of the Food and Drug Administration may obtain samples of any food, drug, device, or cosmetic, the importation of which is governed by section 801 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 381).

[T.D. 73–175, 38 FR 17470, July 2, 1973, as amended by T.D. 75–152, 40 FR 27444, June 30, 1975; T.D. 84–213, 49 FR 41186, Oct. 19, 1984; CBP Dec. 07–02, 72 FR 4430, Jan. 31, 2007; CBP Dec. 15–14, 80 FR 61291, Oct. 13, 2015]

§ 151.12 Accreditation of commercial laboratories.

This section sets forth the requirements for commercial laboratories to obtain accreditation by CBP 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 Information and Technology, or his designee, located in Washington, D.C.

Check samples. ''Check samples'' are samples which have been distributed by CBP 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 CBP-accreditation in a particular commodity group. The brochures and the Customs and Border Protection Laboratory (CBPL) Methods 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 and Border Protection, Attention: Executive Director, Laboratories and Scientific Services, Washington, D.C. 20229 and can also be found on the CBP Web site: *www.cbp.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 the port director, the Executive Director, and the Center director of such matters, their consequences, and any corrective action taken or that needs to be taken; and

(6) To immediately notify the port director, the Executive Director, and the Center 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 accreditation or nonselection.* When Customs evaluation of a laboratory's credentials is completed, the Executive Director will notify the laboratory in writing of its preliminary accreditation or nonselection. (Final accreditation 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). 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 nonselection. The preliminary notice of nonselection will state the specific grounds for the proposed nonselection decision and advise the laboratory that it may file a response addressing the grounds for the action proposed with the Executive Director within 30 calendar days of the date the preliminary notice of nonselection was received by the laboratory.

(ii) *Final notice*—(A) *Based on nonresponse.* If the laboratory does not respond to the preliminary notice, the Executive Director will issue a final notice of nonselection within 60 calendar days of the date the preliminary notice of nonselection was received by the laboratory applicant. The final notice of nonselection will state the specific grounds for the nonselection and advise the laboratory that it may choose to pursue one of the following two options:

(*1*) Submit a new application for accreditation, in accordance with the provisions of paragraph (f)(1) of this section, 180 days after the date of the final notice of nonselection; or

(*2*) Administratively appeal the final notice of nonselection to the Assistant Commissioner within 30 calendar days of the date of the final notice of nonselection.

(B) *Based on response.* If the laboratory files a timely response, the Executive Director will issue a final determination regarding the laboratory's accreditation within 30 calendar days of the date the applicant's response is received by the Executive Director. 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 choose to pursue one of the two options provided at paragraphs (g)(3)(ii)(A)(1) and (2) of this section.

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

(A) Submit a new application for accreditation, in accordance with the provisions of paragraph (f)(1) of this section, 120 days after the date of the appeal 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 of the date of the appeal 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 of adverse action.* 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, 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 final notice of adverse determination. The final notice of adverse determination will state the specific grounds for the immediate suspension or revocation, direct the laboratory to cease performing any

Customs-accredited functions, and advise the laboratory that it may choose to pursue one of the following two options:

(A) Submit a new application for accreditation, in accordance with the provisions of paragraph (f)(1) of this section, 180 days after the date of the final notice of adverse determination; or

(B) Administratively appeal the final notice of adverse determination to the Assistant Commissioner within 30 calendar days of the date of the final notice of adverse determination.

(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 proposed action. The preliminary notice of proposed action will state the specific grounds for the proposed action, inform the laboratory that it may continue to perform those functions requiring Customs-accreditation until the Executive Director's final notice is issued, and advise the laboratory that it may file a response addressing the grounds for the action proposed with the Executive Director within 30 calendar days of the date the preliminary notice of proposed action was received by the laboratory. 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.

(B) *Final notice*—(*1*) *Based on nonresponse.* If the laboratory does not respond to the preliminary notice of proposed action, the Executive Director will issue a final notice of adverse determination within 60 calendar days of the date the preliminary notice of proposed action was received by the laboratory. The final notice of adverse determination will state the specific grounds for the adverse determination, direct the laboratory to cease performing any Customs-accredited functions, and advise the laboratory that it may choose to pursue one of the two options provided at paragraphs (k)(2)(i)(A) and (B) of this section.

(*2*) *Based on response.* If the laboratory files a timely response, the Executive Director will issue a final determination regarding the status of the laboratory's accreditation within 30 calendar days of the date the laboratory's response is received by the Executive Director. If this final determination is adverse to the laboratory, then the final notice of adverse determination will state the specific grounds for the adverse action, advise the laboratory to cease performing any functions requiring Customs accreditation, and advise the laboratory that it may choose to pursue one of the two options provided at paragraphs (k)(2)(i)(A) and (B) of this section.

(*3*) *Publication of final notices of adverse determination.* Any final notices of adverse determination issued by the Executive Director resulting in a laboratory being directed to cease performing Customs-accredited functions will be published in the FEDERAL REGISTER and Customs Bulletin and the notice published will include the effective date, duration, and scope of the determination.

(*4*) *Appeal decision.* The Assistant Commissioner will issue a decision on the appeal within 30 calendar days of the date the appeal is received. If the appeal decision is adverse to the laboratory, then the decision notice will advise the laboratory that it may choose to pursue one of the following two options:

(i) Submit a new application for accreditation, in accordance with the provisions of paragraph (f)(1) of this section, 120 days after the date of the appeal decision; or

(ii) File an action with the Court of International Trade, pursuant to chapter 169 of title 28, United States Code, within 60 days of the date of the appeal decision.

[T.D. 99–67, 64 FR 48534, Sept. 7, 1999; T.D. 99–67, 65 FR 10009, 10010, Feb. 25, 2000]

§ 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