Technical Panel peer review procedure for laboratory seed health Reference Methods

1. Purpose

1.1 The purpose of this procedure is to the events, actions, interfaces and responsibilities which are involved in the establishment of technical panels of experts to peer review and recommend seed health test methods to be published as Reference methods in Reference Manual of the National Seed Health System accreditation program.

2. Scope

2.1 The scope of this procedure cover the period from formation of Technical panels to completion of production of Reference methods.

3. List of References

3.1 NSHS Reference Manual B
3.2 CAB-ABSTRACTS database
3.3 CABI - Database on Seedborne Diseases (DSD)
3.4 EXCERPT Database
3.5 ISTA Annotated List of Seedborne Disease
3.6 Unpublished lists of seedborne pathogens generated by the NSHS AU, ASTA Field crops and Vegetable Technical Subcommittees, and ISHI-Vegetables,
3.7 NSHS Criteria for the Evaluation of Laboratory Seed Health Testing Methodologies

4. Definitions

4.1 AU - Administration Unit of the NSHS
4.2 PPAB - Policy and Procedures Advisory Board of the NSHS
4.3 TP - Technical Panel of experts assigned to provide a peer review of test methods
4.4 ISHI - International Seed Health Initiative
4.5 ASTA - American Seed Trade Association
4,6 TR - Technical report of the TP's
4.7 RM - NSHS Reference Method

5. Responsibilities

5.1 The AU will compile technical packages for pathogen test reviews, send them to members of the TP, and enters approved methods and TRs into Reference Manual B or returns non-approve tests to the TP Chair.
5.2 The PPAB will establish priorities for pathogen test reviews, determine pathogens to be included in each TP, assign Chairpersons to TPs, makes final approval of the test as RMs.
5.3 The TP Chair will establish a 3-4 member panel of experts for the relevant group of pathogens, prioritize pathogens in the group, communicate with the AU re-technical panel package production and distribution, summarize findings of the TP and prepare a TR and recommendation on disposition of the test (on the NSHS Technical Panel review -Summary

Report Form), submit the TR and recommendation to the PPAB, and, if necessary, re-evaluates methods that were not approved.

5.4 TP members will evaluate seed health test methods for pathogens

6. Action Steps

6.1 Formation of Technical panels

6.1.1 The PPAB establishes a priority list of pathogens that require RMs compiled from reference sources 3.3 - 3.6.

6.1.2 The PPAB identifies groups of pathogens for each TP and selects a Chairperson for each panel. Chairs are selected on recommendation of ASTA technical Working groups or by other mechanisms.

6.1.3 The TP Chair selects a panel of 3-4 members from experts from throughout the world with experience of pathogens in a TP. Experts should be drawn from both public and private sectors, and should be from the seed industry.

6.1.4 The TP Chair prioritizes the pathogens in the TP in a sequence for test reviews.

6.2 Preparation of Technical packages

6.2.1 The TP chair informs the AU that Technical packages are required for particular pathogens and provides mailing addresses of members of the TP.

6.2.2 The AU prepares the TP according to the process described in TECH.PACK.PROC

6.2.3 The AU sends a Technical packages for each pathogen to each TP member.

6.3 Review of Technical package

6.3.1.Each TP member will review the technical package according to 3.5 the "NSHS Criteria for the Evaluation of Laboratory Seed Health Testing Methodologies". They may also draw on other relevant data to make a recommendation on the disposition of tests.

6.3.2 The TP member submits their report to the TP Chair on the form under 7.1 NSHS Technical Panel review - Individual Report Form.

6.3.3 The TP Chair evaluates the individual reports from all TP members and prepares a TR that includes a recommendation for disposition of tests and the scientific basis for the recommendations. The recommendation should be made on the form under 7.2 "NSHS Technical Panel review - Summary Report Form". indicating classification of test as described in document 3.5 "NSHS Criteria for the Evaluation of Laboratory Seed Health Testing Methodologies".

6.3.4 The TP Chair submits the TR and recommendation to the PPAB.

6.4 Final Approval of tests as Reference methods

6.4.1 The PPAB provides a report on method approval.

6.4.2 It the method is approved as Class A, the protocol and the TR it is sent to the AU for publication in document 3.1 NSHS Reference Manual B.

6.4.3 If the method is in Class B, it is returned to the TP for a recommendation as to whether it should be published as a pre-full approval *test. The TP should also determine a research plan to bring the test into Class A.

