NCPN REQUIREMENTS AND STANDARDS

National Clean Plant Network

Version 1.2

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NCPN MISSION STATEMENT, PURPOSE and SCOPE

Mission and Purpose Statement of NCPN

Healthy agriculture through clean plants. The mission of the National Clean Plant Network (NCPN) is to generate virus-tested germplasm for use in state certification programs and for the protection of U.S. agriculture from harmful pests and diseases. NCPN centers receive germplasm from domestic and foreign sources and perform: 1) diagnostics for the presence of harmful and economically important viruses and virus-like organisms; 2) virus elimination to remove pathogens detected; and 3) maintenance of virus-tested germplasm in protected foundation collections to distribute to growers, nurseries, and industry members throughout the U.S.

Purpose of the NCPN Quality Program

The purpose of the NCPN quality program is to support NCPN centers to fulfill their roles in the therapy, diagnostics, maintenance, and distribution plant material that has tested free of targeted pathogens. The NCPN quality program enables NCPN centers to follow similar requirements and standards striving to meet consistency, accuracy and timeliness of testing, documenting, reporting, production, maintenance and distribution of high-quality plant materials.

Scope

The scope of the NCPN Quality Program is to provide an overarching framework that supports and provides coordination of effort to enable the development and maintenance of NCPN Centers. NCPN centers participating in this program are expected to follow the general structure of the policies and procedures outlined in the NCPN Requirements & Standards document. Modifications to the policies and procedures are allowable when such modifications are appropriate to an individual center's program standards. The NCPN quality program policies and procedures pertain to diagnostics, therapy, and plant production (maintenance and distribution) standards of an NCPN center. The NCPN quality program policies and procedures currently are not designed for a research laboratory.

The NCPN Quality Program was developed to enable NCPN centers to meet comparable standards of quality for laboratory management, facilities, equipment, and trained personnel for both non-regulatory and regulatory objectives as outlined in this document and in their facility's quality manual.

NCPN CENTER QUALITY PROGRAM OBJECTIVES

Major objectives of this system are:

- To provide a mechanism for objectively reviewing NCPN centers' operations (therapy, diagnostics, maintenance, and distribution of propagative plant material) to meet system quality assurance and quality control (QA/QC),
- To help keep clean plant centers prepared to produce, maintain, and distribute high quality plant material that is tested for targeted plant pathogens,
- To continuously emphasize to stakeholders and collaborating agencies the importance of excellence in NCPN centers' services (therapy, diagnostics, maintenance and distribution of propagative plant material),

- To encourage hiring and retention of dedicated and innovative personnel with appropriate training and experience,
- To encourage acquisition and maintenance of facilities and equipment suitable and adequate to provide quality services,
- To promote appropriate QA/QC activities,
- To provide a legal and scientifically defensible framework to ensure that the product of the center's activities, i.e., the pathogen tested plants generated and maintained, is credible and accepted by both the customer and regulatory authorities.
- To be a resource for participating NCPN Centers for educational and training materials, innovative diagnostic technologies, public and stakeholder outreach.

NOTE:
Centers will create their Quality Manual using the NCPN Requirements and Standards provided in this document and **should** use the numbering system provided. If a section is not applicable to their center, the number of that section should be included and designated "Not Applicable". This will keep the numbering system consistent among NCPN centers and **streamline the auditor processing**. For example, 4.4.2 Not Applicable.

NCPN CENTER QUALITY PROGRAM ORGANIZATION

Organization and Structure of the NCPN Center Quality Program

NCPN Quality Program Executive Committee, comprised of a representative from each NCPN commodity oversees the NCPN quality program, and participates in reviews of center's adherence to their quality program.

USDA-APHIS-PPQ-S&T provides quality manager training as an in-kind contribution.

Center Quality Management Responsibilities

Each NCPN center will build their center-specific quality program in accordance with the basic outlines of the larger NCPN quality program. The individual center Directors, Managers or other assigned staff will ensure compliance with the program as defined.

1.0 MISSION

1.1 The NCPN center shall provide a mission statement that gives details pertaining to their mission within NCPN goals (therapy, diagnostics, maintenance, and distribution of propagative plant material) and how the mission is achieved. The statement should include how the NCPN center implements and maintains a quality system to effectively run their program.

1.2 The NCPN center shall define a purpose pertaining to the NCPN Center quality program. The purpose should define an intended or desired result.

1.3 The NCPN center shall define a scope pertaining to their quality program. The scope should define what the NCPN center delivers to their clients/stakeholders and the logical boundaries (what falls within and what falls outside of the boundaries) of the program.

