220, south of Columbus, NE, was not required for aircraft operations and should be deleted from the National Airspace System. On January 25, 1999, the FAA proposed to amend 14 CFR part 71 to realign V–220 in the vicinity of Columbus, NE (64 FR 3664).

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments were received. Except for editorial changes, this amendment is the same as that proposed in the notice.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) realigns V–220 in the vicinity of Columbus, NE. the FAA is taking this action to enhance the management of air traffic operations, and allow for better utilization of navigable airspace in the vicinity of the Columbus, NE, area.

Domestic VOR Federal airways are published in section 6010(a) of the FAA Order 7400.9F dated September 10, 1998, and effective September 16, 1998, which is incorporated by reference in 14 CFR 71.1. The Federal airway listed in this document will be published subsequently in the order.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a significant regulatory action'' under Executive order 12866; (2) is not a significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E, AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

Paragraph 6010(a)—Domestic VOR Federal Airways

* * * * * *

V–220 [Revised]

From Grand Junction, CO: INT Grand Junction 075° and Rifle, CO, 163° radials; Rifle; Meeker, CO: Hayden, CO: Kremmling, CO; INT Kremmling 081° and Gill, CO, 234° radials; Gill; Akron, CO: INT Akron 094° and McCook, NE, 264° radials; McCook; INT McCook 072° and Grand Island, NE, 241° radials; Kearney, NE; Hastings, NE; Columbus, NE.

* * * * * *

Issued in Washington, DC, on August 25, 1999.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 99–23156 Filed 9–3–99; 8:45 am]

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DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 113, 151, and 178

[T.D. 99–67]

RIN 1515–AB60

Accreditation of Commercial Testing Laboratories; Approval of Commercial Gaugers

AGENCY: Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations relating to the commercial testing and gauging of imported merchandise, pursuant to Customs modernization provisions of the North American Free Trade Agreement Implementation Act. The regulations revise the general procedures for the accreditation/reaccreditation of commercial laboratories, the approval/reapproval of commercial gaugers, and the suspension and revocation of such accreditations/approvals. Further, the regulations provide that Customs will charge such laboratories/gaugers to accredit/approve and periodically reaccredit/reapprove their commercial services pursuant to a reimbursable fee schedule, and make provision for the imposition of monetary penalties for failure to adhere to any of the provisions applicable to the examination, sampling, and testing, or gauging of imported merchandise.

EFFECTIVE DATE: October 7, 1999.

FOR FURTHER INFORMATION CONTACT: Ira Reese, Laboratories and Scientific Services, (202) 927–1060; or Marcelino Borges, Laboratories and Scientific Services, (202) 927–1137.

SUPPLEMENTARY INFORMATION:

Background

On December 8, 1993, the United States enacted the North American Free Trade Agreement Implementation Act (the Act), Pub.L. 103–182, 107 Stat. 2057. Title VI of the Act contains provisions pertaining to Customs Modernization (107 Stat. 2170); section 613 of Subtitle A to Title VI amends section 499 of the Tariff Act of 1930 (19 U.S.C. 1499), which provides Customs with the authority to conduct examinations and detain imported merchandise.

The Commercial Laboratory/Gauger Testing Provisions of Section 613

The provisions of section 613, among other things, codified Customs regulations and administrative guidelines concerning the use of commercial laboratories and gaugers by adding a new paragraph (b) to section 499 (19 U.S.C. 1499(b)). Regarding the accreditation/approval aspects of commercial laboratories/gaugers, the provisions of new paragraph (b) authorize Customs to:

(1) set procedures for the accreditation of commercial laboratories in the United States, which may be used to perform tests relating to the admissibility, quantity, composition, or characteristics of imported merchandise, and the approval of commercial gaugers in the United States, which may be used to perform tests to establish the quantities of imported merchandise;

(2) impose reasonable charges for such accreditations/approvals and periodic reaccreditations/reapprovals; and

(3) establish the conditions regarding the suspension and revocation of such accreditations and approvals, which may include the imposition of monetary

penalties not to exceed $100,000, in addition to penalties for any loss of revenue, in appropriate cases.

Regarding the testing/gauging aspects of commercial laboratories/gaugers, new paragraph (b) further provides that:

(1) in the absence of Customs testing, Customs will accept analysis and quantity results from Customs-accredited laboratories and Customs-approved gaugers; however, this circumstance does not limit or otherwise preclude Customs or any other Federal agency from independently testing, analyzing, or quantifying any sample or merchandise;

(2) testing procedures and methodologies will be made available upon request to any person, except when they are proprietary to the holder of a copyright or patent or developed by Customs for enforcement purposes; information resulting from any Customs testing will be made available to the importer of record and any agents thereof, except when the information meets the above specified exclusions from disclosure; and

(3) laboratories/gaugers may seek judicial review of any final Customs decision that adversely affects their accreditation/approval, *i.e.*, denial, suspension, or revocation, or that imposes a monetary penalty, by commencing an action within 60 days of such decision in the Court of International Trade.

New paragraph (b) (set forth as a note to 19 U.S.C. 1499) also provides that commercial laboratories/gaugers that had already been accredited/approved by Customs may continue the accredited/approved activities without having to seek accreditation/approval under the new statute but that such facilities are subject to the new statutory and regulatory requirements for reaccreditation/reapproval.

On June 9, 1998, Customs published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (63 FR 31385) that proposed to amend the Customs Regulations relating to the commercial testing and gauging of imported merchandise, pursuant to Customs modernization provisions of the North American Free Trade Agreement Implementation Act (19 U.S.C. 1499(b)), and solicited comments in these matters. The comment period closed August 10, 1998; seven comments were received. The comments and Customs responses are set forth below.

Analysis of Comments

Expansion of Program

Comment: Three commenters recommended against the expansion of the current program.

Customs Response: Prior to enactment of the Act, Customs regulations and administrative guidelines concerning the use of commercial laboratories and gaugers only allowed for the accreditation of commercial laboratories and the approval of commercial gaugers to perform selected tests on certain imported merchandise. The provisions of the Act authorizing the establishment of regulations pertaining to testing laboratories (19 U.S.C. 1499(b)) provide that accredited private laboratories may be used to perform tests ''that would otherwise be performed by Customs laboratories.'' Clearly, by this language Congress intended that the Customs laboratory accreditation program be extended to include the testing of many more products.

Accordingly, no change to the scope of the regulatory amendments will be made based on these comments.

Lack of Third-Party Accreditation/ Approval Entities

Comment: Two commenters, both independent accreditation bodies acknowledging Congress' intention in the Act to expand the existing commercial laboratory accreditation program, suggested that Customs could benefit from making use of existing accreditation programs and urged Customs to reconsider expansion of its program to rely on such programs. The commenters suggested that Customs shift from an ''administration'' role to an ''oversight'' role.

Customs Response: Customs is not against third-party accreditation. However, Customs believes it is best positioned to do the accrediting of laboratories in the expanded program. Although Customs may consider third-party accreditation in the future, we note that our current decision not to use a third-body accreditation organization is predicated on several factors including the following:

A. As a public organization, Customs can keep the program costs to a minimum while meeting all of our technical and law enforcement needs;

B. Customs has 20+ years experience in successfully running these types of programs; and

C. Customs interests and determinations go beyond those of other accrediting bodies, to include:

1. The financial independence of the laboratory/gauger;

2. Background investigations of the applicant;

3. Ability to do the extremely broad range of testing required by Customs; and

4. Ability to assist gaugers and laboratories using the Informed Compliance process.

To transfer these interests and concerns to a third body would require time and coordination with a third body organization that could be better used by Customs in the actual accreditation/ approval process.

Accordingly, no change to the regulatory amendments will be made based on these comments.

Methodology

Comment: One commenter expressed concern about Customs specifying which testing methods a laboratory can use and recommends industry input prior to the establishment of such testing requirements.

Customs Response: Although Customs has already approved certain testing methods and designated them for use in Commodity Group Brochures and the U.S. Customs Laboratory Methods Manual, if a laboratory seeking accreditation/reaccreditation believes that other testing methods are more appropriate than those testing methods designated by Customs, then, under the provisions of § 151.12(e), the laboratory can submit to the Executive Director with its application the testing method(s) it believes is more appropriate. Such alternative methods will be considered and approved on a case-by-case basis. (Note that this same latitude in designating approved measurement procedures is afforded gaugers in § 151.13(c).)

Since, as proposed, the regulations provide that commercial laboratories may seek approval of testing methods that they believe are appropriate, no change to the regulatory amendments will be made based on this comment. However, because the proposed laboratory regulations (the gauger regulations are not affected, see discussion below) did not reference the U.S. Customs Laboratory Methods Manual as a source containing testing methods approved by Customs, proposed § 151.12(a) is revised to include this reference as a source of appropriate testing methods and to note its availability on the Internet at Customs' Web Site, discussed below.

Burden of Five (5)-Day Notification in General; Notification of Equipment, etc. Changes in Particular

Comment: One commenter felt that the five (5)-day notification requirement

pertaining to changes in legal name, address, etc., was burdensome, especially for such items as staffing, equipment, and instruments, and suggested that Customs institute a semi-annual notification requirement.

Customs Response: Customs agrees that there is no need to require the reporting of ''managerial or professional or executive staff'' and ''facilities, instruments, or equipment, etc.'' and is removing that requirement by revising the provisions of proposed § 151.12(c)(6) (and the parallel provision for gaugers at § 151.13(b)(6)). However, Customs will retain the five (5)-day notification requirement pertaining to changes in legal name, address, etc., as these items are substantive changes that affect the accreditation/approval of the facility and Customs must be able to maintain accurate records.

Proficiency Training

Comment: One commenter, while supporting the need for proficiency testing, questioned the need for Customs to develop its own program. This commenter opined that industrial programs, such as the American Society for Testing and Materials (ASTM) Laboratory Cross Check Program, are already available, of proven effect and efficiency, and should be allowed to suffice.

Customs Response: Customs agrees with this observation and has revised the provisions of proposed § 151.12(f)(3)(ii) and (iii) (and the applicable provision for gaugers at § 151.13(d)(3)(i)) to modify the requirement that proficiency testing through check samples ''will'' be required to read ''may'' be required. This change will permit accredited/approved laboratories/gaugers to participate in proficiency test programs developed by recognized industrial organizations. A facility's level of proficiency, as determined by such programs, can then be considered by Customs when Customs evaluates the facility for purposes of reaccreditation/reapproval. However, this change will not preclude Customs from developing its own check program if Customs determines that such a program is necessary.

