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(d) *Restriction on diversion or change of Customs entry.* Diversion or change of Customs entry shall not be permitted with movements authorized under paragraph (b) (4) or (5) or paragraph (c) of this section and the inspector at the original port of Customs entry shall appropriately endorse the Customs documents to show that fact: *Provided,* That the inspector at such port of entry may, when consistent with the purposes of this part, approve diversion or change of Customs entry to permit movement to a different foreign country or entry into the United States subject to all other applicable requirements under this part or part 319 of this chapter. If diversion or change of Customs entry is desired at a Customs port in the United States where there is no inspector, the owner may apply to the Plant Protection and Quarantine Programs for information as to applicable conditions. If diversion or change of entry is approved at such a port, confirmation will be given by the Plant Protection and Quarantine Programs to appropriate Customs officers and Plant Protection and Quarantine Programs inspectors.

(e) *Untreated fruit from certain municipalities in Mexico.* Oranges, tangerines, and grapefruit in transit to foreign countries may be imported from certain municipalities in Mexico that meet the criteria of §319.56–5 for freedom from fruit flies in accordance with the applicable conditions in part 319 of this chapter.

(f) *Treated fruit.* Oranges, tangerines, and grapefruit from Mexico that have been treated in Mexico in accordance with part 305 of this chapter may be moved through the United States ports for exportation in accordance with the regulations in part 319 of this chapter.

(g) *Costs.* Costs shall be borne by the owner of the fruit as provided in §352.14. This includes all costs for preinspection and convoying of loaded trucks and supervision of transloading from trucks to approved carriers or storage in United States ports when augmented inspection service has to be provided for such preinspection, convoying, and supervision.

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PART 353—EXPORT CERTIFICATION

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AUTHORITY: 7 U.S.C. 7701–7772 and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

SOURCE: 61 FR 15368, Apr. 8, 1996, unless otherwise noted.

§ 353.1 Definitions.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Agent. An individual who meets the eligibility requirements set forth in §353.6, and who is designated by the Animal and Plant Health Inspection Service to conduct phytosanitary field inspections of seed crops to serve as a basis for the issuance of phytosanitary certificates.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

Consignment. One shipment of plants or plant products, from one exporter, to one consignee, in one country, on one means of conveyance; or any mail shipment to one consignee.

Export certificate for processed plant products. A certificate (PPQ Form 578) issued by an inspector, describing the plant health condition of processed or manufactured plant products based on

inspection of submitted samples and/or by virtue of the processing received.

Family. An inspector or agent and his or her spouse, their parents, children, and first cousins.

Industry-issued certificate. A certificate issued by a representative of the concerned agricultural or forestry industry under the terms of a written agreement with the Animal and Plant Health Inspection Service, giving assurance that a plant product has been handled, processed, or inspected in a manner required by a foreign government. An industry-issued certificate includes an ISPM 15 quality/treatment mark.

Inspector. An employee of the Animal and Plant Health Inspection Service, or a State or county plant regulatory official designated by the Secretary of Agriculture to inspect and certify to shippers and other interested parties, as to the phytosanitary condition of plant products inspected under the Act.

Non-government facility. A laboratory, research facility, inspection service, or other entity that is maintained, at least in part, for the purpose of providing laboratory testing or phytosanitary inspection services and that is not operated by the Federal Government or by the government of a State or a subdivision of a State.

Office of inspection. The office of an inspector of plants and plant products covered by this part.

Phytosanitary certificate. A certificate (PPQ Form 577) issued by an inspector, giving the phytosanitary condition of domestic plants or unprocessed or unmanufactured plant products based on inspection of the entire lot or representative samples drawn by a Federal or State employee authorized to conduct such sampling.

Phytosanitary certificate for reexport. A certificate (PPQ Form 579) issued by an inspector, giving the phytosanitary condition of foreign plants and plant products legally imported into the United States and subsequently offered for reexport. The certificate certifies that, based on the original foreign phytosanitary certificate and/or additional inspection or treatment in the United States, the plants and plant products are considered to conform to the current phytosanitary regulations of the receiving country and have not been subjected to the risk of infestation or infection during storage in the United States. Plants and plant products which transit the United States under Customs bond are not eligible to receive the phytosanitary certificate for reexport.

Plant pests. Any living stage of any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or other products of plants.

Plant products. Products derived from nursery stock, other plants, plant parts, roots, bulbs, seeds, fruits, nuts, and vegetables, including manufactured or processed products.

Plants and plant products. Nursery stock, other plants, plant parts, roots, bulbs, seeds, fruits, nuts, vegetables and other plant products, including manufactured or processed products.

Reference Manual A. The *Reference Manual for Administration, Procedures, and Policies of the National Seed Health System*, published by the National Seed Health System (NSHS). Reference Manual A describes the structure, administration, procedures, policies, and working practices of the NSHS and also contains relevant documentation, forms, and references for the NSHS. Reference Manual A is incorporated by reference at § 300.3 of this chapter, and is available by writing to Phytosanitary Issues Management, Operational Support, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737–1236, and on the APHIS Web site at *http://www.aphis.usda.gov/ppq/pim/accreditation*.

Reference Manual B. The *Reference Manual for Seed Health Testing and Phytosanitary Field Inspection Methods*, published by the National Seed Health System (NSHS). Reference Manual B contains the detailed seed health testing, seed sampling, and inspection procedures for the NSHS. Reference Manual B is incorporated by reference at § 300.4 of this chapter, and is available

by writing to Phytosanitary Issues Management, Operational Support, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737–1236, and on the APHIS Web site at *http://www.aphis.usda.gov/ppq/pim/accreditation*.

State. Any of the States of the United States, the District of Columbia, American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, or the Virgin Islands of the United States.

The Act. Title IV of Public Law 106–224, 114 Stat. 438, 7 U.S.C. 7701–7772, which was enacted June 20, 2000.

[61 FR 15368, Apr. 8, 1996, as amended at 64 FR 1105, Jan. 8, 1999; 64 FR 72264, Dec. 27, 1999; 65 FR 50131, Aug. 17, 2000; 66 FR 21059, Apr. 27, 2001; 66 FR 37116, July 17, 2001; 66 FR 37400, July 18, 2001; 67 FR 8466, Feb. 25, 2002; 72 FR 35917, July 2, 2007]

§ 353.2 Purpose and administration.

The export certification program does not require certification of any exports, but does provide certification of plants and plant products as a service to exporters. After assessing the phytosanitary condition of the plants or plant products intended for export, relative to the receiving country's regulations, an inspector issues an internationally recognized phytosanitary certificate (PPQ Form 577), a phytosanitary certificate for reexport (PPQ Form 579), or an export certificate for processed plant products (PPQ Form 578) if warranted. APHIS also enters into written agreements with industry to allow the issuance of industry-issued certificates giving assurance that a plant product has been handled, processed, or inspected in a manner required by a foreign government. An industry-issued certificate includes an ISPM 15 quality/treatment mark.

[61 FR 15368, Apr. 8, 1996, as amended at 64 FR 72264, Dec. 27, 1999; 72 FR 35917, July 2, 2007]

§ 353.3 Where service is offered.

(a) Information concerning the location of inspectors who may issue certificates for plants and plant products may be obtained by contacting one of the following regional offices:

Region	States
Northeastern, Blason II, 1st Floor, 505 South Lenola Road, Moorestown, NJ 08057.	CT, ME, MA, NH, RI, VT, NY, NJ, PA, MD, DE, VA, WI, MN, IL, IN, OH, MI, WV.
Southeastern, 3505 25th Avenue, Building 1, North, Gulfport, MS 39501.	FL, AL, GA, KY, MS, TN, NC, SC, PR, US VI.
Central, 3505 Boca Chica Blvd., Suite 360, Brownsville, TX 78521–4065.	TX, OK, NE, AR, KS, LA, IA, MO, ND, SD.
Western, 9580 Micron Avenue, Suite I, Sacramento, CA 95827.	HI, CA, CO, ID, MT, UT, WY, WA, OR, NV, NM, AZ, AK.

(b) Inspectors who may issue phytosanitary certificates for terrestrial plants listed in 50 CFR part 17 or 23 are available only at a port designated for export in 50 CFR part 24, or at a nondesignated port if allowed by the U.S. Department of the Interior pursuant to section 9 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1538). The following locations are designated in 50 CFR part 24 as ports for export of terrestrial plants listed in 50 CFR part 17 or 23:

(1) Any terrestrial plant listed in 50 CFR part 17 or 23:

Nogales, AZ
Los Angeles, CA
San Diego, CA
San Francisco, CA
Miami, FL
Orlando, FL
Honolulu, HI
New Orleans, LA
Hoboken, NJ (Port of New York)
Jamaica, NY
San Juan, PR
Brownsville, TX
El Paso, TX
Houston, TX
Laredo, TX
Seattle, WA

(2) Any plant of the family Orchidaceae (orchids) listed in 50 CFR part 17 or 23:

Hilo, HI
Chicago, IL

(3) Roots of American ginseng (*Panax quinquefolius*) listed in 50 CFR 23.23:

Atlanta, GA
Chicago, IL
Baltimore, MD
St. Louis, MO
Milwaukee, WI

(4) Any plant listed in 50 CFR 17.12 or 23.23 and offered for exportation to Canada:

Detroit, MI
Buffalo, NY
Rouses Point, NY
Blaine, WA

(5) Any logs and lumber from trees listed in 50 CFR 17.12 or 23.23:

Mobile, AL
Savannah, GA
Baltimore, MD
Gulfport, MS
Wilmington and Morehead City, NC
Portland, OR
Philadelphia, PA
Charleston, SC
Norfolk, VA
Vancouver, WA

(6) Plants of the species *Dionaea muscipula* (Venus flytrap):

Wilmington, NC

§ 353.4 Products covered.

Plants and plant products when offered for export or re-export.

§ 353.5 Application for certification.

(a) To request the services of an inspector, a written application (PPQ Form 572) shall be made as far in advance as possible, and shall be filed in the office of inspection at the port of certification.

(b) Each application shall be deemed filed when delivered to the proper office of inspection. When an application is filed, a record showing the date and time of filing shall be made in such office.

(c) Only one application for any consignment shall be accepted, and only one certificate for any consignment shall be issued.

(Approved by the Office of Management and Budget under control number 0579–0052)

[61 FR 15368, Apr. 8, 1996, as amended at 64 FR 72264, Dec. 27, 1999; 72 FR 35917, July 2, 2007]

§ 353.6 Inspection.

Inspections shall be performed by agents, by inspectors, or by employees of a State plant protection agency who are authorized by the agency to perform field inspections in accordance with this part and who have successfully completed training in accordance with paragraph (a)(2)(iii) of this section. Employees of a State plant protection agency who are not agents may perform field inspections only under the supervision of an inspector.

(a) *Agent.* (1) Agents may conduct phytosanitary field inspections of seed crops in cooperation with and on behalf of those State plant regulatory agencies electing to use agents and maintaining a Memorandum of Understanding with the Animal and Plant Health Inspection Service in accordance with the regulations. The Memorandum of Understanding must state that agents shall be used in accordance with the regulations in this part. Agents are not authorized to issue Federal phytosanitary certificates, but are only authorized to conduct the field inspections of seed crops required as a basis for determining phytosanitary condition prior to the issuance of a phytosanitary certificate for the crops.

(2) To be eligible for designation as an agent, an individual must:

(i) Have the ability to recognize, in the crops he or she is responsible for inspecting, plant pests, including symptoms and/or signs of disease-causing organisms, of concern to importing countries.

(ii) Have a bachelor's degree in the biological sciences, and a minimum of 1 year's experience in identifying plant pests endemic to crops of commercial importance within the cooperating State, or a combination of higher education in the biological sciences and experience in identifying such plant pests, as follows:

0 years education and 5 years experience;
1 year education and 4 years experience;
2 years education and 3 years experience;
3 years education and 2 years experience; or
4 years education and 1 year experience.

The years of education and experience do not have to be acquired consecutively.

(iii) Successfully complete annual training provided by the State plant regulatory agency. The required training must include instruction in inspection procedures, identification of plant pests of quarantine importance to importing countries, methods of collection and submission of specimens (organisms and/or plants or plant parts) for identification, and preparation and submission of inspection report forms approved by the State plant regulatory agency.

(iv) Have access to Federal or State laboratories for the positive identification of plants pests detected.

(3) No agents shall inspect any plants or plant products in which they or a member of their family are directly or indirectly financially interested.

(b) *Inspector.* (1) An employee of the Animal and Plant Health Inspection Service, or a State or county regulatory official designated by the Secretary of Agriculture to inspect and certify to shippers and other interested parties, as to the phytosanitary condition of plants and plant products inspected under the Act.

(2) To be eligible for designation as an inspector, a State or county plant regulatory official must:

(i) Have a bachelor's degree in the biological sciences, and a minimum of 1 year's experience in Federal, State or county plant regulatory activities, or a combination of higher education in the biological sciences and experience in State plant regulatory activities, as follows:

0 years education and 5 years experience;
1 year education and 4 years experience;
2 years education and 3 years experience;
3 years education and 2 years experience; or
4 years education and 1 year experience.

The years of education and experience do not have to be acquired consecutively.

(ii) Successfully complete, as indicated by receipt of a passing grade, the Animal and Plant Health Inspection Service training course on phytosanitary certification.

(3) No inspectors shall inspect any plants or plant products in which they or a member of their family are directly or indirectly financially interested.

(c) *Applicant responsibility.* (1) When the services of an agent or an inspector are requested, the applicant shall make the plant or plant product accessible for inspection and identification and so place the plant or plant product to permit physical inspection of the lot for plant pests.

(2) The applicant must furnish all labor involved in the inspection, including the moving, opening, and closing of containers.

(3) Certificates may be refused for failure to comply with any of the foregoing provisions.

§ 353.7 Certificates.

(a) *Phytosanitary certificate (PPQ Form 577).* (1) For each consignment of domestic plants or unprocessed plant products for which certification is requested, the inspector shall sign and issue a separate certificate based on the findings of the inspection.

(2) The original certificate shall immediately upon its issuance be delivered or mailed to the applicant or a person designated by the applicant.

(3) One copy of each certificate shall be filed in the office of inspection at the port of certification, and one forwarded to the Administrator.

(4) The Administrator may authorize inspectors to issue certificates on the basis of inspections made by cooperating Federal, State, and county agencies. The Administrator may also authorize inspectors to issue a certificate on the basis of a laboratory test or an inspection performed by a non-government facility accredited in accordance with § 353.8.

(5) Inspectors may issue new certificates on the basis of inspections for previous certifications when the previously issued certificates can be canceled before they have been accepted by the phytopathological authorities of the country of destination involved.

(b) *Export certificate for processed plant products (PPQ Form 578).* (1) For each consignment of processed plant products for which certification is requested, the inspector shall sign and issue a certificate based on the inspector's findings after inspecting submitted samples and/or by virtue of processing received.

(2) The original certificate shall immediately upon its issuance be delivered or mailed to the applicant or a person designated by the applicant.

(3) One copy of each certificate shall be filed in the office of inspection at the port of certification.

(4) The Administrator may authorize inspectors to issue certificates on the basis of inspections made by cooperating Federal, State, and county agencies. The Administrator may also authorize inspectors to issue a certificate on the basis of a laboratory test or an inspection performed by a non-government facility accredited in accordance with § 353.8.

(5) Inspectors may issue new certificates on the basis of inspections/processing used for previous certifications.

(c) *Phytosanitary certificate for reexport (PPQ Form 579).* (1) For each consignment of foreign origin plants or unprocessed plant products for which certification is requested, the inspector shall sign and issue a certificate based on the original foreign phytosanitary certificate and/or additional inspection or treatment in the United States after determining that the consignment conforms to the current phytosanitary regulations of the receiving country and has not been subjected to the risk of infestation or infection during storage in the United States.

(2) The original certificate shall immediately upon its issuance be delivered or mailed to the applicant or a person designated by the applicant.

(3) One copy of each certificate shall be filed in the office of inspection at the port of certification, and one forwarded to the Administrator.

(4) The Administrator may authorize inspectors to issue certificates on the basis of inspections made by cooperating Federal, State, and county agencies. The Administrator may also authorize inspectors to issue a certificate on the basis of a laboratory test or an inspection performed by a non-government facility accredited in accordance with § 353.8.

(5) Inspectors may issue new certificates on the basis of inspections for previous certifications when the previously issued certificates can be canceled before they have been accepted by the phytopathological authorities of the country of destination involved.

(d) *Industry-issued certificate.* A certificate issued under the terms of a written agreement between the Animal and Plant Health Inspection Service and an agricultural or forestry company or association giving assurance that a plant product has been handled, processed, or inspected in a manner required by a foreign government. An industry-issued certificate includes an ISPM 15 quality/treatment mark. The certificate may be issued by the individual who signs the agreement or his/her delegate.

(1) *Contents of written agreement.* In each written agreement, APHIS shall agree to cooperate and coordinate with the signatory agricultural or forestry company or association to facilitate the issuance of industry-issued certificates and to monitor activities under the agreement, and the concerned agricultural or forestry company or association agrees to comply with the requirements of the agreement. Each agreement shall specify the articles subject to the agreement and any measures necessary to prevent the introduction and dissemination into specified foreign countries of specified injurious plant pests. These measures could include such treatments as refrigeration, heat treatment, kiln drying, etc., and must include all necessary preshipment inspections and subsequent sign-offs and product labeling as identified by Plant Protection and Quarantine (PPQ), APHIS, based on the import requirements of the foreign country.

(2) *Termination of agreement.* An agreement may be terminated by any signatory to the agreement by giving written notice of termination to the other party. The effective date of the termination will be 15 days after the date of actual receipt of the written notice. Any agreement may be immediately withdrawn by the Administrator if he or she determines that articles covered by the agreement were moved in violation of any requirement of this chapter or any provision of the agreement. If the withdrawal is oral, the decision to withdraw the agreement and the reasons for the withdrawal of the agreement shall be confirmed in writing as promptly as circumstances permit. Withdrawal of an agreement may be appealed in writing to the Administrator within 10 days after receipt of the written notification of the withdrawal. The appeal shall state all of the facts and reasons upon which the appellant relies to show that the agreement was wrongfully withdrawn. The Administrator shall grant or deny the appeal, in writing, stating the reasons for granting or denying the appeal as promptly as circumstances permit. If there is a conflict as to any material fact and the person from whom the agreement is withdrawn requests a hearing, a hearing shall be held to resolve the conflict. Rules of

practice concerning the hearing shall be adopted by the Administrator. No written agreement will be signed with an individual or a company representative of the concerned agricultural or forestry company or association who has had a written agreement withdrawn during the 12 months following such withdrawal, unless the withdrawn agreement was reinstated upon appeal.

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[61 FR 15368, Apr. 8, 1996, as amended at 64 FR 1105, Jan. 8, 1999; 64 FR 72265, Dec. 27, 1999; 66 FR 37116, July 17, 2001; 72 FR 35917, July 2, 2007]

§ 353.8 Accreditation of non-government facilities.

(a) The Administrator may accredit a non-government facility to perform specific laboratory testing or phytosanitary inspection services if the Administrator determines that the non-government facility meets the criteria of paragraph (b) of this section.[1]

(1) A non-government facility's compliance with the criteria of paragraph (b) of this section shall be determined through an assessment of the facility and its fitness to conduct the laboratory testing or phytosanitary inspection services for which it seeks to be accredited. If, after evaluating the results of the assessment, the Administrator determines that the facility meets the accreditation criteria, the facility's application for accreditation will be approved.

(2) The Administrator may deny accreditation to, or withdraw the accreditation of, any non-government facility to conduct laboratory testing or phytosanitary inspection services upon a determination that the facility does not meet the criteria for accreditation or maintenance of accreditation under paragraph (b) of this section and has failed to take the remedial action recommended to correct identified deficiencies.

(i) In the case of a denial, the operator of the facility will be informed of the reasons for the denial and may appeal the decision in writing to the Administrator within 10 days after receiving notification of the denial. The appeal must include all of the facts and reasons upon which the person relies to show that the facility was wrongfully denied accreditation. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator.

(ii) In the case of withdrawal, before such action is taken, the operator of the facility will be informed of the reasons for the proposed withdrawal. The operator of the facility may appeal the proposed withdrawal in writing to the Administrator within 10 days after being informed of the reasons for the proposed withdrawal. The appeal must include all of the facts and reasons upon which the person relies to show that the reasons for the proposed withdrawal are incorrect or do not support the withdrawal of the accreditation of the facility. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator. However, withdrawal shall become effective pending final determination in the proceeding when the Administrator determines that such action is necessary to protect the public health, interest, or safety. Such withdrawal will be effective upon oral or written notification, whichever is earlier, to the operator of the facility. In the event of oral notification, written confirmation will be given as promptly as circumstances allow. This withdrawal will continue in effect pending the completion of the proceeding, and any judicial review thereof, unless otherwise ordered by the Administrator.

