Proposed Rules

Federal Register
Vol. 65, No. 119
Tuesday, June 20, 2000

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 300 and 353

[Docket No. 99–030–1]

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

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the export certification regulations to provide specific standards under which nongovernment facilities could become accredited to perform laboratory seed testing and seed crop field inspection services that could 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 nongovernment 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.

DATES: We invite you to comment on this docket. We will consider all comments that we receive by August 21, 2000.

ADDRESSES: Please send your comment and three copies to: Docket No. 99–030–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 99–030–1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

FOR FURTHER INFORMATION CONTACT: Mr. Narcy 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.

In a final rule published in the **Federal Register** on January 8, 1999 (64 FR 1098–1106, Docket No. 95–071–2), we amended the regulations to provide for the establishment of a program under which nongovernment facilities (referred to below as facilities) could become accredited to perform specific laboratory seed testing or seed crop field inspection services that could serve as the basis for the issuance of a Federal phytosanitary certificate, phytosanitary certificate for reexport, or export certificate for processed plant products. That final rule broadened the options for persons who needed to obtain inspection and export certification services.

The final rule stated that in order to accredit facilities, standards would have to be developed to evaluate the capability of facilities to perform various laboratory seed testing and seed crop field inspection services. In § 353.8(b), the regulations state, ''APHIS will develop appropriate standards applicable to accreditation in the area for which the nongovernment 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.''

There are two reasons for this approach. First, it would be difficult, if not impossible, for APHIS to develop a single, one-size-fits-all set of accreditation standards for the numerous disciplines that play a role in phytosanitary certification. Secondly, this approach allows APHIS to develop standards with the participation of those best able to recommend valid scientific criteria; i.e., the government, academic, industry, research, and private-sector individuals who have the experience and expertise in the particular area for which standards are being developed.

This proposed rule publishes for comment standards to be used to evaluate facilities for accreditation to perform laboratory seed testing and seed crop field inspection.

Laboratory seed testing and seed crop field inspection comprise a wide variety of technical tests and procedures, including both laboratory tests and visual inspection of plants growing in fields. The laboratory tests include procedures such as various forms of microscopic examination, culturing microorganisms in various media and

subsequently identifying them, and conducting serological and DNA probe tests of organisms. Test protocols are contained in the *Reference Manual for Laboratory Test and Phytosanitary Inspection Methodologies,* a publication of the National Seed Health System (referred to below as Reference Manual B). A copy of Reference Manual B is available on the APHIS Web site at http://www.aphis.usda.gov/ppq/pim/accreditation, and Reference Manual B will be incorporated by reference into the regulations when final action is taken on this proposal.

In § 353.8(b)(3), the regulations state that when evaluating the fitness of a facility to be accredited, APHIS will form an assessment team that will focus on four major areas: Physical plant, equipment, methods of testing or inspection, and personnel. The assessment team will compare the facility's performance in these four areas against the accreditation standards that have been identified for the particular laboratory seed testing or seed crop field inspection services for which the facility is seeking accreditation. The standards we propose to establish for facilities to perform laboratory seed testing and seed crop field inspection are discussed below.

Physical Plant

The facility's physical plant (*e.g.,* laboratory space, office space, greenhouses, vehicles, etc.) would have to conform to all State and local zoning and other ordinances, to ensure consistency with State and local laws and to prevent disruption of services that might occur for exporters of plants and plant products if the local government found the facility's physical plant to be in violation of local ordinances. The facility's physical plant would have to consist of a work area that is dedicated to laboratory functions and that has sufficient space to conduct the required tests. Storage space for test materials and samples would have to be large enough to accommodate the samples within a laboratory at any given time and secure from contamination by other samples within the laboratory and other sources. The laboratory area would have to be enclosed by walls and have locking doors to prevent unauthorized access.

Equipment

Equipment is the second major area evaluated when considering a facility for accreditation under the regulations. We propose that the facility's personnel must possess or have unrestricted access to the equipment identified as necessary to properly conduct the laboratory seed testing or seed crop field inspection services in accordance with the procedures contained in Reference Manual B. Specific test methodologies, materials, and the calibration and monitoring of the equipment would have to conform to Reference Manual B. The general procedures proposed are listed below.

1. *Equipment for Seed Crop Field Inspections:* We propose to require that facilities accredited for seed crop field inspection services have direct access to laboratories that are fully equipped to carry out any required field sample diagnostics. Field inspectors would have to have accurate field maps and transportation to the inspection site. Field inspectors would also have to have hand lenses and secure containers for the collection, storage, and transportation of samples.

