Seed Congress of the Americas

SAA Seed Association of the Americas

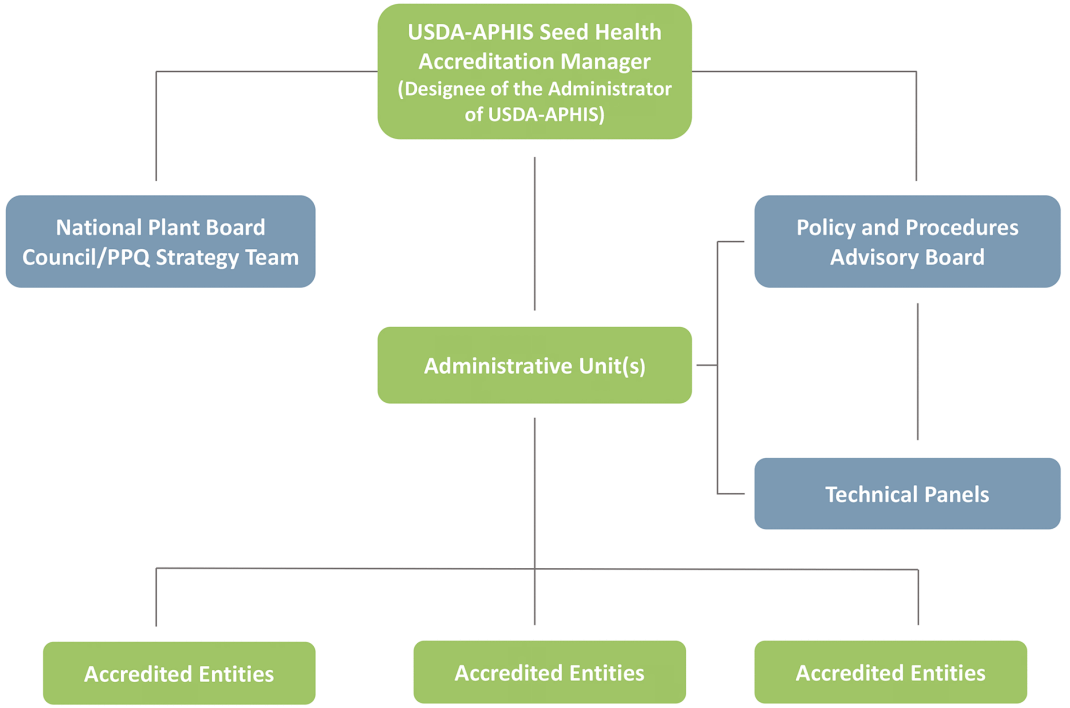
The U.S. National Seed Health System: Public-Private Collaboration to Facilitate Safe Seed Exports