(3) The Administrator will withdraw the accreditation of a non-government

[1] A list of accredited non-government facilities may be obtained by writing to Phytosanitary Issues Management, PPQ, APHIS, 4700 River Road, Unit 140, Riverdale, MD 20737–1236.

facility if the operator of the facility informs APHIS in writing that the facility wishes to terminate its accredited status.

(4) A non-government facility whose accreditation has been denied or withdrawn may reapply for accreditation using the application procedures in paragraph (b) of this section. If the facility's accreditation was denied or withdrawn under the provisions of paragraph (a)(2) of this section, the facility operator must include with the application written documentation specifying what actions have been taken to correct the conditions that led to the denial or withdrawal of accreditation.

(5) All information gathered during the course of a non-government facility's assessment and during the term of its accreditation will be treated by APHIS with the appropriate level of confidentiality, as set forth in the U.S. Department of Agriculture's administrative regulations in §1.11 of this title.

(b) *Criteria for accreditation of non-government facilities.* (1) Specific standards for accreditation in a particular area of laboratory testing or phytosanitary inspection are set forth in this part and may be obtained by writing to APHIS. If specific standards for accreditation in a particular area of laboratory testing or phytosanitary inspection have not been promulgated by APHIS, and the Administrator determines that accreditation in that area is practical, APHIS will develop appropriate standards applicable to accreditation in the area for which the non-government facility is seeking accreditation and publish a notice of proposed rulemaking in the FEDERAL REGISTER to inform the public and other interested persons of the opportunity to comment on and participate in the development of those standards.

(2) The operator of a non-government facility seeking accreditation to conduct laboratory testing or phytosanitary inspection shall submit an application to the Administrator. The application must be completed and signed by the operator of the facility or his or her authorized representative and must contain the following:

(i) Legal name and full address of the facility;

(ii) Name, address, and telephone and fax number of the operator of the facility or his or her authorized representative;

(iii) A description of the facility, including its physical plant, primary function, scope of operation, and, if applicable, its relationship to a larger corporate entity; and

(iv) A description of the specific laboratory testing or phytosanitary inspection services for which the facility is seeking accreditation.

(3) Upon receipt of the application, APHIS will review the application to identify the scope of the assessment that will be required to adequately review the facility's fitness to conduct the laboratory testing or phytosanitary inspection services for which it is seeking accreditation. Before the assessment of the facility begins, the applicant's representative must agree, in writing, to fulfill the accreditation procedure, especially to receive the assessment team, to supply any information needed for the evaluation of the facility, and to enter into a trust fund agreement as provided by paragraph (c) of this section to pay the fees charged to the applicant facility regardless of the result of the assessment and to pay the charges of subsequent maintenance of the accreditation of the facility. Once the agreement has been signed, APHIS will assemble an assessment team and commence the assessment as soon as circumstances permit. The assessment team will measure the facility's fitness to conduct the laboratory testing or phytosanitary inspection services for which it is seeking accreditation against the specific standards identified by the Administrator for those services by reviewing the facility in the following areas:

(i) *Physical plant.* The facility's physical plant (e.g., laboratory space, office space, greenhouses, vehicles, etc.) must meet the criteria identified in the accreditation standards as necessary to properly conduct the laboratory testing or phytosanitary inspection services for which it seeks accreditation.

(ii) *Equipment.* The facility's personnel must possess or have unrestricted access to the equipment (e.g., microscopes, computers, scales, triers,

etc.) identified in the accreditation standards as necessary to properly conduct the laboratory testing or phytosanitary inspection services for which it seeks accreditation. The calibration and monitoring of that equipment must be documented and conform to prescribed standards.

(iii) *Methods of testing or inspection.* The facility must have a quality manual or equivalent documentation that describes the system in place at the facility for the conduct of the laboratory testing or phytosanitary inspection services for which the facility seeks accreditation. The manual must be available to, and in use by, the facility personnel who perform the services. The methods and procedures followed by the facility to conduct the laboratory testing or phytosanitary inspection services for which it seeks accreditation must be commensurate with those identified in the accreditation standards and must be consistent with or equivalent to recognized international standards for such testing or inspection.

(iv) *Personnel.* The management and facility personnel accountable for the laboratory testing or phytosanitary inspection services for which the facility is seeking accreditation must be identified and must possess the training, education, or experience identified in the accreditation standards as necessary to properly conduct the testing or inspection services for which the facility seeks accreditation, and that training, education, or experience must be documented.

