FDA LABORATORY ACCREDITATION FOR ANALYSES OF FOODS (LAAF) PROGRAM

PJLA offers third-party accreditation services to Conformity Assessment Bodies (i.e. Testing and/or Calibration Laboratories, Reference Material Producers, Field Sampling and Measurement Organizations and Inspection Bodies). This procedure outlines PJLA's accreditation process and criteria administered to conformity assessments bodies for the **FDA Accreditation Laboratory Accreditation for Analyses of Food Program (LAAF). This is a Supplemental Procedure to PJLA's Accreditation Procedure (SOP-1). Both procedures shall be followed for the entirety of this accreditation program.**

FDA LABORATORY ACCREDITATION FOR ANALYSES OF FOODS (LAAF) PROGRAM

1.0 BACKGROUND / PURPOSE

1.1 The Food and Drug Administration (FDA) has amended its regulations to establish a program for the testing of food in certain circumstances by accredited laboratories, as required under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This program was established to assist FDA improve the safety of the U.S. food supply and protect U.S. consumers by helping ensure that certain food testing of importance to public health is conducted subject to appropriate oversight and in accordance with appropriate model standards to produce reliable and valid test results.

1.2 The final rule is part of FDA's implementation of the FDA Food Safety Modernization Act (FSMA) through which the FDA intends to better protect public health by adopting a modern, preventive, and risk-based approach to food safety regulation. FDA established the Laboratory Accreditation for Analyses of Foods (LAAF) program as required by FSMA section 202(a), which added section 422 to the FD&C Act. Under the LAAF program, FDA recognized PJLA to accredit laboratories to the standards established in FDA's final rule. Laboratories accredited to the LAAF standard ("LAAF-accredited laboratories") are authorized to conduct certain food testing as described in this rule.

1.3 FDA's final rule went into effect February 1, 2022.

1.4 This procedure includes the process for which PJLA carries out its accreditations in accordance with the LAAF program requirements, as well as obligations of the CAB participating in the program.

2.0 RELATED DOCUMENTS AND DEFINITIONS

2.1 FDA Document Citation: 86 FR 68728; 21 CFR 1, 11, 16, 129
2.2 ISO/IEC 17011:2017, Conformity assessment – Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies
2.3 ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories
2.4 LF-36c-LAAF Conflict of Interest/Impartiality Requirement FDA LAAF
2.5 LF-36 Conflict of Interest Policy
2.6 LF-56-LAAF Working Document

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in subpart R, unless otherwise specified. For the purposes of subpart R, the following definitions also apply:

2.7 ***Analyst*** means an individual who analyzes samples.

2.8 ***Corrective action*** means an action taken by an accreditation body or laboratory to investigate and eliminate the cause of a deficiency so that it does not recur.

2.9 ***Directed food laboratory order*** means an order issued by FDA under § 1.1108 requiring food testing to be conducted under this subpart by or on behalf of an owner or consignee.

2.10 ***Food*** has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

2.11 ***Food testing* and *testing of food*** means the analysis of food product samples or environmental samples.

2.12 ***Laboratory accreditation for analyses of foods (LAAF)****-accreditation* means a determination by a recognized accreditation body that a laboratory meets the applicable requirements of this subpart to conduct food testing under this subpart using one or more methods of analysis.

2.13 ***LAAF-accredited laboratory*** means a laboratory that a recognized accreditation body has determined meets the applicable requirements of this subpart and has been LAAF-accredited to conduct food testing under this subpart using one or more methods of analysis.

2.14 ***Owner or consignee*** means any person with an ownership or consignment interest in the food product or environment that is the subject of food testing conducted under § 1.1107(a).

2.15 ***Recognition*** means a determination by FDA that an accreditation body meets the applicable requirements of this subpart and is authorized to LAAF-accredit laboratories under this subpart.

2.16 ***Recognized accreditation body*** means an accreditation body (PJLA) that FDA has determined meets the applicable requirements of this subpart and is authorized to LAAF-accredit laboratories under this subpart.

2.17 ***Representative sample*** means a sample that accurately, to a statistically acceptable degree, represents the characteristics and qualities of the food product or environment from which the sample was collected.

2.18 ***Sampler*** means an individual who collects samples.

2.19 ***Sampling firm*** means an entity that provides sampling services.

2.20 ***Scope of LAAF-accreditation*** refers to the methods of analysis for which the laboratory is LAAF-accredited.

3.0 SUBSTANCE OF THE AGREEMENT

3.1 PJLA as a LAAF recognized accreditation body is obligated to comply with the rules as outlined in the LAAF program requirements for accreditation bodies and testing laboratories.

4.0 MANUAL / ORGANIZATION

4.1 PJLA maintains a quality manual and operating procedures and work instructions to document its quality system to comply with ISO/IEC 17011. These and other related documents (including this one) state all of the requirements for (CABs) seeking accreditation under the LAAF program. PJLA will follow its organization procedures as specified in these documents in the removal, suspension or withdrawal of a (CAB's) accreditation status based on the (CAB's) failure to meet requirements of the program on an ongoing basis or at the (CAB's) request.

5.0 TRAINING AND QUALIFICATION

5.1 PJLA maintains a training, qualification and on-going continuing education program for assessors based on LAAF program requirements. Assessors are required to be trained on the following:

5.1.1 Laboratory Accreditation for Analyses of Foods (LAAF) Program

5.2 Assessors should meet PJLA education and work experience criteria as outlined in SOP-2 Personnel Procedure. Assessors should be knowledgeable with the test methods and techniques performed by the testing laboratories.

5.3 Assessors must participate in PJLA annual refresher training or any training required by the FDA to support the LAAF program.

6.0 ASSESSMENTS AND DOCUMENTATION

6.1 (CABs) applying for FDA LAAF program must identify which test methods will be under LAAF program.

6.2 PJLA will perform on-site assessments of (CAB's) quality systems to include their general ISO/IEC 17025 requirements and the LAAF Program Requirements.

6.3 Each assessment will include the completion of the LF-56 LAAF Working Document and Technical Assessment Matrix for each test method. All test methods must be fully assessed during initial assessments and reassessments. An assessment report will be provided to the (CAB) upon completion of the assessment. This will include a list of nonconformities detected during the visit. Depending on the severity of the nonconformity the FDA will be notified to remove the (CAB) from the program or to remove a test from the scope of accreditation. CABs will have 60 days to respond to nonconformities utilizing their internal

corrective forms. Corrective action must be supported with relevant objective evidence.

6.4 During the close of the assessment (CABs) will be informed of the recommendation of accreditation.

7.0 ACCREDITATION INTERVAL / CYCLE (ASSESSMENT PROCESS)

7.1 PJLA accredits (CABs) for a two-year accreditation cycle, supplemented with yearly surveillance assessments. Initial assessments and reassessments involve a full system review of the CAB's quality management system and all tests related to the LAAF program. Scope expansions may be performed during routine assessments or separately. On-site assessment is required every 2 years.

7.2 Once the (CAB) has been assessed and all corrective actions have been accepted, PJLA will add the accredited laboratory to the FDA Industry System (FIS) which is an electronic portal that facilitates making submissions to FDA. The page contains four sections, contained within accordion panels, which can be expanded to display content:

7.2.1 Accredited Laboratories
- FEI Number
- Firm Name & Address

7.2.2 Accreditation Information
- Accreditation Date
- Expiration Date

7.2.3 Certification Information
- Certificate Number
- Date of Issuance
- Certificate Expiration Date

7.2.4 Disciplines, Analyses and Test Methods

8.0 CERTIFICATE PROCESS

8.1 PJLA will issue a certificate of accreditation to all (CABs) that have been successfully approved by PJLA's Executive Committee. Certificates will include their adherence to ISO/IEC 17025, the LAAF program requirements with the relevant tests. Certificates will be clearly notated to reflect LAAF and non-LAAF related tests. Any concerns or questions regarding the certificate raised by the FDA to PJLA will be responded to immediately.

8.2 Once all of the information is entered by PJLA, the LAAF accredited laboratory will be displayed in FIS for public viewing. Laboratory is not permitted to claim accreditation to LAAF until on FIS.

9.0 LAAF-ACCREDITATION OF LABORATORIES

§ 1.1138 What are the eligibility requirements for a LAAF-accredited laboratory?

(a) A laboratory that is LAAF-accredited or seeking LAAF-accreditation must demonstrate it is capable of conducting each method of food testing for which it is or will be LAAF-accredited by meeting all of the following requirements:

(1) For each method, the laboratory is accredited by PJLA to ISO/IEC 17025:2017(E) (incorporated by reference, see § 1.1101).

(2)

(i) Except as provided in paragraph (a)(2)(ii) of this section, the laboratory has successfully passed a proficiency test provided by a competent proficiency testing organization within the last 12 months for each method within the scope of LAAF-accreditation.

(ii) If the laboratory determines there is no proficiency testing program available or practicable for a method, it may use a comparison program. A laboratory must request approval from PJLA regarding the determination prior to using a comparison program in lieu of an annual proficiency test. The laboratory is required to demonstrate competency through participation in the comparison program.

For preapproval for participation in alternate PT scheme, refer to PL-1 Proficiency Testing Requirements.

(iii) A laboratory must submit all proficiency test and comparison program results, regardless of outcome, to PJLA within 30 calendar days of receipt.

Submit PT results to pjlabs@pjlabs.com, indicate in the subject line "laboratory name" – PT Results – LAAF Program. Laboratory may make arrangements with PT provider to send PT results directly to PJLA on behalf of the laboratory.

(3) The laboratory ensures that its procedures for monitoring the validity of the results of testing it conducts under this subpart include the use of reference materials or quality control samples with each batch of samples it tests under this subpart.

(b) Will comply with all additional requirements for LAAF-accredited laboratories under this subpart while LAAF-accredited.

10.0 REQUIREMENTS FOR LAAF-ACCREDITED LABORATORIES

§ 1.1147 What are the impartiality and conflict of interest requirements for a LAAF-accredited laboratory?

(a) In addition to the impartiality and conflict of interest requirements in § 1.1138(a)(1), a LAAF-accredited laboratory must, subject to the exceptions in paragraph (b) of this section, prohibit the LAAF-accredited laboratory's employees, contractors, and agents involved in food testing under this subpart and related activities from accepting any money, gift, gratuity, or other item of value from the owner or consignee of the food that is being tested or will be tested by the LAAF-accredited laboratory.

(b) The prohibited items of value in paragraph (a) of this section do not include:

(1) Payment of fees for food testing under this subpart and related services;

(2) Reimbursement of direct costs associated with the food testing by the LAAF-accredited laboratory; and

(3) With respect to a LAAF-accredited laboratory that is owned by the owner or consignee of the food that is or will be tested, payment of the officer's, employee's, contractor's, or agent's compensation in the normal course of business.

(c) The LAAF-accredited laboratory must require the owner's or consignee's payment to the LAAF-accredited laboratory of fees for food testing services and reimbursement of direct costs associated with food testing to be independent of the outcome of the test results.

§ 1.1149 What oversight standards apply to sampling?

(a) ***Documents.*** Before analyzing a sample, the LAAF-accredited laboratory must develop (if it collected the sample) or obtain (if another firm collected the sample) the following information to be submitted with test results (see § 1.1152(c)):

(1) Written documentation of the sampler's applicable qualifications by training and experience. A LAAF-accredited laboratory only needs to develop or obtain documentation of a sampler's qualifications the first time that sampler collects a sample for the LAAF-accredited laboratory under this subpart. If a LAAF-accredited laboratory has previously submitted the sampler's qualifications to FDA under § 1.1152(c), the LAAF-accredited laboratory may refer to its previously submitted qualifications.

(2) The written sampling plan used to conduct the sampling. The written sampling plan must identify the sampler and sampling firm and must list factors that will be controlled to ensure the sampling does not impact the validity of the subsequent analytical testing, including controlling for the representational nature of the sample; and

(3) A written sample collection report for each sample collected. The written sample collection report must include:

(i) The product code of the food product (if product is being sampled) or the location and a description of the environment (if environment is being sampled);

(ii) The date of the sampling;

(iii) The lot number, size, identity, and quantity of the sample;

(iv) Documentation of sample collection procedures and any sample preparation techniques; and

(v) Documentation of the chain of custody of the sample and of measures taken to ensure the validity of the subsequent analytical testing, including controlling for the representational nature of the sample.

(b) ***Potential consequences.*** If any of the requirements in paragraph (a) of this section is not met, FDA may consider the analysis of the sample to be invalid.