Gary Munkvold
Professor
Iowa State University Seed Science Center

U.S. National Seed Health System

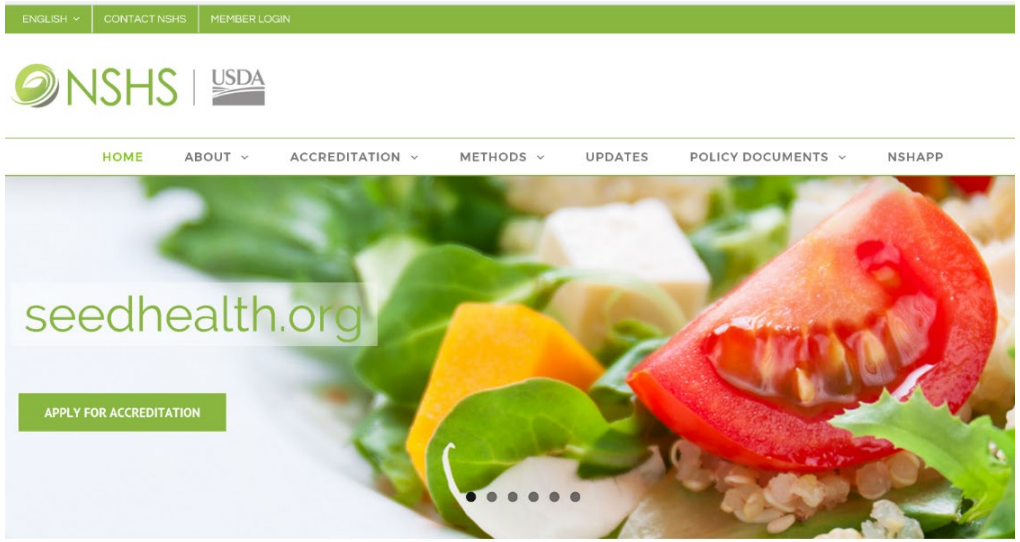
www.seedhealth.org

- Collaboration between USDA-APHIS, state agencies, and the seed industry (ASTA) to facilitate seed exports
- Launched in 2001
- Guided by Policies and Procedures Board (PPAB)
- USDA-APHIS Accreditation Manager Sarika Negi
- ISU Seed Science Center established as NSHS Admin. Unit
  - Co-Directors Gary Munkvold, Charlie Block



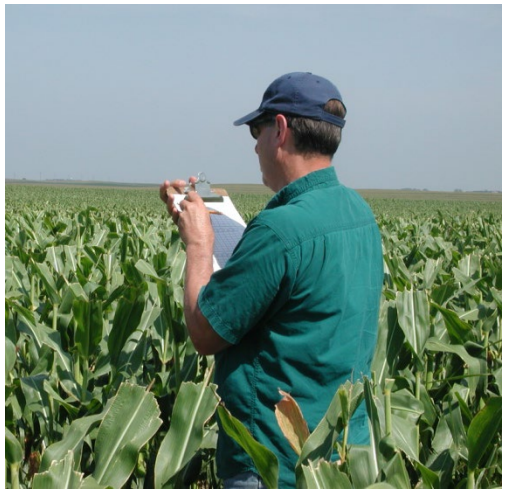
NSHS Objectives

1. Establish standardized seed health laboratory test and phytosanitary inspection procedures
2. Accredit entities to carry out phytosanitary inspections and laboratory testing for export certification of seed
3. Promote phytosanitary reform as a means to foster trade



NSHS Accreditation

1. Laboratory testing for seed health
2. Phytosanitary field (or greenhouse) inspection
3. Sampling for phytosanitary testing
4. Visual inspection for phytosanitary export certification

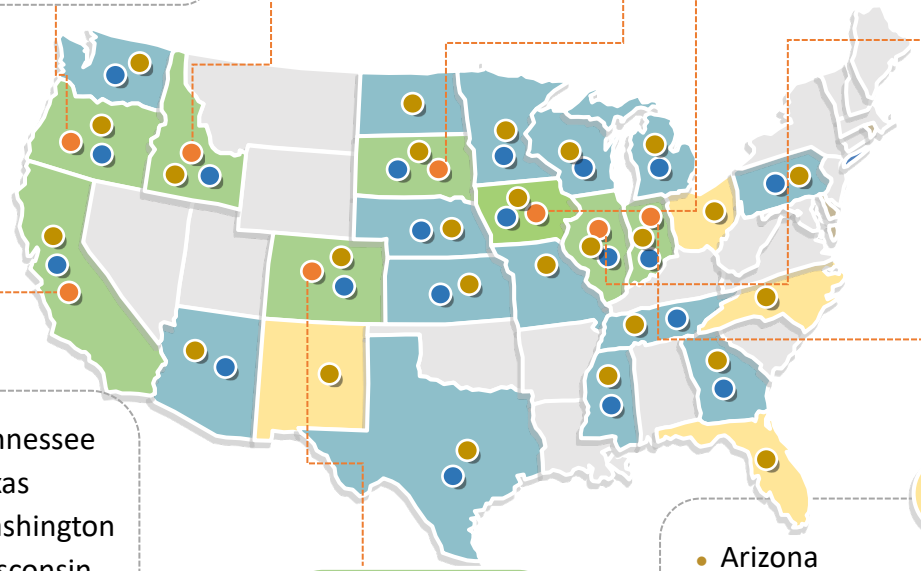



- NSHS testing/inspection results are used by Authorized Certification Officials to issue Phytosanitary Certificates

