NPDN CORE REQUIREMENTS AND STANDARDS FOR AN ACCREDITED PLANT DIAGNOSTIC LABORATORY

National Plant Diagnostic Network Core Accreditation Program

Version 1.1

NPDN Core Standard Table of Contents

NPDN Mission and Accreditation Purpose

The NPDN mission is to enhance agricultural security through the protection of the health and productivity of plants in agricultural and natural ecosystems in the United States. The mission of the NPDN requires member laboratories to: 1) Quickly detect high-consequence plant pathogens, weeds and insect pests that threaten national security and communicate such information to appropriate authorities, 2) Timely and accurately diagnose plant health problems to support industries, clienteles and other stakeholders, and 3) Ensure the accuracy and security of plant diagnostic data. To fulfill the mission, NPDN establishes a Core standard to require all NPDN member laboratories to commit to excellence in plant diagnostics by achieving core accreditation. The purpose of the NPDN Core standard is to provide an overarching framework that helps laboratories to maintain a high level of professionalism and quality of diagnostic results.

1.0 LAB MANAGEMENT

1.1. Lab Mission, Structure, and Accreditation

1.1.1 The laboratory shall have a clearly defined organizational structure specifying the management team and technical staff as well as their responsibilities.

1.1.2 The laboratory shall specify which laboratory functions are included in the laboratory accreditation program.

1.2 Quality System

1.2.1 The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its diagnostic activities. The laboratory management shall document its policies, systems, programs, procedures and instructions. Documentation used in this quality system shall be distributed to and implemented by laboratory personnel.

1.2.2 The laboratory shall have a quality policy statement.

1.2.3 The quality system shall include a quality manual and supporting documents.

1.2.4 The quality manual shall define the roles and responsibilities of laboratory management staff and specify the quality manager including their responsibility for ensuring compliance with the NPDN Accreditation System.

NOTE: In laboratories with a small number of people, individuals may have more than one function.

1.3 Document Control

1.3.1 Documentation used in the quality system shall be communicated to, understood by, available to, and implemented by laboratory personnel.

1.3.2 The document control system shall ensure that only the current version of the correct document is in use in the laboratory.

1.3.3 Documents needed for staff to perform their work shall be accessible at the work location.

1.3.4 The laboratory shall have a document control policy that describes how laboratory documents are reviewed, approved, issued, amended, and how revisions are retained or archived, and discarded. Procedures shall be reviewed and approved by designated staff.

1.3.5 The laboratory shall have a document master list(s) that include the identifiers:

- Document ID
- Document type (form, quality procedure, work instruction)
- Document title
- Authorization date of the original document
- Current version and authorization date

- Date of latest document review (optional but beneficial)
- Comments column (optional)

1.3.6 Amendments and revisions to documents should be identified clearly in the revision history or master document list and shall be reviewed and approved by authorized, qualified staff.

1.3.7 Documents (as defined in the glossary) shall be uniquely identified and accurately cross-referenced.

1.4 Review of Request or Agreement

1.4.1 The sample submission form is an agreement with the submitter to provide the requested service. All sample submissions follow the laboratory's receiving procedure. If necessary, the client is contacted for clarification and agreement on the scope, type and method of diagnosis to be performed.

1.5 Outsourcing of Test Services

1.5.1 The laboratory management determines the use of outside laboratories for services not offered in-house. The laboratory shall have a policy on how to determine what outside laboratory may be consulted or utilized, how to inform the client if there may be additional financial burden, and what data was generated by the outside entity.

1.6 Purchasing Services and Supplies

1.6.1 The laboratory shall have procedures for purchasing services and supplies. The laboratory should document materials, supplies and services that enable the laboratory to fulfill its mission adequately.

1.7 Customer Feedback

1.7.1 The laboratory shall accept and review customer feedback and respond as needed.

1.8 Control of Nonconforming Testing and Test Results

1.8.1 The laboratory shall have written procedures that ensure that nonconforming testing conditions, those which could adversely affect the reliability of test results, are detected and promptly corrected.

1.8.2 These procedures shall describe who has the authority to withhold test results, implement corrective action, authorize resumption of work and inform clients if test results are affected.

1.9 Corrective and Preventive Action

1.9.1 The laboratory shall take corrective actions when nonconforming work or departures from the policies and procedures in the quality system are identified.