Excessive Fee Structure; Organizations With Multiple Locations

Comment: Three commenters expressed concern about the fees associated with the accreditation process for laboratories. Two of these commenters stated that variable costs appeared to be high, especially for background investigations, and one of these commenters inquired how large commercial laboratory organizations with multiple locations would be handled.

Customs Response: Regarding the fee structure, the provisions of the Act were promulgated at the request of industry with the understanding that Customs would be given the authority to recover non-personnel costs. The costs contained in these regulations are consistent with that authority and are Customs best estimates of expenses. These program costs will be reevaluated periodically to see if the assumptions upon which they are based are correct.

Customs has reviewed the fee structure of third-party accreditation bodies, as well as those of other federal and state agencies that have the authority to charge fees, and found that the fees proposed are significantly lower than third-party accreditations and lower than most public-sector run programs. Customs identified certain indeterminate costs as variable costs in an effort to keep these costs as low as possible to the laboratory/gauger.

Regarding organizations with multiple locations, each site within an organization can separately apply for accreditation/approval or all sites within an organization can be designated in a single application. The choice will be with the applicant; however, all applicable variable (for technical inspections) and fixed (for administration) costs associated with processing the application submitted will be assessed for each site designated for accreditation/approval. As stated in the *Background* portion of the NPRM concerning ''variable costs,'' Customs will endeavor to bundle these costs, which include background investigations, so that where these costs apply to more than one site, the costs will be fairly apportioned between applicants.

Accordingly, no change to the fee structure in the regulations will be made based on these comments.

Fee Structure Unfair to Small Entities

Comment: Three commenters objected to the fairness of the proposed fee structure as it will impact on very small laboratories and gaugers. These commenters argue that such gauger/laboratory facilities currently in the program should be exempt from any reapproval/reaccreditation fees because they will not see any benefit from the expansion. Further, these commenters argue that in order for an existing facility to ''expand'' its services, it will have to acquire expertise and equipment, both of which are expensive. These commenters conclude by stating that if Customs wants to recapture the expenses of an expanded program it should do so by charging those facilities that will benefit, and not those already in the program.

Customs Response: Customs is concerned about being fair to all parties in interest. However, paragraph (b) of section 613 of the Act mandates that while those laboratories/gaugers that were accredited/approved prior to December 8, 1993, need not reapply for initial accreditation/approval, such facilities will be subject to reaccreditation/reapproval under the applicable statute and implementing regulations. Accordingly, these grandfathered laboratory and gauger facilities are required to pay the fees that are associated with reaccreditation/reapproval.

Customs believes that the expansion of this program provides an opportunity for any laboratory to participate in the laboratory program on a level playing field. Any company will have the opportunity to look at their position and make a decision as to the degree to which it will participate in the laboratory program. Accordingly, Customs has structured the cost system to be commensurate with the level of laboratory participation in the program. The costs are being fairly leveled against all parties and will be reviewed annually to ensure that all costs are reasonable to the success of the program.

Accordingly, no change to the fee structure in the regulations will be made based on these comments.

Sample Retention Policy

Comment: One commenter stated that the one year sample retention period was too restrictive, and pointed out that special consideration should be made where the sample is perishable or hazardous. This commenter noted that typical storage retention periods in the inspection industry are from 45–90 days.

Customs Response: Regarding the one-year sample-retention period for non-perishable samples and remnants, Customs agrees that in the main this requirement may work a hardship on laboratories. Accordingly, Customs is lessening the retention period for non-perishable items to four months, unless the samples are the subject of litigation. Recently, Customs has authorized its own laboratories to shorten their sample-retention period from one year to four months, and believes that this same retention period could be allowed for commercial laboratories performing Customs testing services.

Regarding the subject of perishable samples, both in the *Background*

portion and the proposed *Amendments to the Regulations* portion of the NPRM (at § 151.12(j)(1)) it was stated that perishable samples and sample remnants could be disposed of more expeditiously, if done in accordance with acceptable laboratory procedures. With regard to hazardous materials, such samples are not considered comparable to perishable samples, and laboratories accredited to test such materials should know how to safely handle and store or dispose of these materials.

Accordingly, to make more clear that there is both a perishable goods and a non-perishable goods retention period, the provisions of proposed § 151.12(j)(1) are revised to separate the early disposal of perishable samples provision from the non-perishable samples provision. Further, the retention period for non-perishable goods is lessened from one year to four months, unless the merchandise sampled is the subject of litigation, in which case the laboratory will retain that sample merchandise until instructed by Customs that it can dispose of it.

Status of an Analysis Report Where Customs also Analyzes the Sample

Comment: One commenter questioned why an importer would use a commercial laboratory if Customs could also analyze shipments and simply ignore an accredited laboratory's report.

Customs Response: The Act provides that the establishment of a program for the accrediting/approving of commercial facilities to perform any of the functions currently performed by Customs facilities does not limit in any way or preclude Customs from independently testing or analyzing any sample or merchandise and basing administrative action upon Customs findings. For this reason, no change will be made to the regulations on this subject. However, Customs would like to make all concerned aware that Customs does not simply ignore the report of an accredited lab or an approved gauger in any situation. Where there is a contradiction between reports, Customs will review the situation in detail and if the report from the accredited lab or an approved gauger is found to be more accurate or controlling in the situation at hand, the Executive Director or his designee will authorize the use of the accredited lab or approved gauger report in lieu of Customs report.

Disclosure of Testing Procedures and Methods

Comment: One commenter stated that Customs should make the following two points clear concerning the disclosure/availability of testing procedures and methods:

(1) that the amount of laboratory analysis methods that cannot be released because of copyright/patent or law enforcement reasons is a very tiny fraction of Customs methods, and that all other methods, including methods to ascertain compliance with other agency requirements, etc., are available to the public at no charge; and

(2) that copies of U.S. Customs lab reports and worksheets are not subject to the Freedom of Information Act (FOIA), and that such lab reports are available free of charge and the associated worksheets are available for a flat fee of $ 10.

Customs Response: Regarding the commenter's first contention concerning the disclosure/availability of laboratory analysis methods, Customs generally agrees. Customs reiterates, however, that there are some laboratory analysis methods that are confidential because of enforcement concerns or because the methods are patented or copyrighted. Regarding the public availability of laboratory analysis methods at no charge, the commenter is correct. As indicated in the NPRM and previously in this document, a listing of the methods in the U.S. Customs Laboratory Methods Manual is available at the Customs Web Site on the Internet (www.customs.gov) and a description of those methods, i.e., those prepared by public sources such as Customs Laboratory personnel, will also be available at the Customs Web Site. But Customs points out that other methods that have been developed by private commercial organizations are not available from Customs. These other methods should be obtained directly from these commercial organizations.

Regarding the commenter's second contention concerning the free availability of U.S. Customs lab reports without resort to FOIA and the availability of associated worksheets for a flat fee without resort to the FOIA, Customs does release, free of charge, to the importer of record and their agents, including the customs broker, laboratory reports that do not include proprietary information or are not related to an investigation. While a FOIA request is not necessary, Customs still requires a written request from the importer of record or agent. When the requested Customs laboratory report is released, it does not include the report's associated worksheets or other supporting data.

Customs laboratory worksheets, including associated spectra, chromatograms, etc., if not containing proprietary or investigation-related information are also released by Customs upon written request by the importer of record and their agents, including the customs broker. However, Customs does assess a charge for this information based on the FOIA guidelines for the costs associated with searching and photocopying the requested materials. This material will not be released prior to the payment of all applicable fees.

No regulatory changes will be made based on these comments.

Subcontracting to another Customs-Accredited/Approved Site

Comment: Two commenters could not see the reason why one Customs-approved laboratory should not be able to subcontract to another Customs-approved laboratory. In this regard, one of these commenters inquired as what constituted subcontracting between companies owned or managed by the same parent organization (an issue visited briefly above under organizations with multiple locations).

Customs Response: Reconsidering this issue and reviewing the position contained in ASTM E548: Standard Guide for General Criteria Used for Evaluating Laboratory Competence (and Guide 25 of the International Organization for Standardization entitled General Requirements for the Competence of Calibration and Test Laboratories, a parallel publication; see discussion below), Customs agrees that subcontracting between Customs accredited/approved facilities should be allowed. Accordingly, the provisions of § 151.12(j)(5) (and the applicable gauger provisions at § 151.13(h)(4)) are revised to allow for subcontracting between Customs-accredited/approved facilities.

Limiting Gaugers Activities to Petroleum Products

Comment: One commenter inquired if the provisions of § 151.13(a) which state that commercial gaugers deal mainly with petroleum was meant to limit commercial gauger activities to just petroleum products.

Customs Response: No, this is not the case. Because gauging activities in general do include the measurement of animal and vegetable oils, as well as petroleum and petroleum products and bulk chemicals, proposed § 151.13(a) is revised to include these endeavors as well. Customs would like to clarify that through the application process, a gauger can list any area of gauging where a commercial activity may be feasible. Further, already approved gaugers can request expanded gauging opportunities at no additional cost to their reapproval.

Gauging Procedures

Comment: One commenter inquired when the Customs Commodity Group brochure dealing with gauging and measurement procedures would be published, so that he could review it.

Customs Response: The proposed regulatory text of § 151.13(c) providing for this was an error, as the definition of Commodity Group Brochure (provided at § 151.12(a)) clearly limits these booklets to laboratory testing procedures; Customs does not intend to prepare such a brochure for gauging activities. Accordingly, the regulatory text of proposed § 151.13(c) is revised to provide that approved gaugers must comply with appropriate procedures published by such organizations as the ASTM and the American Petroleum Institute (API), and other procedures approved in writing by the Executive Director.

Gauger Equipment Requirements in Closed-System Measurements

Comment: One commenter expressed industry concern about the equipment requirements contained at proposed § 151.13(d)(3)(ii)(A), which require that gaugers have all of the equipment and instruments needed to conduct approved services, as it relates to closed system measurement equipment. The commenter states that, unlike other aspects of the industry, there is no standardization of this equipment, even among different models made by the same manufacturer. The concern stems from the fact that many closed petroleum systems have unique piping and fittings that preclude a gauger from having all of the needed connectors to hook up a measurement system. The commenter feels that Customs should specify either minimum required equipment or fittings.

Customs Response: It is noted that the proposed regulations in this area are not different from the existing regulations under which the industry is currently operating, and no radical change is anticipated. Enumeration of minimum required equipment or fittings is not necessary because Customs allows this industry to establish its own requirements (this is another reason why there is no Commodity Group Brochure for gauging). Further, it should be noted that Customs works very positively with this industry, on a case-by-case basis, to permit the use of refinery or facility connectors when they are unique and unavailable to the general gauger industry. But where the situation becomes a routine responsibility of a gauger, Customs expects the gauger to own and calibrate all of the connectors and equipment that are added to a system in order to make the appropriate measurements.

Accordingly, no change to the regulations will be made based on this comment.

Notice of Proposed Assessment of Penalties

Comment: One commenter expressed concern that there was no notice or due process protection before the imposition of penalties, and argued that specific guidelines should be established so that variations in interpretation of these regulatory provisions at different ports could be avoided.

Customs Response: Regarding the due process rights of accredited laboratories/approved gaugers where penalties may be assessed, Customs agrees that advance notice (30 calendar days) of impending penalties should be clearly provided for in the regulations. Accordingly, the provisions of proposed §§ 151.12(k) (1) and (2) and 151.13(i) (1) and (2) are revised to clarify when notices of proposed penalties are issued and when final notices of penalties are issued.

Regarding the uniformity of the program, the fact that all decisions or orders imposing monetary penalties will be made by the Executive Director, Laboratories and Scientific Services, should ensure that the program will be administered in a uniform manner throughout the country. Further, Customs believes the appeal procedure provided for in the regulations enables affected laboratories/gaugers to challenge any decision of the Executive Director the facility believes to be unfair. The expanded program is designed to provide optimum uniformity with checks and balances at all decision points in order to protect the interests of the laboratory/gauger.

Penalties, Loss of Revenue, and Liquidated Damages

Comment: One commenter argued that Customs-accredited laboratories should not be subject to penalties, the recovery of ''lost'' revenue, and liquidated damages under the lab's bond, as the bond is a performance bond, not a revenue bond.

Customs Response: This comment concerns the provisions of § 151.12(k)(1)(iii), entitled ''Assessment of monetary penalties.'' Customs believes that, perhaps, it did not clearly communicate that there is a distinction between the basis for monetary penalties and the basis for liquidated damages. There is a statutory basis for liability for monetary penalties and any loss of revenue in cases of intentional falsification of data in collusion with the importer (19 U.S.C. 1499(b)(1)(B)(i)) and there is a contractual basis for liability under the provisions of the Customs bond for liquidated damages. Customs is revising the third sentences of proposed § 151.12(k)(1)(iii) for laboratories and § 151.13(i)(1)(iii) for gaugers to distinguish between penalties/loss of revenue and liquidated damages.

The Terms ''Current Approval'' and ''Future Regulation''

Comment: One commenter requested clarification of the difference between ''current approval'' and ''future regulation'' regarding reimbursable fees for accreditation/approval and periodic reaccreditation/reapproval.

Customs Response: The thrust of this comment is not clear; however, Customs will attempt to respond, based on the assumption that the comment pertains to already accredited/approved laboratories/gaugers. Both in the *Background* portion and the proposed *Amendments to the Regulations* portion of the Notice of Proposed Rulemaking at § 151.12(j)(1) it was stated that laboratories accredited and gaugers approved under Customs regulations prior to December 8, 1993 (the effective date of the Act) will not be required to pay applicable reaccreditation/reapproval fees until after the third year following the date these regulations become final. Thus, the new fees provided for in these regulations are not applicable to grandfathered laboratories/gaugers until their next scheduled inspection, based on their existing triennial inspection date.

To make this point as clear as possible, the provisions of proposed § 151.12(i) (and the parallel provision for gaugers at § 151.13(g)) are revised to state that accredited/approved facilities will have their status reevaluated on their next triennial inspection date which is no earlier than three years after the effective date of this regulation.

Small Business Administration

Comment: One commenter stated that there are many small businesses that will be impacted by the regulations and inquired if the Small Business Administration was notified of the proposed regulations.

Customs Response: Because Customs expects the number of accredited laboratories and approved gaugers to be small, Customs has certified that, if adopted, these regulations will not have a significant adverse economic impact on a substantial number of small entities. A statement to this effect was published in the NPRM. Customs has

not received any information during the comment period that would indicate any significant economic impact.

Movement of Goods in International Commerce

Comment: One commenter stated that the proposal failed to address that international business is done these days by the importers receiving ''confirmation'' and/or ''production'' samples of products before the shipments of the product are sent so that the importer is assured that what is being made and shipped is what was ordered per specifications. The apparent thrust of the comment goes to whether Customs labs will examine these ''confirmation'' or ''production'' samples rather than samples taken from part of the merchandise actually being imported.

Customs Response: As was stated in the *Background* portion of the NPRM, importers that choose to have merchandise tested by commercial facilities accredited/approved by Customs, must certify that the sample tested was taken from the merchandise in the entry, *i.e.*, from the importer's actual importations. Customs cannot allow for the testing of ''confirmation'' or ''production'' samples that are not in fact samples taken from part of the merchandise actually being imported. The Act clearly provides that the tests/measurements to be allowed by accredited/approved commercial facilities are those that will establish the admissibility, quantity, composition, or characteristics of imported merchandise, not merchandise that someday may be imported.

Accordingly, no change to the regulations will be made based on this comment.

Statement of Fee Schedule and a Clarification

The fee schedule set forth in the proposal is being adopted. The initial fixed fee schedules for accrediting/reaccrediting laboratories and approving/ reapproving gaugers are:

For Laboratories

General Accreditation Fee: $750
Additional Commodities Fee: $200
Laboratory Reaccreditation Fee: $375
Commodity Reaccreditation Fee: $150

For Gaugers

General Approval Fee: $400
Reapproval Fee: $200

The initial variable fee schedules for accrediting/reaccrediting laboratories and approving/reapproving gaugers are approximately $1,000 for travel per visit and $1,700 per background investigation.

Also, Customs wishes to note that laboratories/gaugers may be accredited/approved in Puerto Rico, as the United States is defined to include Puerto Rico, *see*, 19 CFR 101.1, ''Customs territory of the United States.''

Other Changes to the Regulations

In addition to the changes to the proposed regulatory text identified and discussed above in connection with the public comments, Customs has made numerous editorial, nonsubstantive changes to the proposed text (in most cases involving wording, parallel construction, punctuation, or structure) in order to enhance the clarity, readability, and application of the regulatory texts. An example of an editorial change involves the grounds for nonselection/suspension, revocation, or assessment of a monetary penalty in §§ 151.12(g)(2)(ii) and 151.13(e)(2)(ii), and §§ 151.12(k)(1)(ii)(B) and 151.13(i)(1)(ii)(B). Because of the common elements in these four provisions, the language in all these provisions is aligned for purposes of consistency. Several other changes are being made as well; they are summarized below.

Section 151.12(d)

Proposed § 151.12(d)(2) listed sixteen (16) commodity groups for which accreditation could be sought without special permission from the Executive Director. However, for ease of reference it has been decided to merge the commodity group of Wood and Articles of Wood with the commodity group of botanical identification. Accordingly, the final text of this section is revised to list only fifteen (15) commodity groups.

Section 151.12(f)

Proposed § 151.12(f)(3) provided that Customs evaluation of an applicant's professional abilities will be in accordance with the general criteria contained in the ASTM E548: Standard Guide for General Criteria Used for Evaluating Laboratory Competence. Because many Laboratories follow the ISO/IEC Guide 25—General Requirements for the Competence of Calibration and Testing Laboratories, the final text of § 151.12(f) is revised to include this publication as well.

Sections 151.12(j) and 151.13(h)

Proposed § 151.12(j)(3)(F) (and the parallel provision applicable to gaugers at proposed § 151.13(h)(2)(v)(F)) provided that reports must include the signature of the person accepting technical responsibility for the report. Because signatures are frequently illegible, Customs has decided to require the typed name of the person signing the report. Accordingly, these two provisions are revised to add the additional requirement of the typed name of the person signing the report.

Sections 151.13(c)

The proposed heading for § 151.13(c) denominated both gauging and measurement as procedures, which might cause some applicants to believe that there are two separate procedures. Accordingly, the reference to gauging is removed from the heading for this section.

Conclusion

After careful consideration of all the comments received and further review of the matter, Customs has decided to adopt the amendments to part 151 of the Customs Regulations as a final rule with the modifications and changes discussed above and as set forth below.

To reflect the paperwork requirements contained at §§ 151.12(f) and 151.13(d), part 178 of the Customs Regulations is revised to account for the separate application data required for laboratory accreditation and gauger approval.

The Regulatory Flexibility Act, and Executive Order 12866

Because the number of accredited laboratories and approved gaugers is expected to be small, pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is certified that the amendments will not have a significant adverse economic impact on a substantial number of small entities. Accordingly, the amendments are not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604. This amendment does not meet the criteria for a ''significant regulatory action'' as specified in Executive Order 12866.

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget (OMB) in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) under control number 1515–0155. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB.

The collections of information in this final rule are in §§ 151.12(e) and 151.13(c). The information is required so that Customs can make a determination as to which applicants

are competent to receive or maintain accreditation/approval credentials to test/measure imported merchandise. The information will be used to process those applications submitted for Customs accreditation/approval. The likely respondents are individuals and commercial organizations who either analyze merchandise or measure, gauge, or sample merchandise.

The estimated average burden associated with the collection of information in this final rule is five hours per respondent or recordkeeper. Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to the U.S. Customs Service, Information Services Group, Office of Finance, 1300 Pennsylvania Ave., N.W., Washington, D.C. 20229; and to OMB, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, D.C. 20503.

Drafting Information

The principal author of this document was Gregory R. Vilders, Attorney, Regulations Branch, Office of Regulations and Rulings. However, personnel from other offices participated in its development.

List of Subjects

19 CFR Part 113

Bonds, Customs duties and inspection, Exports, Freight, Imports, Reporting and recordkeeping requirements.

19 CFR Part 151

Administrative practice and procedure, Courts, Customs duties and inspection, Examination, Fees assessment, Gaugers, Imports, Laboratories, Licensing, Penalties, Reporting and recordkeeping requirements, Sampling and testing.

19 CFR Part 178

Administrative practice and procedure, Collections of information, Exports, Imports, Paperwork requirements, Reporting and recordkeeping requirements.

Amendments to the Regulations

For the reasons stated above, parts 113, 151, and 178 of the Customs Regulations (19 CFR parts 113, 151, and 178) are amended as set forth below:

PART 113—CUSTOMS BONDS

1. The general authority citation for part 113 continues to read as follows:

Authority: 19 U.S.C. 66, 1623, 1624.

