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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 Any agreement may be immediately withdrawn by the Administrator if he or she determines that articles covered by the agreement were moved in violation of any requirement of this chapter or any provision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 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.

(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 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 non-government 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.

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[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