(c) ***Advance notice of sampling.***

(1) If FDA determines that sampling conducted may materially differ from the sampling documented in the associated sampling plan or sample collection report, or if FDA determines that the sampling otherwise may have been improper, FDA may require the LAAF-accredited laboratory that analyzed the associated sample, and other LAAF-accredited laboratories that have analyzed samples previously collected by the sampling firm, to obtain from the sampling firm, and submit, or require the sampling firm to submit, an advance notice of sampling. The advance notice of sampling must be submitted to FDA at least 48 hours before each of the next 10 occasions that the sampling firm will collect a sample that the LAAF-accredited laboratory will analyze under this subpart.

(2) FDA may, as appropriate:

(i) Specify that the requirement applies to samples collected by a particular sampler;

(ii) Specify the type of food product or environment that requires advance notice of sampling under this subpart;

(iii) Determine that an amount of time other than 48 hours in advance is required, from a minimum of 24 hours up to 7 business days in advance;

(iv) Determine that a number of occasions other than 10 is required, from a minimum of 1 occasion to a maximum of 20 occasions;

(v) Notify affected LAAF-accredited laboratories that submission of additional notices of sampling are not required; and

(vi) Notify the owner or consignee that the advance notice applies to sampling for food testing being conducted on their behalf.

(3) The advance notice of sampling must contain:

(i) A unique identification for the advance notice of sampling;

(ii) The name of the LAAF-accredited laboratory that will conduct analysis of the sample;

(iii) The name and street address of the sampling firm that will conduct the sampling;

(iv) A primary contact (name and phone number) for the sampling firm;

(v) The reason why the food product or environment will be sampled;

(vi) The location of the food product or environment that will be sampled, including sufficient information to identify the food product or environment to be sampled;

(vii) As applicable, the U.S. Customs and Border Protection entry and line number;

(viii) The product code of the food product (if product is being sampled) or the location and a description of the environment (if environment is being sampled); and

(ix) The date and approximate time the sampling will begin.

§ 1.1150 What are the requirements for analysis of samples by a LAAF-accredited laboratory?

In addition to the sample analysis requirements of § 1.1138(a):

(a) The analysis must be conducted on either the sample received from the sampling firm or, if appropriate, on a representative sample of the sample received from the sampling firm.

(b) The analyst must:

(1) Be qualified by appropriate education, training, and/or experience to conduct the analysis;

(2) Have appropriately demonstrated their ability to perform the method properly in the specific context of the food testing to be conducted; and

(3) Be in compliance with the conflict of interest requirements of §§ 1.1138(a) and 1.1147.

(c) The method used to conduct the food testing must meet the requirements of § 1.1151.

(d) The LAAF-accredited laboratory must document the testing information and test results to the extent necessary to account for all information that is required to be included in a full analytical report (*see* § 1.1152(d)).

§ 1.1151 What requirements apply to the methods of analysis a LAAF-accredited laboratory uses to conduct food testing under this subpart?

In addition to the requirements of § 1.1138(a), a LAAF-accredited laboratory must meet the following requirements:

(a) The method of analysis used to conduct food testing under this subpart must be:

(1) Fit for purpose;

(2) Within the laboratory's scope of LAAF-accreditation;

(3) Appropriately validated for use in such food testing, in accordance with paragraph (c) of this section; and

(4) Appropriately verified by the LAAF-accredited laboratory for use in such food testing, in accordance with paragraph (d) of this section.

(b) Food testing must be conducted using the specified method:

(1) Under § 1.1107(a)(1), if the Federal Food, Drug, and Cosmetic Act or implementing regulations prescribe a test method.

(2) Under § 1.1107(a)(2), if the directed food laboratory order prescribes a test method.

(c)

(1) A LAAF-accredited laboratory must validate methods in accordance with the requirements of § 1.1138(a).

(2) A LAAF-accredited laboratory performing validation of a method under this subpart must record the information required by § 1.1138(a) and the supporting analytical data.

(d)

(1) Before a LAAF-accredited laboratory conducts food testing under this subpart using a method for a specific intended use for which the method has been validated, but for which the LAAF-accredited laboratory has not previously applied the method under this subpart, the LAAF-accredited laboratory must have verified it can properly perform the method for the specific intended use.

(2) A LAAF-accredited laboratory performing verification of a method under this subpart must record the method that is the subject of the verification, the intended purpose of the analysis, the results of the verification, the procedure used for the verification, supporting analytical data, and whether the LAAF-accredited laboratory is able to properly perform the method.

