



## **State Level Model Regulatory Standard:**

### **Virus-Tested Certification Program for *Prunus*, *Malus*, *Pyrus*, *Chaenomeles*, and *Cydonia* Nursery Stock Production Systems**

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<b><u>Contents</u></b>	<b><u>Page</u></b>
<b>Review</b>	<b>3</b>
<b>Legislative Authority</b>	<b>3</b>
<b>Approval/Endorsement</b>	<b>3</b>
<b>Implementation</b>	<b>3</b>
<b>Distribution</b>	<b>3</b>
<b>Amendment Record</b>	<b>3</b>
<b>Introduction</b>	<b>3-7</b>
Background	3
Scope	4
References	4
Common Definitions, Abbreviations and Acronyms	4-7
Outline of the Requirements	7
<b>1. General Requirements</b>	<b>7-9</b>
1.1 Regulated Commodities	7-8
1.2 Program Participation	8
1.3 Fruit Tree Pests	8
1.4 Domestic Movement	8
1.5 Application and Fees	8-9
<b>2. Specific Requirements</b>	<b>9-18</b>
2.1 Program Administration	9
2.2 Eligibility and Approvals	10
2.3 Certification Levels	10-12
2.4 Horticultural Management	12-13
2.5 Isolation, Pest Management and Sanitation	13-14
2.6 Inspection and Testing	14
2.7 Documentation, Identification and Tagging	14-16
2.8 Auditing	16-17
2.9 Non-compliance and Corrective Measures	17-18
<b>3. Evaluation and Cooperation with Other Certification Agencies</b>	<b>18-19</b>
3.1 Evaluation/Approval	18-19
3.2 Cooperation with Other Certification Agencies	19
<b>Appendix 1: Virus List</b>	
<b>Appendix 2: Virus-Tested Certification Program Application Forms</b>	
<b>Appendix 3: Personnel Training and Staff Responsibilities</b>	
<b>Appendix 4: G1 Checklist</b>	
<b>Appendix 5: G2 Propagation and Maintenance</b>	
<b>Appendix 6: G3 Propagation and Maintenance</b>	
<b>Appendix 7: G4 Propagation and Maintenance</b>	
<b>Appendix 8: R1 Propagation and Maintenance</b>	

**Appendix 9:** R2 Propagation and Maintenance

**Appendix 10:** Containerized Trees

**Appendix 11:** Pest Management Plan

**Appendix 12:** Inspection and Testing Guidelines for Plant Material and Planting Sites

**Appendix 13:** Nursery Field Map and Inventory

**Appendix 14:** Audit Checklists and Forms

*The following section headings may be included in the regulation, if required by state certifying agency's legal council, who may supply standard language:*

**Review**

**Legislative Authority**

**Approval/Endorsement**

**Implementation**

**Distribution**

**Amendment Record**

*An accurate public record of amendments to this certification program should be maintained. Consult the certifying agency's legal staff on the possibility of posting the amendments on a persistent website that can be referenced within the body of the regulation.*

**Background**

The propagation of fruit trees is considered to be a high risk pathway for the movement of plant viruses. Due to the vegetative nature of propagation techniques, viruses can be spread rapidly during the production of nursery stock. While some viruses are known to have a minor impact on infected trees, others can cause very serious diseases (e.g. Plum Pox Virus). Economic impacts of fruit tree viruses include delayed maturity, increased agricultural inputs, reduced growth, reduced yield, inferior fruit quality, graft incompatibility, and plant mortality. The pests addressed in this standard may also cause diseases in other crops with varying economic impacts. Orchard trees that have been infected by viruses cannot be cured. The only way to remove a virus from an orchard or a block of nursery trees is by destroying the infected host plants and by replanting with tested, clean trees in a sanitized site. A virus-tested certification program, which is based on the propagation of trees from material that has originally tested negative of all detectable viruses, is the most effective way to produce nursery trees that are free of those viruses and other virus-like organisms. This model regulatory standard is a systems and audit based program for the certification of virus-tested fruit tree nursery stock. Independent components such as isolation distances, vector control, virus-testing, and field inspection work together to minimize the presence and spread of viruses.

This is a voluntary certification program. Any nursery stock produced in this program must also meet all other mandatory phytosanitary requirements. A state or agency can certify fruit tree nursery stock for export to a country that has import requirements within the testing and production standards contained in this standard. To qualify for export, the stock must also meet the importing country's requirements for freedom from other regulated pests.

This model regulatory standard was developed in accordance with the Regional Standard for Phytosanitary Measures (RSPM) #25: *Guidelines for International Movement of Pome and Stone Fruit Trees into a NAPPO Member Country.*

## Scope

This standard describes the essential elements of nursery stock virus-tested certification for *Prunus*, *Malus*, *Pyrus*, *Chaenomeles*, and *Cydonia* species, including fruit-bearing and ornamental varieties. Plant pests specifically dealt with in this standard are graft-transmissible viruses, viroids, phytoplasmas, *Xylella fastidiosa* and their vectors. *X. fastidiosa*, a bacterial pathogen, has been included in this standard because it behaves like a virus in terms of its transmission and control. This regulatory standard does not address other pests, abiotic disorders, varietal trueness-to-type, or quality grades and standards.

## References

*Glossary of Phytosanitary Terms*, 2008. ISPM No. 5, FAO, Rome.

*Guidelines for International Movement of Pome and Stone Fruit Trees into a NAPPO Member Country*, 2004. RSPM No. 25, NAPPO

*Guidelines for the Movement of Stone and Pome Fruit Trees and Grapevines into a NAPPO Member Country*, 2009. RSPM No. 35, NAPPO

*United States Nursery Certification Program Pilot*, 2008. USDA-APHIS

State-level virus-tested fruit tree nursery stock certification regulations in existence as of September, 2009

## Common Definitions, Abbreviations and Acronyms

APHIS	Animal and Plant Health Inspection Service (APHIS) within the United States Department of Agriculture.
audit	A systematic and independent examination to determine whether an auditee's activities conform with the objectives of a program.
block	A contiguous grouping of plants separated from other contiguous groupings of plants by a buffer zone.
buffer zone	An area surrounding or adjacent to an area officially delimited for phytosanitary purposes in order to minimize the probability of spread of the target pest or disease into or out of the delimited area, and subject to phytosanitary or other control measures, if appropriate.
certification program	A comprehensive process established and authorized by a state or other governmental entity for the production of plants free of regulated pests and diseases. The regulations for each program define the program participation, plant production, plant identification and labeling, and quality assurance requirements.

certifying agency	The state plant regulatory agency; or any entity approved by the state plant regulatory agency to perform virus certification work.
certified	Having met the requirements and approved for certification under this program.
cover crop	A crop planted to prevent soil erosion and suppress weed growth.
cultivar	A variety or sub-variety of a plant species that is cultivated for a specific trait(s).
fruit tree(s)	Plants and plant parts for propagation of pome and stone fruit. This includes all ornamental and fruit bearing species of the following genera: <i>Prunus</i> , <i>Malus</i> , <i>Pyrus</i> , <i>Chaenomeles</i> , and <i>Cydonia</i> .
G-level	Signifies the degree to which plant stock is related to the original virus-tested plant material distributed by sources approved by USDA-APHIS and the state certifying agency. The designation “G” in G-level is an artifact of the term “generation level” used in international phytosanitary protocols to describe levels of certification.
inspection	Official examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations.
isolation distance	See ‘buffer zone’.
NAPPO	The North American Plant Protection Organization (NAPPO) is a regional Plant Protection Organization of the International Plant Protection Convention. NAPPO coordinates the efforts among Canada, the United States and Mexico to protect their plant resources from the entry, establishment and spread of regulated plant pests and diseases, while facilitating intra/interregional trade.
NCPN-FT	National Clean Plant Network - Fruit Trees. A commodity committee of the National Clean Plant Network, with administration headquartered at Washington State University at Prosser, Washington. In addition to administration of the NCPN-FT, the Prosser facility performs testing and therapy of plant materials in order to produce, maintain, and distribute G1 stock.
official	Established, authorized, or performed by a regulatory agency such as the USDA or a state certification agency.

pathogen	A pathogen is a micro-organism causing disease. Examples of pathogens include viruses, bacteria, fungi, and phytoplasmas.
pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.
pest management plan	A written description of procedures and processes designed to control, suppress or eradicate pest populations to a level that meets the phytosanitary standards of this certification program.
plants	Living plants and parts thereof, and germplasm.
pome fruit	Plants of the genera <i>Malus</i> , <i>Pyrus</i> , <i>Cydonia</i> and <i>Chaenomeles</i> .
off-type	Different from the variety or selection listed on the application for registration or certification.
quarantine	Official confinement of regulated articles for observation and research or for further inspection, testing and/or treatment.
R-level	The R-level concept is designed to define a category of certified plant stock that is produced under a virus testing regimen less strenuous than G-level requirements; R-level requirements are agreed upon within a domestic region of the United States.
registered	A tree that has been enrolled in this virus-tested certification program and meets all requirements to serve as a source of propagating material for virus-tested certified nursery stock; or a block that is enrolled in this program.
regulated pest	A quarantine pest or a regulated non-quarantine pest. Definitions of these terms can be found in FAO ISPM No.5 ( <i>Glossary of phytosanitary terms</i> ).
restriction	A phytosanitary regulation allowing the importation or movement of specified commodities subject to specific requirements.
stone fruit	Plants of the genus <i>Prunus</i> .
test	Official examination, other than visual, to determine if pests are present or to identify pests. This may include biological indexing, serological or molecular procedures, or any other method approved by the certifying agency.

tissue culture	General term for the cultivation of plants (cells, tissues, or organs) under aseptic conditions in a synthetic medium <i>in vitro</i> . It also refers to the cultures themselves.
USDA	United States Department of Agriculture.
virus	Any graft-transmissible agent including viruses, viroids, phytoplasmas and <i>Xylella fastidiosa</i> .

## Outline of Requirements

The objectives of this standard are to:

- Prevent the introduction or spread of viruses in fruit tree production systems.
- Facilitate trade of virus-tested fruit tree nursery stock.

This standard outlines the essential elements of a voluntary certification program for managing viruses and their vectors, achieved through a combination of best management practices and mandatory requirements. It outlines a systems approach for minimizing the risk of virus introductions associated with the production of fruit trees. This standard references appendices designed to be maintained by the certifying agency; they contain details and requirements specific to the individual certifying agency's virus-tested certification program. The certifying agency will make the appendices available on a persistent website and through contact with the agency.

The certifying agency is not responsible for disease, genetic disorders, off-type, failure of performance, or mislabeling in connection with this certification program. No grower, nursery dealer, government official, or other person is authorized to give any expressed or implied warranty, or to accept financial responsibility on behalf of the certification agency.

## 1. General Requirements

### 1.1 Regulated Commodities

All propagative plant parts of both ornamental and fruit-bearing species of the following genera: *Prunus*, *Malus*, *Pyrus*, *Chaenomeles*, and *Cydonia*. Plant material eligible for registration must originate from a source approved by the certifying agency, who will also determine the certification level of the material.

#### 1.1.1 Plant Material from an Approved Virus-Tested Certification Program

Fruit tree plant material may be moved into certification if produced under an official fruit tree virus certification program that has been evaluated using this standard and approved by the certifying agency. The fruit tree nursery stock must originate from a recognized domestic virus certification program, or a foreign virus certification program that is also approved by USDA for import into the United States. The certifying agency may perform an audit inspection, including testing samples for the presence of pests listed in the virus certification program. A certifying agency may disapprove a source that it determines could pose a pest risk to the certification system.

If no documentation of the origin or virus status of the plant material is available, the certifying agency must prohibit entry of the material into the state virus-tested certification program.

Source of any seed used within a participant's production scheme must be declared to the certifying agency. For *Prunus* seed, certain restrictions on use within this certification program apply.

## 1.2 Program Participation

The facility must be actively enrolled in state nursery registration/certification. The facility must also apply with the certifying agency for participation in this virus certification program.

## 1.3 Fruit Tree Pests

An exhaustive list of fruit tree viruses is maintained at a national level, indicating presence or absence of virus in the U.S. Those viruses of domestic concern for testing at the state level are listed in [Appendix 1](#).

