On April 2, 1982, the Department issued final regulations (47 FR 14135) at 7 CFR 253.4(d) prohibiting Indian tribal households living in urban places (towns or cities with a population of 10,000 or more) outside reservation boundaries from participating in FDPIR. Because of the almost total absence of reservations in Oklahoma, the Department changed this policy in that State to apply to all urban places (7 CFR 254.5(b)). The Department implemented these requirements to support the basic purpose of FDPIR as an alternative to the Food Stamp Program—the primary Federal food assistance program. FDPIR was originally authorized out of concern that American Indians living on or near reservations may not have ready access to Food Stamp Program offices, or to food stores that are authorized to accept food stamps and have reasonable prices. However, FDPIR was not intended to replace the Food Stamp Program, particularly in urban areas. The Department believed that American Indian households living in off-reservation urban areas have reasonable access to food stamp services, and therefore, an alternative to the Food Stamp Program would not be needed for these households. Nevertheless, the regulations granted FNS the authority to approve exemption requests from ITOs that provide proper justification (see 7 CFR 253.4(d) and 7 CFR 254.5(b)). Since 1982, 16 exemption requests have been approved, including three from ITOs in Oklahoma. However, the waiver authority granted under FDPIHO regulations at 7 CFR 254.5(b) expired on September 30, 1985.

This rule reinstates FNS' authority to approve waiver requests from ITOs in Oklahoma to allow Indian tribal households living in urban places in that State to participate in FDPIHO. This rulemaking will provide all ITOs participating under either Part 253 or 254 with an equal opportunity to request waivers.

List of Subjects in 7 CFR Part 254

Administrative practice and procedure, Food assistance programs, Grant programs, Social programs, Indians, Reporting and recordkeeping requirements, Surplus agricultural commodities.

Accordingly, 7 CFR Part 254 is amended as follows:

PART 254—ADMINISTRATION OF THE FOOD DISTRIBUTION PROGRAM FOR INDIAN HOUSEHOLDS IN OKLAHOMA

1. The authority citation for Part 254 continues to read as follows:

Authority: Pub L. 97–98, sec. 1338; Pub. L. 95–113.

§ 254.5 [Amended]

2. In § 254.5, remove the last sentence of paragraph (b).

Dated: December 4, 1998.

Samuel Chambers, Jr.,

Administrator, Food and Nutrition Service.

[FR Doc. 99–395 Filed 1–7–99; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 353

[Docket No. 95–071–2]

RIN 0579–AA75

Export Certification; Accreditation of Non-Government Facilities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the export certification regulations to provide for the establishment of a program under which non-government facilities may become accredited to perform specific laboratory testing or phytosanitary inspection services that may serve as the basis for the issuance of a Federal phytosanitary certificate, export certificate for processed plant products, or phytosanitary certificate for reexport. Prior to this rule, only tests conducted by public laboratories or inspections carried out by Federal, State, or county inspectors or by agents could be used as the basis for the issuance of Federal certificates. The accreditation criteria for particular laboratory testing and phytosanitary inspection services will be developed by the Animal and Plant Health Inspection Service in cooperation with other interested government, industry, academic, or research entities. The accreditation program will provide a mechanism for qualified non-government facilities to become accredited to perform testing or inspection services that may be used as supporting documentation for the issuance of certificates for certain plants or plant products.

EFFECTIVE DATE: February 8, 1999.

FOR FURTHER INFORMATION CONTACT: Mr. Narcy G. Klag, Accreditation Program Manager, Phytosanitary Issues Management, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737–1236; (301) 734–8469.

SUPPLEMENTARY INFORMATION:

Background

The export certification regulations 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. Under the regulations, tests conducted by public laboratories or inspections carried out by Federal, State, or county inspectors or by agents may be used as the basis for the issuance of Federal certificates. 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. The regulations also provide for an industry-based certification, under certain conditions, of certain low-risk plant products such as kiln-dried lumber offered for export.

On November 25, 1997, we published in the **Federal Register** (62 FR 62699–62707, Docket No. 95–071–1) a proposal to amend the regulations to provide for the establishment of a program under which non-government facilities could become accredited to perform specific laboratory testing or phytosanitary 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.

