, ease of use but even more importantly their scientific validity.

The search for models for test evaluation in other scientific fields, i.e. chemistry, has shown that no such models exist. Often the fitness for use of a test is reached arbitrarily with little or no scientific review and/or it may be the only test method available for that particular host pathogen combination. In addition, there is no systematic program to evaluate "new" science and replace older, outdated and less sensitive methods with newer, more appropriate methods.

The ad hoc Working Group for the National Seed Health System (USA) has developed the following set of criteria to be used by panels of technical experts during their evaluation of seed health testing methodologies. This set of criteria is a draft only. It is intended that these criteria be used by technical panels to evaluate, on a trial basis, the existing methodologies for a given host/pathogen combination. Based on the results of this evaluation, and the feedback by the reviewing scientists, the appropriateness of these criteria would be reviewed and modified before being released for general use.

Evaluation Procedure

1. A literature review on test methods will be conducted by Iowa State University (ISU) and shall include the following:

- A computerized literature review of the pathogen
- Laboratory seed health tests in use but not published
- Proprietary methodologies in use * (if any)

* The evaluation of proprietary methodologies will be governed by a confidentiality agreement.

2. A list will be made of all methods found with a brief description of method i.e. cultural, serological etc., and the literature citation if available. Proprietary methods will be coded.

ISU will eliminate those laboratory methodologies it judges to be trivial, out of date etc.

3. ISU shall forward to each panel member a description of all laboratory seed health tests. Included in this description will be all relevant scientific documentation on the test development and record of use (if any) as routine tests.

Panel Responsibilities

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

Criterion 1. Empirical Test Data

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

1. 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 whether the methodology in question is sensitive enough, or they may 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.

2. 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.

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

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.)

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 under consideration. These records may be a good indicator of the effectiveness of the assay.

Other Criteria.
Panel members should 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…etc.

Panel Report

The Technical Panel shall prepare a report rating each of the various methodologies evaluated by these criteria and to state their reasons for their rating. The report should also include panel recommendations on any improvements they feel should be made to any aspect of the process.

The panel members can use the following guideline for rating the methodology(s)

Class A. Test or method acceptable as a standard test.

Class B. 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.

Class C. Test should not be accepted as a standard test.

GLOSSARY OF TERMS

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

Accreditation Candidate: An entity from which an application form and appropriate fees has been accepted by APHIS.

Administrative Unit (AU): Any organization authorized by 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.

Administrator: The Administrator of the Animal and Plant Health Inspection Service (APHIS) of the USDA or his designated authority.

Certifying Official: Any federal, state or local government official authorized by USDA-APHIS to issue federal phytosanitary certificates.

Accreditation Manager: An officer of USDA-APHIS appointed by the Administrator of APHIS to administer and direct the accreditation of entities to perform Phytosanitary Inspections and Laboratory Seed Health Testing.

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.

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 National Plant Board (NPB), the American Association of Seed Control Officials (AASCO), the Association of Official Seed Certifying Agencies (AOSCA), the American Seed Trade Association (ASTA) and with ex-officio membership of the Administrator of APHIS.

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 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 APHIS web site.)*

Seed Technical Working Group (STWG): A group representing the seed industry, the National Plant Board, and the AOSCA, AASCO and having as ex-officio members the Administrator of APHIS and the directors of Administrative Unit(s). The STWG provides input to the Administrator on the development and operation of the seed health accreditation program. The STWG also appoints technical panels to evaluate and/or develop seed health testing methodologies and phytosanitary inspection methodologies, which may be approved by the Administrator for use by accredited entities.

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.

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NAPPO, 1997 (Draft Standard)

NAPPO Standards for Phytosanitary Measures: Accreditation of Organizations and Individuals Performing Phytosanitary and Other Export Certification Activities to Ensure Compliance With Import Requirements for Products Moving Into or Within the Regional Territories of the North American Plant Protection Organization. NAPPO Secretariat, Nepean, Ontario, Canada, 1997

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