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(3) A facility that has been denied accreditation or had its accreditation withdrawn may not reapply within 60 days of the date the facility was notified in writing that accreditation was denied or withdrawn.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