

**Seed Health Testing Audit Checklist**

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| --- | --- |
| Organization Legal Name |  |
| Address |  |
| City |  | State |  |
| Telephone |  | Email |  |
| Contact Person/Title |  |
| Auditor, Date, Time |  |

**Auditor Instructions**

*Completion of Checklist*

1. This checklist has been designed as an aid to auditors to ensure the essential elements of the NSHS Accreditation Standards as outlined in Federal Register 7 CFR 353.8(b) on July 18, 2001 for "Phytosanitary Field Inspection ".

2. Auditors can modify the questions on the checklist with additions and/or deletions as appropriate.

3. All questions on this checklist should be completed and marked under the audit findings. If a question is not applicable, write N/A in the audit findings.

4. Auditors should generate their own questions as needed to evaluate the performance of procedures and place them in the last box (Describe any activities observed and additional questions asked during the audit) on the audit checklist.

*Submission of Report*

1. Auditors should complete the attached **Accreditation Audit Report Form** for each Accreditation Option.

2. This Checklist should be submitted with the audit report to:

Kelly Iverson

NSHS Administration Unit

183C Seed Science Center

Iowa State University

Ames, IA 50011

Tel: 515.294.6493

Fax: 515.294.2014

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| --- | --- | --- |
| **Finding** | **Definition/Impact** | **Action/Mitigation** |
| Compliant | Audit finding indicate that program requirements are being met, processes are implemented and documented and records exist to support this.  | No action required. |
| Minor non-compliance | An audit finding that reveals a non-conformance that does not immediately and/ or significantly affect the integrity of the program. * Any amendment to procedural details that is not documented
* An incomplete inspection, testing, or audit record, such as:
	+ No recording of critical test steps
	+ No signing of records and recording of dates
	+ Improper grower identification
	+ Improper sample identification
	+ Incomplete inspection and testing facilities or equipment
	+ Any other deviations from the Entity’s Quality Manual
 | Corrective actions must be undertaken no later than the next audit, or within a time-frame agreed to by the Auditor and Entity. |
| Major non-compliance | An audit finding that reveals an isolated incident(s) that results in decreased confidence of the AE’s inspection, sampling, or testing results; however, it does not have a direct impact on the integrity of the program. Examples include but are not limited to:* A significant difference between the Auditor’s and AE’s inspection and/ or test findings
* The AE fails to identify, classify, or record problems correctly
* Lack of inspection facilities and/or equipment
* Internal audits are not conducted or properly documented
* Actions taken following audits are not recorded
* Documentation is unavailable for auditors
* Corrective action for a Minor Non-Compliance(s) is not implemented within the agreed time-frame
* Three or more Minor Non-Compliance incidents result from any one audit
 | Corrective action is required immediately so that implementation is in place to retain confidence that the conditions of the Standard are being fulfilled. |
| Critical non-compliance | An audit finding that reveals that the integrity of the program is jeopardized. The result of this finding indicates the tests or inspection findings could not be utilized as supporting documentation for the issuance of the phytosanitary certificate.Examples include but are not limited to:* No inspection or test conducted
* Failure to follow inspection/testing methods in accordance with this standard
* A deliberate attempt to provide incorrect results of an inspection or 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
 | The AE is removed from the approved list until: An agreed corrective strategy has been identified by the AU, the AM, and the AE; and an audit is completed of all areas found not to be in compliance, if designated as required by the corrective strategy.  |