1.4 The NCPN center shall define objectives pertaining to their quality program.

2.0 ADMINISTRATIVE REQUIREMENTS

2.1 Organization, Management and Personnel

2.1.1 NCPN centers may be administered by a Federal or a State Department of Agriculture, a university.

2.1.2 The director should possess an educational discipline and level appropriate with managing a clean plant center. At least one, and preferably more than one, of the center's personnel shall be able to provide competence in each of the center's processes as defined in the scope (such as therapy, diagnostics, maintenance, and distribution of propagative plant material) in their quality program.

2.2 Finance and Budget

2.2.1 The overall budget will be evaluated on the basis of salaries for personnel, operations, equipment, travel, supplies and maintenance, and continuing education. The NCPN center shall have sufficient resources to meet the requirements for the quality program as indicated in the support for the various disciplines and the overall administrative function of the center.

2.2.2 As NCPN centers are a vital part of protecting U.S. agriculture from harmful pests and diseases, finances must be available to sustain these assignments. Since these centers serve the public good, they are not intended to be self-sufficient financially, and resources for therapy, diagnostics, maintenance, and distribution may require financial support from multiple sources of funding.

3.0 ACCREDITATION PROCESS

3.1 At present, an NCPN accreditation system does not exist. Should the need for it arise in the future, the idea will be revisited.

4.0 MANAGEMENT REQUIREMENTS

4.1 Organization and Management

4.1.1 The NCPN center is responsible for the therapy, pathogen testing, plant maintenance or distribution conducted at the center. The validity of the results is based on the education, training and experience of the diagnostician, faculty, and technical personnel associated with the center. The center applies current knowledge, technologies, products and tools within the Center's scope, for the testing of plant pathogens of interest and for producing plant propagative materials for distribution that have tested negative for targeted pathogens.

4.1.2 The center shall operate to meet the requirements of this Standard whether carrying out work in its permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

4.1.3 The center shall have a clearly defined organizational system and structure. This shall be supported with organizational charts and job descriptions. Organizational charts shall indicate managerial relationships between key personnel and the center's place within the larger NCPN organization.

4.1.4 The center shall:

a) have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from their quality system or from the procedures for performing the therapy, diagnostics, and plant production for

distribution, and to initiate actions to prevent or minimize such departures;

b) have arrangements to ensure that its management and personnel are free from any undue internal or external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

c) 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;

d) have policies and procedures to avoid involvement in any activities that imply a conflict of interest which may diminish confidence in its competence, impartiality, judgment, or operational integrity;

e) specify the responsibility, authority, and inter-relationships of all personnel who manage, perform, or verify work affecting the quality of the procedures (therapy, diagnostics, plant production, maintenance and distribution);

f) provide adequate supervision of, and training for staff, by persons familiar with the processes and operations of the NCPN center;

g) have technical management which has overall responsibility for the technical operations and financial management responsible for the provision of the resources needed to ensure the required quality of center operations;

h) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have 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 center policy or resources;

i) appoint backups or deputies for key managerial personnel such as the quality manager.

NOTE: In centers with a small number of personnel, individuals may have more than one function and it may be impractical to appoint deputies for every function.

4.2 Quality System

4.2.1 The center shall establish, implement and maintain a quality system appropriate to the scope of its activities, including the type, range, and volume of operations (therapy, diagnostics, maintenance and distribution of propagative plant material) it undertakes. The center management shall document its policies, systems, programs, procedures and instructions to enable the center to ensure to the extent possible, the quality of the product it generates. Documentation used in this quality system shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

4.2.2 The center director will create a quality policy statement that should include the following: a) the purpose of the quality system; b) a statement of the center management's intentions with respect to the standard of service it will provide; c) a requirement that all personnel concerned with clean plant production activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; d) the center management's commitment to good professional practice and quality of its clean plant services to its client; and e) the center management's commitment to compliance with the NCPN Center Requirements and Standard.

NOTE: The quality policy statement and manual should be concise.

4.2.3 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline and list the structure of the documentation used in the quality system. The quality manual shall be maintained up to date.

4.2.4 The quality manual shall define the roles and responsibilities of center management staff and the quality manager including their responsibility for ensuring compliance with the NCPN Center Requirements and Standard.

4.3 Document Control

4.3.1 The document control system shall have a well-defined structure.

4.3.2 The document control system shall ensure that only the current version of the correct document is in use in the center, and that documents needed for staff to perform their work are available at the work location.

4.3.3 The NCPN center shall have documented policy, procedures, and/or work instructions that describe how center documents affecting the quality of procedures, tests and test methods for therapy, diagnostics, maintenance and distribution of propagative plant material, are reviewed, approved, issued, updated, revised, amended, retained or archived, and discarded. Procedures shall be reviewed and approved by authorized, qualified staff. All document master lists will include at least the following information:

- Document ID
- Document type (form, quality procedure, work instruction)
- Document title
- Authorization date of the original document
- Current revision status
- Authorization date of current revision
- Date of latest document review
- Comments column

4.3.4 Amendments and revisions to documents should be identified clearly in the revision history or master document list and shall be reviewed and approved by an authorized, qualified staff member having access to pertinent background information concerning the change.

4.3.5 Documents shall be uniquely identified and accurately cross-referenced.

NOTE: 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 plant production and includes not only the quality manual, policy, procedures, and instructions, but also test methods, worksheets, forms, international standards, and regulations.

4.4 Review of Request or Agreement

4.4.1 The NCPN center shall have documented policy and procedures that describe how an NCPN center submission indicates an agreement between the NCPN center and the client/stakeholder. Appropriate understanding of the plant material handling and decision-making process should be conveyed to the client/stakeholder. The agreement procedures shall be reviewed on a predetermined basis. The NCPN center shall keep a record of the review and of client agreement.

4.4.2 The review should also cover any work that is subcontracted by the NCPN center.

4.5 Subcontracting of Services

4.5.1 The NCPN center management determines the use of outside facilities for services not offered in-house. The client should be informed of and agree to any subcontracting of work if additional charges will be made for that service and if necessary, for clarification of material processing.

4.6 Purchasing Services and Supplies

4.6.1 The NCPN center shall have a policy and procedures to ensure that services and supplies meet pre-established specifications and will not adversely affect the quality of pathogen elimination, test results, or plant production (therapy, diagnostics, maintenance and distribution of plant propagative material that tested negative for targeted pathogens). These procedures shall include a description of the criteria for selection, evaluation, use, handling, and storage of materials and reagents having an effect or potential effect on therapy, diagnostics or plant production and distribution of plant propagative material that tested negative for targeted pathogens.

4.7 Customer Feedback

4.7.1 The NCPN center shall have a policy and procedure for the resolution of complaints received from clients or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the NCPN center. Records of other customer feedback should also be documented.

4.8 Control of Nonconforming Procedures, Testing and Test Results

4.8.1 The NCPN center shall have policies and procedures that ensure that nonconforming procedures (conditions that exist which have or could adversely affect the reliability of test results/the final product) are detected and promptly corrected. The NCPN center shall have procedures for informing clients if the final products are questionable or incorrect, particularly if this possibility is identified after products have been delivered to the client. These procedures shall describe who has the authority to withhold products, implement corrective action, and authorize resumption of work.

4.8.2 The NCPN center shall have a policy and procedure for planned deviations to a policy or procedure. The NCPN center shall have procedures for informing clients if their test results or material are affected.

4.9 Corrective and Preventive Action

4.9.1 The NCPN center shall have a policy and procedures for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system have been identified. The policy and procedures shall ensure: a) designation of appropriate authorities responsible for implementation of corrective action(s); b) investigative procedures are implemented to determine the root cause(s) of the problem; c) upon identification, appropriate corrective action(s) are implemented; d) documentation of any required changes to operational procedures; e) once implemented, corrective action(s) are monitored to ensure effectiveness in overcoming the problem; and f) when appropriate, areas of activity subject to corrective action are audited in accordance with 4.11.

NOTE: Special internal audits need only be initiated when a serious issue or risk to the quality of therapy, diagnostics, plant production, or integrity of the quality system has been the subject of corrective action.

4.9.2 The NCPN center shall identify potential sources of nonconformance and potential needs for improvement, either technical or with the quality system. Preventive action procedures shall include: a) identification and evaluation of potential nonconformance or improvement; b) development and implementation of an action plan, including appropriate controls; and c) monitoring of effectiveness in reducing likelihood of nonconformance or in addressing specific needs for improvement.

NOTE: Preventive action is a pro-active process. Identification of specific technical areas requiring preventive action often involves the ongoing monitoring and review of the validity of the test, pathogen elimination, or plant production methods, and the competence of the center.

4.10 Records

4.10.1 The NCPN center shall have a records management system. All NCPN center records must be maintained in an effective retrieval system and must be accurate, contemporaneous, attributable, and legible. Records should be preserved in accordance with requirements for individual jurisdictions.

4.10.1.1 The NCPN center shall establish and maintain procedures for identification, collection, indexing, access, storage, maintenance, and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews, as well as corrective and preventive action records.

4.10.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.

4.10.1.3 All records shall be held secure and in confidence.

4.10.1.4 The NCPN center shall have procedures to protect and back up data and records held on computers at all times, and to prevent unauthorized access to or amendment of data or records on computers.

4.10.2 Technical records

4.10.2.1 The NCPN center shall retain for a defined period of time, original observations, derived data, calibration records, staff records, a copy of each procedure/report issued, and any other information necessary to recreate the activity. The records for each procedure shall contain sufficient information to facilitate identification of factors affecting the quality of procedure results and to enable the procedure to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel.

4.10.2.2 Observations, data and calculations shall be clearly and permanently recorded and identifiable to the specific procedure at the time they are made.

4.10.2.3 When mistakes occur in records, each mistake shall be crossed out (not erased, made illegible nor deleted), and the correct value entered alongside. All such alterations to records shall be dated, signed or initialed by the person making the correction.

NOTE: Records may be in the form of various types of media, such as hard copy or electronic media. In the case of computer-collected data, similar efforts to prevent loss or change of original data should be made.

4.11 Internal Audits

4.11.1 All aspects of the quality management system and activities related to the production of propagative plant material negative for targeted pathogens shall be internally audited at least every two years. The NCPN center shall periodically and in accordance with a predetermined schedule and procedure conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and the NCPN Standards. The internal audit program shall address all elements of the quality system, including therapy, diagnostics, and production and distribution of plant material. It is the responsibility of the NCPN center quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit can be carried out.

NOTE: In NCPN centers with a small number of personnel, effective internal audits may not be feasible. In such cases, it may be appropriate for two or more NCPN centers to cooperate in auditing each other. External audits conducted by members of the NCPN auditor pool may meet the requirement described here for the internal audit procedure. However, NCPN center members are encouraged to continue a periodic review of their quality management system using internal audit procedures to improve their system.

4.11.2 When audit findings cast doubt on the effectiveness of the operations or on the quality of the center's processes and products, the center shall take timely and effective corrective and preventive action, where appropriate, and shall notify clients in writing if investigations show that the results and the final product may have been affected (see 4.8).

4.11.3 The area of activity audited, the audit findings, and corrective actions that arise from them shall be recorded. The NCPN center management shall ensure that these corrective actions are discharged within an appropriate and agreed-upon timeframe.

4.12 Internal Management Reviews

4.12.1 All aspects of the quality management system and test related activities shall be reviewed by management at least every two years.

4.12.2 The center shall have a procedure for performing an Internal Management Review. The review shall cover (if applicable): a) suitability of policies and procedures; b) reports from managerial and supervisory personnel; c) reports of recent internal audits; d) corrective and preventive actions; e) assessments by external bodies; f) results of inter-center comparisons or proficiency tests; g) changes in the volume and type of work; h) client feedback; i) complaints; j) other relevant factors, such as quality control activities, resources and staff training.

4.12.3 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are discharged within an appropriate and agreed-upon time frame.

4.12.4 This review and subsequent activities shall ensure the continuing suitability and effectiveness of the quality management system and shall ensure the introduction of necessary changes and

improvements.

5.0 TECHNICAL REQUIREMENTS

5.1 General

5.1.1 Many factors can affect the reliability of test results and clean plant production. The extent to which these factors contribute to the reliability of test results and clean plant production differs between procedures. The center 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 and clean plant production.

5.2 Personnel

5.2.1 The NCPN center shall ensure the initial and ongoing competence of all NCPN center personnel to do their assigned work.

5.2.2 The NCPN center shall maintain current job descriptions for managerial, technical and key support personnel involved in diagnostics, diagnostics interpretation, therapy, pathogen elimination, plant production and distribution. The NCPN center management shall authorize only staff who are documented as qualified and competent to perform procedures, training, and related work for therapy, diagnostics, plant maintenance, and distribution.

5.2.3 The NCPN center shall have a system which ensures the establishment and maintenance of a training program relevant to the present and anticipated needs of the center.

5.3 Accommodation and Environmental Conditions

5.3.1 All aspects of the physical facilities within the scope must provide an appropriate environment for conducting activities of the NCPN center's laboratories, plant growth facilities (greenhouses, screenhouses, etc.) Offices and storage space shall be clean, maintained in good repair, and be adequate in number and size for intended function. Adequate lighting and ventilation shall be provided. Appropriate care is taken to safeguard facilities (lighting, heating, ventilation) or ensure other environmental conditions do not adversely affect the quality of the clean plant process. Laboratory surfaces such as walls, floors, and bench tops should be constructed for ease of cleaning and decontamination. Plant growth facilities should be maintained so as to prevent the introduction of pathogens into therapied and/or pathogen tested negative plant material.

