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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 300 and 353

[Docket No. 99-030-2]

Accreditation Standards for Laboratory Seed Health Testing and Seed Crop Phytosanitary Inspection

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the export certification regulations to provide specific standards under which non-government facilities may be accredited to perform laboratory seed testing and seed crop field inspection services to serve as the basis for the issuance of a Federal phytosanitary certificate, export certificate for processed plant products, or phytosanitary certificate for reexport. The accreditation standards for these laboratory testing and field inspection services were developed to provide the basis for non-government facilities to become accredited to perform the testing or inspection services that may be used as supporting documentation for the issuance of certificates for certain plants or plant products.

EFFECTIVE DATE: August 17, 2001. The incorporation by reference provided for by this rule is approved by the Director of the Federal Register as of August 17, 2001.

FOR FURTHER INFORMATION CONTACT: Mr. Nancy G. Klag, Program Manager, Phytosanitary Issues Management, Operational Support, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737-1236; (301) 734-8262.

SUPPLEMENTARY INFORMATION:

Background

The export certification regulations contained in 7 CFR part 353 (referred to

below as the regulations) set forth the procedures for obtaining certification for plants and plant products offered for export or reexport. Export certification is not required by the regulations; rather, it is provided by the Animal and Plant Health Inspection Service (APHIS) as a service to exporters who are shipping plants or plant products to countries that require phytosanitary certification as a condition of entry. After assessing the condition of the plants or plant products intended for export relative to the receiving country's regulations, an inspector will issue 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.

Since 1975, APHIS has participated with State governments in the Cooperative Phytosanitary Export Certification Program, which allows certain State and county officials, as well as APHIS officials, to issue phytosanitary certificates, phytosanitary certificates for reexport, or export certificates for processed plant products. Because the number of Federal inspectors is limited, the use of State and county inspectors is a considerable benefit to exporters of plants and plant products in terms of both time and convenience.

On June 20, 2000, we published in the **Federal Register** (65 FR 38218-38223, Docket No. 99-030-1) a proposal describing standards to be used to evaluate facilities for accreditation to perform laboratory seed testing and seed crop field inspection in accordance with 7 CFR part 353.

We solicited comments concerning our proposal for 60 days ending August 21, 2000. We received 28 comments by that date. They were from seed companies, seed industry associations, plant health associations, and individuals. All the commenters generally supported the proposed rule, although three commenters suggested certain specific changes to it. All issues raised by the commenters are discussed below.

Two commenters suggested that we should replace references to *seed crop field inspection* in the rule with the term *seed crop phytosanitary inspection* or a similar term, and clarify that this activity includes inspection of

greenhouses or growth chambers where plants are grown for seed production as well as visual inspection of seed crops. The same commenters suggested that we replace references to *laboratory seed testing* with the term *laboratory seed health testing*. They stated that in both cases, the terms in the proposal did not unambiguously identify the purpose of the inspection and testing.

We agree, and have made the requested changes. We have also clarified in the discussion of the procedures for seed crop phytosanitary inspection in § 353.9(b)(2)(i) that this activity includes inspection of greenhouses or growth chambers where plants are grown for seed production, as well as visual inspection of seed crops.

One commenter suggested that the rule should specify that the activities performed by approved facilities include seed sampling for the purpose of laboratory seed health testing and visual inspection of seed just prior to export. We believe it is fairly clear in the rule that facilities that perform seed crop phytosanitary inspection and laboratory seed health testing may perform these activities as part of accomplishing the purpose of their inspection and testing. For example, the rule directs facilities to Reference Manual B for detailed procedures on seed sampling. However, we have added these two activities to § 353.9(b)(2)(i) as examples of functions facilities may perform.

Two commenters suggested, regarding the proposal's discussion of physical plant and equipment requirements for facilities, that a laboratory may need all the required equipment for full seed health testing but not for diagnostic activities in support of phytosanitary inspection, which often only requires a hand lens. They suggested that we change the rule to state that the accredited facility must "have access" to this equipment should it be necessary; i.e., make the equipment required test-dependent.

The intent of the proposed rule was to require facilities to have specified equipment only if it is needed to perform the tests for which the facility is accredited. Proposed § 353.9(b)(2) stated that a facility "must use the equipment required to conduct the laboratory testing or seed crop phytosanitary inspections for which it is accredited." To clarify this point, we are

changing that sentence in this final rule to read that a facility "must have access to all equipment required to conduct the laboratory testing or seed crop phytosanitary inspections for which it is accredited."