2. *Equipment for Direct Visual Examination:* We propose to require that facilities accredited to conduct visual examination of seed be equipped with stereo microscopes. Facilities conducting visual examination of tissues would also have to be equipped with compound light microscopes, and those conducting visual examination of loosely attached or accompanying material would have to be equipped with a centrifuge and shaker.

3. *Equipment for Incubation:* We propose to require that facilities accredited to conduct incubations be equipped with 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.

4. *Equipment for Grow Out Tests:* We propose to require that facilities accredited to conduct grow out tests have greenhouse or growth chambers or an outdoor quarantine location, plus access to a laboratory that is fully equipped to carry out any required diagnostic tests.

5. *Equipment for Serological Tests:* We propose to require that facilities accredited to conduct serological tests be equipped with grinding, extraction, and sample purification equipment; fluorescent microscopes; plate readers; spectrophotometers; and the appropriate assay materials.

6. *Equipment for DNA Probes:* We propose to require that facilities accredited to conduct DNA probe tests 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 PCR.

Reference Manual B will contain the complete testing protocols and will be updated with new and improved test protocols from time to time in order to keep abreast of the latest technologies, new diagnostic methods, and equipment.

Methods of Testing or Inspection

The third major area to be evaluated when considering a facility for accreditation under the regulations would be methods of testing or inspection. For testing and inspection to be reliable, they must be conducted in accordance with a quality system. The generally accepted definition of a quality system is that it is the organizational structure, procedures, processes and resources needed to ensure quality in the operation and products of a business. The regulations already require that a facility establish a quality system and follow procedures recorded in a quality manual developed by the facility, or equivalent documentation, to ensure that the facility employs scientifically valid and up-to-date methodology to conduct its laboratory seed testing or seed crop field inspection activities. We propose that, when evaluating a facility for accreditation, the assessment team would review the facility's quality manual or other equivalent documentation that describes the system in place at the facility for the conduct of the laboratory seed testing or seed crop field inspection services for which the facility seeks accreditation. The assessors would verify that the quality manual was available to, and in use by, the facility personnel who perform the tests or services.

We propose that the quality system and other controls on test and inspection methods at the facility would have to meet the following requirements.

The quality system would have to 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.'' This is an internationally accepted guideline for effective quality systems and is available from the American Society for Quality Control (ASQC), 611 East Wisconsin Avenue, Milwaukee, WI 53202. Acceptable models for quality systems for accredited facilities are also described in detail in the ''Reference Manual for Procedures and Policies'' (also known as Reference Manual A), published by the National Seed Health System. Reference Manual A describes quality systems that meet the

requirements of ANSI/ASQC Q9001–1994, but with particular emphasis on how quality systems would be designed for seed laboratories. Reference Manual A will be incorporated by reference when final action is taken on this proposal and is available on the APHIS Web site at http://www.aphis.usda.gov/ppq/pim/accreditation. Reference Manual A describes the industry-accepted structure, administration, procedures, policies, and working practices of facilities engaged in seed testing and field inspection.

We also propose that the facility would have to document its procedures and maintain records that will show it is following its quality system. These records will help APHIS representatives when they visit the facility for audit purposes. The facility would have to maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality system records. The purpose of these records would be to demonstrate conformance to the quality manual and the effective operation of the quality system.

Personnel

Personnel would be the fourth major area evaluated when considering a facility for accreditation under the regulations. We propose to require that facilities have 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 would have to be documented and clearly defined. In particular:

1. Evaluation of plant or tissue samples would have to be undertaken by a plant pathologist or by laboratory technicians under the supervision of a plant pathologist. 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 would have to be evaluated by APHIS and determined to be effective.

2. All staff would have to 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.

Application Procedures, Certification of Accreditation, Monitoring, and Costs

A facility would have to apply to be accredited to perform laboratory seed testing or seed crop field inspection, or to renew such accreditation, by submitting an application in accordance with the procedures already established in § 353.8(b)(2). In addition to the information required in that section, the application would have to be accompanied by a copy of the facility's quality manual and a nonrefundable application fee of $1,000. We would set this application fee at $1,000 based on our experience that processing an application would take 3 days time by employees or contractors with base hourly salary rates of at least $56, a base rate we have used in the past to calculate user fees for activities by employees of Plant Protection and Quarantine, APHIS. We also believe that an initial fee of $1,000, which would go toward the cost of APHIS services for accrediting the facility, would be high enough to prevent frivolous applications or applications from facilities that are not yet ready to qualify for accreditation. We believe the total cost of APHIS services (site visits, evaluation of facility equipment and quality and recordkeeping systems, etc.) required to accredit a facility would always be substantially more than $1,000. Therefore, the applicant would have to make additional deposits into a trust fund, upon request by the Administrator, to cover the costs of gaining and maintaining accreditation. If the cost of approving the initial application comes to less than $1,000, any remainder would be deposited into this trust fund and would be applied toward future costs of maintaining accreditation. However, it is most unlikely that the cost of the initial approval would be less than $1,000. APHIS will adjust the amount of this application fee in future rulemaking if experience in processing the applications for this program indicates that the application fee should be increased or decreased to more closely match actual costs. The procedures for APHIS to recover the costs of its services, and for deposits into a trust fund, are already established in § 353.8(c).