We solicited comments concerning our proposed rule for 60 days ending January 26, 1998. We received 34 comments by that date. The comments were from processors and distributors of agricultural commodities, State and county agricultural agencies, a seed trade association, seed companies, crop improvement associations, a university laboratory, private testing and certification services, an association of State agricultural officials, laboratory accreditation organizations, a foreign plant health agency, and an association of seed certifying officials. Although all of the commenters supported the concept of an accreditation program, all but six of them had specific concerns, questions, or suggestions regarding the proposed accreditation program. The comments are addressed below.

Role of Accredited Facilities

Several commenters referred to accredited facilities as ''private certifiers'' or as having responsibility for the issuance of phytosanitary certificates. We wish to make it clear that accredited facilities will not be ''certifiers,'' nor will accredited facilities issue phytosanitary certificates. Rather, an accredited facility would perform specific tests or inspections that would serve as the basis for phytosanitary certification; phytosanitary certificates will continue to be issued by Federal, State, or county-level inspectors, as provided by the regulations.

Handling of Samples

Two commenters raised the issue of the handling of samples submitted for testing or inspection. The commenters were concerned that the proposed rule did not address issues such as who would collect and prepare samples for testing or inspection and how the integrity of samples would be maintained during movement and while at the accredited facility. One of the commenters stated that APHIS should specify how all samples are to be collected and handled, while the second commenter suggested that a sample handling accreditation program be made part of the regulations.

We agree with the commenters that the proper handling of samples is important to any laboratory testing or inspection program. Because the procedures and requirements for the collection and handling of samples will likely vary to some extent from plant to plant or product to product, we believe that sample collection and handling should be addressed in each set of specific accreditation standards as they are prepared, rather than in a general way in the regulations. Further, because the sample handling requirements will be part of each set of specific accreditation standards, we do not believe that it is necessary to establish a separate sample handling accreditation program.

Conflict of Interest

Two commenters suggested that APHIS or State agencies should act as an intermediary between accredited laboratories and their customers, serving as the conduit for contracting and payment for services and the submission of samples for testing. Two other commenters stated that APHIS must ensure that laboratory analyses are not performed by anyone having an interest in the product to avoid conflicts of interest. These four commenters sought to separate the entity performing an inspection or test from the entity for whom the work is performed in order to prevent any influence or bias. One of them noted that the current regulations in § 353.6(a)(3) prohibit agents from performing inspections of any plants or plant products in which they or a family member are directly or indirectly financially interested, and stated that the same conflict of interest rules should apply to accredited facilities. Two different commenters foresaw the possibility that an accredited facility might be a division or affiliate of a company that would use its testing or inspection services and asked how APHIS would deal with the potential conflicts of interest inherent in a facility testing or inspecting its own plants or plant products.

The issue in all of the comments summarized in the previous paragraph appears to be whether or not an accredited facility that is connected in some way to a commercial entity for which it is performing a service will be able to conduct unbiased tests or inspections and accurately report the results of those tests or inspections. The commenters appear to be worried that an accredited facility might tailor test protocols or alter results in order to get the ''right'' answer that will please the commercial entity with which the facility is associated.

We acknowledge that it is possible that an accredited facility could attempt to provide inaccurate information to an inspector in order to secure a phytosanitary certificate. However, given the investment of time, money, and other resources that becoming accredited would require, we do not believe that an accredited facility would risk having its accreditation withdrawn by falsely certifying that a specific test or inspection had been conducted and its results faithfully reported.

Falsified test or inspection results can be detected by inspectors conducting post-accreditation reviews or audits of facilities or through random checks by certifying officials of plants or plant products for which a phytosanitary certificate is sought. Under § 353.8(b)(4), facilities must agree to be periodically assessed and evaluated by means of proficiency testing or check samples in order to retain accreditation. Further, the tests or inspections that accredited facilities will perform are for pests or diseases that are likely to manifest themselves at some point. Presumably, an importing country is asking for a phytosanitary certificate because a certain pest or disease that may be present in the United States does not exist or is not widely prevalent in that importing country; if the pest or disease is detected in the importing country following the receipt of a shipment certified on the basis of falsified test results, it is likely that the pest or disease will be traced to that shipment. If it can be confirmed that the exporting company, through its accredited facility, used false test results to obtain a phytosanitary certificate, several consequences are possible: The facility's accreditation could be withdrawn, the facility or its parent company could be subject to civil or even criminal penalties in the United States or the importing country, and the parent company would likely lose the trust—and the business—of its customers. We believe that the likelihood of detection and the consequences associated with falsifying results will serve as a deterrent in those cases where such deterrence is necessary.