One commenter noted, regarding the proposal's discussion of serological testing, that some laboratories may use "field ready test kits" that do not require all the equipment listed in § 353.9(b)(2)(v).

We agree. Proposed § 353.9(b)(2)(v) stated regarding serological tests that "These tests require grinding, extraction, and sample purification equipment; fluorescent microscopes; plate readers; spectrophotometers; and the appropriate assay materials." We are adding to the end of that sentence the phrase "or appropriate equipment to use field ready test kits."

The same commenter also asked whether APHIS intended to prohibit field determinations, or to require field determinations to be confirmed by laboratory diagnostics. If laboratory confirmation is required, the commenter asked whether APHIS must accredit the laboratory providing the diagnostic confirmation.

APHIS intends to allow field determinations that are conducted in accordance with the procedures authorized by Reference Manual B. In the normal practice of field inspection, samples are routinely sent to a laboratory for identification or confirmation of a visual identification. It is not APHIS' intention to accredit these laboratories. However, the procedures to provide this laboratory support, including the identity and qualifications of the laboratory, must be detailed in the accredited facility's quality manual. A facility's procedures for confirming field inspections may be reviewed during the initial approval and periodic audits of the accredited facility.

Two comments addressed the proposed requirement in § 353.9(b)(4)(i) that "Evaluation of plant or tissue samples must be undertaken by a plant pathologist or by laboratory technicians under the supervision of a plant pathologist." These commenters noted that by using modern communications and computer technology, technicians may work "under the supervision of a plant pathologist" even if the pathologist is at a different location.

We agree, and have added the following phrase at the end of the sentence in § 353.9(b)(4)(i): "who may provide such supervision either on-site, or from a remote location."

One commenter suggested that the Association of Official Seed Analysts should be added to the National Seed

Health System (NSHS) Working Group identified in Reference Manual A.

Membership in the NSHS Working Group is outside the scope of this rulemaking. This commenter should contact the current chair of the NSHS Seed Technical Working Group to address this issue.

One commenter addressed a sentence in the economic analysis section of the proposed rule that read: "It is expected that, like any business, seed testing laboratories will recoup these expenses by appropriate structuring of the fees they set for their services." This commenter noted that, in addition to laboratories, this is also true for non-laboratory accredited entities providing other phytosanitary inspection services.

We agree, and have modified the language in this final rule's economic analysis accordingly.

One commenter asked for APHIS to clarify whether only non-government entities are eligible to apply for accreditation under the rule. In particular, this commenter asked about the eligibility of public universities that administer seed certification units.

Even though most of the examples discussed in the proposed rule were private, non-government entities, the rule does not preclude accreditation of governmental agencies or other public institutions, including public universities. These agencies may apply for accreditation and, if eligible, will be accredited.

One commenter asked how APHIS will accept and protect confidential business information submitted by applicants for accreditation.

The regulations already in place at § 353.8(b)(5) state that "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." APHIS will protect the confidentiality of such information. To make sure that such information is clearly identified by the applicant, we are adding the following sentence to paragraph § 353.9(a) in the rule, which describes how to submit application material: "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.'"

One commenter asked whether specific test methodologies and materials will be in Reference Manual B, or in a facility's quality manuals. As

stated in the proposal, Reference Manual B will contain specific methodologies to conduct tests, field inspections, sampling, and related procedures. The facility's quality manual will document the quality system designed to ensure that the methodologies in Reference Manual B are followed, and will address matters such as purity of materials, and calibration of equipment, and so forth. Quality manuals may summarize or quote methodologies from Reference Manual B to the extent that facilities find it useful to do so.

One commenter asked whether APHIS accepts liability for incorrect diagnostics or field inspections carried out by accredited entities.

APHIS does not accept liability for inaccurate results. Once accredited, individual facilities retain the same liability for conducting tests that are inaccurate or fraudulent that they bore before becoming accredited. Facilities should be protected against liability if they follow the methodologies required by APHIS and report test and inspection results accordingly. If evidence accumulates that a particular methodology does not yield reliable results, APHIS may have to revise that methodology, but accredited facilities are only responsible for properly conducting and reporting the required procedures.