| **Requirement** (From 7 CFR 353.8(b) and NSHS Reference Manual A) | **Audit Finding** | **Evidence/Observations** | **Opportunities for Improvement** |
| --- | --- | --- | --- |
| Compliant | Minor NC | Major NC | Critical NC |
| **General** |
| Is organized in a manner to assure proficient performance of seed health laboratory test procedures  |  |  |  |  |  |  |
| Has a Quality Manual or equivalent documentation to describe the Quality System  |  |  |  |  |  |  |
| Is organized in a manner that avoids undue pressure or inducement, possibly influencing judgment or results  |  |  |  |  |  |  |
| Staff is aware of specific job duties, including the extent and limitations of responsibilities  |  |  |  |  |  |  |
| Technical manager is sufficiently trained for tests and inspections  |  |  |  |  |  |  |
| **Facility** |
| Provide a work area that is dedicated to laboratory function and is sufficiently removed (by physical barriers) from all residence(s) and food preparation areas |  |  |  |  |  |  |
| Comply with all Federal and local regulations for chemical handling and disposal |  |  |  |  |  |  |
| The facility does not invalidate the test results or adversely affect the accuracy of data |  |  |  |  |  |  |
| Provide adequate protection from adverse environmental conditions (such as dust, contamination, temperature extremes, moisture extremes, etc.) |  |  |  |  |  |  |
| Are maintained to ensure "good housekeeping” |  |  |  |  |  |  |
| Comply with all USDA-APHIS-PPQ requirements for the movement of regulated articles |  |  |  |  |  |  |
| **Records** |
| Clearly state the results of the seed health laboratory test procedures, methodology and other information pertinent to the results  |  |  |  |  |  |  |
| Records are maintained for a period that corresponds to the inventory of the product, and no less than three years  |  |  |  |  |  |  |
| Records are kept secure and are considered confidential, unless otherwise stipulated |  |  |  |  |  |  |
| Evaluation of seed health tests and inspections are performed: by a University-trained plant pathologist, under the supervision of a plant pathologist, or by a person with a related degree and with training approved by the AM |  |  |  |  |  |  |
| Appropriate education, training, technical knowledge, and experience for assigned functions is documented and clearly defined |  |  |  |  |  |  |
| **Quality Documents/Manual** |
| Ensure the accuracy and precision of all tests and data, document control, and sample control |  |  |  |  |  |  |
| Define the policy, purpose, and obligation of the AE |  |  |  |  |  |  |
| Document the structure/ facility |  |  |  |  |  |  |
| Document the operational staff and functional duties and responsibilities |  |  |  |  |  |  |
| Document procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality |  |  |  |  |  |  |
| Appropriate records of training are maintained |  |  |  |  |  |  |
| Document all test procedures |  |  |  |  |  |  |
| Document all feedback and corrective actions |  |  |  |  |  |  |
| Define all customer complaint procedures |  |  |  |  |  |  |
| Document all procedures for new testing, including the assignment, as well as facility requirements prior to initiation |  |  |  |  |  |  |
| Maintains documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with seed health testing standards and to determine the effectiveness of the quality system |  |  |  |  |  |  |
| Quality manual must be available to, and in use by, the facility personnel who perform the services |  |  |  |  |  |  |
| The AE has a system for controlling data throughout the entire process of production and testing; The system for tracing the product is documented and maintained |  |  |  |  |  |  |
| The AE establishes and maintains documented procedures for implementing corrective and preventive action |  |  |  |  |  |  |
| The AE establishes and maintains documented procedures to ensure that all purchased products conform to specified requirements |  |  |  |  |  |  |
| The AE establishes and maintains documented procedures for the control of verification, storage, and maintenance of all seed samples |  |  |  |  |  |  |
| **Other** |
| Seed samples are inspected to ensure they meet the requirements for testing |  |  |  |  |  |  |
| The seed’s inspection and test status are identified by suitable methods to ensure that only a sample which has passed the required inspections and tests is dispatched or used |  |  |  |  |  |  |
| Test results are not issued until the relevant verification has been made and the data is determined to be correct. |  |  |  |  |  |  |
| Seed supplier establishes a maintained and documented procedure to ensure that seed that does not conform to specified requirements is prevented from unintended use  |  |  |  |  |  |  |
| There is an established and documented procedure for delivering data to customers |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **The Laboratory** |
| Controlled access to the testing area |  |  |  |  |  |  |
| Accessed only by persons subject to the rules of testing and inspecting protocols |  |  |  |  |  |  |
| Aseptic techniques and good laboratory practices being used |  |  |  |  |  |  |
| Identification of contamination potential and relevant containment procedures |  |  |  |  |  |  |
| Sterilization and disinfestation of microbiological agents |  |  |  |  |  |  |
| Contains equipment to correctly carry out the designated tests |  |  |  |  |  |  |
| Equipment is properly maintained and repaired and records maintained |  |  |  |  |  |  |
| Equipment is re-calibrated routinely or as necessary to correct erroneous results |  |  |  |  |  |  |
| Equipment verification information is logged as necessary or appropriate (pH meters, incubators, etc.) |  |  |  |  |  |  |
| Records of maintenance requirements, if relevant, are current and accessible |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **Seed Health Testing – General**  |
| Autoclave  |  |  |  |  |  |  |
| Pipets  |  |  |  |  | Calibration date |  |
| Balance |  |  |  |  | Calibration date |  |
| Distilled and sterile water |  |  |  |  |  |  |
| Microscope - Compound |  |  |  |  |  |  |
| Microscope - Dissecting |  |  |  |  |  |  |
| Centrifuge |  |  |  |  |  |  |
| Laminar Flow Hood |  |  |  |  |  |  |
| Destruction of infected material |  |  |  |  | Method |  |
| **Fungal Methods - General** |
| Transparent containers |  |  |  |  |  |  |
| Blotter paper |  |  |  |  |  |  |
| Microscope – Dissecting |  |  |  |  |  |  |
| Microscope – Compound |  |  |  |  |  |  |
| **Bacterial Methods - General** |
| Seed grinding equipment  |  |  |  |  |  |  |
| Specific media as described in methods |  |  |  |  |  |  |
| Positive control isolates |  |  |  |  |  |  |
| Positive process control isolates |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **ELISA Methods - General** |
| Pipets |  |  |  |  |  |  |
| 96 well plates suitable for ELISA |  |  |  |  |  |  |
| Refrigerator  |  |  |  |  |  |  |
| ELISA plate reader |  |  |  |  |  |  |
| Washer bottles or plate washer |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **PCR Methods - General** |
| Pipettes |  |  |  |  |  |  |
| PCR thermo cycler |  |  |  |  |  |  |
| Real-time PCR system |  |  |  |  |  |  |
| Gel electrophoresis setup |  |  |  |  |  |  |
| Gel-imaging system |  |  |  |  |  |  |
| Geno/Grinder OR IKA Mill grinder (pospiviroids) |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **Additional Equipment and Materials** |
| Review accredited methods with NSHS method for meeting specific equipment / materials requirements  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

Describe any activities that were observed during the audit: