

National Plant Board



United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection and Quarantine



Joint National Seed Health System Review

Report and Recommendations

December 30, 2010

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Background:

In 2001, PPQ published a rule in the Federal Register ([7 CFR 353.8](#)) allowing APHIS to accredit non-federal entities to perform laboratory testing or phytosanitary inspection services to support export certification activities. As of July, 2009, the North American Plant Protection Organization (NAPPO) finalized the [Guidelines for Authorization of Entities to Perform Phytosanitary Services](#). These guidelines represent a regional standard for accreditation. Accreditation is official recognition of proficiency resulting in the approval and authority to perform specific tasks or to provide specific services in support of official obligations such as the issuance of Phytosanitary Certificates.

Introduction:

The U.S. Seed Health Accreditation Program, in the form of the National Seed Health System (NSHS) has been established by the U. S. Department of Agriculture, Animal and Plant Health Inspection Service (USDA-APHIS), in cooperation with 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) 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. The accreditation responsibility includes establishing and monitoring accreditation systems within Plant Protection and Quarantine (PPQ).

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.

In 2009, at the annual meeting of the Central Plant Board, Resolution No. 6 was passed, asking for APHIS to fund and implement a program review of the National Seed Health System. This has been the first review since the establishment of the NSHS in 2001.

Team Members and Affiliation:

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Team Members collected information through direct observations, interviews, and the review of documents (e.g. correspondence, program records, data analysis, and reports). Team Members reviewed the information obtained during the site visits as it relates to effectiveness of program delivery, efficiency of operations, and compliance with policies and regulations in achieving established goals. This report outlines the Review Team's findings and provides recommendations for improvement.

The Review Team extends their gratitude to the many NSHS participants and regulatory officials in Iowa, Idaho, Indiana, Illinois, South Dakota, and Riverdale, MD for the time and attention given to this review, and for the support of the Management and Strategy Teams. The Team Leader wishes to express many thanks for the amazing cooperation and collective effort put forth by the Review Team Members in conducting this review and in bringing a valuable product to fruition.

Significant Findings:

Significant findings are identified by the review team as being; 1) quality initiatives that may be implemented to improve the NSHS; or 2) deficiencies that warrant immediate attention. The following were considered significant:

- Funding is the most significant issue identified by the Review Team. The current amount of funding does not cover the cost of program delivery, and is not sufficient to allow for consistent methods development, validation, proficiency testing, and development of protocols.
- Oversight by the Administrative Unit (AU) and the Accreditation Manager (AM) are not sufficient to ensure that necessary corrections to the system are performed when required and that the protocols are sufficient for adequate program delivery. This is directly related to a lack of resources.
- There are apparent conflicts between the administration of the NSHS and the Federal Regulations regarding the use of unaccredited laboratory test results for phytosanitary certification and the certification of disease freedom by exporters, per 7 CFR 353.7(a)(4) and 7 CFR 353.6 (a)(3), respectively. There is no guidance for official testing of plant material.
- The industry is concerned that not enough is being done to foster fair and equitable trade through the promotion of international phytosanitary reform. Frequently, only a small percentage of the general public and seed industry are aware of when and what trade negotiations involving phytosanitary measures are being negotiated.
- The establishment of the NSHS Strategy Team has been movement in a positive direction for facilitating the oversight and outreach of the NSHS.

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done

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The following quality initiatives are suggested to improve validity of the system and program delivery:

- Priority should be given to the funding, as this will resolve many of the findings identified as concerns. Conducting a cost / benefit analysis for maintenance of and participation in the NSHS, and identification of sources of funding for methods development / validation and proficiency testing will strengthen the integrity of the program.
- Providing outreach that informs the stakeholders of the benefits of keeping and using the program may stimulate an interest in participation and increase revenues for the program.
- Establishing a working group composed of Federal, State and Industry representatives to assist in the formulation of revisions to the program should address any conflicts between the NSHS and the Federal Regulations.
- Updated program guidance, manuals and protocols, and providing a streamlined model or template for parties requesting accreditation will enhance the integrity of the program.
- Improved transparency related to current trade negotiations that may affect the activities of Accredited Entities (AE) in the NSHS will open the dialog with the industry and ensure that their interests are heard and are being represented.
- Development of a more frequent reporting requirement of activities performed by an AE, which can be reviewed by the AM and AU, and used for scheduling audits and summarizing the activities of the entire program, will ensure a comprehensive approach to managing any necessary changes to the program.
- Conducting more frequent program reviews will ensure that any program changes that are necessary are implemented in a timely manner.

Findings and Recommendations:

Organization and Resources

Findings:

- The resources devoted to the administration of the NSHS are currently at a minimal level, and if it were not for the generosity of the Iowa State University, the administration of the program would not be sustainable.
- The funding at the AE level is adequate because it is fee based, and is mainly driven by the consumer of the services.

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- There is no research and development funding currently available for methods development, methods validation and proficiency testing.
- The AM is funded only partially by the NSHS, with additional funding from other program budgets within USDA.
- The current fee structure is not covering the cost of program delivery.
- The cost to industry of missing one shipment can pay for the cost of participation in the program.
- The cost to Federal and State regulators if there were no NSHS would be prohibitive. There are not enough human resources to fill the need for phytosanitary inspections and laboratory analysis for export certification.
- There is a reported perception that our trading partners question the validity of the testing being conducted under the NSHS due to the rapid pace at which the methods were developed, and there was concern expressed regarding the validity of testing conducted by our trading partners.

Recommendation:

A program as important as the NSHS would benefit from adequate funding; a mechanism should be identified and developed to provide such funding. A cost / benefit analysis would help in identifying the components of the program that are in need of additional funding and the value of providing that funding. Increased transparency would help in resolving any false perceptions and strengthen the integrity of the program.

Accreditation Management (AM)

Resources

Findings:

- The NSHS was initially the only program that required management by the AM. However, with the addition of other accreditation and certification programs, plus collateral duties, the AM may be beyond the span of control that allows for effective management of the NSHS program.
- Staffing does not appear to be sufficient to cover quality program delivery.

Recommendation:

Examine the span of control for this position and the staffing needed to provide effective program delivery. Resources must be made available to provide depth of personnel at the AM level in order to take the NSHS to the next level. While some scientific expertise is essential, the next level of efficiency requires development

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of greater communication between the AM and AE, along with consistent management coordination that is unhindered by other AM responsibilities. Serious consideration should be given to providing an administrative position at the management level that coordinates with the present AM. This will also ensure depth of historical and institutional knowledge for the NSHS.

Management

Findings:

- Re-accreditation audits are not occurring at the current NSHS requirement of every three years for each AE and in some cases re-accreditation has been granted without the required external audit having been completed.
- Reference manuals, the quality manual template and the NSHS website are outdated.
- There is a lack of specificity in the protocols for handling applications; proficiency testing; selection, oversight and training of auditors; follow up for corrective actions identified during audits; and, reporting.
- There is no mechanism for identification of inaccurate claims of accreditation status. Currently, there is a perception that the industry is self-reporting and policing.
- Test results from un-accredited entities are being used for phytosanitary purposes. (In most cases a USDA Authorized Certifying Official would not be allowed to certify a product for export if the inspection or test results were conducted by an unaccredited entity.)
- There is currently no NSHS approved training program that is consistently applied or approved across the program.
- There is a lack of understanding among industry, regulators and the public regarding the NSHS and what the benefits of the program are.
- The AM was found to be very responsive to any needs or challenges.

