FDA LAAF Working Document

NOTES:

1. This working document is intended as a checklist for the assessor when conducting Testing Laboratory Accreditation Assessments according to ISO/IEC 17025:2017 and the CFR in the FDA LAAF Program Requirements. The ISO/IEC 17025:2017 checklist shall be utilized with this checklist.

2. Nonconformities shall be raised against the CFR requirements in FDA Title 21, Chapter I, Subchapter A, Part1, Subpart R for LAAF-accredited laboratories, as applicable, along with ISO/IEC 17025:2017.

3. This checklist is only a tool and is not considered as the requirements of the FDA LAAF Program. If there is a disagreement between this checklist and CFR requirements as written in FDA Title 21, Chapter I, Subchapter A, Part1, Subpart R document, the FDA document shall prevail.

ASSESSMENT		
Number	**Type**	**Date(s)**
Standard(s):		
Team: (LA, TA, TE)	(Lead)	
CONFORMITY ASSESSMENT BODY (CAB)		
Name	**Location(s)**	

CFR	Area of Requirements	Yes	No	N/A	Comments/Policy/Procedure/Record
	ELIGIBILITY REQUIREMENTS FOR FDA LAAF ACCREDITED LABORATORIES				
§ 1.1138 (a)(2)(i)	Has the laboratory successfully passed a proficiency test provided by a competent proficiency testing provider within the last 12 months for each method within the scope of LAAF-accreditation?				
§ 1.1138 (a)(2)(ii)	*Note: If the laboratory determines there is no proficiency testing program available or practicable for a method, it may use a comparison program.*				
§ 1.1138 (a)(2)(ii)	Has the laboratory requested approval from PJLA regarding the determination prior to using a comparison program in lieu of an annual proficiency test?				
§ 1.1138 (a)(2)(ii)	Has the laboratory demonstrated competency through participation in the comparison program?				
§ 1.1138 (a)(2)(iii)	Has the laboratory submitted all proficiency				

CFR	Area of Requirements	Yes	No	N/A	Comments/Policy/Procedure/Record
	test and comparison program results, regardless of the outcome, to PJLA within 30 calendar days of receipt?				
§ 1.1138 (a)(3)	Does the laboratory ensure 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?				
	REQUIREMENTS FOR FDA LAAF – ACCREDITED LABORATORIES				
	Impartiality and Conflict of Interest Requirements				
§ 1.1147 (a)	Does a LAAF-accredited laboratory 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				

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	consignee of the food that is being tested or will be tested by the LAAF-accredited laboratory?				
§ 1.1147 (b)(1,2,3)	*Note: The prohibited items of value in paragraph (a) of this section do not include:* *Payment of fees for food testing under this subpart and related services;* *Reimbursement of direct costs associated with the food testing by the LAAF-accredited laboratory; and* *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.*				
	Sampling Requirements				
§ 1.1149 (a)	Before analyzing a sample, does the LAAF-accredited laboratory develop (if it				

CFR	Area of Requirements	Yes	No	N/A	Comments/Policy/Procedure/Record
	collected the sample) or obtain (if another firm collected the sample) the following information to be submitted with test results?:				
§ 1.1149 (a)(1)	Written documentation of the sampler's applicable qualifications by training and experience?				
§ 1.1149 (a)(1)	Has the LAAF-accredited laboratory initially developed or obtained documentation of a sampler's qualifications the first time that sampler collects a sample for the LAAF-accredited laboratory under this subpart?				
§ 1.1149 (a)(1)	*Note: 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.*				
§ 1.1149 (a)(2)	Is the written sampling plan used to conduct the sampling?				

CFR	Area of Requirements	Yes	No	N/A	Comments/Policy/Procedure/Record
§ 1.1149 (a)(2)	Does the written sampling plan identify the sampler and sampling firm and 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?				
§ 1.1149 (a)(3)	Is a written sample collection report for each sample collected?				
§ 1.1149 (a)(3)	Does the written sample collection report include the following?:				
§ 1.1149 (a)(3)(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)?				
§ 1.1149 (a)(3)(ii)	The date of the sampling?				
§ 1.1149 (a)(3)(iii)	The lot number, size, identity, and quantity of the sample?				