1.9.2 The laboratory shall identify potential needs for improvement to prevent nonconformance.

1.10 Records

1.10.1 The laboratory shall have a records management system specifying the following:

a) records must be maintained in an effective retrieval system; e.g., secure, protected from deterioration, and confidential;

b) records must be accurate, timely, attributable and legible;

c) records shall be preserved in accordance with requirements for primary home institution, federal standard, and/or NPDN requirement;

d) records shall be protected and backed up at all times, and unauthorized access to or amendment of data or records must be prevented.

e) protection of the integrity and confidentiality of data entry, data storage, and data processing must be described in a written procedure.

1.10.2 The records for each test shall contain sufficient information to:

a) facilitate identification of factors affecting the quality of test results;

b) enable the test to be repeated under conditions as close as possible to the original;

c) identify personnel.

1.10.3 When amendments and revisions occur in records:

a) each change shall be crossed out (not erased, made illegible nor deleted), and the amendments and revisions noted and dated;

b) in the case of computer-collected data, similar measures shall be taken to avoid loss or change of original data. Preserving original copies or versions, inserting comments, database backups, etc. may suffice;

1.10.4 The laboratory shall have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results, and avoiding conflicts of interest.

1.11 Assessment

The assessment shall ensure the continuing suitability and effectiveness of the quality management system and shall ensure the introduction of necessary changes and improvements. If a laboratory routinely conducts internal audits, this may substitute the assessment.

1.11.1 The entirety of the laboratory's quality management system and test-related activities shall be assessed every three years unless major changes have occurred. Major changes are defined as changes to key personnel and/or facilities. These changes must be reported to the NPDN Accreditation Manager within 10 days of the change.

1.11.2 The assessment must be conducted ensuring an unbiased, candid review gauged to

improve the laboratory system.

1.11.3 Assessment discrepancies must be addressed and a record of action taken kept.

1.11.4 Annual reporting of accreditation system must be completed following accreditation policies.

2.0 TECHNICAL REQUIREMENTS

2.1 General

2.1.1 Many factors can affect the reliability of test results. The extent to which these factors contribute to the reliability of test results varies among tests. The laboratory shall take account of these factors in developing or adopting test methods and related procedures for routine use, in the training and qualification of personnel, in the selection and calibration of equipment, and in the assessment of materials and reagents to be used in testing.

2.2 Personnel

2.2.1 The laboratory shall ensure the initial and ongoing qualification and competence of all laboratory personnel to do their assigned work. Training records must be current and retained.

2.2.2 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in testing and diagnostic interpretation.

2.2.3 The laboratory will provide adequate supervision of testing staff by persons familiar with the tests, their purpose, and the analysis of test results

2.2.4 The laboratory shall meet the minimum NPDN Professional Development and Proficiency requirements.

2.3 Accommodation and Environmental Conditions

2.3.1 All physical facilities within the scope of accreditation must have an appropriate environment for performing diagnostic activities. The laboratory should operate in such a way that it meets the requirements set forth in this standard whether carrying out work in its permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities

a) Laboratories, offices and storage space shall be clean, well maintained and adequate in number and size for intended functions.
b) Adequate lighting and ventilation shall be provided.
c) Appropriate care is taken to safeguard facilities (lighting, heating, ventilation) or ensure other environmental conditions do not adversely affect the quality of the test results.
d) Laboratory surfaces such as walls, floors, and bench tops should be constructed for ease of cleaning and decontamination.

2.3.2 The laboratory should monitor, control and record environmental conditions as required by relevant specifications or where they may influence the reliability of the results.

a) Attention should be paid, for example, to humidity, temperature, and vibration levels, as appropriate to the technical activities concerned.
b) Test activities should be stopped when the environmental conditions jeopardize the test results and management shall be notified.

2.3.3 Physical separation between work areas is provided whenever the work activities are incompatible. Measures are taken to prevent cross-contamination and where physical separation is not possible, segregation of activities is achieved through time and space allocation and proper sanitation.

2.3.4 Access to and use of areas affecting test results shall be controlled.

2.3.5 The laboratory shall ensure the establishment and maintenance of safety, biosafety, biocontainment and biosecurity programs relevant to present and anticipated activities. All staff members should be trained in these programs to ensure a safe work environment.