Recommendations:

Again, funding and staffing appear to be the limiting factors in program delivery. Updates to the program protocols and website information will provide additional integrity to the program. Outreach efforts may stimulate interest in participation and result in additional revenues. The AM, with input from the AU, accredits different protocols put forward by different companies. ISPM 10 does not require uniformity of process. Therefore, it is difficult to have a finding that there is no training consistently applied across the program. Training is more or less provided

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by an AE in accordance with their approved Quality Manuals. However, a framework that identifies the minimum elements and structure of the training would help in addressing consistency and uniformity.

Administrative Unit (AU)

Resources

Findings:

- Staffing at the AU level is not sufficient to provide adequate program delivery.
- There is a limited amount of feed-back and guidance to the auditors and the AE, such as audit report results, renewal notifications, summaries of activities, and information sharing.
- The lack of resources limits the amount of validation and proficiency testing that can be conducted.
- There is currently a need for several review panels for methods validation.
- Succession planning is critically needed. If the current AU vacated the position there would be a significant loss of institutional knowledge.
- The pool of auditors is very small and there was concern expressed by AE regarding the use of an auditor from a competing AE.
- Audits are conducted every third year for re-accreditation. However, the regulations state that audits should be conducted yearly.
- The auditor's checklist is outdated.
- The AU has shown a remarkable ability to remain objective and does not participate in the evaluation or audit of the Iowa State University Laboratory, which is an AE.
- Concern was expressed regarding the movement to a method based proficiency testing requirement. Proficiency testing should remain pathogen specific.

Recommendation:

The NSHS would benefit from the development of systems and protocols to address each of the findings above. Particular attention should be paid to the development of systems that more clearly demonstrate adherence to guidelines presented in the NAPPO Regional Standards for Phytosanitary Measures (RSPM

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No. 28). A key component of such systems should include scheduled summary reports at each level of the NSHS. Development of proficiency testing standards based on pathogens would provide increased integrity to the program. The current requirements of the NSHS specify a re-accreditation audit every three years. Per 7 CFR 353.9(a)(4): “After a facility is accredited, the facility must allow APHIS access to the facility and all of its equipment and records for the purpose of conducting unannounced audits to determine the facility's continuing eligibility for accreditation. Such audits will occur at least once a year and may be performed more frequently at the discretion of the Administrator.” There was concern expressed that the frequency of audits every year would increase the cost of participation in the NSHS, which could be prohibitive for smaller organizations that wish to become accredited. Auditors should be provided additional support in training, specialization, and technical competency. Inspectors ≠ Auditors – Auditors by function must have a different approach to evaluating inspection functions as opposed to inspectors. Consideration should be given to the use of audit reports produced as a result of an audit conducted for the purposes of ISO certification.

Management

Findings:

- The AU has essentially become a one person operation.
- There are no formal audits of the AU by the AM.
- No clear criteria are used to select auditors, and the pool of auditors is limited.
- There is no ongoing training required of the auditors.
- There are no clear proficiency measures during audits and audits are not conducted during the inspection season.
- There is no apparent mechanism for feed-back from the stakeholders or the public.
- The technical panel reports on the website were found to be outdated.
- The application materials are outdated and do not clearly indicate what the AE is agreeing to when they sign.
- The temporary methods have been in “temporary status” too long.

Recommendations:

The increasing importance of phytosanitary issues, as well as the very significant worth of seed exports, justifies a greater and undiluted focus of the AU on the

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needs of the NSHS. The steps necessary to make the NSHS more viable will require greater stewardship than presently provided to the AE. Criteria should be developed for the selection, training and proficiency testing of the auditors of the NSHS; an effort should be made to keep the NSHS materials up to date; proficiency methods and temporary analysis methods should be addressed; and, a forum for stakeholder and general public input should be developed.

Training

Findings: Adequate

Recommendations: None

Accredited Entities (AE)

Laboratory Analysis

Resources

Findings:

- Resources appear to be adequate. The services are provided on a fee for service basis. However, more support by the NSHS in regard to methods development and proficiency testing is needed.
- Some protocols for laboratory analyses appear to be proprietary and there is a reluctance to publicize them for fear of lost market share.
- It was suggested that funds for standards development come from those who receive the benefit – ASTA, APHIS, industry, states... Can the Center for Plant Health Science and Technology (CPHST) or the Agricultural Research Service (ARS) assist in standards development?
- There was concern expressed regarding the requirements for testing of pathogens that have never occurred or have been reported erroneously.