(4) To retain accreditation, the facility must agree to:

(i) Observe the specific standards applicable to its area of accreditation;

(ii) Be assessed and evaluated on a periodic basis by means of proficiency testing or check samples;

(iii) Demonstrate on request that it is able to perform the tests or inspection services representative of those for which it is accredited;

(iv) Resolve all identified deficiencies;

(v) Notify APHIS as soon as possible, but no more than 10 days following its occurrence, of any change in key management personnel or facility staff accountable for the laboratory testing or phytosanitary inspection services for which the facility is accredited; and

(vi) Report to APHIS as soon as possible, but no more than 10 days following its occurrence, any change involving the location, ownership, physical plant, equipment, or other conditions that existed at the facility at the time accreditation was granted.

(c) *Fees and trust fund agreement.* The fees charged by APHIS in connection with the initial accreditation of a nongovernment facility and the maintenance of that accreditation shall be adequate to recover the costs incurred by the government in the course of APHIS' accreditation activities. To cover those costs, the operator of the facility seeking accreditation must enter into a trust fund agreement with APHIS under which the operator of the facility will pay in advance all estimated costs that APHIS expects to incur through its involvement in the pre-accreditation assessment process and the maintenance of the facility's accreditation. Those costs shall include administrative expenses incurred in those activities, such as laboratory fees for evaluating check test results, and all salaries (including overtime and the Federal share of employee benefits), travel expenses (including per diem expenses), and other incidental expenses incurred by the APHIS in performing those activities. The operator of the facility must deposit a certified or cashier's check with APHIS for the amount of the costs, as estimated by APHIS. If the deposit is not sufficient to meet all costs incurred by APHIS, the operator of the facility must deposit another certified or cashier's check with APHIS for the amount of the remaining costs, as determined by APHIS, before APHIS' services will be completed. After a final audit at the conclusion of the pre-accreditation assessment, any overpayment of funds will be returned to the operator of the facility or held on account until needed for future activities related to the maintenance of the facility's accreditation.

Approved by the Office of Management and Budget under control number 0579–0130)

[64 FR 1105, Jan. 8, 1999, as amended at 66 FR 37400, July 18, 2001]

§ 353.9 Standards for accreditation of non-government facilities to perform laboratory seed health testing and seed crop phytosanitary inspection.

(a) *Application for accreditation, certification of accreditation, and monitoring of accredited facilities.* A facility may apply to be accredited to perform laboratory seed health testing or seed crop phytosanitary inspection, or to renew such accreditation, by submitting an application in accordance with § 353.8(b)(2) of this part. If there are portions of the application deemed to contain trade secret or confidential business information (CBI), each page of the application containing such information should be marked "CBI Copy." The application must be accompanied by a copy of the facility's quality manual and a nonrefundable application fee of $1,000. The applicant must make additional deposits to cover the costs of gaining and maintaining accreditation into a trust fund established in accordance with § 353.8(c) of this part upon request by the Administrator.

(1) Upon determining that a facility is eligible for accreditation, the Administrator will issue the facility a certificate of accreditation. Accreditation will be for a period of 3 years from the date of issuance of the certificate of accreditation and may be renewed by submitting a new application and application fee in accordance with this paragraph.

(2) The Administrator may deny or withdraw accreditation in accordance with § 353.8(a)(2) of this part. A facility may appeal denial of accreditation in accordance with § 353.8(a)(2)(i) of this part, and may appeal withdrawal of accreditation in accordance with § 353.8(a)(2)(ii) of this part.

(3) A facility that has been denied accreditation or had its accreditation withdrawn may not reapply within 60 days of the date the facility was notified in writing that accreditation was denied or withdrawn.

(4) After a facility is accredited, the facility must allow APHIS access to the facility and all of its equipment and records for the purpose of conducting unannounced audits to determine the facility's continuing eligibility for accreditation. Such audits will occur at least once a year and may be performed more frequently at the discretion of the Administrator.