2.4 Test Methods

2.4.1 The laboratory shall use the current version of SOPs appropriate to the testing requested.

2.4.2 SOPs may be written to address specimen quality and handling, sample preparation, analysis, quality control, data recording, reporting, or use of equipment or instrumentation.

2.4.3 SOPs shall include all steps necessary for a qualified technician to understand and perform the procedures accurately with expected results within the quality control limits.

2.4.4 International, regional or national standards or other recognized specifications that contain sufficient and concise information on any of the above subjects do not need to be rewritten as internal procedures if these standards are published in a way that they can be used as published by the operating staff in a laboratory. Consideration may need to be given to providing additional documentation for optional steps in the assay or additional details. As with all test methods, they shall be subject to document control (see 1.3).

2.4.5 Test methods are fit for the purpose intended, and are chosen from various sources including those endorsed by reputable technical agencies and organizations (e.g. APS, ASM, SON, ASV), required by regulatory agencies (USDA, FDA, EPA, Dept. of Ag., NIH), validated and licensed by commercial companies, or adopted from published methods in relevant scientific textbooks or journals that have undergone suitable verification.

2.4.6 Methods used in the laboratory should be scientifically valid and/or appropriate for use. Appropriate controls, when applicable, shall be used to validate a test as outlined in section 2.8.

2.5 Equipment

2.5.1 The laboratory shall possess or have access to all equipment necessary for the performance of all services in their scope. All equipment shall be identified and properly

maintained. Equipment should be protected from unintended adjustment.

2.5.2 In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this NPDN standard are met.

2.5.3 Equipment shall be operated by authorized and qualified personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available to the appropriate laboratory personnel.

2.5.4 Each item of equipment used for test activities shall be uniquely identified.

2.5.5 Records shall be maintained for each item of equipment and instruments that are significant to the tests performed. The records shall include at least the following: a) identity of the item of equipment; b) serial number or other unique identification; c) dates, results and copies of reports and certificates of all calibrations, adjustments, certification, and/or the due date of next calibration; d) maintenance and repair performed.

2.5.6 Maintenance and calibration programs shall be established, for all testing equipment and measuring devices that have a significant effect on test results.

2.5.7 If equipment gives suspect results or has been shown to be defective or outside specified limits, it shall be taken out of service, clearly labeled or marked, and appropriately stored until it has been repaired and shown to perform correctly.

2.5.8 The laboratory ensures that if, for any reason, the equipment goes outside of laboratory control (e.g., equipment in storage, loaned to other users), the function and calibration status of the equipment is re-checked and shown to be satisfactory before returning the equipment to service.

2.6 Reference Materials

2.6.1 The laboratory will have protocols that outline handling, transport, storage and use of reference standards, and other materials in order to prevent contamination or deterioration and to protect their integrity and proper performance *if they are used.* Where possible, reference materials are traceable to accepted standards.

NOTE: Not all labs will have or use reference materials.

2.7 Samples and Sample Handling

2.7.1 Guidelines for collecting and shipping of appropriate samples are provided by the laboratory to clients.

2.7.2 Each sample received must be assigned a unique identification number and this number must be referenced in all stages of testing and final reporting.

2.7.3 The laboratory shall outline the procedures for the numbering, receipt, tracking, communication, handling, protection, storage, retention, disposal, and internal and external transfers of samples including provisions necessary to protect the integrity and identity of the samples.

2.7.4 Upon receipt of a sample, if the specimen and/or accompanying information is insufficient, the laboratory shall make best possible efforts to consult the client before

proceeding further and shall document the facts and results of that discussion.

2.8 Test Results Quality Control

2.8.1 Technical supervisors or their authorized designees will review quality control data and trends, *where applicable.* Records shall be maintained of relevant quality control activities. The extent of quality control performed is based on the type and volume of testing. Quality control measures can range from direct observation of positive and negative test materials to more quantitative methods as appropriate.

2.9 Sample Result Documentation, Uploading and Reporting

2.9.1 The results of each test performed by the laboratory shall be documented accurately, clearly, on a timely basis, and in accordance with any specific instructions in the test method.

2.9.2 The results of the diagnosis by the laboratory shall be reported to the clients accurately, on a timely basis, and uploaded to the NPDN Data Repository in compliance with NPDN policies and data management requirements

Appendix 1 GLOSSARY OF TERMS

3.0 DEFINITIONS AND TERMS

Accreditation: A process by which an authoritative body (Accreditation Program) gives formal recognition that an organization or person is competent to carry out specific tasks as outlined in accreditation requirements.