Composition of Assessment Teams

One commenter asked if competitors of a facility seeking accreditation would be involved in a facility's pre-accreditation assessment. The commenter stated that such participation would be inappropriate because the assessment team members must be completely impartial and assess the facility on the standards established by the rule without any appearance of bias. Another commenter asked if State plant regulatory agencies would be involved in the pre-accreditation assessment process and post-accreditation activities.

We do not anticipate that we will seek the participation of operators or employees of commercial laboratories or inspection services in the pre-accreditation assessment process. We do expect that there will be instances when we will seek the formal assistance of our cooperators in State plant regulatory agencies in the pre-accreditation assessment process or in post-accreditation facility visits and reviews. In addition, we would welcome the participation of our State cooperators in any accreditation activities being conducted in their respective States.

Post-Accreditation Supervision

One commenter stated that his organization could support the concept of accreditation only if APHIS maintained continuous, day-to-day oversight of the program through the appointment of an accreditation manager who would administer the application procedures and audits, arrange for proficiency testing, develop and provide training for seed health tests and field inspection procedures, issue accreditation credentials, maintain accreditation records, and establish

standard tests for laboratory and field inspection procedures.

The need for program management such as that described by the commenter was recognized by APHIS at the time the proposed rule was being prepared, so there are already plans to appoint an accreditation manager within APHIS' Plant Protection and Quarantine program to perform the tasks identified by the commenter.

Another commenter questioned whether APHIS had sufficient staff to implement and adequately monitor the accreditation program. The commenter stated that there are universities and State departments of agriculture that could serve as accreditors to more efficiently perform the actual accreditation work for APHIS; APHIS' role could be purely administrative, with the bulk of operational work being accomplished by the State-level accreditors.

As noted above, an accreditation manager will be appointed in APHIS to oversee the program's operation. We anticipate that the accreditation manager will work closely with the export certification program's traditional cooperators at the State and county level, relying on them for advice and assistance with regard to accreditation activities in their geographic area or within their realm of expertise. As with other aspects of the program, the extent to which State cooperators will become involved in accreditation-related activities will depend largely on demand for accreditation and the number of facilities that become accredited.

One commenter had several questions regarding post-accreditation supervision of facilities: What will be the frequency of post-accreditation audits or inspections? Will State plant regulatory agencies be able to request an audit or inspection if an irregularity is noted or a complaint is received? Will State plant regulatory agencies be notified of the results of those audits or inspections?

The frequency of post-accreditation audits and inspections will be determined, at least in part, by the type of service a facility becomes accredited to perform. The performance of field inspections and even some types of laboratory testing will be subject to seasonal changes and other variables, so it would be difficult to prescribe a universal audit schedule as part of this final rule. Thus, the frequency of post-accreditation audits and inspections for a particular area of accreditation will be determined at the same time the specific standards for accreditation in that area are developed.

We would encourage State plant regulatory agencies, as well as other entities that have dealings with an accredited facility, to report any observed deficiencies or irregularities in an accredited facility to the APHIS accreditation manager or to an inspector. APHIS will review all reports received and, as appropriate, will perform an inspection or audit in order to resolve any issues that arise regarding accredited facilities. As cooperators in APHIS' phytosanitary export certification program, State plant regulatory agencies will be kept informed of developments in the program, including those related to accredited facilities.

One other commenter was concerned that the quality of inspection could suffer under an accreditation plan. Although he offered no specific examples, the commenter stated that in some situations where self-inspection has been performed, quality problems such as overlooking specific infestations or diseases have manifested themselves. If the quality of inspection is reduced or is unacceptable to an importing country, the commenter concluded, the U.S. phytosanitary inspection system as a whole may come under scrutiny.

We agree with the commenter's assertion that the quality of inspection must be maintained to ensure the continued confidence of our trading partners. We believe that the accreditation program provided for by this final rule, with its focus on standards and required levels of performance, will preserve—and even enhance—the quality and credibility of the U.S. phytosanitary certification program.

Issuance of Certificates

One commenter asked if accredited facilities would apply to APHIS or to State cooperators for export certificates and, if application for a certificate was made to a State cooperator, whether the State cooperator would be required to issue a certificate.

The regulations in § 353.7 state that phytosanitary certificates are signed and issued by inspectors; an inspector, as defined in § 353.1, could be either an APHIS employee or a State or county plant regulatory official designated by the Secretary of Agriculture to inspect and certify to shippers and other interested parties as to the phytosanitary condition of plant products. Any shipment offered for certification that meets the requirements of the importing country and is in compliance with the regulations is expected to be certified; to do otherwise would be a disservice to—and likely challenged by—those individuals seeking a certificate.