* * * * *

§ 113.67 [Amended]

2. Section 113.67 is amended as follows:

a. Paragraph (a)(1)(ii) is amended by removing the words ''terms of the Commercial Gauger Agreement [see § 151.13(b)(9)] and by the''; and by removing the citations ''§§ 151.13 and 151.14'' and adding, in their place, the citation ''§ 151.13(b)''.

b. Paragraph (b)(1)(ii) is amended by removing the words ''terms of the Commercial Laboratory Agreement [see § 151.13(b)(9)] and by the''; and by removing the citation ''§ 151.13'' and adding, in its place, the citation ''§ 151.12(c)''.

PART 151—EXAMINATION, SAMPLING, AND TESTING OF MERCHANDISE

1. The general authority citation for part 151 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Notes 20 and 21, Harmonized Tariff Schedule of the United States (HTSUS)), 1624. Subpart A also issued under 19 U.S.C. 1499.

* * * * *

2. In subpart A, § 151.12 is added to read as follows:

§ 151.12 Accreditation of commercial laboratories.

This section sets forth the requirements for commercial laboratories to obtain accreditation by Customs for the testing of certain commodities, and explains the operation of such accredited laboratories. This section also provides for the imposition of accreditation and reaccreditation fees, sets forth grounds for the suspension and revocation of accreditation, and provides for the imposition of a monetary penalty for an accredited commercial laboratory that fails to adhere to the provisions of this section.

(a) *Definitions.* For purposes of this section, the following words and phrases have the meanings indicated:

Analysis record. An ''analysis record'' is a compilation of all documents which have been generated during the course of analysis of a particular sample which, under normal circumstances, may include, both in paper and electronic-form, such documents as work sheets, notes, associated spectra (both spectra of the actual product and any standard spectra used for comparison), photographs and microphotographs, and the laboratory report.

Assistant Commissioner. In §§ 151.12 and 151.13, references to the ''Assistant Commissioner'' mean the Assistant Commissioner, Office of Field Operations, located in Washington, D.C.

Check samples. ''Check samples'' are samples which have been distributed by Customs to accredited laboratories to test their proficiency in a certain area of accreditation.

Commodity Group Brochure. A ''Commodity Group Brochure'' is a booklet which contains a listing of laboratory methods which commercial laboratories are required to have the capability to perform to qualify for Customs-accreditation in a particular commodity group. The brochures and the U.S. Customs Laboratory Methods Manual will specify the particular laboratory testing methods required for particular commodity groups, unless written permission from the Executive Director is given to use an alternate method. Procedures required by the Executive Director may reference applicable general industry testing standards, published by such organizations as the American Society for Testing and Materials (ASTM) and the American Petroleum Institute (API). Commodity Group Brochures and a listing of the methods found in the U.S. Customs Laboratory Methods Manual are available from the U.S. Customs Service, Attention: Executive Director, Laboratories and Scientific Services, Washington, D.C. 20229 and can also be found on the Customs Internet Web Site: www.customs.gov.

Executive Director. In §§ 151.12 and 151.13, references to the ''Executive Director'' mean the Executive Director, Laboratories and Scientific Services, located in Washington, D.C.

(b) *What is a ''Customs-accredited laboratory''?* ''Commercial laboratories'' are individuals and commercial organizations that analyze merchandise, *i.e.,* determine its composition and/or characteristics, through laboratory analysis. A ''Customs-accredited laboratory'' is a commercial laboratory, within the United States, that has demonstrated, to the satisfaction of the Executive Director, pursuant to this section, the capability to perform analysis of certain commodities to determine elements relating to the admissibility, quantity, composition, or characteristics of imported merchandise. Customs accreditation extends only to the performance of such functions as are vested in, or delegated to, Customs.

(c) *What are the obligations of a Customs-accredited laboratory?* A commercial laboratory accredited by Customs agrees to the following conditions and requirements:

(1) To comply with the requirements of part 151, Customs Regulations (19 CFR part 151), and to conduct professional services in conformance

with approved standards and procedures, including procedures which may be required by the Commissioner of Customs or the Executive Director;

(2) To have no interest in or other connection with any business or other activity which might affect the unbiased performance of duties as a Customs-accredited laboratory. It is understood that this does not prohibit acceptance of the usual fees for professional services;

(3) To maintain the ability, *i.e.*, the instrumentation, equipment, qualified staff, facilities, etc., to perform the services for which the laboratory is accredited, and allow the Executive Director to evaluate that ability on a periodic basis by such means as on-site inspections, demonstrations of analysis procedures, reviews of submitted records, and proficiency testing through check samples;

(4) To retain those laboratory records beyond the five-year record-retention period and samples (see paragraph (j)(1) of this section) specified by Customs as necessary to address matters concerned in pending litigation, and, if laboratory operations or accreditation cease, to contact Customs immediately regarding the disposition of records/samples retained;

(5) To promptly investigate any circumstance which might affect the accuracy of work performed as an accredited laboratory, to correct the situation immediately, and to notify both the port director and the Executive Director of such matters, their consequences, and any corrective action taken or that needs to be taken; and

(6) To immediately notify both the port director and the Executive Director of any attempt to impede, influence, or coerce laboratory personnel in the performance of their duties, or of any decision to terminate laboratory operations or accredited status. Further, within 5 days of any changes involving legal name, address, ownership, parent-subsidiary relationships, bond, other offices or sites, or approved signatories to notify the Executive Director by certified mail.

(d) *What are the commodity groups for which accreditation may be sought?* (1) Commercial laboratories may apply for accreditation to perform tests for any of the commodity groups listed in paragraph (d)(2) of this section. Applicable test procedures are listed in Commodity Group Brochures and the U.S. Customs Laboratory Methods Manual. Application may be made for accreditation in more than one commodity group. At the discretion of the Executive Director accreditation may be granted for subgroups of tests within a commodity group or for commodity groups not specifically enumerated. Once accredited, a Customs-accredited laboratory may apply at any time to expand its accreditation, to add new testing sites, or increase the number of commodity groups or subgroups accredited.

(2) The commodity groups for which accreditation may be sought without special permission from the Executive Director are:

(i) Dairy and Chocolate Products entered under Chapters 4, 18, and 21 of the Harmonized Tariff Schedule of the United States (HTSUS);

(ii) Food and Food Products entered under Chapters 7–12, 15, 16, and 19–21, HTSUS;

(iii) Botanical Identification—materials and products entered under Chapters 14 and 44–46, HTSUS;

(iv) Sugar, Sugar Syrups, and Confectionery products entered under Chapter 17, HTSUS;

(v) Spirituous Beverages entered under Chapter 22, HTSUS;

(vi) Building Stone, Ceramics, Glassware, and Other Mineral Substances entered under Chapters 25 and 68–70, HTSUS;

(vii) Inorganic Materials, including Inorganic Compounds and Ores, entered under Chapters 26, 28, 31, and 36–38, HTSUS;

(viii) Petroleum and Petroleum Products entered under Chapters 27 and 29, HTSUS;

(ix) Organic Materials, including Intermediates and Pharmaceuticals, entered under Chapters 29, 30, 34, 35, and 38, HTSUS;

(x) Rubber, Plastics, Polymers, Pigments and Paints entered under Chapters 32, 39, and 40, HTSUS;

(xi) Essential Oils and Perfumes entered under Chapter 33, HTSUS;

(xii) Leather and Articles of Leather entered under Chapters 41 and 42, HTSUS;

(xiii) Paper and Paper Products entered under Chapters 47–49, HTSUS;

(xiv) Textiles and Related Products, including footwear and hats, entered under Chapters 50–67, HTSUS; and,

(xv) Metals and Alloys entered under Chapters 72–83, HTSUS.

(e) *What are the approved methods of analysis?* Customs-accredited laboratories must follow the general or specific testing methods set forth in Commodity Group Brochures and the U.S. Customs Laboratory Methods Manual in the testing of designated commodities, unless the Executive Director gives written permission to use an alternate method. Alternative methods will be considered and approved on a case-by-case basis.

(f) *How would a commercial laboratory become a Customs-accredited laboratory?* (1) *What should an application contain?* An application for Customs accreditation must contain the following information:

(i) The applicant's legal name and the address of its principal place of business and any other facility out of which it will work;

(ii) Detailed statements of ownership and any partnerships, parent-subsidiary relationships, or affiliations with any other domestic or foreign organizations, including, but not limited to, importers, other commercial laboratories, producers, refiners, Customs brokers, or carriers;

(iii) A statement of financial condition;

(iv) If a corporation, a copy of the articles of incorporation and the names of all officers and directors;

(v) The names, titles, and qualifications of each person who will be authorized to sign or approve analysis reports on behalf of the commercial laboratory;

(vi) A complete description of the applicant's facilities, instruments, and equipment;

(vii) An express agreement that if notified by Customs of pending accreditation to execute a bond in accordance with part 113, Customs Regulations (19 CFR part 113), and submit it to the Customs port nearest to the applicant's main office. (The limits of liability on the bond will be established by the Customs port in consultation with the Executive Director. In order to retain Customs accreditation, the laboratory must maintain an adequate bond, as determined by the port director);

(viii) A listing of each commodity group for which accreditation is being sought and, if methods are being submitted for approval which are not specifically provided for in a Commodity Group Brochure and the U.S. Customs Laboratory Methods Manual, a listing of such methods;

(ix) A listing by commodity group of each method according to its Customs Laboratory Method Number for which the laboratory is seeking accreditation;

(x) An express agreement to be bound by the obligations contained in paragraph (c) of this section; and,

(xi) A nonrefundable pre-payment equal to 50 percent of the fixed accreditation fee, as published in the **Federal Register** and Customs Bulletin, to cover preliminary processing costs. Further, the applicant agrees to pay Customs within 30 days of notification of preliminary accreditation the associated charges assessed for accreditation, i.e., those charges for actual travel and background

investigation costs, and the balance of the fixed accreditation fee.

(2) *Where should an application be sent?* A commercial laboratory seeking accreditation or an extension of an existing accreditation must send a letter of application to the U.S. Customs Service, Attention: Executive Director, Laboratories & Scientific Services, 1300 Pennsylvania Ave., NW, Washington, D.C. 20229.

(3) *How will an application be reviewed?*

(i) *Physical plant and management system.* The facility of the applicant will be inspected to ensure that it is properly equipped to perform the necessary tests and that staff personnel are capable of performing required tests. Customs evaluation of an applicant's professional abilities will be in accordance with the general criteria contained in either the American Society for Testing and Materials (ASTM) E548 (Standard Guide for General Criteria Used for Evaluating Laboratory Competence) or the ISO/IEC Guide 25 (General Requirements for the Competence of Calibration and Testing Laboratories). This review will ascertain the laboratory's ability to manage and control the acquisition of technical data. The review will be performed at the time of initial application and upon reaccreditation at three-year intervals.

(ii) *Ability to perform tests on specified commodity groups.* For each commodity group applied for, the applicant will undergo a separate review of testing capabilities. The specific accreditation will be based on the laboratory's ability to perform the tests required for that commodity group. This will include the qualifications of the technical personnel in this field and the instrument availability required by the test methods. Maintenance of accreditation will be ongoing and may require the submission of test results on periodic check samples. The criteria for acceptance will be based on the laboratory's ability to produce a work product that assists in the proper classification and entry of imported merchandise.

(iii) *Determination of competence.* The Executive Director will determine the applicant's overall competence, independence, and character by conducting on-site inspections, which may include demonstrations by the applicant of analysis procedures and a review of analysis records submitted, and background investigations. The Executive Director may also conduct proficiency testing through check samples.

(iv) *Evaluation of technical and operational requirements.* Customs will determine whether the following technical and operational requirements are met:

(A) *Equipment.* The laboratory must be equipped with all of the instruments and equipment needed to conduct the tests for which it is accredited. The laboratory must ensure that all instruments and equipment are properly calibrated, checked, and maintained.

(B) *Facilities.* The laboratory must have, at a minimum, adequate space, lighting, and environmental controls to ensure compliance with the conditions prescribed for appropriate test procedures.

(C) *Personnel.* The laboratory must be staffed with persons having the necessary education, training, knowledge, and experience for their assigned functions (e.g., maintaining equipment, calibrating instruments, performing laboratory analyses, evaluating analytical results, and signing analysis reports on behalf of the laboratory). In general, each technical staff member should hold, at a minimum, a bachelor's degree in science or have two years related experience in an analytical laboratory.

(g) *How will an applicant be notified concerning accreditation?*

(1) *Notice of approval or nonselection.* When Customs evaluation of a laboratory's credentials is completed, the Executive Director will notify the laboratory in writing of its preliminary approval or nonselection. (Final approval determinations will not be made until the applicant has satisfied all bond requirements and made payment on all assessed charges and the balance of the applicable accreditation fee). Notices of nonselection will state the specific grounds for the determination. All final notices of accreditation, reaccreditation, or extension of existing Customs accreditation will be published in the **Federal Register** and Customs Bulletin.

(2) *Grounds for nonselection.* The Executive Director may deny a laboratory's application for any of the following reasons:

(i) The application contains false or misleading information concerning a material fact;

(ii) The laboratory, a principal of the laboratory, or a person the Executive Director determines is exercising substantial ownership or control over the laboratory operation is indicted for, convicted of, or has committed acts which would:

(A) Under United States federal or state law, constitute a felony or misdemeanor involving misstatements, fraud, or a theft-related offense; or

(B) Reflect adversely on the business integrity of the applicant;

(iii) A determination is made that the laboratory-applicant does not possess the technical capability, have adequate facilities, or management to perform the approved methods of analysis for Customs purposes;

(iv) A determination is made that the laboratory has submitted false reports or statements concerning the sampling of merchandise, or that the applicant was subject to sanctions by state, local, or professional administrative bodies for such conduct;

(v) Nonpayment of assessed charges and the balance of the fixed accreditation fee; or

(vi) Failure to execute a bond in accordance with part 113 of this chapter.

(3) *Adverse accreditation decisions; appeal procedures.*

(i) *Preliminary notice.* A laboratory which is not selected for accreditation will be sent a preliminary notice of action which states the specific grounds for nonselection and advises that the laboratory may file a response with the Executive Director within 30 calendar days of receipt of the preliminary notice addressing the grounds for nonselection.

(ii) *Final notice.* If the laboratory does not respond to the preliminary notice, a final notice of nonselection will be issued by the Executive Director after 30 calendar days of receipt of the preliminary notice which states the specific grounds for the nonselection and advises that the laboratory may administratively appeal the final notice of nonselection to the Assistant Commissioner within 30 calendar days of receipt of the final notice. If the laboratory files a timely response, then the Executive Director, within 30 calendar days of receipt of the response, will issue a final determination regarding the laboratory's accreditation. If this final determination is adverse to the laboratory, then the final notice of nonselection will state the specific grounds for nonselection and advise the laboratory that it may administratively appeal the final notice of nonselection to the Assistant Commissioner within 30 calendar days of receipt of the final notice.

(iii) *Appeal decision.* The Assistant Commissioner will issue a decision on the appeal within 30 calendar days of receipt of the appeal. If the appeal decision is adverse to the laboratory, then the laboratory may choose to pursue one of the following two options:

(A) Submit a new application for accreditation to the Executive Director after waiting 90 days from the date of the Executive Director's last decision; or

(B) File an action with the Court of International Trade, pursuant to chapter

169 of title 28, United States Code, within 60 days after the issuance of the Executive Director's final decision.

(h) *What are the accreditation/reaccreditation fee requirements?*

(1) *In general.* A fixed fee, representing Customs administrative overhead expense, will be assessed for each application for accreditation or reaccreditation. In addition, associated assessments, representing the actual costs associated with travel and per diem of Customs employees related to verification of application criteria and background investigations will be charged. The combination of the fixed fee and associated assessments represent reimbursement to Customs for costs related to accreditation and reaccreditation. The fixed fee will be published in the Customs Bulletin and the **Federal Register**. Based on a review of the actual costs associated with the program, the fixed fee may be adjusted periodically; any changes will be published in the Customs Bulletin and the **Federal Register**.

(i) *Accreditation fees.* A nonrefundable pre-payment equal to 50 percent of the fixed accreditation fee to cover preliminary processing costs must accompany each application for accreditation. Before a laboratory will be accredited, it must remit to Customs, at the address specified in the billing, within the 30 day billing period, the associated charges assessed for the accreditation and the balance of the fixed accreditation fee.

(ii) *Reaccreditation fees.* Before a laboratory will be reaccredited, it must submit to Customs, at the billing address specified, within the 30 day billing period the fixed reaccreditation fee.

(2) *Disputes.* In the event a laboratory disputes the charges assessed for travel and per diem costs associated with scheduled inspection visits, it may file an appeal within 30 calendar days of the date of the assessment with the Executive Director. The appeal letter must specify which charges are in dispute and provide such supporting documentation as may be available for each allegation. The Executive Director will make findings of fact concerning the merits of an appeal and communicate the agency decision to the laboratory in writing within 30 calendar days of the date of the appeal.

(i) *Can existing Customs-accredited laboratories continue to operate?* Commercial laboratories accredited by the Executive Director prior to December 8, 1993, will retain that accreditation under these regulations provided they conduct their business in a manner consistent with the administrative portions of this section. This paragraph does not pertain to any laboratory which has had its accreditation suspended or revoked. Laboratories which have had their accreditations continued under this section will have their status reevaluated on their next triennial inspection date which is no earlier than three years after the effective date of this regulation. At the time of reaccreditation, these laboratories must meet the requirements of this section and remit to Customs, at the address specified in the billing, within the 30 day billing period, the fixed reaccreditation fee. Failure to meet these requirements will result in revocation or suspension of the accreditation.

(j) *How will Customs-accredited laboratories operate?*

(1) *Samples for testing.* Upon request by the importer of record of merchandise, the port director will release a representative sample of the merchandise for testing by a Customs-accredited laboratory at the expense of the importer. Under Customs supervision, the sample will be split into two essentially equal parts and given to the Customs-accredited laboratory. One portion of the sample may be used by the Customs-accredited laboratory for its testing. The other portion must be retained by the laboratory, under appropriate storage conditions, for Customs use, as necessary, unless Customs requires other specific procedures. Upon request, the sample portion reserved for Customs purposes must be surrendered to Customs.

(i) *Retention of non-perishable samples.* Non-perishable samples reserved for Customs and sample remnants from any testing must be retained by the accredited laboratory for a period of four months from the date of the laboratory's final analysis report, unless other instructions are issued in writing by Customs. At the end of this retention time period, the accredited laboratory may dispose of the retained samples and sample remnants in a manner consistent with federal, state, and local statutes.

(ii) *Retention of perishable samples.* Perishable samples reserved for Customs and sample remnants from any testing can be disposed of more expeditiously than provided for at paragraph (j)(1)(i) of this section, if done in accordance with acceptable laboratory procedures, unless other instructions are issued in writing by Customs.

(2) *Reports.* (i) *Contents of reports.* Testing data must be obtained using methods approved by the Executive Director. The testing results from a Customs-accredited laboratory that are submitted by an importer of record with respect to merchandise in an entry, in the absence of testing conducted by Customs laboratories, will be accepted by Customs, provided that the importer of record certifies that the sample tested was taken from the merchandise in the entry and the report establishes elements relating to the admissibility, quantity, composition, or characteristics of the merchandise entered, as required by law.

(ii) *Status of commercial reports where Customs also tests merchandise.* Nothing in these regulations will preclude Customs from sampling and testing merchandise from a shipment which has been sampled and tested by a Customs-accredited laboratory at the request of an importer. In cases where a shipment has been analyzed by both Customs and a Customs-accredited laboratory, all Customs actions will be based upon the analysis provided by the Customs laboratory, unless the Executive Director advises otherwise. If Customs tests merchandise, it will release the results of its test to the importer of record or its agent upon request unless the testing information is proprietary to the holder of a copyright or patent, or developed by Customs for enforcement purposes.

(3) *Recordkeeping requirements.* Customs-accredited laboratories must maintain records of the type normally kept in the ordinary course of business in accordance with the provisions of this chapter and any other applicable provision of law, and make them available during normal business hours for Customs inspection. In addition, these laboratories must maintain all records necessary to permit the evaluation and verification of all Customs-related work, including, as appropriate, those described below. All records must be maintained for five years, unless the laboratory is notified in writing by Customs that a longer retention time is necessary for particular records. Electronic data storage and transmission may be approved by Customs.