Recommendation:

Provide up to date and validated protocols. Provide outreach that informs each AE that only protocols approved and verified by the NSHS are authorized. By virtue of the requirement for review and acceptance into the NSHS, such protocols are no longer exclusive to the developer, but rather a tool for determination of phytosanitary condition by all NSHS participants. It is only through refereed acceptance that the NSHS can provide assurances of impartiality. A source of funding for validation and proficiency testing needs to be identified. An effort should be made to remove any requirements by importing countries for testing if a pathogen has never occurred or has been reported erroneously. A suggestion was

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made to explore the development of “Seed Health Testing Committees” in collaboration with the ASTA, International Seed Testing Association (ISTA) and the NSHS.

Management

Findings:

- Changes in management and facilities are not always communicated to the AU / AM.

- No regular reporting to the AU / AM is required of an AE.
- Non-accredited laboratories are being used for reporting disease freedom for phytosanitary purposes.
- Laboratories would like to see additional procedures added for testing pathogens. Can ISTA methods be adopted by the NSHS?
- There are no protocols for accreditation of an AE to do laboratory testing of seeds outside the continental US (i.e. Hawaii and Puerto Rico).
- It is not clear how an AE can request addition of testing procedures under the NSHS.
- AE would like to see additional methods for devitalization, and recognition of “Official Samplers” accredited by ISTA.

Recommendations:

An AE should be required to submit a monthly, quarterly or semi-annual report to the AU / AM. The reports would provide a summary of activities and records that the AU / AM can compare and evaluate, thus enabling additional oversight. The AU / AM can use the reports to provide periodic summaries of the program. Protocols for the accreditation of entities outside of the continental US should be developed and audits conducted at those entities. Audits should be conducted by specialists in laboratory analysis and conducted more frequently. A protocol should be developed to allow for a request to add testing procedures under the NSHS.

Training

Findings:

- Proficiency testing is not consistently being conducted. How is proficiency testing done in other programs?

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- There is not consistent training across the NSHS, core requirements and solutions for providing training to a smaller AE.
- There was a request to consider the incorporation of other companies under the “umbrella” of an AE who provides training to those companies which is relevant to the phytosanitary certification of seed.

Recommendations:

A formal mechanism for proposing lab testing protocols should be developed. The AM and AU, on behalf of USDA and with inputs from an AE, can prioritize the order for evaluating the testing protocols. It was suggested that grants could be awarded to qualified private and public laboratories in the evaluation of protocols, or possible performance of ring-testing when pathogen shipment is feasible. Notice of proposed acceptance for a particular protocol should be communicated to each AE for a specified comment period. Upon resolution of any comments, the protocol should be accepted and available to any AE that has demonstrated adequate proficiency to perform the test.

Accredited Entities (AE)

Phytosanitary Inspection

Resources

Findings:

- Resources appear to be adequate.
- There is a lack of protocols for collecting field samples when there is a suspect plant, and for rates of seed sampling for research materials.

Recommendation:

Although protocols are provided in the quality manual of an AE, and ISPM 10 allows for methods tailored to individual circumstances such as common pests and production environment, some general guidelines or requirements for sampling suspect material would strengthen the field inspection procedures. Information is needed for the rates of seed sampling for both research and commercial fields.

Management

Findings:

- Audits are not occurring during the growing season, while the work is being conducted.