(e) A LAAF-accredited laboratory may submit a written request to FDA requesting permission to use a method outside of its scope of LAAF-accreditation for food testing. FDA may approve the request if both following conditions are satisfied:

(1) A new method or methodology has been developed and validated but no reasonably available laboratory has been LAAF-accredited to perform such method or methodology, and

(2) The use of such method is necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak.

§ 1.1152 What notifications, results, reports, and studies must a LAAF-accredited laboratory submit to FDA?

(a) ***General requirements.***

(1) All notifications, results, reports, and studies required to be submitted to FDA by a LAAF-accredited laboratory under this subpart must:

(i) Include the name and street address of the LAAF-accredited laboratory;

(ii) Identify a point of contact for the LAAF-accredited laboratory, including email and telephone number, whom FDA may contact with questions or comments;

(iii) Display an identification unique to the test results, report, notification, or study; and

(iv) Be true, accurate, unambiguous, and objective.

(2) The LAAF-accredited laboratory that conducts the analysis of the sample under this subpart is responsible for the submission of all notifications, results, reports, and studies to FDA as required by this section.

(3) If the LAAF-accredited laboratory becomes aware that any aspect of the submitted material is inaccurate, the LAAF-accredited laboratory must immediately inform FDA and submit a corrected version. Such corrections must meet the requirements for amendments to reports specified by ISO/IEC 17025:2017(E) (incorporated by reference, see § 1.1101) section 7.8.8.

(4) Any opinions and interpretations in any notification, result, report, or study submitted to FDA under this subpart must meet the requirements in ISO/IEC 17025:2017(E) section 7.8.7 and any statements of conformity to a specification or standard in any notification, result, report, or study submitted to FDA under this subpart must meet the requirements of ISO/IEC 17025:2017(E) section 7.8.6.

(b) ***Test results.***

(1) The LAAF-accredited laboratory must submit the results of all testing required to be conducted under this subpart directly to FDA via the location specified by the website described in § 1.1109, unless another location is specified by FDA regarding testing conducted under § 1.1107(a)(2) or (3).

(2) The test results must be clear and identify:

(i) The name and street address of the owner or consignee for which the testing was conducted,

(ii) As appropriate, the U.S. Customs and Border Protection entry and line number(s), and

(iii) The associated notifications, reports, and studies required to be submitted with the test results under this subpart.

(c) ***Documentation required to be submitted with test results.*** The following documentation must be included with each full analytical report (see paragraph (d) of this section) and each abridged analytical report (see § 1.1153) submitted to FDA under this subpart:

(1) All sampling plans and sample collection reports related to the food testing conducted as developed or obtained by the LAAF-accredited laboratory in accordance with § 1.1149;

(2) Written documentation of the sampler's qualifications or an indication that the sampler's qualifications have been submitted previously, in accordance with § 1.1149(a)(1);

(3) For any validation studies required by § 1.1151(c)(1), the documentation required by § 1.1151(c)(2);

(4) For any verification studies required by § 1.1151(d)(1), the documentation required by § 1.1151(d)(2);

(5) The justification for any modification to or deviation from the method(s) of analysis used and documentation of the LAAF-accredited laboratory's authorization for the modification or deviation; and

(6) A certification from one or more members of the LAAF-accredited laboratory's management certifying that the test results, notifications, reports, and studies are true and accurate; and that the documentation includes the results of all tests conducted under this subpart. The certification must include the name, title, and signature of any certifiers.

(d) ***Full analytical report contents.*** In addition to the documentation required to be submitted with all test results (see paragraph (c) of this section), a full analytical report must include:

(1) All information described by ISO/IEC 17025:2017(E) sections 7.8.2.1(a) through (p) and 7.8.3.1(a) through (d);

(2) Documentation of references for the method of analysis used;

(3) Name and signature of the analyst who conducted each analytical step, including any applicable validation and verification steps, and the date each step was performed;

(4) Calculations, presented in a legible and logical manner;

(5) As applicable, references to chromatograms, charts, graphs, observations, photographs of thin layer chromatographic plates, and spectra. References must be in color when appropriate and presented in a clear order;