On a similar note, a commenter from a county agricultural agency stated that she was concerned about the possibility of placing the county in a position of greater liability if she had to issue a phytosanitary certificate based on laboratory analysis or field inspections completed by a private company rather than a public agency.

No liability should attach to a certifying official as long as the certification is made in accordance with the regulations. The certifying statement on the phytosanitary certificate states that ''This is to certify that the plants or plant products described below have been inspected according to appropriate procedures and are considered free from quarantine pests * * *'' Using test or inspection results provided by an accredited facility is an appropriate and defensible procedure.

Costs of Accreditation

Several commenters were opposed to the provisions of the proposed rule that would require the operator of a facility seeking accreditation to enter into a trust fund agreement with APHIS prior to accreditation. Several commenters stated that private entities need to know in advance what the costs associated with the accreditation process will be in order to be able to accurately calculate all costs and benefits of the system. The commenters further stated that the failure to accurately calculate all costs of accreditation, at all levels of administration, could lead to an accreditation system that is not viable, cost effective, or competitive in delivering phytosanitary certification services. The commenters suggested that the trust fund requirement apply only to entities that have not completed the necessary cost analyses for implementing an accreditation scheme for their constituents, or for entities that have not established a cash reserve to cover the startup and long-term administration costs of accreditation.

Given the tenor of those comments, it appears that the purpose and scope of the trust fund agreement may not have been fully explained in the proposed rule. We do not intend for the trust fund to be a single pool of money funded by a particular industry segment from which APHIS will draw to fund its activities in a certain area of accreditation. Associations representing certain industry sectors may certainly play a role in helping to develop accreditation standards that will be applied to facilities within their industry, but when it comes to the actual accreditation of facilities, those

facilities will individually enter into trust fund agreements with APHIS to cover the costs of their accreditation.

Under a trust fund agreement, APHIS will, in advance, provide the facility's operator with an estimate of the costs it expects to incur through its involvement in the pre-accreditation assessment process. As particular standards are developed, we will be better able to forecast that cost and the costs of the maintenance of the facility's accreditation. The operator of the facility would then deposit a certified or cashier's check with APHIS for the amount of the estimated costs, and the pre-accreditation assessment process would begin. If the deposit is not sufficient to meet all costs incurred by APHIS, the facility operator, under the terms of the trust fund agreement, would deposit another certified or cashier's check with APHIS for the amount of the remaining costs before APHIS' services would be completed. After a final audit at the conclusion of the pre-accreditation assessment, any overpayment of funds would 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.

Because this is a new program, we cannot say with certainty what all the costs will be and whether this trust fund agreement process will be the best way of handling the recovery of the costs of our participation in the accreditation process. Trust fund agreements have been used successfully in other APHIS programs, and we believe that they will be useful in this accreditation program. However, if the agreement process proves unwieldy or unworkable, we will propose to amend the regulations to modify the way in which APHIS recovers its costs.

Costs of Services

One commenter was concerned that APHIS' intention to recover all costs associated with its administration of the accreditation program would result in fees that would be so high that they would render the program infeasible.

As explained in the proposed rule, the administrative expenses that we expect to incur and recover will be for items such as laboratory fees for evaluating check test results and all salaries, travel expenses, and other incidental expenses incurred by APHIS in performing the pre-accreditation assessment. As long as we could determine that it would be feasible and practical to establish an accreditation program in a particular area to begin with, we do not expect that costs related to those activities would be prohibitive. To make that consideration clear, we have amended § 353.8(b)(1) in this final rule to provide that APHIS will make a determination regarding the practicality of establishing an accreditation program in a particular area before beginning the process of developing the standards that would be applicable to accreditation in that area. Further, participation in the accreditation program will be voluntary, and an estimate of costs will be provided to each applicant before APHIS begins any accreditation-related activities, so there will be ample opportunity for the applicant to consider whether accreditation will be desirable from a cost perspective.