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- There was concern that the lack of suspect samples submitted for diagnosis is an indication that there is a lack of disease recognition.
- It is unclear how the amount of seed inspected and tested is reconciled with the amount of seed certified for export.
- Field inspections need to be standardized. What is an “appropriate” number of samples to submit for testing? (This is directly related to the required number of samples a laboratory may need to complete testing, which does not necessarily correlate to the number of samples needed to declare a field free from a pathogen or attesting to disease freedom in a field identified as having suspected pathogens.)
- Not all of the AE are conducting the required internal audits.
- Follow-up on requested corrective actions does not take place in a timely manner and may not be confirmed as corrected for several years.
- It is not clear that there is consistent handling of regulated fields across the program.
- There are no protocols for accreditation of an AE to do field inspections and seed sampling outside the continental US (i.e. Hawaii and Puerto Rico).
- Fields rejected due to phytosanitary concerns are not always being tracked.
- Some of the AE have excellent training programs and proficiency testing. Some of the Quality Manuals were very well presented.

Recommendations:

Scheduled reports by the AE, including specific elements addressing some of the findings above, should be developed to provide information that can be used during audits and to alert the AM of situations that may require attention. The NSHS regulations do not address submission of plant samples for testing. Laboratory test results for phytosanitary certification and the certification of disease freedom should be regulated in accordance with 7 CFR 353.8 for plant samples. Per RSPM No 28, auditors should be required to pass an introductory audit course such as ISO 19011, which the current pool of auditors has done. However, there has been no training conducted since the initial training nine years ago. It may be beneficial to the auditors if there was refresher training. As stated previously, the current requirements of the NSHS specify a re-accreditation audit every three years. Per 7 CFR 353.9(a)(4): “After a facility is accredited, the facility must allow APHIS access to the facility and all of its equipment and records for the purpose of conducting unannounced audits to determine the facility's continuing eligibility for accreditation. Such audits will occur at least

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once a year and may be performed more frequently at the discretion of the Administrator.” Either external yearly audits or a combination of internal audits and reporting may correct some of the findings identified above. The finding that most audits are desk audits of paperwork could be addressed by a two tiered approach – field audits during the inspection season and a paperwork audit. More specific guidance for the handling of regulated fields would reduce the likelihood of accidental transmission of a regulated pest or pathogen, and increased safeguarding of genetically regulated materials.

Training

Findings:

- It is not clear that the minimum requirements for education and experience are being met, per 7 CFR 353 (a) (2).
- Proficiency testing is not consistently being conducted. How is proficiency testing done in other programs?
- There is not consistent training across the NSHS, core requirements and solutions for providing training to a smaller AE.

Recommendations:

Minimum requirements for education and experience may be sufficient, but there is a need to ensure that the requirements have been properly documented by the AE. The development of proficiency testing for field inspectors would help to resolve the question of recognition of symptomatic material. Development of modules for training purposes could be used, and testing upon completion of a module would measure the understanding of the participants. When a participant has successfully completed the general principles training module and shown proficiency in recognition of symptomatic material, they can be certified to conduct field inspections for the AE according to the approved protocol submitted by the AE. As indicated previously - ISPM 10 does not require uniformity of process. Therefore, it is difficult to have a finding that there is no training consistently applied across the program. Training is more or less provided by an AE in accordance with their approved Quality Manuals. However, a framework that identifies the minimum elements and structure of the training would help in addressing consistency and uniformity.

Interactions and Communications

Findings:

- There was some tension apparent between some of the participants in the NSHS and regulators.

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- There is a lack of information exchange between the AU / AM and AE.
- Some of the AE have excellent working relationships and good collaboration with regulators and stakeholders.
- Interactions on a one-on-one basis with the Review Team were very productive and the participants in the review were very cooperative.
- All of the entities the Review Team worked with during this review showed a high level of professionalism in conducting NSHS related activities.

Recommendations:

Communication between all levels of the NSHS would improve if there was additional outreach to regulators and industry on the value of the program. In general, a train the trainer program and reciprocal training with regulators may reduce the perception that there is not enough training and oversight. Inclusion of regulators in the review and audit processes, and increased transparency would result in increased visibility and understanding.