(i) *Sample records.* Records for each sample tested for Customs purposes must be readily accessible and contain the following information:

(A) A unique identifying number;

(B) The date when the sample was received or taken;

(C) The identity of the commodity (*e.g.* crude oil);

(D) The name of the client;

(E) The source of the sample (*e.g.*, name of vessel, flight number of airline,

name of individual taking the sample); and

(F) If available, the Customs entry date, entry number, and port of entry and the names of the importer, exporter, manufacturer, and country-of-origin.

(ii) *Major equipment records.* Records for each major piece of equipment or instrument (including analytical balances) used in Customs-related work must identify the name and type of instrument, the manufacturer's name, the instrument's model and any serial numbers, and the occurrence of all servicing performed on the equipment or instrument, to include recalibration and any repair work, identifying who performed the service and when.

(iii) *Records of analytical procedures.* The Customs-accredited laboratory must maintain complete and up-to-date copies of all approved analytical procedures, calibration methods, etc., and must document the procedures each staff member is authorized to perform. These procedures must be readily available to appropriate staff.

(iv) *Laboratory analysis records.* The Customs-accredited laboratory must identify each analysis by sample record number (see paragraph (j)(3)(i) of this section) and must maintain all information or data (such as sample weights, temperatures, references to filed spectra, etc.) associated with each Customs-related laboratory analysis. Each analysis record must be dated and initialed or signed by the staff member(s) who did the work.

(v) *Laboratory analysis reports.* Each laboratory analysis report submitted to Customs must include:

(A) The name and address of the Customs-accredited laboratory;

(B) A description and identification of the sample, including its unique identifying number;

(C) The designations of each analysis procedure used;

(D) The analysis report itself (*i.e.*, the pertinent characteristics of the sample);

(E) The date of the report; and

(F) The typed name and signature of the person accepting technical responsibility for the analysis report (*i.e.*, an approved signatory).

(4) *Representation of Customs-accredited status.* Commercial laboratories accredited by Customs must limit statements or wording regarding their accreditation to an accurate description of the tests for the commodity group(s) for which accreditation has been obtained. Use of terms other than those appearing in the notice of accreditation (see paragraph (g) of this section) is prohibited.

(5) *Subcontracting prohibited.* Customs-accredited laboratories must not subcontract Customs-related analysis work to non Customs-accredited laboratories or non Customs-approved gaugers, but may subcontract to other facilities that are Customs-accredited/approved and in good standing.

(k) *How can a laboratory have its accreditation suspended or revoked or be required to pay a monetary penalty?*

(1) *Grounds for suspension, revocation, or assessment of a monetary penalty.* (i) *In general.* The Executive Director may immediately suspend or revoke a laboratory's accreditation only in cases where the laboratory's actions are intentional violations of any Customs law or when required by public health or safety. In other situations where the Executive Director has cause, the Executive Director will propose the suspension or revocation of a laboratory's accreditation or propose a monetary penalty and provide the laboratory with the opportunity to respond to the notice of proposed action.

(ii) *Specific grounds.* A laboratory's accreditation may be suspended or revoked, or a monetary penalty may be assessed because:

(A) The selection was obtained through fraud or the misstatement of a material fact by the laboratory;

(B) The laboratory, a principal of the laboratory, or a person the port director determines is exercising substantial ownership or control over the laboratory operation is indicted for, convicted of, or has committed acts which would: under United States federal or state law, constitute a felony or misdemeanor involving misstatements, fraud, or a theft-related offense; or reflect adversely on the business integrity of the applicant. In the absence of an indictment, conviction, or other legal process, the port director must have probable cause to believe the proscribed acts occurred;

(C) Staff laboratory personnel refuse or otherwise fail to follow any proper order of a Customs officer or any Customs order, rule, or regulation;

(D) The laboratory fails to operate in accordance with the obligations of paragraph (c) of this section;

(E) A determination is made that the laboratory is no longer technically or operationally proficient at performing the approved methods of analysis for Customs purposes;

(F) The laboratory fails to remit to Customs, at the billing address specified, within the 30 day billing period the associated charges assessed for the accreditation and the balance of the fixed accreditation fee;

(G) The laboratory fails to maintain its bond;

(H) The laboratory fails to remit to Customs, at the billing address specified, within the 30 day billing period, the fixed reaccreditation fee; or

(I) The laboratory fails to remit any monetary penalty assessed under this section.

(iii) *Assessment of monetary penalties.* The assessment of a monetary penalty under this section, may be in lieu of, or in addition to, a suspension or revocation of accreditation under this section. The monetary penalty may not exceed $100,000 per violation and will be assessed and administered pursuant to published guidelines. Any monetary penalty under this section can be in addition to the recovery of:

(A) Any loss of revenue, in cases where the laboratory intentionally falsified the analysis report in collusion with the importer, pursuant to 19 U.S.C. 1499(b)(1)(B)(i); or

(B) Liquidated damages assessed under the laboratory's Customs bond.

(2) *Notice.* When a decision to suspend or revoke accreditation, and/or assess a monetary penalty is made, the Executive Director will immediately notify the laboratory in writing of the decision, indicating whether the action is effective immediately or is proposed.

(i) *Immediate suspension or revocation.* Where the suspension or revocation of accreditation is immediate, the Executive Director will issue a notice of determination which will state the specific grounds for the immediate suspension or revocation and advise the laboratory that, in accordance with paragraph (k)(3) of this section, it may administratively appeal the determination to the Assistant Commissioner within 30 calendar days of the notice of determination. The laboratory may not perform any Customs-accredited functions during the appeal period.

(ii) *Proposed suspension, revocation, or assessment of monetary penalty.*

(A) *Preliminary notice.* Where the suspension or revocation of accreditation, and/or the assessment of a monetary penalty is proposed, the Executive Director will issue a preliminary notice of action which will state the specific grounds for the proposed action and advise the laboratory that it has 30 calendar days to respond. The laboratory may respond by accepting responsibility, explaining extenuating circumstances, and/or providing rebuttal evidence. The laboratory also may ask for a meeting with the Executive Director or his designee to discuss the proposed action. The laboratory may continue to perform

functions requiring Customs-accreditation during this 30-day period. If the laboratory does not respond to the preliminary notice, a notice of adverse determination, in accordance with paragraph (k)(2)(ii)(B) of this section, will be issued by the Executive Director after 30 calendar days of receipt of the preliminary notice. If the laboratory files a timely response, then the Executive Director, within 30 calendar days of receipt of the response, will issue a notice of determination. If this determination is adverse to the laboratory, a notice of adverse determination, in accordance with paragraph (k)(2)(ii)(B) of this section, will be issued by the Executive Director after 30 calendar days of receipt of the response.

(B) *Notice of adverse determination.* A notice of adverse determination will state the action being taken, specific grounds for the determination, and advise the laboratory that it may administratively appeal the adverse determination to the Assistant Commissioner, in accordance with paragraph (k)(3) of this section. The laboratory may not continue to perform any Customs-accredited functions upon receiving a notice of adverse determination that its accreditation has been suspended or revoked.

(3) *Appeal.* A Customs-accredited laboratory receiving an adverse determination from the Executive Director that its accreditation has been suspended or revoked, and/or that it has been assessed a monetary penalty may file an administrative appeal to the Assistant Commissioner within 30 calendar days of the notice of determination. If the laboratory does not file an administrative appeal, the determination made by the Executive Director in paragraph (k)(2) of this section will become a final agency decision which will be communicated to the laboratory by a notice of final action issued 30 days after the notice of determination. If the laboratory does file a timely appeal, then the Assistant Commissioner, within 30 calendar days of receipt of the appeal, will make a final agency decision regarding the laboratory's suspension or revocation of accreditation, and/or assessment of a monetary penalty. If the final agency decision is adverse to the laboratory, the decision will be communicated to the laboratory by a notice of final action. Any adverse final agency decision will be communicated to the public by a publication in the **Federal Register** and Customs Bulletin, giving the effective date, duration, and scope of the decision. Any notice of adverse final action communicated to a laboratory will state the action taken, the specific grounds for the action, and advise the laboratory that it may choose to :

(i) If suspended or revoked, submit a new application to the Executive Director after waiting 90 days from the date of the Executive Director's notice of final action; or

(ii) File an action with the Court of International Trade, pursuant to chapter 169 of title 28, United States Code, within 60 days after the issuance of the Executive Director's notice of final action.

3. Section 151.13 is revised to read as follows:

§ 151.13 Approval of commercial gaugers.

This section sets forth the requirements for commercial gaugers to obtain approval by Customs for the measuring of certain merchandise, and explains the operation of such approved gaugers. This section also provides for the imposition of approval and reapproval fees, sets forth grounds for the suspension or revocation of approval, and provides for the imposition of a monetary penalty for an approved commercial gauger that fails to adhere to the provisions of this section.

(a) *What is a ''Customs-approved gauger''?* ''Commercial gaugers'' are individuals and commercial organizations that measure, gauge, or sample merchandise (usually merchandise in bulk form) and who deal mainly with animal and vegetable oils, petroleum, petroleum products, and bulk chemicals. A ''Customs-approved gauger'' is a commercial concern, within the United States, that has demonstrated, to the satisfaction of the Executive Director (defined at § 151.12(a)), pursuant to this section, the capability to perform certain gauging and measurement procedures for certain commodities. Customs approval extends only to the performance of such functions as are vested in, or delegated to, Customs.

(b) *What are the obligations of a Customs-approved gauger?* A commercial gauger approved by Customs agrees to the following conditions and requirements:

(1) To comply with the requirements of part 151, Customs Regulations (19 CFR part 151), and to conduct professional services in conformance with approved standards and procedures, including procedures which may be required by the Commissioner of Customs or the Executive Director;

(2) To have no interest in or other connection with any business or other activity which might affect the unbiased performance of duties as a Customs-approved gauger. It is understood that this does not prohibit acceptance of the usual fees for professional services;

(3) To maintain the ability, *i.e.*, the instrumentation, equipment, qualified staff, facilities, etc., to perform the services for which the gauger is approved, and allow the Executive Director to evaluate that ability on a periodic basis by such means as on-site inspections, demonstrations of gauging procedures, and reviews of submitted records;

(4) To retain those gauger records beyond the five-year record-retention period specified by Customs as necessary to address matters concerned in pending litigation, and, if gauger operations or approval cease, to contact Customs immediately regarding the disposition of records retained;

(5) To promptly investigate any circumstance which might affect the accuracy of work performed as an approved gauger, to correct the situation immediately, and to notify both the port director and the Executive Director of such matters, their consequences, and any corrective action taken or that needs to be taken; and

(6) To immediately notify both the port director and the Executive Director of any attempt to impede, influence, or coerce gauger personnel in the performance of their duties, or of any decision to terminate gauger operations or approval status. Further, within 5 days of any changes involving legal name, address, ownership, parent-subsidiary relationships, bond, other offices or sites, or approved signatories to notify the Executive Director by certified mail.