Upon determining that a facility is eligible for accreditation, the Administrator would issue the facility a certificate of accreditation. Accreditation would be for a period of 3 years from the date of issuance of the certificate of accreditation and could be renewed upon request and the submission of a new application and application fee. We believe that requiring reaccreditation every 3 years would be a valuable tool, along with the monitoring audits discussed below, to ensure that accredited facilities continue to meet the requirements for accreditation.

The existing regulations state that the Administrator could deny or withdraw accreditation in accordance with the procedures in § 353.8(a)(2). A facility could appeal denial or withdrawal of accreditation in accordance with § 353.8(a)(2)(i) and (ii).

We propose to require that a facility that has been denied accreditation or had accreditation withdrawn must wait at least 60 days from the date the facility was notified in writing that accreditation was denied or withdrawn before applying again. We believe this delay is justified because accreditation would not be denied or withdrawn unless there were flaws in the facility or its procedures that required time to correct.

We propose to require facilities that are accredited to allow APHIS access to the facility and all of its equipment and records for the purpose of audits to determine the facility's continuing eligibility for accreditation. Such audits would occur as necessary, based on quality system criteria contained in Reference Manual A. These monitoring audits would ensure that facilities continue to meet the requirements for accreditation throughout their period of accreditation.

Executive Order 12866 and Regulatory Flexibility Act

This proposed 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 been reviewed by the Office of Management and Budget.

This proposed rule would amend the export certification regulations to provide standards under which facilities could become accredited to perform laboratory seed testing or seed crop field inspection services that could 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 7CFR 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, if facilities are accredited under the accreditation criteria proposed here for seed laboratories and field inspection facilities, that action would 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 would 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 pre-accreditation 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 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 seed crop field 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 accreditation of 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 pre-harvest inspections; accredited inspection facilities may be able to make such timely reports. In general, nongovernment testing and inspection services are expected to be completed with minimal delay, leading to greater marketing flexibility and lower risk of lost sales.

Overall, the economic benefits that would result from the availability of accredited nongovernmental seed laboratories and field inspection facilities would greatly exceed the costs. By providing access to the accreditation needed to issue the phytosanitary certificates that many trading partners require as a condition of entry for U.S. goods, this action would greatly enhance export opportunities for U.S. producers.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would 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 proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed 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, Plant diseases and pests, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 7 CFR parts 300 and 353 as follows:

PART 300—INCORPORATION BY REFERENCE

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

Authority: 7 U.S.C. 150ee, 154, 161, 162 and 167; 7 CFR 2.22, 2.80, and 371.2(c).

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

§ 300.1 Materials incorporated by reference.

* * * * *

(c) *Reference Manual A.* The Reference Manual for Procedures and Policies, published 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 5U.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; 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 Laboratory Test and Phytosanitary Inspection Methodologies,* published 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; 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.

PART 353—EXPORT CERTIFICATION

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

Authority: 7 U.S.C. 147a; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.2(c).

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

§ 353.1 Definitions.

* * * * *

Reference Manual A. The *Reference Manual for Procedures and Policies,* 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 Laboratory Test and Phytosanitary Inspection Methodologies,* published by the National Seed Health System (NSHS). Reference Manual B contains the detailed seed health testing, seed sampling, and seed crop field 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.

§ 353.8 [Amended]

5. Section 353.8 would be 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 would be added to read as follows:

§ 353.9 Standards for accreditation of nongovernment facilities to perform laboratory seed testing and seed crop field inspection.

(a) *Application for accreditation, certification of accreditation, and monitoring of accredited facilities.* A facility may apply to be accredited to perform laboratory seed testing or seed crop field inspection, or to renew such accreditation, by submitting an application in accordance with § 353.8(b)(2). 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) 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). A facility may appeal denial of accreditation in accordance with § 353.8(a)(2)(i), and may appeal withdrawal of accreditation in accordance with § 353.8(a)(2)(ii).

(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), applies to be accredited to perform laboratory seed testing or seed crop field 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 use the equipment required to conduct the laboratory testing or seed crop field 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 field inspections.* Field inspectors must use accurate field maps, hand lenses, and secure containers for the collection, storage, and transportation of samples. Field 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.