Accreditation Program: The group responsible for determining accreditation status and associated auditing, policies, and procedures governing the Core Standard. This program will also provide a "promotion ladder" for member labs to pursue high levels of recognition for commitment to additional areas, which promote the quality of the diagnostics and laboratory operations.

Accreditation Schedule: needs definition;

Accuracy: The closeness of agreement between the measured value and the accepted, "true," or reference value. Recovery analysis is the primary means of evaluating accuracy.

Amendment: An addition of information or specific details to a document. Revisions and amendments both refer to changes and therefore can be used interchangeably.

Assay: Synonymous with test or test method.

Assessment: A process of collecting and analyzing data in a systematic way to determine the compliance of an organization with specific accreditation requirements.

Audit: A systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which agreed criteria are fulfilled.

Calibration: The set of operations that establish, under specified conditions, the relationship between values of quantities by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

Client/Clientele: An entity (customer, agency, company, person, etc.) that submits a sample for analysis and receives a test result performed in accordance to specified requirements.

Competence: The demonstrated ability to generate accurate result by possessing the required skill, knowledge, qualification or capacity. May refer to the laboratory or to an individual.

Compliance: The ability to reasonably ensure conformity and adherence to organization policies, plans, procedures, regulations and contracts. Refers to the individual laboratory quality management system as well as Core Standard.

Corrective Action: *A reactive process.* The steps taken to reduce or eliminate the cause of an existing nonconformity or other undesirable situation. Corrective actions prevent *recurrence* of nonconformities. See also Preventive Action. **Note:** An initial correction is an immediate step taken to fix a detected nonconformity or get a process back under control prior to conducting the root cause analysis of a corrective action.

Root Cause: *The initiating reason for the presence of* a *defect or problem. When removed or corrected, the nonconformance is eliminated.*

Root Cause Analysis: *The process of problem solving used to identify the underlying or initiating source of* a *nonconformance.*

Correction: Action taken to eliminate a detected nonconformity.

Customer Feedback: Information received directly from customers about the satisfaction or dissatisfaction of a product or service.

Deviation: Distinct from a change or an update, as a deviation is an uncommon event. The deviation should not compromise the assay or technique nor impact the quality or the outcome of the test but must be noted if an adverse result is detected at a later date

Document: In this context "document" means any information or instructions, in any format or medium, that have direct bearing on or affect the quality of test results, and includes not only the quality manual, policy, procedures, and instructions, but also test methods, worksheets, forms, international standards, and regulations.

> ***Standard Operating Procedure (SOP):*** *A written document that details the laboratory method for operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved* as *the method for performing certain routine or repetitive tasks. It answers the question of who performs what laboratory procedure or action and when they do* so.
>
> ***Work Instruction (WI):*** *A document containing detailed instructions that specify exactly what steps to follow to carry out an activity. A work instruction contains much more detail than* a *Quality Procedure or Standard Operating Procedure and is only created if very detailed instructions are needed. It explains how the process is accomplished.*

Effectiveness: The state of having produced an intended or desired effect. The extent to which planned activities are realized and planned results achieved.

Guideline: A document stating recommendations or suggestions.

Improvement: The positive effect of a process change effort.

Internal Audit: A formal review of the performance of a quality system conducted by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

Major Changes: Change in key personnel, location, scope or other changes that drastically affect the capability of the laboratory.

Management Review: An evaluation of the suitability, adequacy, and effectiveness of an organization's quality policy and quality objectives, address resource needs and look for opportunities for improvement.

Nonconformance: Any activity that does not meet the requirements set in the NPDN standards and NPDN/laboratory quality system documents. It is an issue discovered *after* it has happened.

Original Document: An authorized hard copy of a master document with the official colored NPDN logo on it.

Policy: An overarching plan (direction), used for the basis of making decisions, and for achieving an organization's goals. ---Is this different from Quality Policy (suggest removing ...)

Preventive Action: A pro-active process. Action taken to eliminate or *prevent* the cause of a potential nonconformity or other potentially undesirable situation.

Process: A set of interrelated work activities characterized by a set of specific inputs that develop a procedure for a set of specific outputs.

Proficiency: The measure of a person's or organization's ability to perform specific activities in a consistent and quality manner.