NSHS accreditees 2022

- 26 accredited organizations
  - 10 private testing labs/inspection services
  - 10 seed companies
  - 4 crop improvement associations
  - 2 public seed testing labs
- Sampling: 12 accredited
- Visual Inspection: 4 accredited
- Field inspection: 6 accredited
- Laboratory testing: 13 accredited
- Most are accredited for 1 or 2 options of the 4

NSHS Accreditations



California

- CA Agri Diag.
- CSPL
- Heinz Seed
- HM Clause
- Seminis
- Sakata
- United Genetics
- US Agriseeds
- Wonderful Labs.

Oregon

- Nunhems USA
- Oregon State Univ.
- Smith Seed Services
- Universal Seed

Idaho

- Idaho Crop Improv.
- Syngenta

South Dakota

- SGS
- SoDak Labs

Iowa

- Iowa Crop Improv.
- Iowa State Univ.
- Pioneer

Illinois

- Illinois Crop Improv.

Indiana

- Indiana Crop Improv.

Field Inspection

- Arizona
- California
- Colorado
- Georgia
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Michigan
- Minnesota
- Mississippi
- Nebraska
- Oregon
- Pennsylvania
- Puerto Rico
- South Dakota
- Tennessee
- Texas
- Washington
- Wisconsin

Colorado

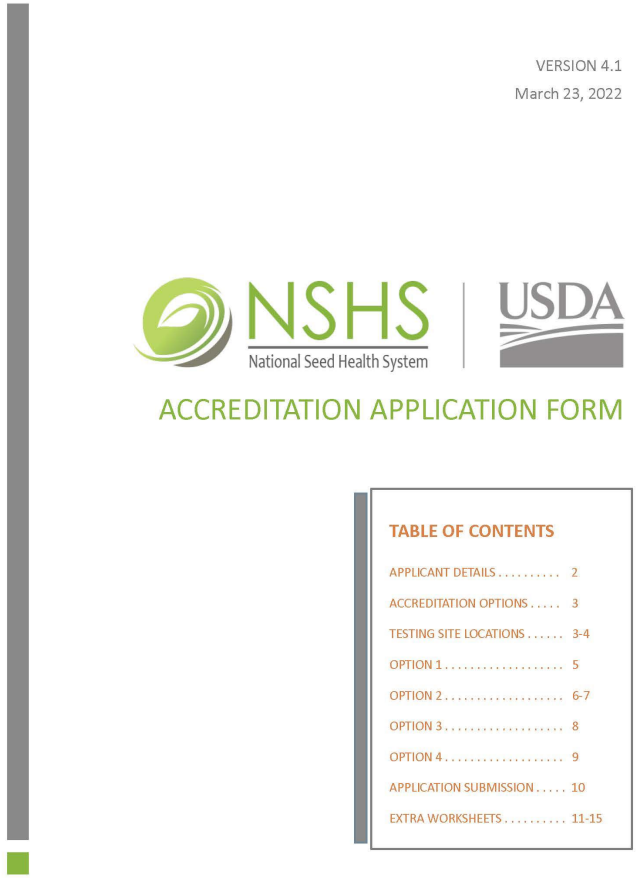
- Eurofins
- Summit

Sampling & Visual Inspection

- Arizona
- California
- Colorado
- Florida
- Georgia
- Hawaii
- Idaho
- Illinois
- Indiana
- Iowa
- Kansas
- Michigan
- Minnesota
- Mississippi
- Missouri
- Nebraska
- New Mexico
- North Carolina
- North Dakota
- Ohio
- Oregon
- Pennsylvania
- Puerto Rico
- South Dakota
- Tennessee
- Texas
- Washington
- Wisconsin

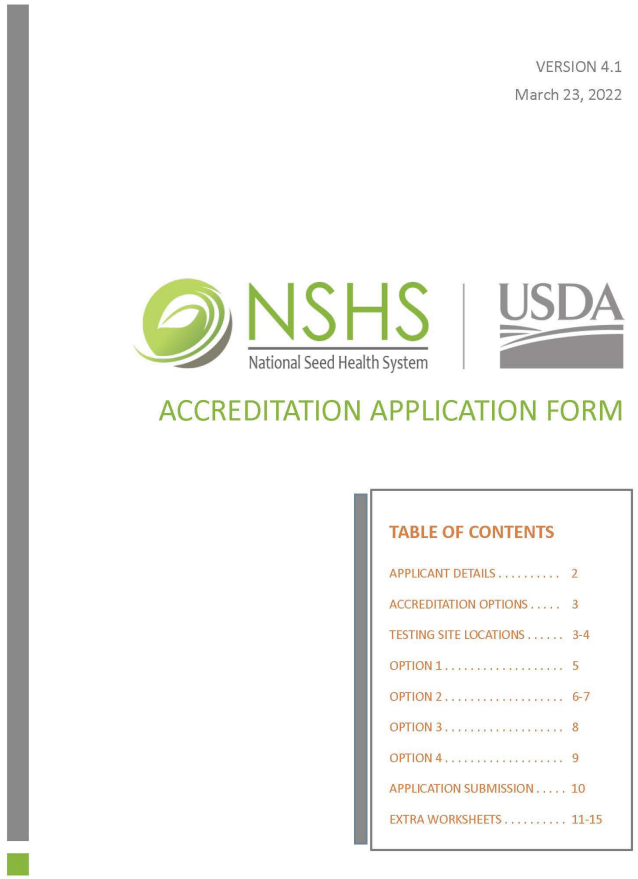
NSHS application and approval process

- Application form can be downloaded from www.seedhealth.org
  - Completed and transmitted electronically or mailed to NSHS Administration Unit at Iowa State University Seed Science Center
  - Must include supporting documents (Quality Management documents, procedures, training program, etc.)
  - Fees determined by scope of application
- Initial review by Administration Unit
- Accreditation audit conducted
  - Quality system and technical aspects



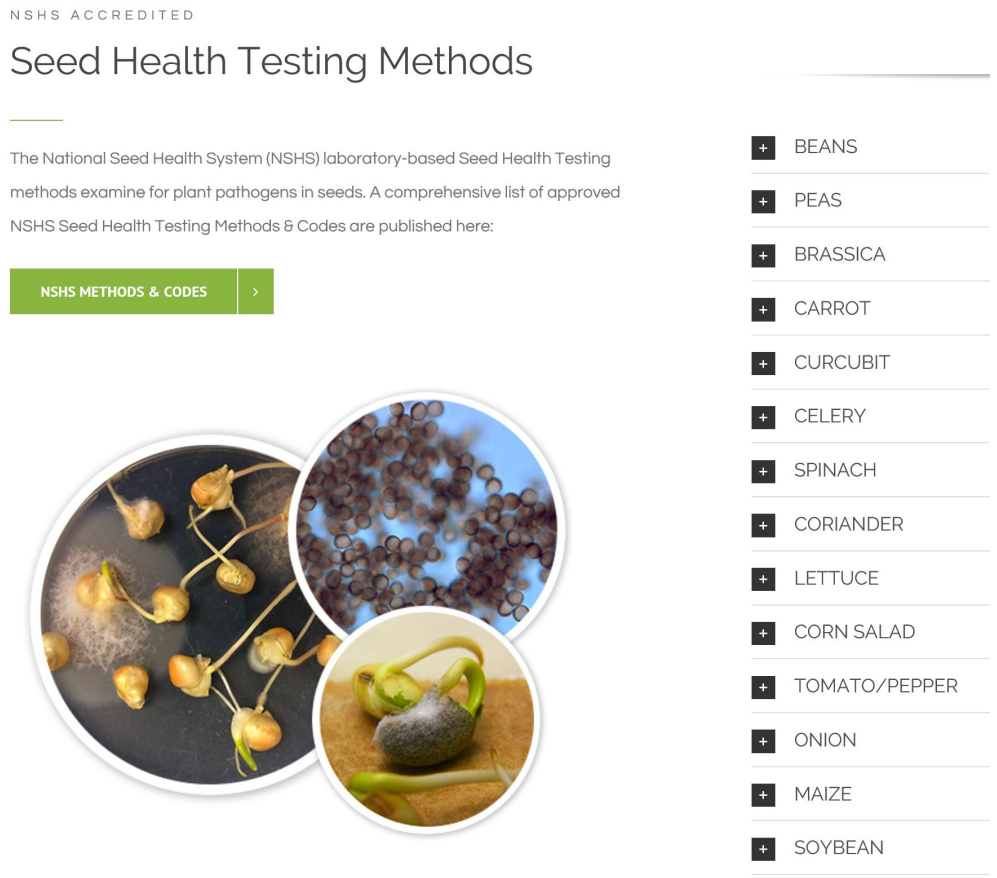
NSHS application and approval process

- Audit completed by NSHS Admin Unit personnel, USDA-APHIS personnel, or external auditor
- Audit report submitted to Administration Unit
- Administration Unit recommendation goes to USDA-APHIS Accreditation Manager
- Approval & notification from USDA-APHIS to applicant
- Must reapply every three years
- Must report operational changes to Admin Unit
- Interim audits may be conducted



NSHS Accreditation

- Laboratory testing for seed health – must use NSHS-approved methods (https://seedhealth.org/seed-health-testing-methods/)
- Phytosanitary field (or greenhouse) inspection – Must follow NSHS guidelines (https://seedhealth.org/phytosanitary-field-inspection/)
- Sampling for phytosanitary testing – ISTA or AASCO procedures
- Visual inspection for phytosanitary export certification – NSHS guidleines and USDA-APHIS Export Manual (https://seedhealth.org/visual-inspection/)



- Methods for 72 host-pathogen combinations
- Harmonization with ISTA/ISHI

NSHS National Seed Health System

National Seed Health System

TITLE: Technical Panel Procedures and Criteria for the Evaluation of Laboratory Seed Health Testing Methods for the NSHS

VERSION: 3.0 **DATE:** 01/22/2019

Reference Manual A-Section 3.1

3.1 TECHNICAL PANEL PROCEDURES AND CRITERIA FOR THE EVALUATION OF LABORATORY SEED HEALTH TESTING METHODS FOR THE NSHS

This document replaces *"Technical panel peer review procedure for laboratory seed health Reference Methods"* Version: 1.1, Date: 04.01.2016

3.1.1 Introduction:

The National Seed Health System (NSHS) has developed a peer review system to evaluate and approve seed health test methods to be used for phytosanitary certification.

Seed health testing methods may be proposed by NSHS-accredited entities, the NSHS Administration Unit (AU) at Iowa State University, or other stakeholders in phytosanitary certification of seeds for export. Methods should be submitted using the NSHS method template available on the NSHS website, www.seedhealth.org. Proposed methods should meet the criteria described in Appendix 1, "Development and Validation Data Targets for Proposed NSHS Seed Health Testing Methods", and should be submitted to the AU with supporting data as described in Appendix 1.