The certifying agency has the responsibility to address the virus list in [Appendix 1](#), but it must adapt the list to reflect high risk pests of current concern in their state or region that are appropriately addressed through this certification program. Any changes to the list will be based on criteria to include:

- Credible information on virus presence or absence in the state or surrounding area
- Patterns of nursery stock movement
- Reasonable testing criteria

## 1.4 Domestic Movement

Any plant material certified under this program being shipped domestically must include documentation that the shipping nursery maintains active state nursery certification or registration, and that the shipment complies with any applicable laws, regulations, and quarantines of the originating and destination locations. The shipment may also include documentation related to certification under this program, such as a statement declaring:

*“[State of Production Name](#) Virus-Tested Certified Nursery Stock. The accompanying nursery stock is certified to have been produced in compliance with requirements of virus certification of [State of Production Name](#).”*

## 1.5 Application and Fees

An initial application for participation in the virus certification program shall be made on a form prescribed by the certifying agency. An application form template is available in [Appendix 2](#). Upon receipt of the initial application, the certifying agency will begin a dialogue with the facility that will result in a cooperative agreement or, at the discretion of the certifying agency, a cooperative agreement enhanced with a facility-specific pest management plan. An initial program entrance review of the facility will also be completed by the certifying agency.

By applying, the facility is granting the certifying agency access to all production areas, records, and plant material for audit, inspection and testing purposes.

The certifying agency will establish and post fees for program participation and/or certification-related activities.

Except as otherwise provided, fees charged by the certifying agency for participation in the virus certification program are for the sole purpose of defraying expenses incurred by the certifying agency for implementation and documentation procedures provided for in this certification program, and for providing funds to the certifying agency to support appropriate plant virus surveys and related research. Payment thereof shall not be construed as granting any right or privilege to the applicant.

## **2. Specific Requirements**

This standard deals specifically with essential elements of a certification program to mitigate the risk of viruses of fruit trees as listed in [Appendix 1](#).

This fruit tree virus-tested certification program is carried out by or under the authority of the state certifying agency. The agency will be charged with the administration of program requirements such as terminology, testing, eligibility, nomenclature of certification levels, horticultural management, isolation and sanitation requirements, inspection and re-testing, documentation, identification and labeling, quality assurance, noncompliance and corrective measures.

### **2.1 Program Administration**

Responsibility for administration of the fruit tree virus-tested certification program resides with the certifying agency. While the certifying agency has oversight for all aspects of virus certification, it may establish a system of approval or accreditation for certification work to be performed by others. The certifying agency employs or accredits administrative, inspection and laboratory diagnostic personnel that have the appropriate training, experience, education and proficiency requirements necessary to implement the fruit tree virus-tested certification program. The certifying agency will maintain this personnel information, and will allow for full transparency of these records to appropriate parties. Personnel training and staff responsibilities can be found in [Appendix 3](#).

The certifying agency must have a process established to ensure that no conflicts of interest compromise program integrity.

All required documentation will be maintained by the certifying agency in either paper or electronic format. Documents must be formatted to meet all required security and integrity standards of the certifying agency. Any Right-To-Know requirements or exceptions must be clearly indicated on any documents containing potentially sensitive business information.

## 2.2 Eligibility and Approvals

Eligibility of potential participants is conferred by the certifying agency upon fulfillment of the application process (see section 1.5), if the conditions of this certification program have been met.

All plant material to be enrolled in this certification program, and each site for planting of registered blocks, must be approved by the certifying agency.

## 2.3 Certification Levels

Certification levels represent a categorical measure of the virus-tested status of plants certified under this program. This certification program supports production of stock at certification levels appropriate for international and national commerce (G-levels) as well as regional or intrastate commerce (R-levels).

### 2.3.1 G-level

The G-level, signifies the degree to which plant stock is related to the original virus-tested plant material entering a production system. G-levels represent successive steps of propagation from the original tested material, and may have additional phytosanitary measures applied depending on this propagative step. This certification program specifies the conditions under which each G-level must be maintained in order to qualify for certification at that level, including testing specifications, regular inspections, isolation requirements and other conditions under which the plants must be grown to prevent (re)infection.

#### 2.3.1a G1

G1 refers to the original plants (nuclear materials) that have tested negative in the most extensive battery of virus tests available, and subsequently maintained in isolation to prevent (re)infection. G1 also refers to replacement trees or foundation blocks produced from the original sources of virus-tested plant material and maintained under equivalent conditions.

Production and maintenance of G1 material must be within a system approved by USDA-APHIS or its official designee. All G1 material, whether of domestic or foreign origin, will meet the same testing criteria and requirements.

The state certifying agency has the authority to review the systems used by a G1 producer. The state certifying agency must approve a G1 producer before any of its G1 material may be accepted into the state's virus-tested certification program. A checklist that functions as a basis for approval can be found in [Appendix 4](#).

#### 2.3.1b G2

G2 plant material is propagated from G1 stock and is maintained under specific conditions to prevent (re)infection. Propagation and maintenance of G2 plantings (including testing) is described in [Appendix 5](#). G2 stock is frequently

maintained by nurseries as source material for subsequent propagation of virus-tested certified nursery stock.

When using seed for G2 rootstock production, the source of seed must be approved by the certifying agency. Any vegetatively-propagated material (rootstock, scion, or interstems) used for the production of a G2 tree must originate from G1 trees. Budding, regrafting or top working of G2 trees is not permitted, unless the propagative material is from G1 material and with prior approval by the certifying agency.

#### 2.3.1c G3

G3 plant material must be propagated from G1 or G2 stock, and grown in accordance with the propagation and maintenance requirements in [Appendix 6](#). G3 stock is frequently maintained by nurseries to increase the amount of available source material for the production of virus-tested certified nursery stock.

When using seed for G3 rootstock production, the source of seed must be approved by the certifying agency. Any vegetatively-propagated material (rootstock, scion, or interstems) used for the production of a G3 tree must originate from G1 or G2 trees. Budding, regrafting or top working of G3 trees is not permitted, unless the propagative material is from G1 or G2 material and with prior approval by the certifying agency.

#### 2.3.1d G4

G4 stock is commonly grown in certified nursery blocks, and is often the material distributed for sale (i.e. wholesale and retail nursery stock). When using seed for G4 rootstock production, the source of seed must be approved by the certifying agency. Any vegetatively-propagated material (rootstock, scion, or interstems) used for G4 production shall have originated from a registered G1, G2, or G3 source. Propagation and maintenance (including testing) are described in [Appendix 7](#).

G4 stock grown for virus-tested certification must be planted sufficiently apart to maintain its identity. The G4 field must be kept clean-cultivated, and the surrounding buffer zone must be planted in a manner approved by the certifying agency. Rebudding or regrafting of G4 stock must not be allowed unless such stock is reworked with material from a registered G1, G2, or G3 block.

#### 2.3.2 R-level

The R-level concept is used to define additional plant material categories in state-level clean stock virus-tested certification programs that do not meet full G-level standards but are subject to voluntary virus mitigation measures of a higher standard than a mandatory state nursery licensing/registration program provides.

#### 2.3.2a R1 (R-level 1)

R-level 1 (R1) refers to source trees for scion or rootstock that have been inspected for virus symptoms, and have been tested for domestic viruses of concern as listed by the state certifying agency. The propagation and maintenance (including testing) is described in [Appendix 8](#).

#### 2.3.2b R2 (R-level 2)

R-level 2 (R2) refers to nursery trees produced from R1 sources. This may include nursery stock produced from registered G1-G3 scion sources and R1 seed and rootstock sources, or from R1 scion sources and G1-G3 seed and rootstock sources. The propagation and maintenance (including testing) is described in [Appendix 9](#).

### 2.4 Horticultural Management of Trees at All Certification Levels

#### 2.4.1 Field Plantings

All fruit trees in a block must be kept in good horticultural condition. Planting sites must be selected to minimize the introduction of soil-borne viruses from the surrounding land via virus-vectoring nematodes, and through drainage, flooding, irrigation or other means.

G1, G2 and G3 blocks must only be planted on land which has been free from grapevines, non-certified trees and other non-certified *Rosaceous* species for a period of at least two years.

Chosen planting sites will not be approved for production if tests are positive for nematode-transmitted viruses, or for nematodes capable of transmitting those viruses. Sites that are not initially approved may be re-evaluated if the facility undertakes corrective measures as approved by the certifying agency.