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§ 1.1149 (a)(3)(iv)	Documentation of sample collection procedures and any sample preparation techniques?				
§ 1.1149 (a)(3)(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?				
§ 1.1149 (c)(1)	Is the advance notice of sampling 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?				
§ 1.1149 (c)(2)	If requested by the FDA, does the LAAF-accredited laboratory do the following?:				
§ 1.1149 (c)(2)(i)	Specify that the requirement applies to samples collected by a particular sampler?				
§ 1.1149 (c)(2)(ii)	Specify the type of food product or environment that requires advance notice of				

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	sampling under this subpart?				
§ 1.1149 (c)(2)(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?				
§ 1.1149 (c)(2)(iv)	Determine that a number of occasions other than 10 is required, from a minimum of 1 occasion to a maximum of 20 occasions?				
§ 1.1149 (c)(3)	Does the advance notice of sampling contain the following?:				
§ 1.1149 (c)(3)(i)	A unique identification for the advance notice of sampling?				
§ 1.1149 (c)(3)(ii)	The name of the LAAF-accredited laboratory that will conduct analysis of the sample?				
§ 1.1149 (c)(3)(iii)	The name and street address of the sampling firm that will conduct the sampling?				
§ 1.1149 (c)(3)(iv)	A primary contact (name and phone number) for the sampling firm?				

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§ 1.1149 (c)(3)(v)	The reason why the food product or environment will be sampled?				
§ 1.1149 (c)(3)(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?				
§ 1.1149 (c)(3)(vii)	As applicable, the U.S. Customs and Border Protection entry and line number?				
§ 1.1149 (c)(3)(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)?				
§ 1.1149 (c)(3)(ix)	The date and approximate time the sampling will begin?				
	Requirements for Analysis of Samples				
§ 1.1150 (a)	Is the analysis conducted on either the sample received from the sampling firm or, if appropriate, on a				

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	representative sample of the sample received from the sampling firm?				
§ 1.1150 (b)	Is the analyst?:				
§ 1.1150 (b) (1)	Qualified by appropriate education, training, and/or experience to conduct the analysis?				
§ 1.1150 (b) (2)	Have appropriately demonstrated their ability to perform the method properly in the specific context of the food testing to be conducted?				
§ 1.1150 (b) (3)	Is in compliance with the conflict of interest requirements of §§ 1.1138(a) and 1.1147?				
§ 1.1150 (c)	Does the method used to conduct food testing meet the requirements of § 1.1151?				
§ 1.1150 (d)	Does the LAAF-accredited laboratory document testing information and test results to the extent necessary to account for all information that is required to be				

CFR	Area of Requirements	Yes	No	N/A	Comments/Policy/Procedure/Record
	included in a full analytical report?				
	Methods of Analysis Requirements				
§ 1.1151 (a) (1)	Is the method of analysis used to conduct food testing under this subpart fit for purpose?				
§ 1.1151 (a) (2)	Is the method of analysis used to conduct food testing under this subpart within the laboratory's scope of LAAF-accreditation?				
§ 1.1151 (a) (3)	Is the method of analysis used to conduct food testing under this subpart appropriately validated for use in such food testing, in accordance with paragraph (c) of this section; and				
§ 1.1151 (a) (4)	Is the method of analysis used to conduct food testing under this subpart appropriately verified by the LAAF-accredited laboratory for use in such food testing, in accordance with paragraph (d) of this section.				

CFR	Area of Requirements	Yes	No	N/A	Comments/Policy/Procedure/Record
§ 1.1151 (b) (1)	Is food testing conducted using the specified method if the Federal Food, Drug, and Cosmetic Act or implementing regulations prescribe a test method?				
§ 1.1151 (b) (2)	Is food testing conducted using the specified method if the directed food laboratory order prescribes a test method?				
§ 1.1151 (c) (1)	Does LAAF-accredited laboratory validate methods in accordance with the requirements of § 1.1138(a)?				
§ 1.1151 (c) (2)	Does LAAF-accredited laboratory performing validation of a method under this subpart record the information required by § 1.1138(a) and the supporting analytical data?				
§ 1.1151 (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				

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	LAAF-accredited laboratory has not previously applied the method under this subpart, has the LAAF-accredited laboratory verified it can properly perform the method for the specific intended use?				
§ 1.1151 (d) (2)	Does a LAAF-accredited laboratory performing verification of a method under this subpart 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?				
§ 1.1151 (e)	If necessary, has a LAAF-accredited laboratory submitted a written request to FDA requesting permission to use a method outside of its scope of				