One commenter stated that the services of accredited facilities could become very expensive for industry if private entities providing services charged enough to cover their expenses. The commenter concluded that because some State agencies charge less than what is actually necessary to cover their expenses, the fees charged by private facilities will likely exceed the fees charged by government facilities. Although it is possible that an accredited entity could charge a higher fee than a public agency, a customer may still choose to use the accredited entity's services if the customer receives an added benefit such as faster reporting of results. However, if an accredited entity charges fees that are perceived to be too high by prospective customers, it is likely that those customers would take their business elsewhere, i.e., to a government facility or other accredited facility. Private entities providing inspection or testing services will be subject to the same market forces as any other entity providing services and will have to maintain a competitive fee schedule to remain in business.

Standards for Field Inspection

One commenter agreed that the four major accreditation assessment areas (physical plant, equipment, methods of testing or inspection, and personnel) were appropriate, but stated that quality control is more problematic regarding the accreditation of field inspectors. The commenter noted that an accreditor cannot place a diseased or infested plant in a field as part of a pre-accreditation assessment to see if it is detected and reported. The commenter concluded by stating that special attention must be given to the need for credible assessment mechanisms when standards are set for accrediting private entities to perform field inspections.

We acknowledge that assessing proficiency in the area of field inspection may prove to be more of a challenge than assessing proficiency in the somewhat more easily quantifiable area of laboratory testing. The development of specific standards for accreditation to conduct field inspections (as well as all other specific standards) will be a collaborative process, as APHIS will seek the input, cooperation, and comments of industry, academic, government, or other personnel with expertise or interest in the areas that will be assessed. We are confident that this collaborative process will result in field inspection accreditation standards that will provide an accurate assessment of an individual or entity seeking accreditation in that area.

Withdrawal or Denial of Accreditation

One commenter was concerned that the 10 days that would be provided for the operator of a facility to appeal a denial or withdrawal of accreditation would not allow enough time to develop an adequate appeal. The commenter stated that 30 days should be provided to file an appeal, and that the Administrator's decision regarding an appeal should also be made within 30 days, rather than the proposed ''as promptly as circumstances permit.''

We do not believe that it is necessary to extend the time for a person to submit an appeal. To appeal a denial, the operator must provide the reasons why he or she believes that accreditation was wrongfully denied; to appeal a withdrawal, the operator must provide all of the facts and reasons upon which he or she relies to show that the reasons for the proposed withdrawal are incorrect or do not support the withdrawal. Because APHIS will inform the operator of all of the reasons on which it based its denial or withdrawal of accreditation, and the appeal is, in essence, the operator's specific response to each of those stated reasons, we believe that 10 days is a sufficient amount of time for an operator to prepare an appeal. Although the Administrator will, in most cases, be able to respond to an appeal in less than the 30-day limit suggested by the commenter, we have retained ''as promptly as circumstances permit'' as the time frame for the Administrator's decision so as not to limit our ability to investigate or review the circumstances surrounding a withdrawal or denial in light of the information provided in the appeal.

Two other commenters were concerned about the length of time that could potentially pass before the withdrawal of a facility's accreditation became effective due to the proposed provisions for the operator to appeal the withdrawal. Both commenters stated

that allowing an accredited entity to continue to perform phytosanitary work while an appeal was filed and heard could result in the issuance of additional invalid phytosanitary certificates. One of those commenters further stated that the proposed provision for immediate withdrawal to protect ''public health, interest, or safety'' constituted a high legal standard that might be easily and often challenged.

As noted by one of the commenters, the regulations will provide for the withdrawal of a facility's accreditation to become effective immediately when the Administrator determines that an immediate withdrawal action is necessary to protect the public health, interest, or safety. The withdrawal will be effective upon oral or written notification, whichever is earlier, to the operator of the facility and will continue in effect pending the completion of the proceeding, and any judicial review of the proceeding, unless otherwise ordered by the Administrator. Because a credible phytosanitary export certification program, which greatly facilitates U.S. export trade in plants and plant products, is clearly in the public interest, we believe that we can justify the immediate withdrawal of a facility's accreditation when circumstances warrant.

Accreditation of Government Facilities

Several commenters discussed the apparent disparity between the requirements for government and non-government facilities, each making an argument for a different degree of uniformity between the public and private facilities. One commenter stated that APHIS should provide government facilities with copies of the standards and procedures and minimum recordkeeping guidelines, and should provide training in the standards at no charge to the government facility as part of the cooperative agreement between APHIS and the States. A second commenter stated that APHIS should require all entities, both government and non-government, to conduct their diagnostic tests or field inspections in accordance with the standards and procedures. A third commenter suggested that government facilities should be able to become accredited if they choose to do so, while a fourth commenter stated that accreditation should be required for both government and non-government facilities. Another commenter stated that the draft North American Plant Protection Organization (NAPPO) accreditation standards mentioned in the proposed rule clearly state that all personnel carrying out the same phytosanitary certification inspection functions, be they government or non-government personnel, must meet the same standards, so government facilities should be required to be accredited. All of these commenters cited the need for standard testing and inspection protocols and warned that failure to provide for coordination in that area could result in discrepancies in the U.S. phytosanitary certification system and a subsequent erosion in the confidence of importing countries with regard to that system.

The accreditation provided for by the final rule is, in essence, the means by which APHIS can approve a non-government facility to perform, in an official capacity, the same tests or inspections that Federal and State laboratories and personnel currently perform in support of the phytosanitary export certification program. As such, there is no reason to require facilities operated by a State or other governmental entity to become accredited. That being said, we do agree with those commenters who have pointed out the need for standardization and uniformity in phytosanitary testing and inspection. When developing specific standards for a particular area of accreditation, we will solicit and encourage the participation of all interested parties in the public and private sectors and academia, and we expect the resulting standards will reflect the best available science, processes, and methods. Once completed, those standards will be used not only to evaluate facilities seeking accreditation, but will be distributed to Federal and State facilities performing phytosanitary certification work to ensure that they are using the best available science, processes, and methods.

Promulgation of Standards

Several commenters were concerned that the specific standards for accreditation would be subject to notice and comment rulemaking after they had been developed and before they could be applied to the accreditation of non-government facilities. These commenters stated that having to publish standards in the **Federal Register** would result in delays that would have a negative effect on the entire accreditation program. Most of these commenters stated that APHIS must make a clear distinction between those standards that would require publication in the **Federal Register** and those that would not, suggesting that basic, generally applicable standards might be promulgated through rulemaking, while items with more limited applicability, such as the protocols for a specific test, could be made available as part of the guidelines that apply to a specific area of accreditation.

We recognize the commenters' concerns and agree that the development and promulgation of specific standards must be accomplished in a manner that will allow the program to grow and adapt to new technologies without undue process-driven delays. At the same time, however, we must balance that desire for responsiveness and flexibility with the need for program standards that are enforceable and that have been developed with the necessary level of public participation. Because this final rule only makes specific accreditation programs possible and does not itself contain any specific standards, it is difficult to conclusively define what will and will not be included when standards are published. As an example, an accreditation standard might call for a particular test to be performed; while the type and purpose of the test will be published with the criteria for interpreting test results and other aspects of the standard, the detailed instructions and protocols for conducting the actual test itself would not necessarily have to be published. Our goal is to develop and promulgate standards in a manner that will allow the process to be responsive and flexible while ensuring that the standards themselves are fair and enforceable.

Use of Subcontractors

Four of the commenters were concerned about the provisions of the proposed rule that would allow the use of subcontractors by accredited facilities. One comment, from a foreign agricultural agency, stated that his agency viewed the use of subcontractors as a further delegation by APHIS of its phytosanitary certification duties. The commenter closed by saying that APHIS must negotiate such delegations with its foreign counterparts before proceeding with allowing the use of contractors. The second commenter noted that although the proposed rule would provide for a review of a subcontractor's qualifications, there are no limits placed on the services the subcontractor could provide. The commenter was concerned that an accredited facility might use a subcontractor to, for example, entirely conduct a test that the facility had been accredited to conduct. The commenter also pointed out that the proposed rule did not prohibit a subcontractor to itself use a subcontractor. The third commenter was concerned that an

accredited facility that was facing the withdrawal of its accreditation might attempt to shift the blame for their shortcomings to a subcontractor and simply fire one subcontractor and hire another in an effort to retain accreditation. The fourth commenter stated that allowing the use of subcontractors by accredited facilities would make it very difficult to maintain program credibility and would allow for too much extended liability.

We believe that all four of the commenters have made valid points that bring into question the advisability of allowing accredited facilities to use subcontractors. Therefore, in this final rule, we have eliminated the reference to the use of subcontractors that had been in § 353.8(b)(3)(iv) of the proposed rule.

Use of International Standards

Two of the commenters recommended that APHIS utilize private sector accreditation services for government and non-government laboratories. These commenters stated that accrediting laboratories in accordance with the International Standards Organization's (ISO's) internationally recognized ISO Guide 25 would be a more reasonable and less burdensome approach to accreditation and would be more easily recognized internationally. One commenter noted that other Federal agencies accept third-party laboratory accreditation in areas such as environmental lead and asbestos or electromagnetic compatibility testing. Additionally, that commenter stated, Public Law 104–113 mandates the utilization of private sector laboratory accreditation services.