Expansion or addition of new material to an existing registered block is possible upon request to the certifying agency. All requirements that must be met for a new block will also be required for expansion of a registered block.

#### 2.4.2 Containerized Trees

Containerized trees at any certification level may be accepted into the virus-tested certification program if they meet all general requirements for registered trees at the specified certification level, in addition to meeting the following requirements:

a) The growing medium and containers must introduce no pest risks of concern for this certification program. The certifying agency may approve methods of risk mitigation.

b) The containers must be at a site appropriate to the certification level. In the event that containerized trees are moved, the trees will only maintain their certification level if the new site has been approved by the certifying agency.

c) The containerized stock must be labeled in a manner that allows for proper identification and tracking.

Risk mitigation measures for containerized trees may be found in [Appendix 10](#).

#### 2.4.3 Tissue Culture

Tissue culture material may be registered in this program if it meets all general requirements for registered trees at the specified certification level.

### 2.5 Isolation, Pest Management and Sanitation

#### 2.5.1 Isolation Requirements

Buffer zones are necessary to reduce the chance of infection by vectored and pollen-borne viruses. The isolation requirements will vary according to the level of certification, and should be based on the biology of the listed pests and vectors present in the area of the certified blocks. Isolation requirements for each G-level can be found in [Appendices 4-7](#).

#### 2.5.2 Sanitation and Pest Management

The participating facilities may, as a component of their cooperative agreement, produce and implement a pest management plan that addresses the measures they apply to prevent virus introduction into their certified plantings. A pest management plan is a written description of procedures or processes designed to eradicate, control, or suppress pest populations to a level that meets this virus certification standard. The pest management plan addresses the following critical control points:

- a) source material procurement
- b) site selection processes
- c) production processes

If a pest management manual is not a required component, the participating facility must still agree to and abide by all conditions set forth in the signed cooperative agreement.

Just as the risk of certain viruses varies due to geographical differences affecting vectors and conditions of virus transmission, so too will each facility's pest management plan vary due to regional differences. A pest management plan template is available in [Appendix 11](#). A facility's pest management plan should be reviewed and approved by the certifying agency; major revisions to a plan should also be submitted for approval.

A facility's pest management plan should include procedures for the removal and destruction of trees that are diseased or deemed at risk by the certifying agency.

The plan should describe how production and maintenance activities are designed to ensure that workers start with the blocks that have the most stringent certification level requirements and proceed downwards through the lower levels (e.g. G2 to G3 to G4 to uncertified plants). This minimizes the potential movement of virus infected nematodes from blocks with less stringent isolation and control measures to blocks with more stringent requirements. A similar principle is applied to any equipment that travels between blocks of differing certification levels; for example, soil and debris picked up in G4 or uncertified blocks should be removed prior to entering G2 or G3 blocks.

General pest management practices, while not directly related to this virus-tested certification program, may impact the status of the certified material. While the pest management plan produced under this program specifically deals with the critical control points listed above, the certifying agency has the authority to require any additional practice or documentation it deems necessary for the verification of certification status.

## 2.6 Inspection and Testing

Registered trees in the virus-tested certification program will be inspected during the growing season at times appropriate for the detection of disease symptoms according to accepted survey patterns. Inspection and testing is also required for candidate sites, registered blocks, and within buffer zones. The inspectors will follow the protocols established in the inspection and testing guidelines maintained in [Appendix 12](#). These guidelines address the following considerations:

- a) frequency and timing of inspection and testing necessary to address perceived risks
- b) sampling and testing procedures
- c) process to be undertaken upon suspicion or confirmation of pest presence

## 2.7 Documentation, Identification and Tagging

The primary purpose of the records required in this section is to document the virus-tested status and maintain the identity of the material being produced and sold under this program.

All material used in the production of G4-level certified virus-tested nursery stock must be traceable to approved G1- G3 sources. All R2-level nursery stock must be traceable to virus-tested sources.

### 2.7.1 Certifying Agency Responsibilities

The certifying agency will document inspection, certification and testing activities undertaken in compliance with this standard to ensure the eligibility and status of

the plant material, production sites, participants and all certification levels of the fruit trees. These documents will be available, upon request, to the USDA or other certifying agencies for audit, traceback and other regulatory purposes.