6.4.4 The TP chair then re-submits the recommendation and test plan to the PPAB for approval.

7. Records

7.1 NSHS Technical Panel Review - Individual Report Forms.

7.2 NSHS Technical Panel Review - Summary Report Forms

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

8. Flowchart

8.1 Flowchart

7.1 NSHS TECHNICAL PANEL REVIEW - Individual Report Form

Host Pathogen Combination

1) Assay Status (Check only one for each assay)

Assay #	Class A	Class B	Class C
1			
2			
3			
4			
5			

2) Specific comments/criticisms/concerns/recommendations for research:

Assay # 1:

Assay # 2

Assay # 3:

Etc:

7.2 NSHS TECHNICAL PANEL REVIEW - Summary Report Form

Host Pathogen Combination

1) Assay Status Summary (Check individual reports of all panel members)

Assay #	# Reports recommending: Class A	Class B	Class C	Final Designation (A, B, or C)
1				
2				
3				
4				
5				

2) Summary recommendations

Assay # 1:

Assay # 2

Assay # 3:

Etc:

7.3 **Technical Panel Procedures and Criteria for the Evaluation of Laboratory Seed Health Testing Methods for the NSHS**

Introduction

The National Seed Health System (USA) has developed a peer review system to evaluate and approve seed health test methods to be used for phytosanitary certification under the NSHS. Under this system, Technical Panels of 3-4 international experts are formed to evaluate seed health test methods that are proposed for specific host-pathogen combinations. Technical Panel members have expertise in pathogens of the assigned crop. They are drawn from academia, government, and the seed industry.

The following criteria are to be used by the Technical Panels to evaluate seed health testing methods for each host/pathogen combination. Based on the results of these evaluations the appropriateness of methods for approval by NSHS will be determined.

Evaluation Procedure

1. 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 be submitted to the AU with supporting data in order to meet the criteria described below.

2. The NSHS AU will develop a technical package of scientific information on each host/pathogen combination and available data on the proposed seed health testing methods. This will be accomplished by summarizing information provided by the submitter of the method (if applicable), conducting a literature review of the pathogen, and contacting seed scientists to obtain information on:

    - Relevant data on seedborne and seed transmission aspects of the pathogen
    - Existing seed health test methods
    - Validation data included with the proposed method
    - Other validation data available from ISHI, ISTA, or other sources

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

4. The AU will not consider laboratory methods judged to be unsubstantiated, out of date, or unneeded.

Technical Panel Responsibilities

It will be the responsibility of panel members to evaluate seed health test methods included in the technical package based upon the following criteria:

Sample size – Methods should specify a minimum sample size. Appropriate sample size may differ among crop seeds and pathogens. Panel members will use their expertise and judgement to assess whether the proposed sample size is appropriate.

Sensitivity – Methods should be supported by data demonstrating the sensitivity of the assay in terms of either percent infected seed or target pathogen quantification, such as CFU, number of conidia, etc.
Appropriate sensitivity levels may differ among crop seeds and pathogens. Panel members will use their expertise and judgement to evaluate whether the method in question is adequately sensitive.

Specificity – Methods should be supported by data demonstrating the specificity of the assay, including results from a range of isolates of the pathogen from different origins. This may include different hosts, geographical regions, or different pathogen races, as appropriate. Data also should be provided that demonstrate that the method can distinguish the target pathogen from closely related organisms.

Repeatability and Reliability – Supporting data should include evidence that the method produces repeatable results. This can be demonstrated through replicated testing of samples. Reliability can be demonstrated by including varying types of seed (varieties, production areas, etc.).

Comparative Test Data – If there is an established method for the host/pathogen combination in question, data should include a comparison of results between the proposed and established method. To be approved, a proposed method should perform as well or better than the established method, and/or demonstrate other advantages in terms of efficiency, cost, or ease of use. This information can be generated internally through the developmental process or through group comparative testing.

Historical Data – If a method has been routinely used in industry or academia, available data on frequency of use should be provided. 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 may consider other criteria which might have significant impact on the recommendation for use of a method. These may include cost, facilities required, time to obtain results, or other practical aspects of method implementation.

Technical Panel Report

1. Each Technical Panel reviewer shall prepare a report on the form titled "NSHS TECHNICAL REVIEW PANEL - Report Form" rating each of the methods evaluated by these criteria. He or she then should state their justification for their rating, and if the rating is B or C, make recommendations for revisions to the method or further data collection that may be needed.

The panel members should use the following rating system to make a recommendation for each method.

- Class A-Standard Method: The method is acceptable as a standard method and should be added to the list of NSHS-approved methods (following approval by the NSHS PPAB).
- Class B-Temporary Standard Method: The method meets an immediate testing need, but requires revision or additional validation data before acceptance as a standard method. Temporary Standards may be added to the list of NSHS-approved methods for a period of 24 months from the time of the approval by the NSHS PPAB. After 24 months, temporary standards must be re-reviewed on the basis of revisions or new data. If no revisions or new data are available, the method is removed from the list.
- Class C: The method should not be accepted. A recommendation may be made for improvements to the method, which can be re-reviewed at a later time.

2. Panel members then return their individual report to the AU.

3. The AU evaluates the individual reports from all TP members and prepares a Technical Report which includes a recommendation for disposition of tests and the scientific basis for the recommendations. The

recommendation should be made on the form under “NSHS TECHNICAL REVIEW PANEL - Summary Report Form”.

4. The AU submits the Technical Panel Report and recommendation to the Policies and Procedures Advisory Board (PPAB) of NSHS for final approval.

5. The NSHS PPAB conducts a vote to approve the method at the A level or B level, or reject the method (C level) based on the Technical Panel report.