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	LAAF-accreditation for food testing? *Note: FDA may approve the request if both following conditions are satisfied:*				
§ 1.1151 (e) (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?				
§ 1.1151 (e) (2)	Is the use of such method necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak?				
	General Requirements for Submissions to FDA				
§ 1.1152 (a)	***General Requirements.***				
§ 1.1152 (a) (1)	Do all notifications, results, reports, and studies required to be submitted to FDA by a LAAF-accredited laboratory under this subpart include the following?:				

CFR	Area of Requirements	Yes	No	N/A	Comments/Policy/Procedure/Record
§ 1.1152 (a) (1) (i)	The name and street address of the LAAF-accredited laboratory?				
§ 1.1152 (a) (1) (ii)	Point of contact for the LAAF-accredited laboratory, including email and telephone number, whom FDA may contact with questions or comments?				
§ 1.1152 (a) (1) (iii)	Display an identification unique to the test results, report, notification, or study?				
§ 1.1152 (a) (1) (iv)	Are true, accurate, unambiguous, and objective?				
§ 1.1152 (a) (2)	Does the LAAF-accredited laboratory that conducts the analysis of the sample under this subpart submit all notifications, results, reports, and studies to FDA as required by this section?				
§ 1.1152 (a) (3)	If the LAAF-accredited laboratory becomes aware that any aspect of the submitted material is inaccurate, does the LAAF-accredited laboratory immediately inform FDA				

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	and submit a corrected version?				
§ 1.1152 (a) (3)	Do such corrections meet the requirements for amendments to reports specified by ISO/IEC 17025:2017(E) (incorporated by reference, see § 1.1101) section 7.8.8?				
§ 1.1152 (a) (4)	Do opinions and interpretations in any notification, result, report, or study submitted to FDA under this subpart meet the requirements in ISO/IEC 17025:2017(E) section 7.8.7?				
§ 1.1152 (a) (4)	Do statements of conformity to a specification or standard in any notification, result, report, or study submitted to FDA under this subpart meet the requirements of ISO/IEC 17025:2017(E) section 7.8.6?				
§ 1.1152 (b)	***Test Results.***				

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§ 1.1152 (b) (1)	Does the LAAF-accredited laboratory submit 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))*				
§ 1.1152 (b) (2)	Are the test results clear and identify the following?:				
§ 1.1152 (b) (2) (i)	The name and street address of the owner or consignee for which the testing was conducted?				
§ 1.1152 (b) (2) (ii)	The U.S. Customs and Border Protection entry and line number(s)? (As appropriate)				
§ 1.1152 (b) (2) (iii)	The associated notifications, reports, and studies required to be submitted with the test results under this subpart?				
§ 1.1152 (c)	***Documentation required to be submitted with test results.***				

CFR	Area of Requirements	Yes	No	N/A	Comments/Policy/Procedure/Record
§ 1.1152 (c)	Is the following documentation 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?:				
§ 1.1152 (c) (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?				
§ 1.1152 (c) (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)?				
§ 1.1152 (c) (3)	For any validation studies required by § 1.1151(c)(1), the documentation required by § 1.1151(c)(2)?				
§ 1.1152 (c) (4)	For any verification studies required by § 1.1151(d)(1), the documentation required by § 1.1151(d)(2)?				

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§ 1.1152 (c) (5)	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?				
§ 1.1152 (c) (6)	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? Does the certification include the name, title, and signature of any certifiers?				
§ 1.1152 (d)	***Full analytical report contents.***				
§ 1.1152 (d)	Does the full analytical report include the following?:				

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§ 1.1152 (d) (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)?				
§ 1.1152 (d) (2)	Documentation of references for the method of analysis used?				
§ 1.1152 (d) (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?				
§ 1.1152 (d) (4)	Calculations, presented in a legible and logical manner?				
§ 1.1152 (d) (5)	References to chromatograms, charts, graphs, observations, photographs of thin layer chromatographic plates, and spectra? As applicable.				
§ 1.1152 (d) (5)	Are references in color when appropriate and presented in a clear order?				
§ 1.1152 (d) (6)	Identification of the source and purity of reference standards used? As applicable.				