### 2.7.2 Facility Responsibilities

The facility must document and identify plants during growth, post-harvest, and at sale to ensure traceability. The facility must maintain records on its premises for a period of time established by the certifying agency, and must update critical records within a timeframe agreed upon with the certifying agency. The facility must make these records available to the agency upon request. Record-keeping requirements for each G-level and R-level can be found in [Appendices 4-9](#). Depending on certification level, required documents may include:

a) Records indicating botanical (genus and species) and cultivar names, rootstock name, rootstock source (seed or vegetative), scion and interstem source, certification level, date of introduction of stock to the facility, date of budding, field name, nursery row planting and accession number.

Facilities are encouraged to develop systems that would allow identification of sources for nursery trees that would trace back to individual source trees, or smaller groups of trees. Examples might include designations by bud lot, where an entire bud lot was collected on one date from one site.

b) Copies of certification of virus-testing received with incoming plant material (rootstock, scionwood, source trees, G4 nursery stock for resale).

c) Data collected from monitoring, control or eradication of disease and surveillance activities and dates.

d) If produced for the cooperative agreement, the written pest management plan and any records generated through implementation of the plan.

e) Maps or planting records of the facility indicating the geographical location of blocks, and the location of certified trees within the blocks. Guidance on the creation of facility maps is located in [Appendix 13](#).

f) Records of sale and purchaser's identity, for all wholesale or commercial sales.

g) Records maintained for other regulatory purposes (e.g. general phytosanitary documents, pesticide records) must be available for inspection and audit if the certifying agency deems it necessary to ensure virus status of material.

### 2.7.3 Identifying Marks

The certifying agency and the facility manager must agree upon appropriate labels for all certification levels of virus-tested material at the facility. The labels must be weather-resistant and must distinguish material grown under the virus-tested certification program from other types of material. The facility manager must notify the certifying agency in advance if the facility wishes to modify the labeling system. Failure to properly label and identify certified plant material will result in the removal of that material from certification, and may jeopardize the certification status of adjacent material.

#### 2.7.3a. Source Materials

A system to correctly identify and maintain traceability of any seed, budstick, whip, tissue culture explant, or other material to be used in the production of virus-certified trees must be agreed upon by the facility and the certifying agency.

#### 2.7.3b. Trees Planted in the Ground

In G1, G2 and G3 blocks, each tree must bear permanent identification. A system of identification for R1 trees must be agreed upon by the facility and the certifying agency.

In G4 blocks, or in nursery propagation of G2 or G3 trees, all stock must be clearly marked to identify cultivar/rootstock combination. Labeling may be by any clearly identifiable unit of the same cultivar/rootstock (e.g. tree, partial row, row, or block). Although this standard does not address trueness to type, an auditor may disqualify a variety from virus certification if off-types or other indicators of problems with traceability are detected.

#### 2.7.3c. Containerized Trees

Identifying marks of any containerized tree must be directly attached to the tree.

#### 2.7.3d. Harvested Stock

Harvests of individual trees, bundles or crates must be labeled to maintain their identity and clearly separate them from material not in the virus-tested certification program.

## 2.8 Auditing

Audits continually monitor and verify the status of the production facility's plant material, records, and administrative procedures to ensure conformity with the virus-tested certification program. Audits evaluate whether the facility has the resources, infrastructure, and staff in place to successfully implement the procedures outlined for acceptance into the virus-tested certification program.

The certifying agency will conduct an initial program entrance review upon application. After a facility has entered into a cooperative agreement, the certifying agency will conduct at least one systems audit per year in addition to the surveillance audits that

fulfill the requirements of section 2.6 Inspection and Testing. Any audit may include inspection and/or testing of records, plants or sites, especially in reference to ongoing, new, or perceived risks. The certifying agency may adjust the frequency of audits as necessary.

#### 2.8.1 Initial Program Entrance Review and Subsequent Systems Audits

Systems audits are systematic examinations of the organizational structure, procedures, processes, and resources used within the participating facility to implement the virus-tested certification program. The objective of a systems audit is to align the facility's production system, with the standards of the virus-tested certification program.