One commenter asked for details regarding how often Reference Manuals A and B will be revised, and when they will be incorporated by reference. These manuals are currently posted on the APHIS website (<http://www.aphis.usda.gov/ppq/pim/accreditation>) in the form in which they have been incorporated by reference by this final rule. We expect that the manuals, especially Reference Manual B, will require updating as new tests are added or as improved test and inspection methodologies are validated. APHIS intends to update the copies of the Reference Manuals on the website, and the copies incorporated by reference with the Office of the Federal Register, as needed, perhaps about twice per year.

One commenter noted that APHIS has stated that the Iowa State Seed Science Center will be used on the assessment team to evaluate and audit facilities applying for accreditation. This commenter stated that APHIS would need additional help to meet its evaluation workload in order to process all the applications from interested facilities, and stated that State governmental agencies could also be used to meet this need.

We agree that APHIS will likely need additional assistance to meet the workload involved in evaluating and auditing facilities. Since APHIS does not have the capability or expertise to provide the necessary testing and auditing, we will utilize selected public facilities to conduct these activities. The Iowa State Seed Science Center will be used as the initial "accreditation unit" under this system; however, it is anticipated that APHIS may need to utilize other organizations, including State agencies, to properly evaluate all the private facilities that wish to be accredited.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This rule will amend the export certification regulations to provide standards under which facilities may become accredited to perform laboratory seed health testing or inspection services that can serve as the basis for the issuance of Federal phytosanitary certificates for export, phytosanitary certificates for reexport, or export certificates for processed plant products. Accrediting such facilities is currently allowed under 7 CFR 353.8. The existing regulations provide a framework upon which accreditation programs could be established, but they do not, in and of themselves, entail any costs to APHIS or any facility. However, when facilities are accredited under the accreditation criteria contained in this rule for seed laboratories and field inspection facilities, that action will entail costs to both the entities being accredited and the accrediting body (i.e., APHIS). Those costs, and the benefits expected from the accreditation program, are summarized below and were fully evaluated in the economic analysis section of the previous final rule that established a program for accrediting facilities, published in the **Federal Register** on January 8, 1999 (64 FR 1098–1106, Docket No. 95–071–2).

The accreditation program is expected to be self-supporting, and any costs to APHIS should be recouped through accreditation fees. Costs for establishing each accredited facility will vary, depending on the range of activities for which a facility seeks accreditation, the

initial cost of the APHIS preaccreditation assessment, the type and number of any proficiency tests that will have to be conducted, and the frequency with which post-accreditation evaluation activities such as check tests and site visits will have to be conducted. It is expected that, like any business, seed testing laboratories and other accredited facilities will recoup these expenses by appropriate structuring of the fees they set for their services.

The seed industry is expected to benefit from this action because domestic seed exporters routinely require the services of inspectors and agents in order to obtain the phytosanitary certification required by most, if not all, importing countries; benefits can be realized in terms of more timely certifications, which in turn can lead to reduced costs as well as increased U.S. exports.

The value of seed exported from the United States to other countries continues to grow rapidly, from \$665 million in 1994–95 (July to June), to \$705 million in 1995–96, to more than \$800 million in 1996–97. There has been a concomitant rise in demand for laboratory testing and inspection services to meet other countries import requirements. The ability of Federal, State, and county testing and inspection services to meet this growing demand will be increasingly strained. Already there are instances in which the availability of accredited facilities would have prevented the loss of export sales.

For example, some seed export opportunities have been forfeited because the results of preharvest field inspections are usually not known until after harvest, due to the limited number and heavy workload of government laboratories available to perform seed testing. It is common for seed from several fields to be blended after harvest and before shipment. If the sample from one field is subsequently reported to contain an actionable pest, then none of the blended seed—which may have been harvested from as many as eight or nine fields—could be exported. In one case in which this occurred, the affected seed company lost foreign sales worth \$250,000. Such losses are much less likely to occur if there is more timely reporting of preharvest inspections; accredited inspection facilities may be able to make such timely reports. In general, we expect that adding a number of non-government facilities providing testing and inspection services will allow the future demand for these services to be distributed among facilities in a manner that will readily

adjust to fluctuations in the demand for these services, and will allow both government and non-government facilities to report results in a timely manner.