As explained above in the response to a previous comment, the accreditation program provided by this final rule is a way for APHIS to approve a non-government facility to perform tests or inspections in support of the phytosanitary export certification program. The program is not intended as, nor has it been presented as, a full-blown laboratory evaluation and accreditation program such as those provided under the auspices of the ISO. The underlying principles of ISO certification, such as quality documentation and accountability, certainly will be applied when specific standards are developed, but we do not believe that it is necessary for a non-government facility to receive ISO 25 certification before it can perform testing or inspection services under the phytosanitary export certification program.

Qualifications

One commenter asked what the minimum qualifications for the accreditation of these private phytosanitary services would be, and how and when the standards would be established. Two other commenters stated that the minimum qualifications for accredited inspectors must be established and should be at least equal to the minimum qualifications required of county, State, or Federal inspectors.

Specific qualifications for personnel involved in any particular area of accreditation are not within the scope of this final rule. As discussed in the proposed rule, personnel standards are one of the areas in which non-government facilities will be assessed and will, therefore, be one of the areas for which specific standards will be developed. Generally speaking, the qualifications of employees of non-government facilities will be similar to those of government laboratory personnel and inspectors. The draft NAPPO standard for accreditation mentioned in the proposed rule states that accredited personnel should not be held to standards that are higher than those for government personnel, a concept with which we agree.

Availability of Information

Two of the commenters wanted to know if the information generated by accredited facilities in the course of their inspection or testing activities would be available for review by APHIS or its State cooperators. One of the commenters stated such data must be available for review to ensure the validity of the testing process. The other commenter stated that because State plant regulatory agencies are cooperators with APHIS in both pest detection and export commodity certification, it is essential that States have access to such information in order to maintain the credibility of their own activities in those areas.

As standards are developed for specific areas of accreditation, we will ensure that recordkeeping is addressed in a manner appropriate to each area of accreditation. In general, we expect to require that records related to a facility's area of accreditation be made available to APHIS during the pre-accreditation assessment and during subsequent post-accreditation reviews or audits. Similarly, the specific standards will include, as appropriate, provisions for each accredited facility to report pests and diseases to APHIS or the State plant health agency for further action.

Notification of Changes

Two commenters noted that the proposed regulations call for a facility to notify APHIS ''as soon as circumstances permit'' when there is a change in key management personnel or facility staff, or when there is a change involving the location, ownership, physical plant, equipment, or relevant conditions at the plant. Both commenters stated that ''as soon as circumstances permit'' was too vague a time frame given the potential importance of such changes. One of those commenters suggested that a facility should be required to notify APHIS within 48 hours of such changes, while the other recommended that notice be given to APHIS within 10 days. We agree with the commenters that a more concrete time frame for notification is desirable given the potential impact of such changes, so we have amended paragraphs (b)(4)(v) and (b)(4)(vi) of § 353.8 to require the operator of a facility to notify APHIS as soon as possible, but no more than 10 days following its occurrence, of any change in the elements set forth in those paragraphs.

Therefore, based on the rationale set forth in the proposed rule and in this document, we are adopting the provisions of the proposal 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 significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

This rule amends the export certification regulations to provide for the establishment of a program under which non-government facilities may become accredited to perform specific laboratory testing or phytosanitary inspection services that could serve as the basis for the issuance of Federal phytosanitary certificates, phytosanitary certificates for reexport, or export certificates for processed plant products. The accreditation criteria for particular laboratory testing and phytosanitary inspection services will be developed by APHIS in cooperation with other interested individuals or government, industry, academic, or research entities. As specific accreditation criteria are developed, the accreditation program will provide a mechanism for qualified non-government facilities to become accredited to perform testing or inspection services that may be used as supporting documentation for the

issuance of certificates for certain plants or plant products.