(c) *What are the approved measurement procedures?* Customs-approved gaugers must comply with appropriate procedures published by such professional organizations as the American Society for Testing and Materials (ASTM) and the American Petroleum Institute (API), unless the Executive Director gives written permission to use an alternate method. Alternative methods will be considered and approved on a case-by-case basis.

(d) *How would a commercial gauger become a Customs-approved gauger?* (1) *What should an application contain?* An application for Customs approval must contain the following information:

(i) The applicant's legal name and the address of its principal place of business and any other facility out of which it will work;

(ii) Detailed statements of ownership and any partnerships, parent-subsidiary relationships, or affiliations with any other domestic or foreign organizations, including, but not limited to, importers,

producers, refiners, Customs brokers, or carriers;

(iii) A statement of financial condition;

(iv) If a corporation, a copy of the articles of incorporation and the names of all officers and directors;

(v) The names, titles, and qualifications of each person who will be authorized to sign or approve gauging reports on behalf of the commercial gauger;

(vi) A complete description of the applicant's facilities, instruments, and equipment;

(vii) An express agreement that if notified by Customs of pending approval to execute a bond in accordance with part 113, Customs Regulations (19 CFR part 113), and submit it to the Customs port nearest to the applicant's main office. (The limits of liability on the bond will be established by the Customs port in consultation with the Executive Director. In order to retain Customs approval, the gauger must maintain an adequate bond, as determined by the port director);

(viii) An express agreement to be bound by the obligations contained in paragraph (b) of this section; and,

(ix) A nonrefundable pre-payment equal to 50 percent of the fixed approval fee, as published in the **Federal Register** and Customs Bulletin, to cover preliminary processing costs. Further, the applicant agrees to pay Customs within 30 days of notification of preliminary approval the associated charges assessed for approval, *i.e.,* those charges for actual travel and background investigation costs, and the balance of the fixed approval fee.

(2) *Where should an application be sent?* A commercial gauger seeking approval or an extension of an existing approval must send a letter of application to the U.S. Customs Service, Attention: Executive Director, Laboratories & Scientific Services, 1300 Pennsylvania Ave., NW, Washington, D.C. 20229.

(3) *How will an application be reviewed?*

(i) *Determination of competence.* The Executive Director will determine the applicant's overall competence, independence, and character by conducting on-site inspections, which may include demonstrations by the applicant of gauging procedures and a review of records submitted, and background investigations. The Executive Director may also conduct proficiency testing through check samples.

(ii) *Evaluation of technical and operational requirements.* Customs will determine whether the following technical and operational requirements are met:

(A) *Equipment.* The facility must be equipped with all of the instruments and equipment needed to conduct approved services. The gauger must ensure that all instruments and equipment are properly calibrated, checked, and maintained.

(B) *Facilities.* The facility must have, at a minimum, adequate space, lighting, and environmental controls to ensure compliance with the conditions prescribed for appropriate measurements.

(C) *Personnel.* The facility must be staffed with persons having the necessary education, training, knowledge, and experience for their assigned functions (*e.g.,* maintaining equipment, calibrating instruments, performing gauging services, evaluating gauging results, and signing gauging reports on behalf of the commercial gauger). In general, each technical staff member should have, at a minimum, six months training and experience in gauging.

(e) *How will an applicant be notified concerning approval?*

(1) *Notice of approval or nonselection.* When Customs evaluation of a gauger's credentials is completed, the Executive Director will notify the gauger in writing of its preliminary approval or nonselection. (Final approval determinations will not be made until the applicant has satisfied all bond requirements and made payment on all assessed charges and the balance of the applicable accreditation fee). Notices of nonselection will state the specific grounds for the determination. All final notices of approval, reapproval, or extension of existing Customs approval will be published in the **Federal Register** and Customs Bulletin.

(2) *Grounds for nonselection.* The Executive Director may deny a gauger's application for any of the following reasons:

(i) The application contains false or misleading information concerning a material fact;

(ii) The gauger, a principal of the gauging facility, or a person the Executive Director determines is exercising substantial ownership or control over the gauger operation is indicted for, convicted of, or has committed acts which would:

(A) Under United States federal or state law, constitute a felony or misdemeanor involving misstatements, fraud, or a theft-related offense; or

(B) Reflect adversely on the business integrity of the applicant;

(iii) A determination is made that the gauger-applicant does not possess the technical capability, have adequate facilities, or management to perform the approved methods of measurement for Customs purposes;

(iv) A determination is made that the gauger has submitted false reports or statements concerning the measurement of merchandise, or that the applicant was subject to sanctions by state, local, or professional administrative bodies for such conduct;

(v) Nonpayment of assessed charges and the balance of the fixed approval fee; or

(vi) Failure to execute a bond in accordance with part 113 of this chapter.

(3) *Adverse approval decisions; appeal procedures.*—(i) *Preliminary notice.* A gauger which is not selected for approval will be sent a preliminary notice of action which states the specific grounds for nonselection and advises that the gauger may file a response with the Executive Director within 30 calendar days of receipt of the preliminary notice addressing the grounds for nonselection.

(ii) *Final notice.* If the gauger does not respond to the preliminary notice, a final notice of nonselection will be issued by the Executive Director after 30 calendar days of receipt of the preliminary notice which states the specific grounds for the nonselection and advises that the gauger may administratively appeal the final notice of nonselection to the Assistant Commissioner within 30 calendar days of receipt of the final notice. If the gauger files a timely response, then the Executive Director, within 30 calendar days of receipt of the response, will issue a final determination regarding the gauger's approval. If this final determination is adverse to the gauger, then the final notice of nonselection will state the specific grounds for nonselection and advise the gauger that it may administratively appeal the final notice of nonselection to the Assistant Commissioner within 30 calendar days of receipt of the final notice.

(iii) *Appeal decision.* The Assistant Commissioner will issue a decision on the appeal within 30 calendar days of receipt of the appeal. If the appeal decision is adverse to the gauger, then the gauger may choose to pursue one of the following two options:

(A) Submit a new application for approval to the Executive Director after waiting 90 days from the date of the Executive Director's last decision; or

(B) File an action with the Court of International Trade, pursuant to chapter 169 of title 28, United States Code,

within 60 days after the issuance of the Executive Director's final decision.

(f) *What are the approval/reapproval fee requirements?*

(1) *In general.* A fixed fee, representing Customs administrative overhead expense, will be assessed for each application for approval or reapproval. In addition, associated assessments, representing the actual costs associated with travel and per diem of Customs employees related to verification of application criteria and background investigations will be charged. The combination of the fixed fee and associated assessments represent reimbursement to Customs for costs related to approval and reapproval. The fixed fee will be published in the Customs Bulletin and the **Federal Register**. Based on a review of the actual costs associated with the program, the fixed fee may be adjusted periodically; any changes will be published in the Customs Bulletin and the **Federal Register**.

(i) *Approval fees.* A nonrefundable pre-payment equal to 50 percent of the fixed approval fee to cover preliminary processing costs must accompany each application for approval. Before a gauger will be approved, it must submit to Customs, at the address specified in the billing, within the 30 day billing period the associated charges assessed for the approval and the balance of the fixed approval fee.

(ii) *Reapproval fees.* Before a gauger will be reapproved, it must submit to Customs, at the billing address specified, within the 30 day billing period, the fixed reapproval fee.

(2) *Disputes.* In the event a gauger disputes the charges assessed for travel and per diem costs associated with scheduled inspection visits, it may file an appeal within 30 calendar days of the date of the assessment with the Executive Director. The appeal letter must specify which charges are in dispute and provide such supporting documentation as may be available for each allegation. The Executive Director will make findings of fact concerning the merits of an appeal and communicate the agency decision to the gauger in writing within 30 calendar days of the date of the appeal.

(g) *Can existing Customs-approved gaugers continue to operate?* Commercial gaugers approved by the Executive Director prior to December 8, 1993, will retain approval under these regulations provided that they conduct their business in a manner consistent with the administrative portions of this section. This paragraph does not pertain to any gauger which has had its approval suspended or revoked. Gaugers which have had their approvals continued under this section will have their status reevaluated on their next triennial inspection date which is no earlier than three years after the effective date of this regulation. At the time of reapproval, these gaugers must meet the requirements of this section and remit to Customs, at the address specified in the billing, within the 30 day billing period the fixed reapproval fee. Failure to meet these requirements will result in revocation or suspension of the approval.

(h) *How will Customs-approved gaugers operate?*

(1) *Reports.* (i) *Contents of reports.* The measurement results from a Customs-approved gauger that are submitted by an importer of record with respect to merchandise in an entry, in the absence of measurements conducted by Customs, will be accepted by Customs, provided that the importer of record certifies that the measurement was of the merchandise in the entry. All reports must measure net landed quantity, except in the case of crude petroleum of Heading 2709, Harmonized Tariff Schedule of the United States (HTSUS), which may be measured by gross quantity. Reports must use the appropriate HTSUS units of quantity, *e.g.*, liters, barrels, or kilograms.

HTSUS	Product	Unit of quantity
Headings 1501–1515	Animal and vegetable oils	Kilogram.
Subheadings 2707.10–2707.30 and 2902.20–2902.44.	Benzene, toluene and xylene	Liter.
Heading 2709	Crude Petroleum	Barrel.
Heading 2710 (various subheadings)	Fuel oils, motor oils, kerosene, naphtha, lubricating oils.	Barrel.
Chapter 29 (various subheadings)	Organic compounds in bulk and liquid form	Kilogram, liter, etc.

(ii) *Status of commercial reports where Customs also gauges merchandise.* Nothing in these regulations will preclude Customs from gauging a shipment which has been gauged by a Customs-approved gauger at the request of an importer. In cases where a shipment has been gauged by both Customs and a Customs-approved gauger, all Customs actions will be based upon the gauging reports issued by Customs, unless the Executive Director advises other actions. If Customs gauges merchandise, it will release the report of its measurements to the importer of record or its agent upon request unless the gauging information is proprietary to the holder of a copyright or patent, or developed by Customs for enforcement purposes.