Overall, the economic benefits that should result from the availability of accredited non-governmental seed laboratories and field inspection facilities greatly exceed the costs. By providing access to services by accredited non-government facilities to support the issuance of phytosanitary certificates that many trading partners require as a condition of entry for U.S. goods, this action should greatly enhance export opportunities for U.S. producers. While this rule does not directly create or open any new markets for U.S. seed exports, it makes it easier for exporters to obtain necessary certification in a timely manner. This should result in U.S. companies obtaining more contracts in which delivery time is of the essence. While we do not have data to exactly estimate the value of such potential contracts, comments from seed companies suggest that their value may be on the order of \$10 million per year.

We do not have detailed information on the number of small businesses engaged in exporting seeds or in testing seeds. Seed and bulb producers are combined in Standard Industrial Classification (SIC) 0181 with several other types of businesses, and seed testing laboratories are combined with other types of testing laboratories under SIC 8734. From the data available, there appear to be several hundred seed producers that may be small businesses, but very few of these engage directly in export. Instead, they sell seed to wholesale seed brokers who sell to export markets. None of these wholesale seed brokers appear to be small businesses. Several very large seed production companies are known to sell their products directly to export markets. With regard to seed testing laboratories, we estimate that a dozen or so laboratories, some of which are small businesses, will become accredited in accordance with this rule and will increase their revenue from inspection and testing services.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires

intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

List of Subjects

7 CFR Part 300

Incorporation by reference, Plant diseases and pests, Quarantine.

7 CFR Part 353

Exports, Incorporation by reference, Plant diseases and pests, Reporting and recordkeeping requirements.

Accordingly, 7 CFR parts 300 and 353 are amended as follows:

PART 300—INCORPORATION BY REFERENCE

1. The authority citation for part 300 continues to read as follows:

Authority: 7 U.S.C. 7701–7772; 7 CFR 2.22, 2.80, and 371.3.

2. In § 300.1, new paragraphs (c) and (d) are added to read as follows:

§ 300.1 Materials incorporated by reference.

* * * * *

(c) *Reference Manual A*. The *Reference Manual for Administration, Procedures, and Policies of the National Seed Health System*, which was published on February 25, 2000, by the National Seed Health System (NSHS), has been approved for incorporation by reference in 7 CFR chapter III by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of Reference Manual A:

(1) Are available for inspection at the Office of the Federal Register Library, 800 North Capitol Street NW, Suite 700, Washington, DC, and the APHIS Library, U.S. Department of Agriculture, 4700 River Road, Riverdale, MD 20737; or

(2) May be obtained 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>.

(d) *Reference Manual B*. The *Reference Manual for Seed Health Testing and Phytosanitary Field Inspection Methods*, which was published on February 27, 2001, by the National Seed Health System (NSHS), has been approved for incorporation by reference in 7 CFR chapter III by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of Reference Manual B:

(1) Are available for inspection at the Office of the Federal Register Library, 800 North Capitol Street NW, Suite 700, Washington, DC, and the APHIS Library, U.S. Department of Agriculture, 4700 River Road, Riverdale, MD 20737; or

(2) May be obtained by writing to Phytosanitary Issues Management, Operational Support, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737–1236, and on the A APHIS Web site at <http://www.aphis.usda.gov/ppq/pim/accreditation>.

PART 353—EXPORT CERTIFICATION

3. The authority citation for part 353 continues to read as follows:

Authority: 7 U.S.C. 7711, 7712, 7718, 7751, and 7754; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

4. In § 353.1, definitions of *Reference Manual A* and *Reference Manual B* are added, in alphabetical order, to read as follows:

§ 353.1 Definitions.

* * * * *

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 § 300.1 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 § 300.1 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>.

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§ 353.8 [Amended]

5. Section 353.8 is amended by adding a new sentence at the end of the section to read as follows: “(Approved by the Office of Management and Budget under control number 0579–0130)”.

6. A new § 353.9 is added to read as follows:

§ 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 § 300.1 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 § 300.1 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.)

Done in Washington, DC, this 11th day of July 2001.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 01-17839 Filed 7-17-01; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 01-048-1]

Pine Shoot Beetle; Addition to Quarantined Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the pine shoot beetle regulations by adding counties in Illinois, Indiana, Maine, Maryland, New York, Ohio, Pennsylvania, Vermont, and West Virginia to the list of quarantined areas. This action is necessary to prevent the spread of pine shoot beetle, a pest of pine products, into noninfested areas of the United States. We are also making nonsubstantive revisions to the entries