5.3.2 The NCPN center should monitor, control, and record environmental conditions as required by relevant specifications or where they may influence the reliability of the operations and the quality of the product. Environmental conditions that negatively impact results shall be corrected and management shall be notified.

5.3.3 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.

5.3.4 Access to and use of areas affecting the quality of the products of the NCPN center shall be controlled.

5.3.5 The NCPN center shall ensure the establishment and maintenance of safety, biosafety, biocontainment and biosecurity programs relevant to present and anticipated needs, and those

work areas are kept clean, disinfected, and clutter free to allow for ease of operations and to ensure health and safety of employees. The programs will provide staff training and address all necessary elements to ensure a safe work environment.

5.4 Test and Process Methods and Method Validation

The NCPN center's plant diagnostics, therapy, plant production, and maintenance processes shall be performed by authorized and qualified personnel using the current version of the SOPs and/or work instructions that are appropriate to the plant type. SOPs and/or work instructions may address specimen quality and handling, sample preparation, analysis, quality control, data recording, reporting, equipment and instrumentation. The SOPs and/or work instructions include all steps necessary for a qualified technician to accurately perform and report the results of the plant diagnostics, therapy, plant production and maintenance processes within the required quality control limits. Plant diagnostics, therapy, plant production, and maintenance methods shall be approved for use by qualified, authorized personnel, according to established procedures. NCPN centers using methods prepared by national and international standards-setting bodies and other external technical organizations shall have a system to receive updates of these methods in a timely manner.

NOTE: 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 methods, they shall be subject to document control (see 4.3).

5.4.1 Selection of Methods

5.4.1 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, CAPS, NPPLAP, FDA), validated and licensed by commercial companies, or adopted from published methods in relevant scientific textbooks and journals that have undergone suitable in-house assessment.

5.4.2 The NCPN center uses methods that lead to the production of pathogen tested negative material. The NCPN center selects the appropriate methods.

5.4.3 The NCPN center management authorizes and assigns qualified personnel to perform diagnostics, therapy, and plant production. Records of the relevant training, skills, and competence to perform the procedures are maintained. Such training and competence records may include, but are not limited to, training dates, performance on testing of blind samples, and internal audit reports.

5.4.2 Validation of Test and Process Methods

In-house development or introduction of new diagnostic tests, therapy procedures, or plant production methods is a planned activity and is assigned to qualified personnel equipped with adequate resources. Methods developed in-house are evaluated for their fitness for purpose and bench-validated or shown to be equivalent to established approved methods and authorized before use.

5.4.3.1 Validation data, including all original observations, calculations, equipment monitoring, and calibration records, and archived procedures used to formulate performance characteristics, shall be retained by the NCPN center for at least as long as the assay is used for diagnostic purposes and for at least seven years after the assay has been retired from use.

5.4.4 Control of Data

5.4.4.1 The NCPN center shall ensure, using appropriate procedures that all data resulting from test or method validation and all data relating to the production of pathogen tested negative material for distribution is secure, retrievable, and approved for use by specified, qualified personnel.

5.4.4.2 Computer software modified by the NCPN center and software calculations developed by the NCPN center (e.g., spreadsheet formulae) are documented and periodically verified for accuracy, and protection is provided to prevent unauthorized changes to the calculations.

5.4.4.3 The NCPN center has procedures that define protecting the integrity and confidentiality of data entry, data storage, and data processing.

NOTE: Commercial software in general use within its designed application range may be considered sufficiently validated.

5.5 Equipment

The NCPN center shall possess or have access to all equipment necessary for the correct performance of all services. All equipment shall be identified and properly maintained. Equipment critical to diagnostics shall be calibrated, with maintenance, calibration, procedures, and records documented.

5.5.1 The NCPN center shall be furnished with all equipment and consumables needed to perform the defined in the Center's Scope. In those cases where the NCPN center needs to use equipment outside its permanent control, it shall ensure that the requirements of this NCPN standard are met.

5.5.2 Equipment shall be operated by authorized, 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 for use by the appropriate NCPN center personnel.

5.5.3 Each piece of equipment used for activities significant to the outcome of the final product shall be uniquely identified. Activities can be any part of the process of diagnostics, therapy, maintenance, or distribution of pathogen tested negative plant material.

5.5.4 Records shall be maintained of each piece of equipment significant to the procedures performed. The records shall include at least the following: a) identity of the piece of equipment; b) serial number or other unique identification; c) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and/or the due date of next calibration; d) maintenance carried out to date; and e) damage, malfunction, modification or repair to the equipment. The records should include f) the current location, where appropriate; g) the manufacturer's instructions or manual, if available, or reference to their location; and h) and the maintenance plan.