The regulations in this rule are intended only to provide a framework upon which accreditation programs for specific functions may be established, so they will not, in and of themselves, entail any costs to APHIS or any non-government facility. However, any specific accreditation program that is established under these regulations will entail costs to both the entities being accredited and the accrediting body, i.e., APHIS. Because the accreditation program is expected to be self-supporting, the costs to APHIS will be recouped through accreditation fees. The fees charged by APHIS in connection with the initial accreditation of a non-government facility and the maintenance of that accreditation will, therefore, have to be adequate to recover the costs incurred by the government in the course of APHIS' accreditation activities. We expect that the costs that will be reimbursed will be largely attributable to the cost of transportation for the assessors to travel to the site of the facility, lodging for the assessors, their salary and per diem, any laboratory fees charged for evaluating check test results, and administrative expenses. Costs for specific accreditation programs will vary depending on the range of activities for which a facility seeks accreditation, the number of assessors needed to adequately conduct a 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.

The regulations stipulate that APHIS will provide an estimate of its anticipated fees to the operator of the facility prior to undertaking any activities that will result in fees being charged to a facility. Participation in any accreditation program developed under these regulations will be voluntary. At this time, we estimate that 15 individual non-government facilities are likely to seek and maintain accreditation annually on about 82 accredited procedures, as long as the costs of participating in an accreditation program are lower than the benefits they receive from the program. As a result, this program will have to meet the test of the marketplace.

The domestic seed industry, through the American Seed Trade Association, has indicated its interest in establishing an accreditation program for seed health testing and field inspection of seed, so we have used the domestic seed industry to illustrate the potential benefits that may result from the establishment of specific accreditation programs.

The seed industry is expected to benefit from the establishment of an accreditation program 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 projected for 1996–97. There has been a concomitant rise in demand for laboratory testing and phytosanitary 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 non-government facilities would have prevented the loss of export sales.

For example, some seed export opportunities have been forfeited because the results of pre-harvest field inspections are usually not known until after harvest. It is common for seed from several fields to be blended 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 non-government inspection facilities may be able to make such timely reports. In general, non-government testing and inspection services are expected to be completed with minimal delay, leading to greater marketing flexibility and lower risk of lost sales.

Additional benefits, of even greater potential significance, can be gained through the standardization of testing and inspection protocols that will result from the establishment of accreditation standards, particularly when internationally recognized standards are used. Major seed trading partners of the United States, such as Canada, France, and The Netherlands, have national seed health organizations that address seed health issues in part by employing laboratory accreditation protocols. The standards that will underlie the accreditation of non-government facilities in the United States can help reduce the differences among international phytosanitary regulations, thereby expediting U.S. seed exports.

Accreditation of non-government facilities, by promoting more streamlined exports based on internationally recognized standards, can also be expected to benefit exports outside of the seed industry. As a self-supporting system, private firms that expect benefits in excess of costs of accreditation are likely to participate. In addition to the net benefits received by these firms directly, society as a whole will benefit from enhanced trade.

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

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0130.

Regulatory Reform

This action is part of the President's Regulatory Reform Initiative, which, among other things, directs agencies to remove obsolete and unnecessary regulations and to find less burdensome ways to achieve regulatory goals.

List of Subjects in 7 CFR Part 353

Exports, Plant diseases and pests, Reporting and recordkeeping requirements.

Accordingly, we are amending 7 CFR part 353 as follows:

PART 353—EXPORT CERTIFICATION

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

Authority: 7 U.S.C. 147a; 21 U.S.C. 136 and 136a; 44 U.S.C. 35; 7 CFR 2.22, 2.80, and 371.2(c).

2. In § 353.1, a definition of *non-government facility* is added, in alphabetical order, to read as follows:

§ 353.1 Definitions.

* * * * *

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

* * * * *

3. In § 353.7, paragraphs (a)(4), (b)(4), and (c)(4) are each amended by adding a new sentence at the end of each paragraph to read as follows:

§ 353.7 Certificates.

(a) * * *

(4) * * * The Administrator may also authorize inspectors to issue a certificate on the basis of a laboratory test or an inspection performed by a non-government facility accredited in accordance with § 353.8.

* * * * *

(b) * * *

(4) * * * The Administrator may also authorize inspectors to issue a certificate on the basis of a laboratory test or an inspection performed by a non-government facility accredited in accordance with § 353.8.

* * * * *

(c) * * *

(4) * * * The Administrator may also authorize inspectors to issue a certificate on the basis of a laboratory test or an inspection performed by a non-government facility accredited in accordance with § 353.8.

* * * * *

4. A new § 353.8 is added to read as follows:

§ 353.8 Accreditation of non-government facilities.

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

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

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

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

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

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

[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.

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.

Done in Washington, DC, this 5th day of January 1999.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–07–AD; Amendment 39–10978; AD 99–01–13]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A319, A320, and A321 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.