(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 testing and seed crop field inspection procedures in accordance with Reference Manual B. The facility must have a quality manual documenting its quality system for laboratory seed testing and seed crop field 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. 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 14th day of June 2000.

Richard L. Dunkle,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00–15493 Filed 6–19–00; 8:45 am]

BILLING CODE 3410–34–U

SMALL BUSINESS ADMINISTRATION

13 CFR Part 107

Small Business Investment Companies

AGENCY: Small Business Administration.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a provision of Public Law 106–9, enacted April 5, 1999, under which certain types of consideration paid to a small business investment company (SBIC) by a small business are excluded from ''cost of money'' limitations.

DATES: Submit comments on or before July 20, 2000.

ADDRESSES: Address comments to Don A. Christensen, Associate Administrator for Investment, U.S. Small Business Administration, 409 3rd Street, SW, Suite 6300, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Leonard W. Fagan, Investment Division, at (202) 205–7583.

SUPPLEMENTARY INFORMATION: This proposed rule would implement a provision of Public Law 106–9, enacted April 5, 1999, that amended section 308(i)(2) of the Small Business Investment Act of 1958. The amendment provided that certain types of consideration paid to an SBIC by a small business are excluded from the regulatory limitations on ''Cost of Money'' established by the Small Business Administration (SBA). The amendment excluded from these Cost of Money limits any consideration consisting of ''contingent obligations'' granting the SBIC an interest in the ''equity or increased future revenue'' of the small business.

To implement this change, SBA is proposing to broaden one of the exclusions from Cost of Money in § 107.855(g) and to add another. First, § 107.855(g)(12) would be revised to allow the exclusion of royalty payments for all SBIC financings. Currently, this exclusion applies only to ''LMI Investments'' as defined in § 107.50. To qualify for the exclusion, the royalty must be based on improvement in the performance of the small business after the date of the financing. The royalty could be expressed, for example, as a percentage of any increase in an underlying unit of measurement (*e.g.,* revenues or sales) after the date of the financing. As discussed in the preamble to the final rule establishing the original provision for LMI Investments (64 FR 52641), the royalty can be based on an increase in more than one unit of measurement. For example, a royalty could provide for payment to the SBIC if either the revenue or the profits of the small business increased.

If an SBIC makes an investment through a holding company or an investment vehicle, as permitted under § 107.720(b), performance improvements will be evaluated in the same manner already established for LMI Investments. In determining whether a business's performance has improved, SBA will look through any holding company or investment vehicle to the performance of the operating business itself.

SBA is proposing one additional change with respect to royalty payments. In § 107.815(a), the definition of a Debt Security would be revised to include a loan with a right to receive royalties that are excluded from the Cost of Money. The effect of this change is that a financing of this type will be subject to the lower Cost of Money ceiling applicable to Debt Securities, rather than the higher ceiling applicable to Loans with no upside potential.

SBA also proposes to add § 107.855(g)(13), which would exclude from Cost of Money any gains realized by an SBIC from the disposition of Equity Securities issued by a small business. This provision has been added as a clarification, since SBA's longstanding practice has been to exclude such gains from the Cost of Money limits. For example, if an SBIC receives warrants that qualify as Equity Securities, or converts debt to an Equity Security, any gains realized on the disposition of these interests do not count against the Cost of Money ceiling.

Finally, SBA proposes to remove paragraph § 107.855(i). This paragraph allows an SBIC that is lending to a small business to receive a one-time ''bonus'' at the end of the loan term, contingent upon one or more factors reflecting the performance of the business during the loan period. Such bonus payments are excluded from the Cost of Money. The proposed revision of § 107.855(g)(12), which would provide a broader exclusion of contingent payments from the Cost of Money, renders the bonus provision redundant.

Compliance With Executive Orders, 12866, 12988, and 13132, the Regulatory Flexibility Act (5 U.S.C. 601, et seq., and the Paperwork Reduction Act (44 U.S.C. Ch. 35)

SBA has determined that this proposed rule does not constitute a significant rule within the meaning of section 3(f) of Executive Order 12866.

Under the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, SBA has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities. The purpose of the proposed rule is to implement a provision of Public Law 106–9 allowing small business investment companies (SBICs) to realize contingent payments, such as royalties, from small businesses without being subject to regulatory limits on the amount of consideration received. Interest and other non-contingent payments made to SBICs by small businesses would continue to be subject to the existing Cost of Money regulations. This provision is expected to be attractive primarily to SBICs considering investments in small businesses that are seeking to grow, but whose owners do not want to give substantial equity interests to outside investors. In such cases, the SBIC can