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§ 1.1152 (d) (6)	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)?				
§ 1.1152 (d) (7)	A copy of the label from any immediate container sampled, if available, and any additional labeling needed to evaluate the product?				
§ 1.1152 (d) (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				

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	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?				
§ 1.1152 (d) (9)	Any other relevant 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?				
§ 1.1152 (d) (10)	Identification of software used?				
§ 1.1152 (d) (11)	Certificate of analysis for standards and software?				
§ 1.1152 (d) (12)	Does the full analytical report include the following information about the qualifications of each analyst involved in the				

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	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)				
§ 1.1152 (d) (12) (i)	The analyst's curriculum vitae? *(Note: a curriculum vitae is a short-written summary of a person's career, qualifications, and education.)*				
§ 1.1152 (d) (12) (ii)	Training records for the applicable methods that the analyst is qualified to perform, including the dates of such training and the				

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	name of the trainer or training provider?				
§ 1.1152 (d) (12) (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)?				
§ 1.1152 (e)	***Additional information about non-standard methods.***				
§ 1.1152 (e)	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 does the LAAF-accredited laboratory submit documentation of the method to FDA?				
§ 1.1152 (f)	***Immediate notification of significant changes.***				
§ 1.1152 (f)	Does the LAAF-accredited laboratory notify FDA and PJLA of any changes that affect the LAAF-				

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	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? *Note: LAAF-accredited laboratories are not required to notify FDA of changes that a PJLA must provide to FDA under § 1.1123(d).*				
§ 1.1152 (g)	***Consequence of omission.***				
§ 1.1152 (g)	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.				
	Requirements for Submitting Abridged Reports				
§ 1.1153 (a)	***Requesting permission.***				

CFR	Area of Requirements	Yes	No	N/A	Comments/Policy/Procedure/Record
§ 1.1153 (a)	Does the LAAF-accredited laboratory request permission to submit abridged analytical reports for each major food testing discipline: Biological, Chemical, and Physical?				
§ 1.1153 (a) (1) (ii)	Has the LAAF-accredited laboratory successfully implemented any required corrective action under § 1.1121(a) or § 1.1161(a)?				
§ 1.1153 (a) (1) (iii)	Are 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?				
§ 1.1153 (c)	***Contents of abridged analytical reports.***				
§ 1.1153 (c)	Does the abridged analytical report include the following?:				
§ 1.1153 (c) (1)	All information described by ISO/IEC 17025:2017 sections 7.8.2.1(a) - (p) and 7.8.3.1(a) - (d)?				

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§ 1.1153 (c) (2)	Quality control results (including the expected result and whether it is acceptable)?				
	Requirements for Records				
§ 1.1154 (a)	Does the LAAF-accredited laboratory maintain records for 5 years after the date of creation, records created and received while it is LAAF-accredited that relate to compliance with this subpart?				
§ 1.1154 (a) (1)	Does the LAAF-accredited laboratory retain documents related to grant of LAAF-accreditation (and, if applicable, extensions and reductions of scope of LAAF-accreditation) from PJLA, including all required proficiency test and comparison program records for each method?				
§ 1.1154 (a) (2)	Does the LAAF-accredited laboratory retain documentation of food testing conducted under this subpart sufficient to account				

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	for all information required by § 1.1152(d), in accordance with § 1.1150(d)?				
§ 1.1154 (a) (3)	Does the LAAF-accredited laboratory retain all documents that are 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?				
§ 1.1154 (a) (4)	Does the LAAF-accredited laboratory retain all requests for food testing from an owner or consignee that would be conducted under this subpart?				
§ 1.1154 (a) (5)	Does the LAAF-accredited laboratory retain documentation of any internal investigations, internal audits, and				

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	corrective action taken to address any problems or deficiencies related to activities under this subpart?				
§ 1.1154 (a) (6)	Does the LAAF-accredited laboratory retain all documentation related to suspension, probation, reduction of scope, or withdrawal of LAAF-accreditation, or laboratory disqualification under this subpart?				
§ 1.1154 (a) (7)	Does the LAAF-accredited laboratory retain documentation of changes to its management system or food testing activities that may affect its compliance with this subpart?				
§ 1.1154 (b)	Does the LAAF-accredited laboratory make 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?				

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§ 1.1154 (b)	If FDA requests records for inspection and copying, does the laboratory make such records promptly available at the physical location of the laboratory or at another reasonably accessible location?				
§ 1.1154 (b)	If the authorized officer or employee of FDA requests electronic submission, are the records submitted within 10 business days of the request?				
§ 1.1154 (c)	Does the LAAF-accredited laboratory ensure that significant amendments to records described by this section can be tracked to previous and original versions?				
§ 1.1154 (c)	If a significant amendment is made, are both the original document and amended document maintained by the LAAF-accredited laboratory during the time period for which the amended document				

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	must be maintained under this subpart?				
§ 1.1154 (c)	Does the laboratory 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?				