(2) *Recordkeeping requirements.* Customs-approved gaugers must maintain records of the type normally kept in the ordinary course of business in accordance with the provisions of this chapter and any other applicable provisions of law, and make them available during normal business hours for Customs inspection. In addition, these gaugers must maintain all records necessary to permit the evaluation and verification of all Customs-related work, including, as appropriate, those described below. All records must be maintained for five years, unless the gauger is notified in writing by Customs that a longer retention time is necessary for particular records. Electronic data storage and transmission may be approved by Customs.

(i) *Transaction records.* Records for each Customs-related transaction must be readily accessible and have the following:

(A) A unique identifying number;

(B) The date and location where the transaction occurred;

(C) The identity of the product (*e.g.* crude oil);

(D) The name of the client;

(E) The source of the product (*e.g.*, name of vessel, flight number of airline); and

(F) If available, the Customs entry date, entry number, and port of entry and the names of the importer, exporter, manufacturer, and country-of-origin.

(ii) *Major equipment records.* Records for each major piece of equipment used in Customs-related work must identify the name and type of instrument, the manufacturer's name, the instrument's model and any serial numbers, and the occurrence of all servicing performed on the equipment or instrument, to include recalibration and any repair work,

identifying who performed the service and when.

(iii) *Records of gauging procedures.* The Customs-approved gauger must maintain complete and up-to-date copies of all approved gauging procedures, calibration methods, etc., and must document the procedures that each staff member is authorized to perform. These procedures must be readily available to appropriate staff.

(iv) *Gauging records.* The Customs-approved gauger must identify each transaction by transaction record number (see paragraph (h)(2)(i) of this section) and must maintain all information or data (such as temperatures, etc.) associated with each Customs-related gauging transaction. Each gauging record (*i.e.*, the complete file of all data for each separate transaction) must be dated and initialed or signed by the staff member(s) who did the work.

(v) *Gauging reports.* Each gauging report submitted to Customs must include:

(A) The name and address of the Customs-approved gauger;

(B) A description and identification of the transaction, including its unique identifying number;

(C) The designations of each gauging procedure used;

(D) The gauging report itself (*i.e.*, the quantity of the merchandise);

(E) The date of the report; and

(F) The typed name and signature of the person accepting technical responsibility for the gauging report (*i.e.*, an approved signatory).

(3) *Representation of Customs-approved status.* Commercial gaugers approved by Customs must limit statements or wording regarding their approval to an accurate description of the commodities for which approval has been obtained. Use of terms other than those appearing in the notice of approval (see paragraph (e) of this section) is prohibited.

(4) *Subcontracting prohibited.* Customs-approved gaugers must not subcontract Customs-related work to non Customs-approved gaugers or non Customs-accredited laboratories, but may subcontract to other facilities that are Customs-approved/accredited and in good standing.

(i) *How can a gauger have its approval suspended or revoked or be required to pay a monetary penalty?*

(1) *Grounds for suspension, revocation, or assessment of a monetary penalty.* (i) *In general.* The Executive Director may immediately suspend or revoke a gauger's approval only in cases where the gauger's actions are intentional violations of any Customs law or when required by public health or safety. In other situations where the Executive Director has cause, the Executive Director will propose the suspension or revocation of a gauger's approval or propose a monetary penalty and provide the gauger with the opportunity to respond to the notice of proposed action.

(ii) *Specific grounds.* A gauger's approval may be suspended or revoked, or a monetary penalty may be assessed because:

(A) The selection was obtained through fraud or the misstatement of a material fact by the gauger;

(B) The gauger, a principal of the gauging facility, or a person the port director determines is exercising substantial ownership or control over the gauger operation is indicted for, convicted of, or has committed acts which would: under United States federal or state law, constitute a felony or misdemeanor involving misstatements, fraud, or a theft-related offense; or reflect adversely on the business integrity of the applicant. In the absence of an indictment, conviction, or other legal process, the port director must have probable cause to believe the proscribed acts occurred;

(C) Staff gauger personnel refuse or otherwise fail to follow any proper order of a Customs officer or any Customs order, rule, or regulation;

(D) The gauger fails to operate in accordance with the obligations of paragraph (b) of this section;

(E) A determination is made that the gauger is no longer technically or operationally proficient at performing the approved methods of measurement for Customs purposes;

(F) The gauger fails to remit to Customs, at the billing address specified, within the 30 day billing period the associated charges assessed for the approval and the balance of the fixed approval fee;

(G) The gauger fails to maintain its bond;

(H) The gauger fails to remit to Customs, at the billing address specified, within the 30 day billing period the fixed reapproval fee; or

(I) The gauger fails to remit any monetary penalty assessed under this section.

(iii) *Assessment of monetary penalties.* The assessment of a monetary penalty under this section, may be in lieu of, or in addition to, a suspension or revocation of approval under this section. The monetary penalty may not exceed $100,000 per violation and will be assessed and administered pursuant to published guidelines. Any monetary penalty under this section can be in addition to the recovery of:

(A) Any loss of revenue, in cases where the gauger intentionally falsified the gauging report in collusion with the importer, pursuant to 19 U.S.C. 1499(b)(1)(B)(i); or

(B) Liquidated damages assessed under the gauger's Customs bond.

(2) *Notice.* When a decision to suspend or revoke approval, and/or assess a monetary penalty is made, the Executive Director will immediately notify the gauger in writing of the decision, indicating whether the action is effective immediately or is proposed.

(i) *Immediate suspension or revocation.* Where the suspension or revocation of approval is immediate, the Executive Director will issue a notice of determination which will state the specific grounds for the immediate suspension or revocation and advise the gauger that, in accordance with paragraph (i)(3) of this section, it may administratively appeal the determination to the Assistant Commissioner with 30 calendar days of the notice of determination. The gauger may not perform any Customs-approved functions during the appeal period.

(ii) *Proposed suspension, revocation, or assessment of monetary penalty.—(A) Preliminary notice.* Where the suspension or revocation of approval, and/or the assessment of a monetary penalty is proposed, the Executive Director will issue a preliminary notice of action which will state the specific grounds for the proposed action and advise the gauger that it has 30 calendar days to respond. The gauger may respond by accepting responsibility, explaining extenuating circumstances, and/or providing rebuttal evidence. The gauger also may ask for a meeting with the Executive Director or his designee to discuss the proposed action. The gauger may continue to perform functions requiring Customs-approval during this 30-day period. If the gauger does not respond to the preliminary notice, a notice of adverse determination, in accordance with paragraph (i)(2)(ii)(B) of this section, will be issued by the Executive Director after 30 calendar days of receipt of the preliminary notice. If the gauger files a timely response, then the Executive Director, within 30 calendar days of receipt of the response, will issue a notice of determination. If this determination is adverse to the gauger, a notice of adverse determination, in accordance with paragraph (i)(2)(ii)(B) of this section, will be issued by the Executive Director after 30 calendar days of receipt of the response.

(B) *Notice of adverse determination.* A notice of adverse determination will state the action being taken, specific grounds for the determination, and advise the gauger that it may administratively appeal the adverse determination to the Assistant Commissioner, in accordance with paragraph (i)(3) of this section. The gauger may not continue to perform any Customs-approved functions upon receiving a notice of adverse determination that its approval has been suspended or revoked.

(3) *Appeal.* A Customs-approved gauger receiving an adverse determination from the Executive Director that its approval has been suspended or revoked, and/or that it has been assessed a monetary penalty may file an administrative appeal to the Assistant Commissioner within 30 calendar days of the notice of determination. If the gauger does not file an administrative appeal, the determination made by the Executive Director in paragraph (i)(2) of this section will become a final agency decision which will be communicated to the gauger by a notice of final action issued 30 days after the notice of determination. If the gauger does file a timely appeal, then the Assistant Commissioner, within 30 calendar days of receipt of the appeal, will make a final agency decision regarding the gauger's suspension or revocation of approval, and/or assessment of a monetary penalty. If the final agency decision is adverse to the gauger, the decision will be communicated to the gauger by a notice of final action. Any adverse final agency decision will be communicated to the public by a publication in the **Federal Register** and Customs Bulletin, giving the effective date, duration, and scope of the decision. Any notice of adverse final action communicated to a gauger will state the action taken, the specific grounds for the action, and advise the gauger that it may choose to:

(i) If suspended or revoked, submit a new application to the Executive Director after waiting 90 days from the date of the Executive Director's notice of final action; or

(ii) File an action with the Court of International Trade, pursuant to chapter 169 of title 28, United States Code, within 60 days after issuance of the Executive Director's notice of final action.

§ 151.14 [Amended]

4. In § 151.14, the first sentence is amended by removing the words ''`sediment and water' characteristic as set out in § 151.13(a)(2)'' and adding, in its place, the words ''analysis method for crude petroleum contained in ASTM D96 or other approved analysis method''.

PART 178—APPROVAL OF INFORMATION COLLECTION REQUIREMENTS

1. The authority citation for part 178 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1624; 44 U.S.C. 3501 *et seq.*

2. Section 178.2 is amended by removing the entry for § 151.13(i), and adding, in its place, separate listings for §§ 151.12(f) and 151.13(d) to read as follows:

§ 178.2 Listing of OMB control numbers.

19 CFR section	Description	OMB control no.
*	* * * * * *	*
§ 151.12(f)	Application and other documents pertaining to accreditation of commercial laboratories.	1515–0155
§ 151.13(d)	Application and other documents pertaining to approval of commercial gaugers	1515–0155

Raymond W. Kelly,

Commissioner of Customs.

Approved: July 30, 1999

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 99–23033 Filed 9–3–99; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for an additional package size of oxytetracycline hydrochloride soluble powder to be used to make a medicated drinking water for chickens, turkeys, cattle, swine, and sheep for control and/or treatment of various bacterial diseases.

EFFECTIVE DATE: September 7, 1999.

FOR FURTHER INFORMATION CONTACT: William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6966.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed supplemental ANADA 200–146 that provides for use of 6.4 ounce (181.5 gram (g)) packet of oxytetracycline hydrochloride soluble powder (10 g oxytetracycline hydrochloride per packet) for use in making medicated drinking water for chickens, turkeys, cattle, swine, and sheep for treatment and/or control of various bacterial diseases. The supplemental ANADA is approved as of July 26, 1999, and the regulations are amended in 21 CFR 520.1660d(a)(7) to reflect the approval.

This supplemental ANADA concerns an additional packet size of product to be used as currently approved. The safety and effectiveness of the product does not change. A freedom of information summary as described in 21 CFR part 20 and 514.11(e)(2)(ii) is not required.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.