(6) Identification of the source and purity of reference standards used, and, as applicable: Certified reference materials, certified reference cultures traceable to a nationally or internationally recognized type culture collection (including concentration, units, preparation, and storage conditions), and reference standard preparation information (including who prepared the reference standard, date of preparation, expiration date, chemical balance, and solvent used);

(7) A copy of the label from any immediate container sampled, if available, and any additional labeling needed to evaluate the product;

(8) All original compilations of raw data secured in the course of the analysis, including discarded, unused, or re-worked data, with the justification for discarding or re-working such data, corresponding supporting data, and quality control results (including the expected result and whether it is acceptable), all identified with unique sample identification, date, and time, associated with the test;

(9) Any other relevant additional supporting information such as the storage location of analyzed samples, appropriate attachments such as instrument printouts, computer generated charts and data sheets, and photocopies or original labels for the product analyzed;

(10) Identification of any software used;

(11) Any certificate of analysis for standards and software; and

(12) The following information about the qualifications of each analyst involved in the analysis conducted under this subpart, if the LAAF-accredited laboratory has not previously submitted documentation of the analyst's qualifications to FDA or the analyst's qualifications have significantly changed since the LAAF-accredited laboratory last submitted documentation of the analyst's qualifications to FDA:

(i) The analyst's curriculum vitae;

(ii) Training records for the applicable methods that the analyst is qualified to perform, including the dates of such training and the name of the trainer or training provider; and

(iii) Any other documentation of the analyst's ability to perform the method properly in the context of the food testing to be conducted, pursuant to § 1.1150(b).

(e) ***Additional information about non-standard methods.*** If the LAAF-accredited laboratory conducts the analysis using a method that is not published in a reputable international or national standard or that is otherwise not publicly and readily available, upon request by FDA the LAAF-accredited laboratory must submit documentation of the method to FDA.

(f) ***Immediate notification of significant changes.*** The LAAF-accredited laboratory must notify FDA and the recognized accreditation body that LAAF-accredited the laboratory of changes that affect the LAAF-accreditation of the laboratory within 48 hours, including a detailed description of such changes, and an explanation of how such changes affect the LAAF-accreditation of the laboratory. LAAF-accredited laboratories are not required to notify FDA of changes that a recognized accreditation body must provide to FDA under § 1.1123(d).

(g) ***Consequence of omission.*** If FDA does not receive all information required to be submitted to FDA under this section, FDA may consider the related food testing to be invalid.

§ 1.1153 What are the requirements for submitting abridged analytical reports?

(a) ***Requesting permission.*** A LAAF-accredited laboratory may request permission to submit abridged analytical reports for each major food testing discipline: Biological, chemical, and physical.

(1) FDA will grant permission to submit abridged analytical reports for a single major food testing discipline if all of the following conditions are met:

(i) The LAAF-accredited laboratory is not on suspension or probation for any method within the major food testing discipline that is the subject of its request (see § 1.1121(b) or § 1.1161(b));

(ii) The LAAF-accredited laboratory has successfully implemented any required corrective action under § 1.1121(a) or § 1.1161(a); and

(iii) The last five full analytical reports for the major food testing discipline contain no shortcomings that call into question the validity of the test results or repeated administrative errors.

(2) FDA will notify the LAAF-accredited laboratory if permission is granted or denied.

(b) ***FDA review of abridged analytical reports.***

(1) FDA will review all abridged analytical reports submitted.

(2) FDA will notify the LAAF-accredited laboratory if FDA identifies a shortcoming that calls into question the validity of the test results or repeated administrative errors, will require corrective action under § 1.1161(a), and may revoke permission to submit abridged analytical reports for the specific major food testing discipline.

(3) If FDA identifies a shortcoming that calls into question the validity of the test results or repeated administrative errors in abridged analytical reports from a LAAF-accredited laboratory that has previously had its permission to submit abridged analytical reports revoked for any major food testing discipline, FDA may put the LAAF-accredited laboratory on probation for one or more methods under § 1.1161(b). Under § 1.1162(a), a laboratory on probation for one or more methods may not submit abridged analytical reports for the major food testing disciplines of which the probationary methods are a part.

(4) A LAAF-accredited laboratory that has had permission to submit abridged analytical reports revoked for one or more major food testing disciplines may request permission to submit abridged analytical reports as described in paragraph (a) of this section for each major food testing discipline.