5.5.5 Maintenance and calibration programs shall be established and results documented for all equipment and measuring devices that have a significant effect on the final product results. A calibration or validation check of each piece of equipment used for activities significant to the

outcome of the final product is done prior to placing it into operation to ensure that it meets the required specifications. Where practical, all equipment requiring calibration is labeled, coded or otherwise identified to indicate the status of calibration including the date when last calibrated and the date when recalibration is due. Equipment calibrations shall be performed by qualified personnel using procedures appropriate to intended use, accuracy and precision required, and at appropriate intervals as historical data indicate.

5.5.6 Equipment that has been subjected to overloading or mishandling, or that gives suspect results, or that has been shown to be defective or outside specified limits, shall be taken out of service, clearly labeled or marked, and appropriately stored until it has been repaired and shown to perform correctly.

5.5.7 The NCPN center ensures that if, for any reason the equipment goes outside the control of the section (e.g., equipment in storage, loaned to other laboratories or centers), then the function and calibration status of the equipment is checked and shown to be satisfactory before returning the equipment to service.

5.5.8 Test equipment, including both hardware and software, shall be safeguarded from adjustments that would invalidate the test results.

5.6 Reference Materials

5.6.1 Where possible, reference materials are traceable to Standard International (SI) units of measurement or to certified reference materials, and reference standards used for calibration are traceable to National Institute of Standards and Technology (thermometers, weights, etc.). Note: The use and maintenance of these materials are provided in the NCPN center documentation.

5.6.2 Where traceability to certified reference materials is not possible, internal reference materials and controls are checked for accuracy for the purpose intended, and their performance is documented. Other methods such as internal quality control, comparison to another standard method or participation in NCPN inter-center comparison or external proficiency testing program are used.

5.6.3 Periodic and scheduled in-house checks, as defined in the NCPN center procedures shall be performed on reference standards and materials to ensure the materials are maintaining their performance characteristics.

5.6.4 The NCPN center shall have protocols that outline handling, transport, storage, and use of manufactured reference standards and materials in order to prevent contamination or deterioration and to protect their integrity and proper performance. These materials are securely stored per manufacturer's recommendations to ensure accuracy and are used only for calibration purposes.

5.6.5 Efforts should be considered so that biological reference materials are traceable and accepted standards are established.

5.7 Samples and Sample Handling

5.7.1 Plant material collection by clients is not under control of the NCPN center. However, assistance with selection and guidelines for shipping of appropriate material is provided by the NCPN center staff through their new variety/introduction submission guidelines, available at the center's website, or through written, electronic and phone consultations with the NCPN center employees in compliance with the NCPN center permits (State and Federal).

5.7.2 The NCPN center shall outline the procedures for the receipt, handling, protection, storage, retention, disposal, and internal and external transfers of plant material including provisions necessary to protect the integrity of the plant material, and the interests of the NCPN center and the client/stakeholder.

5.7.3 The NCPN center shall have a system for identifying plant material that ensures no confusion between original plant material and the final product. The identification shall be retained throughout the life of the plant material and its derived final product in the NCPN center, and linked to the report.

5.7.4 Upon receipt of the plant material, any abnormalities or departures from normal or specified conditions, as described in the relevant procedure, shall be recorded. If there has been a departure from specifications, new material should be requested. Because there may be no opportunity to obtain replacement in situations where material does not meet method specifications, the NCPN center shall consult with the client for further instructions before proceeding and shall record the facts and results of that discussion. (e.g. as in comments and a disclaimer on reports).

5.8 Test Results and Processes Quality Control

5.8.1 Quality control procedures, to monitor the validity of diagnostics, therapy, maintenance, and distribution of pathogen tested negative plant material, are addressed in the NCPN center documentation. The extent of quality control performed is based on the type and volume of production. Quality control measures can range from direct observation of positive and negative test materials to more quantitative methods using control charts and statistical evaluation. Development of quality control monitoring shall include, but not be limited to, the following:

- recording and tracking of positive and negative control results.
- re-testing.

It may also include:

- participation in NCPN inter-center comparison or proficiency testing programs.
- replicate tests or procedures using the same or different methods and/or different individuals.
- internal quality control schemes using statistical techniques (e.g., control charts);
- use of international reference reagents for preparation of national and/or working standards for internal quality control.

5.8.2 Technical supervisors or their authorized designees review quality control data and trends, where applicable. Records are maintained of all quality control activities and any action taken.