Appendix 1 - Development and Validation Data Targets for Proposed NSHS Seed Health Testing Methods

Criterion	Sub-Criteria	Definition	Evidence	Preferred minimal data collection	Notes
Sensitivity-Method	Limit of Detection	The lowest level of contamination by the target organism that is consistently detected by the method	Dilution series performed with known contaminated seeds into clean (non-contaminated) seeds to show the limit of detection.	Minimally 5 samples at LOD	Also can be measured by spiking seed sample with cells, virions, DNA concentration, etc. Would be ideal to show this against a direct method (such as grow out) to show biological relevance of contamination rates vs. detection capability
	Diagnostic sensitivity	Rate of false negative results (percentage of true positives detected by the method)	Consistent detection of contaminated samples at appropriate levels of contamination	Minimally 5 samples at each level of contamination	Diagnostic sensitivity differs for different levels of contamination
Sensitivity-Assay	Limit of Detection	The lowest concentration of target pathogen that is consistently detected (>95%) by the (PCR, ELISA, etc.) assay	Dilution series performed with cells, virions, DNA concentration, etc. and replicated to show the limit of detection.	Minimally 20 replicates at LOD (with 19 detects) will achieve 95%	Not applicable to all assays (e.g., blotter tests)
Specificity	Inclusivity	Method detects all relevant variants of the target pathogen	Assay should be evaluated against an appropriate collection of strains/isolates/variants that represent different origins in geography, host, and time as are available; method should be evaluated using seed samples contaminated with variants of the target pathogen	Replicated samples of appropriate variants	Per availability of seed samples; method should detect all lots as positive that result in disease occurrence
	Exclusivity	Method excludes (minimally cross reacts with) non-target microbial strains including closely related species and look-alikes; method does not produce positive results for samples free of the target organism	Assay should be evaluated against an appropriate collection of microbial strains or isolates that reflect populations associated with routine testing samples; Method should be evaluated using seed samples from different geographic origins, production years, crop species that are free of target pathogen populations.	Minimally 5 negative control samples from different origins	
	Diagnostic specificity	Rate of false positive results (percentage of clean samples testing positive by the method)	See Exclusivity		
Selectivity		Ability of the method to detect the target pathogen(s) without being affected by seed matrix variations	Method should be evaluated using contaminated samples of seeds of different origins	Minimally 5 contaminated samples from different origins	Diverse samples can be spiked with a single variants of the pathogen; or naturally contaminated samples of different origins can be used
Repeatability		Agreement between a series of measurements obtained from multiple sampling of the same homogeneous sample under the same lab and operating conditions over a short interval of time	Method should be repeated in a lab on replicate seed samples by the same technician, using the same reagents to show results (positive and negative) are replicable.	40 (10 positive and 10 negative replicates X 2 days)	
Reproducibility		Agreement between a series of measurements obtained from multiple sampling of the same homogeneous sample under operating conditions existing across different laboratories	Method should be performed across labs (minimally 3) on replicate seed samples with varying levels of pathogen contamination rates to show results (positive and negative) are reproducible. Lab conditions should include: different technicians, reagent sets, equipment, etc.	20 replicates per lab (10 positive and 10 negative replicates)	Temporary standard methods can be approved without reproducibility data
Robustness		A measure of the capacity to remain unaffected by small but deliberate variations in method parameters; provides an indication of reliability during normal usage	Can be demonstrated through reproducibility data and through systematic variation of method parameters (e.g., pipetting volumes, incubation times, etc.)	3 levels of each crucial parameter that is varied	Method parameter selection must be considered carefully but needn't be comprehensive

- Ad hoc peer review system for method validation reports
- Current projects:
  - *P. stewartii* subsp. *stewartii*
  - *P. savastanoi* pv. *glycinea*

SAA

Thank you!

- Dr. Charles Block, Co-Director U.S. National Seed Health System Administration Unit
- Kelly Iverson, NSHS Program Specialist
- Sarika Negi, USDA-APHIS Accreditation Manager

Contact Information
Gary Munkvold
Professor of Plant Pathology
Co-Director U.S. National Seed Health System Administration Unit
Iowa State University Seed Science Center
munkvold@iastate.edu
+1 515-294-7560

Chair, ISU Online Graduate Program in Seed Technology & Business, www.seedgrad.iastate.edu