(b) *Standards for accreditation.* A facility that, in accordance with § 353.8(b)(2) of this part, applies to be accredited to perform laboratory seed health testing or seed crop phytosanitary inspection will be evaluated for accreditation against these standards:

(1) *Physical plant.* The facility's physical plant (e.g., laboratory space, office space, greenhouses, vehicles, etc.) must:

(i) Have laboratory and office spaces enclosed by walls and locking doors to prevent unauthorized access;

(ii) Conform to all State and local zoning and other ordinances; and

(iii) Provide a work area that is dedicated to laboratory functions and has sufficient space to conduct the required tests and store the materials and samples required for the tests in a manner that prevents contamination by other samples in the laboratory and from other sources.

(2) The facility must have access to all equipment required to conduct the laboratory testing or seed crop phytosanitary inspections for which it is accredited. Specific test methodologies, materials, and the calibration and monitoring of the equipment must conform to Reference Manual B, which is incorporated by reference at § 300.4 of this chapter. The general requirements for each test category are as follows:

(i) *Seed crop phytosanitary inspections.* Seed crop phytosanitary inspection may also include related activities such as collection of seed samples for later laboratory testing, visual inspection of seed just prior to export, and inspection of greenhouses or growth chambers where plants are grown for seed production, as well as visual inspection of seed crops. In the field, inspectors must use accurate field maps, hand lenses, and secure containers for the collection, storage, and transportation of samples. Inspectors must have direct access to a laboratory that is fully equipped to carry out any necessary diagnostic tests needed for field samples.

(ii) *Direct visual examination.* Visual examination of seed requires a stereo

microscope. Visual examination of tissue requires a compound light microscope. Visual examination of loosely attached or accompanying material requires a centrifuge and shaker.

(iii) *Incubation.* Required equipment includes incubation chambers, laminar flow hoods, media preparation equipment, scales, pH meters, distilled and sterile water, gas burners, an autoclave, and the appropriate media for the specified tests.

(iv) *Grow-out tests.* Grow-out tests require a greenhouse, growth chamber, or an outdoor quarantine location, and access to a laboratory that is fully equipped to carry out any required diagnostic tests.

(v) *Serological tests.* These tests require grinding, extraction, and sample purification equipment; fluorescent microscopes; plate readers; spectrophotometers; and the appropriate assay materials; or the appropriate equipment to use field ready test kits.

(vi) *DNA probes.* To conduct these tests, a laboratory must be equipped with polymerase chain reaction (PCR) equipment, including thermal cyclers, electrophoresis and gel blotting equipment, and the reagents and DNA polymerases necessary to conduct the PCR.

(3) *Methods of testing and inspection.* The facility must conduct its laboratory seed health testing and seed crop phytosanitary inspection procedures in accordance with Reference Manual B. The facility must have a quality manual documenting its quality system for laboratory seed health testing and seed crop phytosanitary inspection procedures. The quality system must follow the general guidelines described in ANSI/ASQC Q9001–1994, *American National Standard: Quality Systems-Model for Quality Assurance in Design, Development, Production, Installation and Servicing.* Acceptable models for quality systems for accredited facilities are also described in detail in Reference Manual A, which is incorporated by reference at §300.3 of this chapter. The personnel who perform the testing and inspection services must comply with the quality manual, and management must enforce this compliance. The facility must maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality system records. The facility must maintain quality system records to demonstrate conformance to the quality manual and the effective operation of the quality system.

(4) *Personnel.* There must be a selection procedure and a training system to ensure technical competence of all staff members. The education, technical knowledge, and experience required to perform assigned test and inspection functions must be documented and clearly defined. In addition:

(i) Evaluation of plant or tissue samples must be undertaken by a plant pathologist or by laboratory technicians under the supervision of a plant pathologist, who may provide such supervision either on-site, or from a remote location. Where personnel are required to be trained at a facility to evaluate the particular types of plants or tissue samples handled by the facility, the training program must be evaluated by APHIS and determined to be effective.

(ii) All staff must have access to and be familiar with the reference materials, guides, and manuals required for the routine performance of the tests and inspections they conduct.

(Approved by the Office of Management and Budget under control number 0579–0130)

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PART 354—OVERTIME SERVICES RELATING TO IMPORTS AND EXPORTS; AND USER FEES

Sec.

354.1 Overtime work at border ports, sea ports, and airports.
354.2 Administrative instructions prescribing commuted traveltime.
354.3 User fees for certain international services.
354.4 User fees for certain domestic services.
354.5 Penalties for nonpayment or late payment of user fees.

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