The initial program entrance review and annual systems audits will assess all systems elements of this program using the checklists in [Appendix 14](#). To the extent possible, the certifying agency's audit team will include the principal virus certification officer and a nursery inspector. One member of the audit team should have basic audit training. The systems audit will take place at a time agreed to by the certifying agency and the approved facility.

#### 2.8.2 Surveillance Audits

Surveillance audits are any audits in addition to the annual systems audit, each targeting one aspect of the implementation of the virus-tested certification program at the facility. All program requirements defined in section 2.6 Inspection and Testing will be addressed in surveillance audits; additional surveillance audits may be performed if deemed necessary by the certifying agency. Surveillance audits should be directed by the certifying agency's principal virus certification officer.

### 2.9 Non-compliance and Corrective Measures

#### 2.9.1 Non-Compliance

System elements which are not in compliance may be detected by the certifying agency or the facility. If detected by the certifying agency, the facility will be informed in writing of the corrective actions required for compliance. The facility must make corrections promptly, within a timeline at the discretion of the certifying agency. If detected by the facility, the certifying agency may require notification and/or documentation of any actions the facility took to correct the non-compliance.

Activities or products found to be non-compliant shall be classified as critical, major, or minor:

a) **Critical Non-Compliance:** Any single finding that reveals that the integrity of the program, the certified production facility or virus-tested product is in jeopardy. A critical non-compliance would result in immediate suspension from the virus-tested certification program.

b) **Major Non-Compliance:** Any isolated incident of non-compliance, which has no direct impact on the integrity of the virus-tested certified product, provided

corrective actions are completed within a specified timeframe. If the facility fails to carry out the required corrective actions within the specified time period, the facility must be suspended from the virus-tested certification program.

c) Minor Non-Compliance: Isolated incidents, which do not immediately and/or significantly affect the integrity of the program or the virus-tested certified product, but require corrective action.

The number and type of non-compliance found determines the status of the facility and the subsequent auditing frequency. [Appendix 14](#) provides guidelines for classification of non-compliance; however, the certifying agency may modify classification in a situation, based on an evaluation of the associated risk and whether the integrity of the virus-tested certification program has been compromised.

A template for a corrective action request form can be found in [Appendix 14](#). Each corrective action request includes a detailed description of the measures that the certified facility will implement to prevent recurrences of the non-conformance and a timeframe for completing the corrective actions. Failure to follow the prescribed actions may result in suspension of the facility from the virus-tested certification program.

#### 2.9.2 Suspension or Cancellation of Registration

Non-compliance with program requirements may result in cancellation or suspension of the registration status of the facility, block, or registered trees managed by the facility. The certifying agency will specify the consequences of non-compliance, which may vary depending on the nature and severity of the infraction. The corrective measures to enable a suspended or de-certified participant, production area, or variety to become eligible for reinstatement or re-certification will be determined on a case-by-case basis by the certifying agency.

Registration of the facility may be cancelled if virus-tested certification claims are misused or misrepresented. Program participation may be suspended if program fees are not paid. Following suspension or cancellation of registration, a facility must re-apply to be evaluated for re-instatement into the virus-tested certification program.

### 3. Evaluation of External Sources and Cooperation with Other Certifying Agencies

#### 3.1 Evaluation of Programs and/or Certified Materials from Other Virus-Tested Fruit Tree Certification Programs

Prior to allowing inclusion of plant material from other certification programs into this virus-tested certification program, the certifying agency may choose to evaluate the certification program of the exporting entity. Evaluation may include a document review, a site visit, or testing of plants to ensure they meet the standard of this virus-tested certification program. Following approval of a virus-tested certification program,

additional temporary restrictions such as preclearance testing may be used. The certifying agency may periodically audit/review approved certification programs to ensure they continue to meet all certification standards and requirements. Detection of pests or vectors controlled under the virus-tested certification program or deficiencies of documentation, etc. may indicate that the integrity of the certification system is compromised.

### 3.2 Cooperation with Other Regulatory Agencies

The certifying agency has the authority to establish, through a Letter of Agreement or a Memorandum of Understanding, joint certification program administration or operation with other states.

If the NCPN-FT or the USDA develops a process to approve or accredit fruit tree virus-tested certification programs, the certifying agency may accept that approval of outside virus-tested certification programs without performing additional auditing or approval processes.