5.9 Sample Results Reporting

5.9.1 For each process performed by the NCPN center for diagnostics, therapy, maintenance, and distribution of pathogen tested negative plant material, results shall be reported accurately, clearly, unambiguously, and objectively, and in accordance with any specific instructions in the method or contract.

5.9.2 The report shall include: a) a title (e.g., “Test Report”); b) name and address of NCPN center; c) unique identification; and d) results. When possible, when the information is known, the

report should also include: a) name and address of the client; b) date of material submission; and c) date of NCPN center receipt of material. Regulatory samples should use the documents required by the applicable regulatory agencies.

5.9.3 When opinions and diagnostic interpretations are included in the report, the NCPN center should document the basis upon which the opinions and interpretations have been made.

5.9.4 When the report contains results of activities performed by subcontractors, these results shall be clearly identified.

5.9.5 When a portion of the center processes is completed, interim reports may be issued to the client. These reports should indicate procedures completed and procedures pending. Such reports shall be uniquely identified as interim reports and shall contain a reference to any and all preceding interim reports. Upon completion of the diagnostics, therapy, maintenance and distribution of pathogen tested negative plant material, a final report shall be issued that is uniquely identified and shall contain a reference to any and all interim reports that it replaces.

5.9.6 When an amendment to a report that has been issued is necessary, a supplement to the report shall be issued to the client. Such amendments shall be uniquely identified as such and shall contain a reference to the original report.

Glossary of Terms

6.0 DEFINITIONS AND TERMS

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

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.

Audit Finding: The result(s) of the evaluation between collected audit evidence and audit criteria

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.

Center Quality Manager (CQM): The member of NCPN/center who has responsibility and authority for ensuring that the center quality system is implemented and followed at all times.

Center Management: The Center Director, the Quality Manager, and others as identified.

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.

Check Sample: See Proficiency Check Sample.

Client: An entity (customer, agency, company, person, etc.) that submits or receives services or materials.

Competence: The demonstrated ability to get the correct result by possessing the required skill, knowledge, qualification or capacity.

Compliance: The ability to reasonably ensure conformity and adherence to organization policies, plans, procedures, regulations and contracts.

Corrective Action: 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.

Correction: An initial correction is the 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.

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

Cut-off: Test result value selected for distinguishing between negative and positive results. The cut-off also may include the indeterminate or suspicious zone. Also known as threshold.

Distribution of propagative plant material: Increase, arrangement, packaging and shipment of foundation material to the client.

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.

Document Master lists: Internal documents that contain the NCPN logo and the official signatures of the personnel in charge of review and approval.

Effectiveness: The state of having produced a decided on or desired effect. The extent to which

planned activities are realized and planned results achieved.

External Training: Training conducted by a person or organization outside of the NCPN center.

Foundation plant material: Plant material tested negative for target pathogens and maintained in such a way to prevent reinfection (G1 Material).

Guideline: A document stating recommendations or suggestions.

Improvement: The positive effect of a process change effort.

In-house Checks: All center quality assurance activities directly related to the monitoring and maintaining of technical proficiency.

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.

Internal Auditor: The NCPN or center personnel that performs an internal audit. This person is trained to audit and is independent of the activities that are being audited.

Internal Training: Training conducted by a member of NCPN center.

Maintenance: Maintenance of candidate plants to ensure survival and prevent additional infection and or pathogen spread through proper containment.

Maintenance and distribution of propagative plant material: The process by which tested material is propagated, securely stored, and increased for distribution to clients.

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

Management System: The organizational structure, responsibilities, procedures, processes and resources for implementing policy and achieving objectives.

National Clean Plant Network (NCPN) Center: Any NCPN-affiliated location/unit; any entity receiving funding from NCPN

NIST (National Institute of Standards and Technology): An agency of the U.S. Department of Commerce that develops and promotes measurements, standards and technology.

Nonconformance: Any activity that does not meet the requirements set in the NCPN standards and NCPN/center quality system documents.

Objective Evidence: The evidence supporting the existence or verity of something. It may be obtained through observation, measurement, test, or other means.

Planned Deviations: This occurs when an unexpected event prevents the procedure from being followed exactly as written. The technician knows about it before a problem may occur and before the procedure is run. Deviating from the procedure needs to be approved by the approval designate of the center.

Policy: An overarching plan (direction), used for the basis of making decisions, and for achieving an organization's goals.

Precision: A measure of agreement among replicate analyses of the same sample under the same conditions. Duplicate analysis is the primary means of evaluating precision. Precision is frequently expressed in terms of Relative Percent Difference (RPD).

Preventive Action: Action taken to eliminate 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 make up 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 by means of inter-center comparisons.

Proficiency Test Sample: Test material with a target that is tested periodically by a number of locations to determine the proficiency of recovery, where appropriate. Also known as a check sample.

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 Management (QM): An integrated system of management activities involving planning, implementation, documentation, assessment, reporting, training, audit, review, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

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 NCPN center.

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 a quality management system procedure or action and when they do so.

Range: The range of an analytical procedure is the interval between the upper and lower concentration (amounts) of target in the sample (including these concentrations) for which it has been demonstrated that the analytical procedure has a suitable level of uncertainty.

Record: Any and all written materials that document activities performed using the quality management system and may provide evidence that a specified activity has been performed. They may be in hard copy or electronic form and should be attributable to an individual.

Reference Collection: A verified source of infected material maintained by an institution that may be distributed for use as positive controls.

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.

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

Repeatability (of results of measurements): Closeness of the agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement. These conditions, which are called repeatability conditions, include: the same measurement procedure, the same observer, the same measuring instrument (used under the same conditions), the same location, and repetition over a short period of time.

Replicate Tests: An analysis of a laboratory sample or reference material performed more than once. The result of each individual analysis is a replicate test result.

Reproducibility (of results of measurements): Closeness of the agreement between the results of measurements of the same measurand carried out under changed conditions of measurement.
A valid statement of reproducibility requires specification of the conditions changed, which may include: the principle of measurement, the method of measurement, the observer, the measuring instrument, the reference standard, the location, the conditions of use, and the 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.

Robustness: A measure of an analytical method's capacity to remain unaffected by small but deliberate variations in method parameters. It provides an indication of its reliability during normal usage.

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.

Sample: Material to be tested or analyzed for possible plant pathogens.

Sample Handling: Manipulation to which samples are exposed during the sampling process, from the selection from the original material through to the disposal of all samples and test portions.

Sample Preparation: The procedures followed to select the test portion from the sample (or subsample).

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.

Selectivity: The extent to which the analytical method can determine particular target(s) in a complex mixture without interference from the other components in the mixture. A method that is perfectly selective for a target is said to be specific.

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.

Specification: The requirements to which a given service must conform, usually stated in a document.

Specificity (Analytical): The degree to which targets other than that in question react in an assay; the higher the level of cross-reactions, the lower the level of specificity. (See also Selectivity.)

Specificity (Diagnostic): The proportion of known uninfected reference plants that test negative in an assay compared touninfected reference plants that test positive. Uninfected positive plants are considered to have false-positive results.

Specificity (Relative): The proportion of reference samples, defined as negative by one or a combination of test methods, which also test negative in the assay being compared.

Standard Operating Procedure (SOP): A written document that details the laboratory method for an 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.

Supervisor: A generic term for referring to any person that provides direction to others.

Test: A technical operation that consists of the determination of one or more characteristics or the performance of a given product, material, equipment, organism, physical phenomenon, process, or service according to a specified procedure.

Therapy: Pathogen elimination services; this can include shoot-tip grafting, thermotherapy, tissue culture and other techniques.

Threshold: See cut-off.

Traceability: The property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

Trend: The measure of a variable's tendency, over time, to increase, decrease, or remain unchanged. It is typically represented graphically or through statistical means.

Validated Test Method: A test method that has been confirmed by objective evidence to be fit for the intended purpose, or alternatively, a method whose performance characteristics have been established and verified at a defined level of statistical confidence and evaluated against the specific requirements for a particular application.

Validation: Confirmation by examination and the provision of objective evidence that the

particular requirements for a specific intended use are fulfilled.

Work Instructions (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.

7.0 Acronyms

APHIS: USDA Animal and Plant Health Inspection Service

ASV: American Society for Virology

APS: American Phytopathological Society

FDA: United States Food and Drug Administration

NIST: National Institute of Standards and Technology

NPPLAP: APHIS National Plant Pathogen Laboratory Accreditation System

PPQ S&T: Plant Health, Plant Protection and Quarantine, Science and Technology

QA/QC: Quality Assurance/Quality Control

QC: Quality Control

QM: Quality Manual

QP: Quality procedure

SI: Standard International System of Units, e.g., meter (unit of length), kilogram (unit of mass), and second (unit of time)

SON: Society of Nematologists

SOPs: Standard Operating Procedures

SYS: Systemwide Procedures

USDA: United States Department of Agriculture

WI: Work Instruction

Document Revision History

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Revision	1.1	04/13/2022	First draft proposed by the NCPN Quality Steering Committee
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