(c) ***Contents of abridged analytical reports.*** In addition to the documentation required to be submitted with all test results (see § 1.1152(c)), an abridged analytical report must include:

(1) All information described by ISO/IEC 17025:2017(E) (incorporated by reference, see § 1.1101) sections 7.8.2.1(a) through (p) and 7.8.3.1(a) through (d); and

(2) Quality control results (including the expected result and whether it is acceptable).

(d) ***Exceptions.*** FDA may require additional documentation or a full analytical report from a LAAF-accredited laboratory permitted to submit abridged analytical reports in the following circumstances:

(1) FDA may require a full analytical report related to an FDA investigation or FDA enforcement proceeding.

(2) Occasionally, for the purposes of auditing abridged analytical reports and otherwise protecting the public health and the integrity of this food testing program,

FDA will require additional documentation or a full analytical report within 72 hours of FDA's request.

(e) ***Consequence of omission.*** If FDA does not receive all information required to be submitted to FDA under paragraph (c) of this section, FDA may consider the related food testing to be invalid.

§ 1.1154 What other records requirements must a LAAF-accredited laboratory meet?

(a) In addition to the records requirements of § 1.1138(a), a LAAF-accredited laboratory must maintain, for 5 years after the date of creation, records created and received while it is LAAF-accredited that relate to compliance with this subpart, including:

(1) Documents related to the LAAF-accredited laboratory's grant of LAAF-accreditation (and, if applicable, extensions and reductions of scope of LAAF-accreditation) from its recognized accreditation body, including all required proficiency test and comparison program records for each method within the scope of LAAF-accreditation under § 1.1138(a)(2);

(2) Documentation of food testing the LAAF-accredited laboratory conducted under this subpart sufficient to account for all information required by § 1.1152(d), in accordance with § 1.1150(d);

(3) All documents that the LAAF-accredited laboratory was required to submit to FDA under §§ 1.1152 and 1.1153, and associated correspondence between the LAAF-accredited laboratory (and its officers, employees, and other agents) and the owner or consignee (and its officers, employees, and other agents) regarding food testing under this subpart;

(4) All requests for food testing from an owner or consignee that would be conducted under this subpart;

(5) Documentation of any internal investigations, internal audits, and corrective action taken to address any problems or deficiencies related to activities under this subpart;

(6) All documentation related to suspension, probation, reduction of scope, or withdrawal of LAAF-accreditation, or laboratory disqualification under this subpart; and

(7) Documentation of changes to its management system or food testing activities that may affect its compliance with this subpart.

(b) Make the records required by paragraph (a) of this section available for inspection and copying or for electronic submission upon written request of an authorized officer or employee of FDA. If FDA requests records for inspection and copying, the laboratory must make such records promptly available at the physical location of the laboratory or at another reasonably accessible location. If the authorized officer or employee of FDA requests electronic submission, the records must be submitted within 10 business days of the request.

(c) Ensure that significant amendments to records described by this section can be tracked to previous and original versions. If such a significant amendment is made, both the original document and amended document must be maintained by the LAAF-accredited laboratory during the time period for which the amended document must be maintained under this subpart. The laboratory must also document the date of amendment, the personnel responsible for the amendment, and a conspicuous indication on the original document stating that the document has been altered and that a more recent version of the document exists.

11.0 SUSSPENSION / WITHDRAWAL PROCESS

11.1 PJLA will follow its suspension and withdrawal procedure (SOP-11) for all (CABs) accredited under this program. The FDA will be notified within 5 business days if a CAB is suspension or withdrawn for the accreditation program.

12.0 COMPLAINT PROCESS

12.1 PJLA will follow its Procedure for Handling Complaints SOP-9. All complaints regardless if corrective action is required, will be documented for this program and provided to the FDA as requested.

13.0 APPLICATION CONCERNS RECEIVED BY THE FDA

13.1 If the FDA notifies PJLA of any issues with a CAB's analytical results that resulted in a rejection of a particular test method, SOP-9 complaint procedure or SOP-11 suspension, reduction of scope, withdrawal procedure will be utilized. This may require PJLA to remove test methods or the entire accreditation until an investigation is completed either through on-site assessment or documentation review.

14.0 RECORD RETENTION (RECORDS)

14.1 PJLA currently retains records from three (3) to five (5) years (depending on the record).