> ***Proficiency Testing:*** *Determination of laboratory calibration or testing performance through interlaboratory comparisons.*

Quality Control (QC): Activities that are performed during an analysis to fulfill the requirements for assuring quality. Examples include control charting, blank determinations, spiked samples, repeat determinations and blind samples.

Quality Manager: The person who, irrespective of other duties and responsibilities, has defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources. The quality manager or lab director, as appropriate, may appoint individual(s) to make document approvals and reviews.

Quality Management System (QMS): A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services.

Quality Manual (QM): A document specifying the quality management system of an organization. The quality manual may cite other documentation relating to the quality arrangements of the laboratory.

Quality Policy: An organization's general statement of its beliefs about quality, how quality will come about and its expected result. It should define top management's commitment to quality and describe an organization's basic intent.

Quality Procedure (QP): A written document that details the method for a quality management system operation or action with a general overview of policy or steps. A Quality Procedure defines the "who, what, and when" of the process. It answers the questions of who performs quality management system procedure or action and when they do so.

Record: Any materials that provide proof of compliance with the quality system and evidence that a specified activity has been performed. Hard copy or electronic form and should be attributable to an individual.

Reference Material: A material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials (ISO Guide 30: 1992, 2.1), e.g., a Standard Reference Material available with a Certificate of Analysis from NIST.

Reference Standard: A standard, generally having the highest metrological quality available at a given location in a given organization, from which measurements made are derived. Generally, this refers to standards, e.g., thermometers and weights, traceable to recognized national standards such as those of the National Institute of Standards and Technology.

> ***Certified Reference Material (CRM):*** *A reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation that is issued by a certifying body*

Referral: Seeking advice from a subject matter expert. Typically, the advice is compiled with other observations and information of the laboratory to produce a report for the client.

Reliability: The ability of an item to perform a required function under stated conditions for a stated period of time.

Requirement: Provision that conveys criteria to be fulfilled.

Review: Activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives.

Revision: A change of information or deletion of details to a document. Revisions and amendments both refer to changes and therefore can be used interchangeably.

Sample: Material to be tested or analyzed for possible plant pathogen, pest or abiotic presence and/or damage.

Scope: A definition of the activities in which the laboratory intends to meet the requirements of the standard. It describes the products and services provided by the laboratory that will be covered under their quality management system.

Self-Assessment: The laboratory reviews *its own* QMS to check for efficacy and efficiency and ensures they comply with its own requirements. **This is the term in lieu of internal audit.**

Self-Certification: The process of certifying to NPDN Accreditation Group that your laboratory is meeting the minimum standards for compliance with the core standard. The Self-Certification checklist is used to verify that the laboratory's operations continue to comply with the requirements of the NPDN Core Accreditation Standard.

Shall: Use of the verb shall in a sentence; policy or procedure indicates that the action of the sentence, policy or procedure must be performed.

Should: Use of the verb should in a sentence, policy or procedure indicates that the action of the sentence, policy or procedure is recommended but not imperative.

4.0 Acronyms

APHIS: USDA Animal and Plant Health Inspection Service

APS: American Phytopathological Society

CAP: Core Laboratory Accreditation Program

EPA: Environmental Protection Agency

FDA: United States Food and Drug Administration

ISO: International Organization for Standardization

NIH: National Institute of Health

NIST: National Institute of Standards and Technology

NPDN: National Plant Diagnostic Network

QC: Quality Control

QM: Quality Manual

QMS: Quality Management System

QP: Quality procedure

SOP: Standard Operating Procedures

USDA: United States Department of Agriculture

WI: Work Instruction

Document Revision History

Status (Original/Revision/ Cancelled)	Document Version Number	Effective Date	Description
Original	1.0	08-11-2021	The first version of the core standard (originally referred to as draft 4.3)
Revision	1.1	05-18-2022	A few minor changes have been to help clarify requirements. -Section 1.3.5-made two items optional -Section 1.9 simplified. -Section 1.11 assessments was re-structured. -Changed each requirement in 2.2. -Section 2.3 was “should” but sub-requirements said “shall” under the overall “shall”, changed overall to “should” so sub-requirements could be combination of “shall” and “should”. -Section 2.4.5 missing shifted 2.4.6 up to be 2.4.5. -Section 2.5.2 first sentence removed, was similar to 2.5.1. -Section 2.7 added requirement for sample unique ID in 2.7.2.